Chicago, IL
Orleans, LA
, Australia
Grand, OH
Dallas, TX
ngeles, CA
ington, DC
nnounced)
Chicago, IL
Orleans, LA

AMERICAN ASSOCIATION FOR DENTAL RESEARCH

734 Fifteenth Street, NW • Suite 809 • Washington, DC 20005

Annual Session – March 20-23, 1980
Hotel Bonaventure, Los Angeles, California

SUMMARY OF ACTIVITIES

Tuesday, March 18

5:00 P.M. Craniofacial Genetics Society . . . . . San Fernando

Wednesday, March 19

9:00 A.M. AADR Council Meeting . . . . . San Gabriel B
1:30 P.M. Federation of Dental Diagnostic Sciences . . . . . Los Feliz
2:00 P.M. AADS/AADR Symposium: "Microbiology in Clinical Teaching" . . . . . Santa Anita B
3:00 P.M. AADS/AADR Symposium: "Oral Biology in the Dental Curriculum" . . . . . Santa Anita C

Thursday, March 20

7:00 A.M. Naval Dental Research Breakfast . . . . . San Fernando
7:00 A.M. Dental Materials Executive Committee Breakfast . . . . . Los Feliz
7:30 A.M. Group Program Chairmen's Breakfast (Planning for 1981) . . . . . San Bernardino
9:00 A.M. OPENING MEETING . . . . . San Francisco
10:15 A.M. NIDR Consultation Sessions . . . . . Los Cerritos
10:15 A.M. AADS/AADR Symposium: "Grants and Fellowships: Clinical Investigators/Young Investigators" . . . . . Santa Anita A & B
Symposium I: "Promoting the Use of Fluorides in Communities: Past Accomplishments and Future Perspectives" (NB: This Symposium will last until 1 P.M.) . . . . . Santa Anita C
Symposium II: "Small is Beautiful: Ultramicroanalytical Techniques in Dental Research" . . . . . San Pedro
Symposium III: "Mechanisms of Anti-bacterial Non-specific Immune Factors in Saliva" . . . . . San Jose
Symposium V: "Bacterial/Host Interactions in Periodontal Disease—A Scientific Debate" . . . . . Emerald Bay
Symposium IX: "Relationship of Specific Bacterial Surface Receptors to Plaque Formation" . . . . . Sacramento
2:00 P.M. Symposium VI: "Symposium on the Temporomandibular Joint" . . . . Santa Anita A & B
Session A: Salivary Research I—Protein-Mineral Interactions . . . . . Palos Verdes
Session B: Behavioral Sciences I—Esthetics . . . . . San Fernando
Symposium VII: "Periodontal Prostheses" . . . . . San Gabriel A,B,C
Symposium VIII: "Pulpal Response to Dental Caries" . . . . . Santa Barbara A & B
Session C: Pharmacology, Therapeutics, and Toxicology I—Treatment of Bacterial & Viral Infections of the Oral Cavity . . . . . Santa Barbara C
Session D: Cell Biology—Oral Mucosa . . . . . San Pedro
Session E: Prosthodontics—Implants . . . . . San Bernardino
Session F: Cariology I—Fluoride Uptake and Remineralization . . . . . San Jose
Session G: Dental Materials I—Orthodontics and Impression Materials . . . . . San Francisco
Session H: Microbiology/Immunology I—Adherence, Colonization . . . . . Sacramento
Session I: Dental Materials II—Amalgam I . . . . . San Diego
Session J: Periodontal Research I—Clinical Studies A . . . . . Avalon
Session K: Periodontal Research II—Bone . . . . . Emerald Bay
5:00 P.M. GROUP BUSINESS MEETINGS
Behavioral Science Group . . . . . San Fernando
Cariology Group . . . . . San Jose
Craniofacial Biology Group . . . . . Santa Anita C
Dental Materials Group . . . . . San Francisco
Microbiology/Immunology Group . . . . . Sacramento
Mineralized Tissue Group . . . . . Emerald Bay
Neuroscience Group . . . . . Los Feliz

ClearCorrect Exhibit 1002, Page 944 of 3373

Karl Heinz Höhne Ron Kikinis (Eds.)

Visualization in Biomedical Computing

4th International Conference, VBC '96
Hamburg, Germany, September 22-25, 1996
Proceedings

With 18 Color Pages
and Numerous Halftones



Springer

THIS MATERIAL IS SUBJECT TO THE UNITED STATES COPYRIGHT LAW: FURTHER REPRODUCTION IN VIOLATION OF THAT LAW IS PROHIBITED

Series Editors

Gerhard Goos, Karlsruhe University, Germany

Juris Hartmanis, Cornell University, NY, USA

Jan van Leeuwen, Utrecht University, The Netherlands

Volume Editors

Karl Heinz Höhne
University of Hamburg, University Hospital Eppendorf
Martinistraße 52, D-20246 Hamburg, Germany
E-mail:hoehne@uke.uni-hamburg.de

Ron Kikinis
Harvard Medical School and Brigham and Women's Hospital
Department of Radiology
75 Francis Street, Boston, MA 02115, USA
E-mail: kikinis@bwh.harvard.edu

Cataloging-in-Publication data applied for

Die Deutsche Bibliothek - CIP-Einheitsaufnahme

Visualization in biomedical computing : 4th international conference ; proceedings / VBC '96, Hamburg, Germany, September 22 - 25, 1996. Karl H. Höhne ; Ron Kikinis (ed.). - Berlin ; Heidelberg ; New York ; Barcelona ; Budapest ; Hong Kong ; London ; Milan ; Paris ; Santa Clara ; Singapore ; Tokyo : Springer, 1996
(Lecture notes in computer science ; Vol. 1131)
ISBN 3-540-61649-7
NE: Höhne, Karl H. [Hrsg.]; VBC <4, 1996, Hamburg>; GT

CR Subject Classification (1991): I.3, I.4, I.5, I.2.10

ISSN 0302-9743
ISBN 3-540-61649-7 Springer-Verlag Berlin Heidelberg New York

This work is subject to copyright. All rights are reserved, whether the whole or part of the material is concerned, specifically the rights of translation, reprinting, re-use of illustrations, recitation, broadcasting, reproduction on microfilms or in any other way, and storage in data banks. Duplication of this publication or parts thereof is permitted only under the provisions of the German Copyright Law of September 9, 1965, in its current version, and permission for use must always be obtained from Springer - Verlag. Violations are liable for prosecution under the German Copyright Law.

© Springer-Verlag Berlin Heidelberg 1996
Printed in Germany

Typesetting: Camera-ready by author
SPIN 10513550 06/3142 - 5 4 3 2 1 0 Printed on acid-free paper

Kurt F. Wendt Library
University of Wisconsin - Madison
215 N. Randall Avenue
Madison, WI 53706-1688

An Advanced System for the Simulation and Planning of Orthodontic Treatments

Alcañiz, M.[1] ; Chinesta, F.[2] ; Monserrat, C.[1] ; Grau, V.[1] ; Ramón, A.[2]

[1] Departamento de Expresión Gráfica en la Ingenieria
[2] Departamento de Mecánica de los Medios Contínuos y Teoria de Estructuras,
Universidad Politécnica de Valencia, Camino de Vera, s/n, 46071, SPAIN.

Abstract. This paper describes a new method for 3D orthodontic treatment simulation developed for an orthodontic planning system (MAGALLANES). We develop an original system for three-dimensional reconstruction of dental anatomy. Data are acquired directly from the patient with low cost 3D digitizers avoiding use of dental casts in orthodontic treatments. We apply these 3D dental models to simulate three-dimensional movement of teeth, including rotations, during orthodontic treatment. We develop an original simplified model of arch-wire behavior and a viscoplastic behavior law for the alveolar bone, to simulate teeth displacements during orthodontic treatments. The proposed algorithm enables to quantify the effect of orthodontic appliances on teeth movement. Preliminary results are very promising.

1 Introduction

Orthodontics is the branch of dentistry that is concerned with the study of the craniofacial complex growth. Detection and correction of malocclusions and other dental abnormalities is one of the most important and critical phases of orthodontic diagnosis. In orthodontics, information concerning the shape and positional change of a tooth is a fundamental reference for diagnostic and treatment evaluation. When an orthodontic force is applied to a tooth over a long period of time, it moves owing to resorption of the alveolar bone on the pressurized side and apposition of new bone on the opposite side. In daily practice, orthodontists carry out patient diagnosis and treatment evaluation analyzing tooth shape and movement during treatment. To do this, they base their diagnosis on the craniofacial information provided by X-ray sagital images (cephalographies) and plaster dental casts. Cast analysis is carried out using simple instruments such as a caliper and a ruler, which do not give accurate measures. Furthermore, plaster model obtention is a complex operation for the orthodontist, and a very unpleasant experience for the patient. Plaster cast storage is also a huge problem in orthodontics consultancies. Once plaster casts have been obtained, the clinician plans the orthodontic treatment to be applied to the patient (dental extraction, teeth movements and appliances). Actually treatment planning is based exclusively on clinician experience, as there is no simulation tool that allows him to visualize the time evolution of the treatment on an arcade model

ClearCorrect Exhibit 1002, Page 947 of 3373

of the patient. To modelize orthodontics treatments, the rehological behavior of both the arch-wire and the alveolar bone will be considered. The bending model of the arch-wire shows as main peculiarities the capability to operate with geometrical shapes represented by curves in space; an elastic behavior that can be linear (steel) or non-linear (NiTi, β-Titanium); and the necessity to solve an inverse problem, as we know both the unstressed and the strained configurations of the arch-wire in contact with teeth, but we don't know the value of the loads applied on each tooth by the arch-wire. The quantification of these loads has a great importance to evaluate the possibility of teeth displacement in the bone, and to simulate numerically the teeth trajectory during the orthodontic treatment. At this point we will obtain a one-dimensional simplified model from the minimum complementary energy theorem, resulting in the linear case the Castigliano theorem, which is generalizable to the non-linear case. On the other hand, to modelize the bone rehological behavior, a viscoplastic law is used. It is assumed that the strain takes place in the direction of the load transmitted by the tooth. It is also assumed that teeth interact only through the coupling induced by the arch-wire. The coupled solution will be obtained solving uncoupled problems with the following iterative scheme:

1. Being known the unstressed configuration and being established the strained configuration.
2. Strain values will be obtained in the points where the arch-wire is fixed to teeth (u_i) (fig. 1).
3. The arch-wire model will be solved, obtaining the loads (P_i) transmitted to the teeth by the arch-wire. These loads will be finally transmitted to the bone by the teeth (fig. 2).
4. Displacement for each tooth will be obtained in a time step by solving the rehological model of the bone (fig. 3).
5. Teeth positions will be actualized by obtaining the new strained configuration for the arch-wire (fig. 4).
6. The process continues iteratively until the acting stress in each tooth is lower than critical stress required to start (or maintain) the motion.

In this paper we propose an accurate and optimized 3D dental anatomy reconstruction system, starting from data captured directly from the patient's mouth with a low cost 3D digitizer, as well as a treatment editor. Furthermore, we propose a simplified model of the biomechanical behavior and a computational algorithm to simulate numerically teeth displacements in orthodontic treatments.

2 Dental anatomy 3D reconstruction

In order to reconstruct three-dimensional dental anatomy, many plaster cast measurement techniques have been attempted. An indirect technique such as stereophotogrammetry has been applied for the morphological study of the tooth [4]. Although this technique has been used successfully to measure three-dimensional shapes, it requires a sophisticated procedure to digitize shape. Direct measurement techniques have also been applied. Van der Linden et al [6]

ClearCorrect Exhibit 1002, Page 948 of 3373

have described the Optocom, which can measure x and y coordinates using a microscope, and z coordinate by mechanical contact with a dental cast. The Duret system [2] makes use of a hand-held optical probe to produce images of the patient's mouth, that are processed using Moire fringe techniques. There are two main problems with this system: the need of commercial solutions for the 3D reconstruction and the high cost of the capturing peripheral. The CEREC system [3] also uses an optical topographic scanning procedure. This system has demonstrated a great accuracy, but it can only capture and reconstruct oclusal teeth faces, and not the global 3D tooth anatomy. Yamamoto [7] has described a system for measuring three-dimensional profiles of dental casts and three-dimensional tooth movement during orthodontic treatment. The profile measurement is based on a triangulation method which detects a laser spot on a cast using an image sensor. This system does not capture directly the patient teeth anatomy, thus not avoiding the use of plaster casts, and has the additional problem of the high cost of the laser capturing system. The proposed algorithm performs an accurate 3D dental anatomy reconstruction from a few points directly captured from the patient by using an anatomical database of dental pieces. The process is divided in three phases:

2.1 Anatomy capturing

Two curves are directly captured for each tooth, as shown in fig. 6: the mesio-distal oclusal curve and the vestibular-lingual external curve. These two curves define the position and orientation of each tooth and, according to clinician suggestions and several realized tests, give a sufficiently accurate dental shape description for the orthodontists. The curves can be captured on the plaster casts or directly on the patient's mouth by means of a 3D digitizer. We have tested an ultrasonic device (Freedom from SAC, CT, USA) and a mechanical arm (Space-Arm from FARO Technologies, FL, USA), both with a customized dental probe attached. The accuracy is 0.5 mm for the sonic device and 0.3 mm for the mechanical arm. Measures taken with the mechanical arm have proved more satisfactory due to the environmental and air speed sensibility of the sonic device.

2.2 Model preparation

Once dental curves have been captured, the system adjusts automatically a standard dental model to the patient anatomy. We make use of a standard dental anatomy database in which each tooth is defined by several contours (level curves). The number of contours depends on the tooth type. Spacing between contours is lower in the region where the tooth geometry is highly variable (fosae and cuspid regions). Taking the two captured curves as preliminary information, the algorithm retrieves from the dental database the contours corresponding to the tooth type. These two curves define the mesio-distal and vestibulo-lingual ratios of the patient dental anatomy at different heights. The system adjusts and

ClearCorrect Exhibit 1002, Page 949 of 3373

scales each contour in order to fit these ratios to obtain an accurate anatomical description of each patient tooth (fig. 7).

2.3 3D reconstruction

For the 3D reconstruction from dental contours, we have implemented a version of the Delaunay 3D reconstruction algorithm [1]. This algorithm has been chosen for its important data reduction, polyhedral representation and low data processing time.

3 Biomechanic modelling

3.1 Rehological behaviour of the arch-wire

For each material we know the local stress-strain relationship:

$$\sigma = g(\epsilon) \tag{1}$$

The bending moment - curvature relationship is obtained from the equation 1, Bernoulli Kinematic hypothesis and the cross-section geometry (see figure 5):

$$\frac{-y}{\Delta dx} = \frac{\rho}{dx} \rightarrow \epsilon = -\frac{y}{\rho}$$

From this, the stress distribution results

$$\sigma = g(-\frac{y}{\rho})$$

and integrating in the cross-section it results

$$M_z = -\int_A y\, g(-\frac{y}{\rho})\, dA \tag{2}$$

We can write the bending moment - curvature relationship as:

$$\left.\begin{array}{l} M_z = f(\frac{1}{\rho}) \\ \frac{1}{\rho} = f^{-1}(M_z) \end{array}\right\}$$

Simplified model. We start from the complementary work variational formulation of the elastic problem

$$\int_\Omega \mathrm{Tr}(\underline{\underline{\epsilon}}\ \underline{\underline{\delta\sigma}})\, d\Omega = \int_{\delta\Omega} \underline{\delta F}^T\ \underline{u}\, dS$$

being $\underline{\underline{\sigma}}$ and $\underline{\underline{\epsilon}}$ the stress and strain tensors.

If we denote the complementary work by R, and a system of N concentrated loads $\underline{P}_1, \cdots, \underline{P}_N$ is applied on the elastic body, from the above equation results

ClearCorrect Exhibit 1002, Page 950 of 3373

$$\delta\bar{R} = \int_{\Omega} \delta R \, d\Omega = \sum_{i=1}^{i=N} \underline{\delta P}_i \, \underline{u}_i = \sum_{i=1}^{i=N} \left(\frac{\partial \bar{R}}{\partial \underline{P}_i} \right)^T \underline{\delta P}_i$$

From this results Castigliano's theorem

$$\frac{\partial \bar{R}}{\partial \underline{P}_i} = \underline{u}_i \qquad \forall i \in [1, \cdots, N]$$

Since $\underline{P}_i$ and $\underline{u}_i$ have the same direction, the relationship above may be written in a scalar form, although with the direction fixed by the vector load $\underline{P}_i$.

In the bending of the arch-wire, stresses are in the axes direction, thus $\delta R = \epsilon_z \, \delta\sigma_z = \epsilon \, \delta\sigma$ and from the integration in the elastic body it results

$$\delta\bar{R} = \int_L \int_S \delta R \, dS \, ds = \int_L \delta R_S \, ds$$

being L the arch-length of the arch-wire and S the cross-section. For δR_S we have the following relationship

$$\delta R_S = \int_S \delta R \, dS = \int_S \epsilon \, \delta\sigma dS = \int_S \frac{-y}{\rho} \, \delta\sigma \, dS = \frac{1}{\rho} \int_S -y \, \delta\sigma \, dS = \frac{\delta M_z}{\rho}$$

Thus, it results

$$\bar{R} = \int_L \{ \int_0^{M_z} \delta R_S \} \, ds = \int_L \{ \int_0^{M_z} \frac{\delta M_z}{\rho} \} \, ds$$

Applying Castigliano's theorem, we obtain

$$u_k = \frac{\partial \bar{R}}{\partial P_k} = \int_L \{ \frac{\partial}{\partial P_k} \int_0^{M_z} \frac{\delta M_z}{\rho} \} \, ds$$

taking into account $M_z(s) = P_1 \, \overline{M}_1(s) + \cdots + P_N \, \overline{M}_N(s)$ being $\overline{M}_i(s)$ the unitary bending diagram associated with a unitary load applied in the point i in the direction of the real load $\underline{P}_i$, results

$$\frac{\partial M_z}{\partial P_k} = \overline{M}_k$$

and using the Leibnitz integration rule

$$u_k = \int_L \frac{\partial M_z}{\partial P_k} \, \frac{1}{\rho}(M_z(s)) \, ds$$

in conclusion

$$\left. \begin{array}{l} u_k = \int_L \frac{1}{\rho} \, \overline{M}_k \, ds \\ \frac{1}{\rho} = f^{-1}(M_z) \end{array} \right\} \qquad (3)$$

ClearCorrect Exhibit 1002, Page 951 of 3373

Linearization. Equation 3 depends on the loads P_i, $i \in [1,\cdots,N]$, and this relationship is non-linear. In this case a linearization of equation 3 is required. Using a Newton-Raphson method result

$$R_k^{(n)} = u_k - \int_L \left(\frac{1}{\rho}\right)^{(n)} \overline{M}_k \, ds \quad \forall\, k \in [1,\cdots, N]$$

where (n) es the iteration number and R_k is the residual vector.
We obtain the tangent matrix from

$$R_k^{(n+1)} = 0 \approx R_k^{(n)} + \sum_{i=1}^{i=N} \left(\frac{\partial R_k}{\partial P_i}\right)^{(n)} \Delta P_i^{(n)} \quad \forall\, k \in [1,\cdots, N]$$

where

$$\left(\frac{\partial R_k}{\partial P_i}\right)^{(n)} = -\int_L \left(\frac{\partial f^{-1}(M_z)}{\partial M_z}\right)^{(n)} \overline{M}_i \, \overline{M}_k \, ds$$

Solving $\forall\, k$ we obtain $\Delta P_i^{(n)}$, and $P_i^{(n+1)} = P_i^{(n)} + \Delta P_i^{(n)}$

3.2 Bone rehological behaviour

The alveolar bone, where the teeth are located, has a behaviour characterized by an elastic component and other viscous component, with irreversible deformation. Due to this, we can consider its behaviour to be equal to an elastoviscoplastic solid. We evaluate in an uncoupled form the displacement of each tooth, with respect to the rest of teeth because they only interact in a direct form through the contact zone or through the arch wire. In this way, the analysis is reduced to an onedimensional simplified model. Asuming the initial hypothesis, we can say that the global deformation is given by the expresion:

$$\epsilon = \epsilon^e + \epsilon^v$$

The elastic component is:

$$\epsilon^e = \frac{\sigma}{E}$$

and the viscous component is, according to law:

$$\frac{d\epsilon^v}{dt} = \left(\frac{\sigma}{\lambda}\right)^N$$

where N is the viscous law exponent and λ is the viscous law coeficient.
Then:

$$\frac{d\epsilon}{dt} = \frac{1}{E}\frac{d\sigma}{dt} + \left(\frac{\sigma}{\lambda}\right)^N$$

This differential equation is solved with Finite Differences :

$$\frac{\epsilon_{i+1} - \epsilon_i}{\Delta t} = \frac{1}{E}\frac{\sigma_{i+1} - \sigma_i}{\Delta t} + \left(\frac{\sigma_{i+1}}{\lambda}\right)^N \tag{4}$$

ClearCorrect Exhibit 1002, Page 952 of 3373

On the other hand, the stress that tooth makes on the bone is determined by the arch wire deformation; and that is in relation to teeth position, so we obtain a coupled sistem.

For each time step we need to solve the bending moment of the arch wire, that is a consequence of teeth determinated position; and the deformation that we can obtain in a following time step, is a consequence of this deformation.

The expression 4 is an implicit model that results to be a non linear and coupled one. We can write this equation as an explicit model:

$$\frac{\epsilon_i - \epsilon_{i-1}}{\Delta t} = \frac{1}{E}\frac{\sigma_i - \sigma_{i-1}}{\Delta t} + \left(\frac{\sigma_i}{\lambda}\right)^N$$

expression that we can solve in an uncoupled form.

4 The 3D treatment simulation editor

In the 3D treatment simulation editor, the user can simulate different orthodontics treatments and visualize the effect on teeth movements. For this task, the system presents a 3D realistic dental arcade model of the patient and the orthodontic appliances used. Based on these models, the editor facilitates treatment simulation by providing realistic visualization of dental arcades, as shown in figure 8, and 3D navigation tools (zoom, rotations, translations, etc.). The editor allows to obtain morphometric measurements through several implemented algorithms. Using the digital arcade models, the system has information about relevant morphometric points of dental pieces, making the clinician labor in data capture and arcade analysis less time consuming. Furthermore, the system can compare automatically the morphometric measurements against ergonomic established models, enabling an automated selection of the best suited devices. In addition, the user can make direct measurement of distances on the arcade model. The editor implements several teeth movement functions. With these functions, the user can apply to each teeth several standard operations performed in orthodontics, like teeth extraction, mesio-distal translations, rotations, etc. For this task, the user can select orthodontics appliances from system libraries and place them on teeth trough placement functions (Fig 8). Then the system automatically simulates teeth movements. This feature allows to visualize on the screen the time evolution of the dental pieces due to the treatment, the movements of the dental pieces due to the application of orthodontic devices, and a space-time digital animation of a period of the treatment or the whole of it. Stereoscopic visualization has been implemented, trough stereoscopic glasses directly connected to the computer. Proposed system has been implemented in C++ language using Open-GL graphic library and can be run in PC compatible platform under Windows 95 operating system using low cost graphic accelerator cards.

ClearCorrect Exhibit 1002, Page 953 of 3373

5 Discussion and conclusions

Preliminary results are very promising showing a standard deviation of the data of 0,2 mm, and 92% of the data distributed with an error of less than 0.4 mm for 3D reconstruction method.

We have presented a new method for low cost digitizing of 3D dental anatomy andtooth movement prediction, thus enabling a low cost orthodontics global simulation system. Obtained results are very promising. The proposed techniques are being integrated in an advanced system for simulation and planning of orthodontics treatments (Magallanes). This system, in addition to the 3D treatment simulation module described here, includes an algorithm for automatically locating certain characteristic anatomical points called landmarks on cephalographies (sagital skull X-ray images). The algorithm uses digital image processing and feature recognition techniques to locate the landmarks. These features increase considerably the diagnostic and assistential quality in the orthodontic field, avoiding routine patient visits for arcade measurements and/or orthodontic devices checking.

6 Acknowledgments

MAGALLANES is a joint academic-industrial project supported by IBM Corp (Healthcare Industry Europe, Advanced Health Applications Division, Proj. contract n ° 20067). The authors express our gratitude to our clinical collaborators, the team lead by Dr. Jose Antonio Canut from the Dentistry Faculty of Valencia.

References

1. **Boissonat.** "Shape reconstruction from planar cross-sections". Comp Vis Graph and Image Processing. Vol. 44. Pp 1-29. 1988
2. **Duret, J.L. Blouin and B. Duret.** "CAD/CAM in dentistry". Journal of American Dental Association.. vol. 117. Pp. 715-720. 1988.
3. **Moermann, H. Jans, M. Brandestini, A Ferru and F. Lutz.** "Computer machined adhesive porcelain inlays: margin adaptation after fatigue stress" [Abstract]. J. Dent. Res. Vol. 65. Pp 762. 1986
4. **Rekow.** "CAD/CAM for dental restorations-some of the curious challenges". IEEE Trans. Biomedical Engineering. Vol. 38. Pp. 314-318.1991
5. **Ricketts, R. W. Bench, J. J. Hilgers, and R. Schulhof.** "An overview of computerized cephalometrics". Amer. J. Orthod. Vol. 61. Pp 1-28. 1972.
6. **Van der Linden, H. Boersma, T. Zelders, K.A. Peters, and J.H. Raaben.** "Three-dimensional analysis of dental casts by means of the Optocom". J. Dent. Res., vol. 51, p 1100. 1972
7. **Yamamoto, S. Hayashi, H. Nishikawa, S. Nakamura and T. Mikami.** "Measurement of dental cast profile and three-dimensional tooth movement during orthodontic treatment". IEEE Trans. Biomed. Eng. Vol. 38-4 pp 360-365. 1991.
8. **Nikolai, Robert J.** "Bioengineering Analysis of orthodontic Mechanics".

ClearCorrect Exhibit 1002, Page 954 of 3373

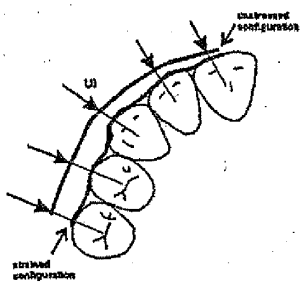


Fig. 1. Arch-wire fixed to teeth

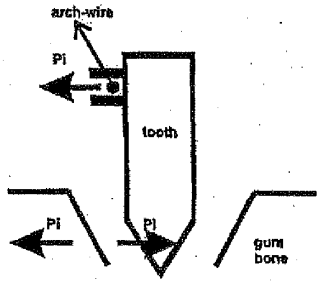


Fig. 2. Loads transmitted to teeth by arch-wire

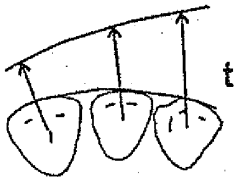


Fig. 3. Tooth position update

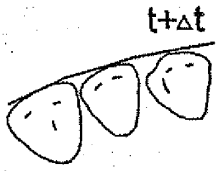


Fig. 4. Strained arch-wire update

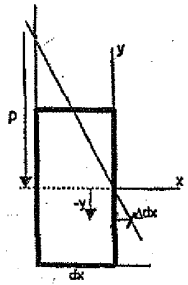


Fig. 5. Bending moment-curvature relationship

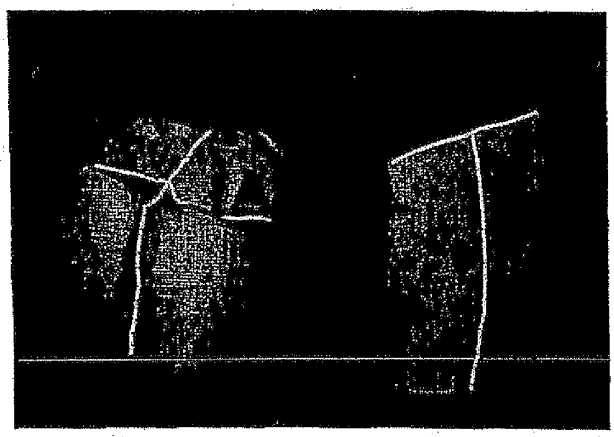


Fig. 6. Image showing the mesio–distal and vestibulo-lingual curves captured on patient mouth for first molar and central teeth



Fig. 7. Fitting process showing captured curves and tooth contours for a first molar and a central teeth

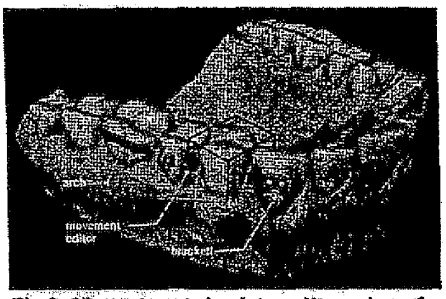


Fig 8. 3D treatment simulator editor: view of a reconstructed arcade with orthodontic appliances and movement editor tool

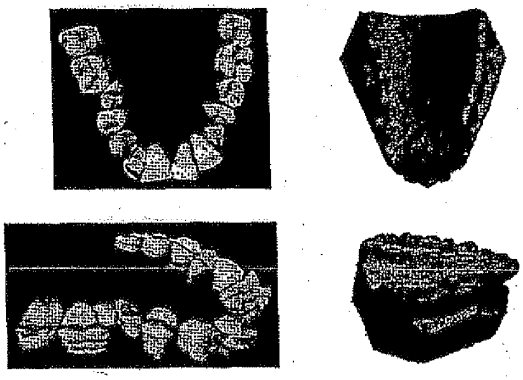


Fig. 9. Computer graphic display, using a shading method, of 3D reconstructed arcade and plaster cast of the same arcade.

The DigiGraph Work Station Part 2 Clinical Management

RICHARD G. ALEXANDER, DDS, MS
JOHN C. GORMAN, DMD, MS
DUANE C. GRUMMONS, DDS, MSD
RICHARD L. JACOBSON, DMD,MS
MARC S. LEMCHEN, DMD

The DigiGraph Work Station (Fig. 23) is a unique device that allows the clinician to perform non-radiographic cephalometric tracings and analyses, video imaging, and treatment planning, including manipulation of the patient's tracing overlaid on the video image. It also takes facial, intraoral, and model photographs (see Part 1, JCO, June 1990).

Location of the Equipment

The DigiGraph performs many record-taking functions, so the orthodontist's first inclination is usually to place it in the same room as the cephalostat and/or photographic equipment. This seems to work well when the practice also has one or more DigiGraph Consultation Stations.

In this situation, record-taking procedures require little modification. The patient is sent to the records area to have the DigiGraph records taken (Fig. 24). These records, stored on 3½" disks, are immediately transferred to the Consultation Station in the consultation room (Fig. 25).

If only one consultation unit is available, it can be kept in the operatory for on-the-spot progress and post-treatment consultations. It can easily be rolled into the consultation room if required for a case presentation.

If the main DigiGraph Work Station is the only unit in the office, the best location may not be the traditional records or x-ray area. Because the DigiGraph makes it possible to see records in the operatory and to use the records for consultations with the patient before, during, and following treatment, a popular site for offices with only one station is the consultation room or doctor's private office.

Actually, the DigiGraph may be placed in any open area of the office. Since there are no x-ray emissions, the machine can be placed almost anywhere there is space. Patients appreciate it as a symbol of the high level of technology involved in their care, and so we suggest that it be visible.

ClearCorrect Exhibit 1002, Page 957 of 3373

Information Storage

Another decision related to the DigiGraph is where to store the patient information. As discussed in Part 1, each patient has two 3½" disks (one a backup) on which all recorded DigiGraph data are stored. The first time records are taken for a patient, two blank disks are loaded into the DigiGraph. At the end of this initial session, when the information is recorded, the operator labels both disks with the patient's name and number.

It is advisable to have the two disks together only while DigiGraph records are being taken. Otherwise, they should be stored separately to minimize the chance of both disks being destroyed.

One successful approach is to keep one disk in the patient folder, and the other in a box of disks on top of or near the main DigiGraph unit. Whenever records are taken during treatment, the patient folder is brought with the patient to the DigiGraph, and both the disk in the folder and the disk stored near the DigiGraph are loaded into the machine.

The disk from the patient folder can also be used at any Consultation Station. However, records are taken at the main Work Station only and cannot be taken at the Consultation Station.

Paper, Photographic, and Slide Records

The DigiGraph can produce "hard copy" output of any screen image on three devices: a Sony video imager for 5"×7" color prints; a Polaroid freeze-frame camera (with an optional 35mm slide back for making slides); and a Hewlett Packard PaintJet printer for paper color copies.

If the office has at least one Consultation Station, there is no need to go to the time and expense of making photos, slides, or other printed copies of every patient record routinely; Sometimes, however, the orthodontist may wish to print specific pictures or slides for the patient or referring dentist.

If there is only a main DigiGraph unit in the office, it may be desirable to make hard copies of all records as they are taken. These can be stored in the patient folder along with one of the patient disks, and they can then be viewed anywhere in the office, or used for consultations, without the need for the Consultation Station.

The Initial Appointment

An important benefit of the DigiGraph is the ability to obtain and analyze diagnostic records at the first appointment, complete the consultation at the same appointment, and even

ClearCorrect Exhibit 1002, Page 958 of 3373

initiate treatment at that same appointment. Patients and their parents want to receive as much information as possible at the initial exam. In our experience, practices that seek a commitment to treatment at the first visit have a higher rate of case acceptance than those following the more traditional scheme of two to three appointments before case presentation.

One schedule for this all-inclusive first appointment that we have found successful is as follows:

The patient and parent are first taken to the consultation room. The customary short description of the office and orthodontic treatment is provided by the staff or orthodontist. The patient is then taken to the DigiGraph Work Station, where an assistant takes complete records. It will take about 10 minutes to enter all cephalometric data using the sonic digitizer, take all facial and intraoral video images, and store all records onto the floppy disks. Meanwhile, the parent can be completing forms such as the patient history and credit information.

The patient is then returned to the consultation area to receive additional information about treatment, or returned to the reception room. During this period (10 to 15 minutes), the orthodontist can analyze the records, perform Visual Treatment Objectives, and prepare the presentation.

Finally, in the consultation room (if a Consultation Station is present), or at the main DigiGraph, the doctor presents the proposed treatment plan. The patient's images, superimposed over the initial tracings, are shown to help explain the malocclusion and the need for elastics, headgear, extractions, etc. (Fig. 26). The orthodontist may choose to show a modified facial image depicting what the patient might look like following treatment. Similar cases and patients with similar appliances can also be shown.

The fee is presented, and if the patient or parent accepts, any required radiographs and impressions are taken. If time has been reserved, the initial clinical appointment can be started.

If the patient initially appears uncertain about the need for treatment, it may be helpful to take a frontal or lateral video image of the patient with the DigiGraph rather than the entire diagnostic series. Then the doctor can discuss the screen image and manipulate it so the patient can more easily see the potential benefits of orthodontic treatment (Fig. 27). After this discussion, the patient may elect to have full DigiGraph records taken.

Monitoring Progress and Cooperation

An operatory station is especially valuable during treatment. The DigiGraph provides the ability to recall intraoral images from previous appointments for comparison to what the

ClearCorrect Exhibit 1002, Page 959 of 3373

clinician observes in the patient's mouth at that moment (Fig. 28). It's easier to remember what went on at the last visit when one can visually demonstrate dental changes.

Since there is no radiation exposure from the DigiGraph, an updated cephalometric analysis can be performed as often as desired. This allows the orthodontist to monitor the patient more thoroughly, to gain more control over treatment, and to intercept potential problems earlier. The DigiGraph appeals to those who have been in practice a number of years and have stopped taking progress cephalograms in the interest of radiation hygiene.

Progress records can be taken in a few minutes at any appointment. The patient is escorted, along with the treatment folder, to the DigiGraph Work Station, and the desired records are taken. The patient returns with the folder to the operatory. If there is a Consultation Station in the operatory, the disk is loaded from the folder into the DigiGraph, and the clinician can call up the old and new records for viewing. If the office has only one unit, hard copies of the new records are put into the patient folder along with the disk.

Post-Treatment Records

Most orthodontists take post-treatment records, often with the underlying motive of protection against any future legal procedures. However, an important positive use of records is to evaluate post-orthodontic needs, while increasing patient and parent appreciation of the high quality of care received.

How many doctors have collected posttreatment records over the years intending to see how specific mechanics affected certain malocclusions, but never had time to follow through? One would have to go through hundreds of radiographs, tracings, models, and photos to collect the sample. Then one would have to compare measurements manually and do some sort of analysis. Very few of us have that much time.

The DigiGraph stores a set of summary data for each patient on the unit's hard disk. Such information as patient name, number, age, race, sex, and malocclusion classification can be retrieved simply by turning on the DigiGraph. (It is not possible to store complete patient data on the hard disk, because the video images would quickly fill up the disk.) To find cases with specific pretreatment characteristics, one merely runs a "sort" on the complete list of patients . The names of all patients matching these characteristics will appear on the monitor. At that point, the appropriate patient disks can be loaded into the machine to begin analyzing the data. This makes it easier to see if that new technique really speeds up treatment time, or produces more consistent results.

Post-Treatment Consultation

Because orthodontics is a gradual process, many patients forget how much their

ClearCorrect Exhibit 1002, Page 960 of 3373

appearance changed during treatment. The DigiGraph offers the opportunity to show the patient video images that graphically illustrate improved appearance as a result of orthodontic treatment.

Immediately after debonding, new DigiGraph records can be taken, and the post-treatment consultation can be presented by the doctor or staff member.

One of the highlights of the consultation is the presentation of "before and after" images on the screen (Fig. 29). A printed copy of this image can be made immediately and given to the patient and family to take home. This is an outstanding marketing tool, as happy patients will show the pictures to friends and relatives while discussing their orthodontic treatment and orthodontist.

Patient Reactions

Based on our early use of the DigiGraph, patients and parents tend to be impressed by several aspects of the system:

1. Patients can see more clearly their present dentofacial status. It becomes apparent after using the DigiGraph that most patients never completely understood the significance of radiographs, tracings, and models. In fact, many are put off by the records. This is especially evident in consultations with parents whose older children were given a more traditional presentation. Many comments have been made about how the DigiGraph approach is much easier to understand. Now, when the orthodontist begins the diagnostic portion of the consultation by showing the lateral image with the tracing superimposed and says, "This is you", the patient knows exactly what the doctor means.
2. Patients and parents understand more about what treatment can accomplish. It is surprising how often patients, even those with severe maxillomandibular imbalances, do not know that orthodontics can change facial appearance dramatically. Most people think that orthodontics is simply for straightening teeth. It is surprising how often a patient, upon seeing the proposed improved facial appearance in photographic form, becomes more enthusiastic and ready to start treatment.

On the other hand, there are times when compromises in the facial balance are required to treat the case without orthognathic surgery or extractions. It is important for the patient to be aware prior to treatment of the limitations involved. From a legal standpoint, clearly informing the patient and parent of the treatment alternatives and limitations is the most important part of a case presentation.

3. Patients are more accepting of headgear, elastics, extractions, and orthognathic surgery. The two most common questions asked by patients and parents in consultations involve

ClearCorrect Exhibit 1002, Page 961 of 3373

extractions and the need for headgear. If the orthodontist can demonstrate visually how extractions would improve the patient's appearance, the patient can assume a more active role in the treatment decisions. After seeing how the headgear will improve the profile, the patient will be more highly motivated to wear it diligently. Many cooperation problems are the result of not understanding the benefits of following the treatment plan.
4. X-ray exposure can be eliminated or reduced, even if a panoramic x-ray and perhaps an initial cephalogram are still taken. Many patients and parents have heard about the dangers associated with radiation exposure. Explanations about grids, screens, and the minimal dosage associated with cephalograms do not completely assuage the fears. Have you ever asked prospective patients whether they are concerned about x-rays? You might be surprised at the results of an informal survey.
5. Patients like the DigiGraph's up-to-date image. Many patients are aware of similar developments in the fields of facial reconstruction, aerospace design, diagnostic imaging, cosmetology, optometry, hair styling, and other fields. People are ever more impressed with video displays and computers. Patients talk about "this new video machine at the orthodontist's office" to their friends. When given photographic output from the machine, they almost always show the pictures to others.

Orthodontist Reactions

Orthodontists who have used the DigiGraph cite several benefits beyond patient acceptance:

1. Treatment can be initiated as soon as desired, even at the first appointment. There's no need to "best guess" a preliminary treatment plan to satisfy initial patient curiosity and then change plans at the consultation appointment. Moreover, because of the clear and understandable presentation at the initial appointment, more patients are willing to accept treatment. Beginning treatment at the initial appointment insures highly motivated patients. Waiting three or four weeks invites wavering in the decision to commit to treatment.
2. Diagnostic records can be taken more easily, reliably, and quickly. There are never any cephalograms that don't come out or intraoral photos that were not taken properly. As the clinician or assistant takes the records, the outcome is visible on the monitor. Therefore, there is never a need to call a patient back to retake records. There is no gap of several days or weeks while film is being developed, and film-processing costs are greatly decreased or eliminated.
3. Storage space can be reduced considerably. Many offices are filled with dental casts and diagnostic-record folders. The 3½" disks occupy much less space. Tracings, photos, and other records can be printed in paper or photographic form only as needed. Even headfilms can be recorded on the DigiGraph by attaching a light box to the head holder and taking video images. According to the American Dental Association, in many states it is now legal to save

ClearCorrect Exhibit 1002, Page 962 of 3373

video images of models rather than the models themselves.
4. Aside from the potential increase in patient starts, a number of clinicians have found DigiGraph usage to increase per-case income. Many assess an additional fee for DigiGraph records, and some of these offer the patient the choice of whether to have DigiGraph or conventional records taken. Some orthodontists who use x-ray labs or diagnostic services have reduced expenses in those areas; fees that used to go to the lab or service are being retained in the practice.

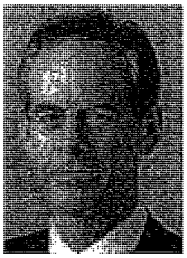
Conclusion

The DigiGraph Work Station allows the patient to understand thoroughly, prior to treatment, what can and cannot be expected, increasing the desire for treatment and willingness to cooperate. It provides information for the orthodontist to plan treatment during the initial appointment, and to start treatment immediately if desired. It offers comprehensive treatment-monitoring information without exposing patients to additional radiation.

It allows all of a patient's radiographs, tracings, cephalograms, photos, and models to be stored on one small disk, thereby reducing storage requirements. Most of all, it is a valuable tool for improving communication among orthodontists, patients, and staff.

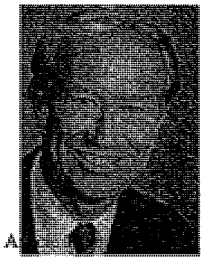
(TO BE CONTINUED)

RICHARD G. ALEXANDER



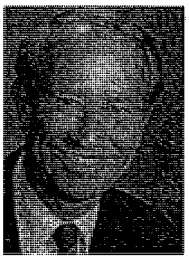
Dr. Alexander is in the private practice of orthodontics in Arlington, TX.

JOHN C. GORMAN



A

ClearCorrect Exhibit 1002, Page 963 of 3373



Dr. Gorman is in the private practice of orthodontics in Marion, IN.

DUANE C. GRUMMONS



Dr. Grummons is in the private practice of orthodontics in Marina del Rey, CA.

RICHARD L. JACOBSON



Dr. Jacobson is in the private practice of orthodontics and is Chairman of the Ricketts Bioprogressive Institute, Pacific Palisades, CA.

MARC S. LEMCHEN





Dr. Lemchen is in the private practice of orthodontics in New York City.

Work Station

Dolphin Imaging Systems, 24841 Avenue Tibbetts, Valencia, CA 91355. Dolphin and DigiGraph are trademarks.

FIGURES

Fig. 23

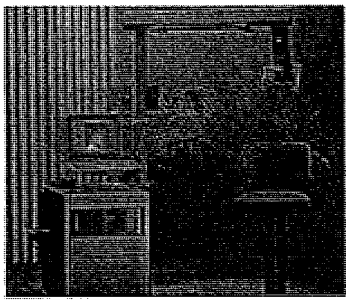


Fig. 23 DigiGraph Work Station.

ClearCorrect Exhibit 1002, Page 965 of 3373

Fig. 24



Fig. 24 Taking DigiGraph records.

Fig. 25



Fig. 25 DigiGraph Consultation Station.

ClearCorrect Exhibit 1002, Page 966 of 3373

Fig. 26



Fig. 26 Patient video image superimposed over initial tracing.

Fig. 27

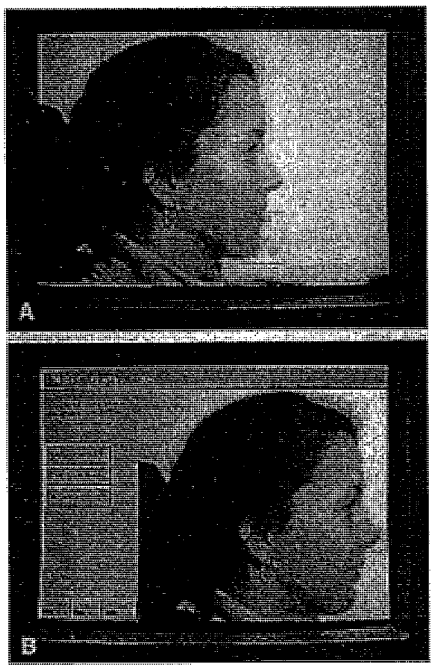


Fig. 27 Manipulation of patient screen image. Note change in chin position between A and B.

ClearCorrect Exhibit 1002, Page 967 of 3373

Fig. 28



Fig. 28 Progress intraoral records taken with DigiGraph.

Fig. 29

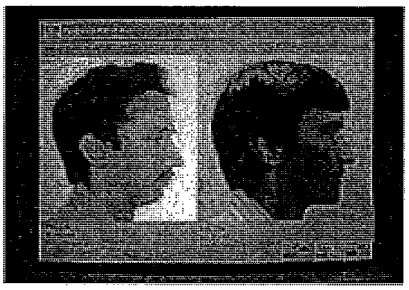


Fig. 29 "Before and after" images

ClearCorrect Exhibit 1002, Page 968 of 3373

Journal of Dental Research

January 1979 • Volume 58 • Special Issue A

RK
1
J6

PUBL

Program and Abstracts

of papers

LIBRARY
MAR 2 1979

57th General Session

International Association for Dental Research

Annual Session

American Association for Dental Research

March 29 — April 1, 1979 • New Orleans (Louisiana) Marriott

510

Analysis of 3-D Data for Comparative 3-D Serial Growth Pattern Studies of Oral-Facial Structures. M.D. ALTSCHULER,* and B.R. ALTSCHULER. Department of Computer Sciences, State University of New York and the Dental Investigation Service, USAF School of Aerospace Medicine, Brooks AFB, Texas.

Recent advances in three-dimensional imaging methodologies using remote, non-destructive testing now permit the accurate collection of three-dimensional data for use in serial growth studies of oral-facial structures. For example, dental casts collected at suitable intervals may record a patient's orthodontic rehabilitation during treatment, or may record the progress of a congenital anomaly. Non-destructive testing permits three-dimensional topographic mapping of these casts. A computer calculated topographic map defines surfaces as points in a specified coordinate system. It is extremely important that this new 3-D data is interpreted in a 3-D form. A fully 3-D mathematical technique was developed for the 3-D comparison by computers of 3-D oral-facial topographic data. Completely 3-D growth, surface, or volume analysis can be derived.

511

3-D Surface Mapping of Internal Oral-Facial Structures with a Modification of Computer Tomography. B. R. ALTSCHULER,* and G. HERMAN. Dental Investigation Service, USAF School of Aerospace Medicine, Brooks AFB, Texas; Department of Computer Sciences, State University of New York at Buffalo.

Serial computed tomographic (CT) radiographic scans of oral structures may be mathematically compiled to produce TV-like computer calculated views of the surfaces of hidden internal structures. Maxillo-facial bones, tempomandibular joint areas, and the root structures of teeth may be mathematically dissected for diagnostic display. The 3-D surfaces of the internal structures appear as if the diagnostician's eye were within the structure. Unlike a single CT scan, or series of scans, which produce single cross-sectioned slices of the volume to be inspected, the surface maps generated by the computer are holographic-like. Interactive multiplexing of views permit surface maps of internal structures with full parallax effect. A movie or a videotape can be recorded for observation and diagnostic study of the internal surface. An advanced computer programming methodology permits holographic-like viewing of internal oral-facial structures.

512

TLD Dosimetry of Critical Organ Exposure to Dental Xrays. A.M.Speiser and W.M. Kaplan. Fairleigh Dickinson University, Hackensack, New Jersey 07601

TLD dosimetry of one panagraphic, one cephalometric and six dental xray units of varying kVp and mAs was performed and compared to that of a routine screening chest xray and to ten hours of mid-day sun exposure. The dosimeters were placed in the region of each critical organ (± ½") in an Alderson-Rando Phanthom. A lead apron was not used. The TLD's were read by computer on a Teledyne TLD Reader No. 8300.

The data indicate that dental xrays appear to be safe, a full mouth series being only a fraction of a percentage of the $TD_{50/5}$ for each critical organ. However, dental xray doses to all organs exceeded that of the chest xray and of sun exposure, in many cases by orders of magnitude.

The greatest difference between dental and chest xray doses were those to the thyroid and lens.

Supported by FDU-RIA Grant #05-94-12

513

Initial Clinical Applications of Intraoral Source Radiography. C.M. SCHOENFELD*, T.M. LUND, and P.J. LIN. American Dental Association Health Foundation, Chicago. Northwestern University, Chicago.

Analytical studies have led to an expectation of the diagnostic usefulness of intraoral source radiography. In view of favorable laboratory results, initial clinical applications of intraoral source radiography were undertaken. Panaramic images of the oral-facial region were made by the intraoral source method for patients in need of screening radiographic examinations. Image receptors of different speeds were used. These included both calcium tungstate and rare earth screen-film combinations. The diagnostic usefulness of the images was subjectively compared to that of conventional techniques. Initial results revealed some problems in the geometry of projection and in the intensity distribution of the useful beam. These problems were solved respectively by positioning guides and selective filtration. Diagnostic usefulness of the intraoral source images is apparent, however, much more research is needed regarding image receptor choices, special purpose projection geometries, and the relative usefulness of intraoral source and conventional techniques for specific diagnostic tasks.

ClearCorrect Exhibit 1002, Page 970 of 3373

Laser electro-optic system for rapid three-dimensional (3-D) topographic mapping of surfaces

Martin D. Altschuler
Hospital of the University of Pennsylvania
Department of Radiation Therapy
3400 Spruce Street (Mail Stop 522)
Philadelphia, Pennsylvania 19104

Bruce R. Altschuler
United States Air Force School of Aerospace Medicine
Dental Investigation Service
Brooks AFB, Texas 78235

J. Taboada
United States Air Force School of Aerospace Medicine
Laser Effects Branch
Brooks AFB, Texas 78235

Abstract. A method is described for high-resolution remote thr dimensional mapping of an unknown and arbitrarily complex surface rapidly determining the three-dimensional locations of M×N sam points on that surface. Digital three-dimensional (3-D) locations defin a surface are acquired by (1) optically transforming a single laser be into an (expanded) array of M×N individual laser beams, (2) illuminat the surface of interest with this array of M×N (simultaneous) la beams, (3) using a programmable electro-optic modulator to very rapi switch on and off specified subsets of laser beams, thereby illuminati the surface of interest with a rapid sequence of mathematical patter (space code), (4) image recording each of the mathematical patterns they reflect off the surface using (a) a wavelength-specific optica filtered video camera positioned at a suitable perspective angulati and (b) appropriate image memory devices, (5) analyzing the stored i ages to obtain the 3-D locations of each of the M×N illuminated poi on the surface which are visible to the camera or imaging device, and determining which of the laser beams in the array do not provide refl tions visible to the imaging device. Space coding of the light bea allows automatic correlation of the camera image (of the reflected sp pattern from the surface) with the projected laser beam array, thus e abling triangulation of each illuminated surface point. Whereas ordina laser rangefinders aim and project one laser beam at a time and expe to receive one laser beam reflection (bright dot image) at a time, the pr ent system is optical (nonmechanical and vibration-free) and can colle all the data needed for high-resolution 3-D topographic mapping (of M×N sample of surface points) with the projection of as few as 1 $\log_2 N$ light patterns. In some applications involving a rapidly changi time-dependent environment, these $1 + \log_2 N$ patterns can be project simultaneously in different wavelengths to allow virtually instantaneo data collection for a surface topography. The hardware and softwa used in determining the (x,y,z) location of each surface dot can be ma highly parallel and can handle noise as well as multiple-grazing refle tions of laser beams. In common with many other active rangefind devices, the proposed method is unambiguous in determining tl topography of all nonspecular, illuminated, and visible surfaces with its operating (stereo) range, is simple to set up and calibrate, requires r *a priori* knowledge of the object to be inspected, has a high signal-t noise ratio, and is largely insensitive to material textures, pai schemes, or epidermal properties that mask surface features to inspe tion by passive topographic devices.

Keywords: three-dimensional (3-D) imaging; automated replication; robot visic topographic mapping; pattern recognition; artificial intelligence; photogra metry; electro-optics; laser; imaging.

Optical Engineering 20(6), 953-961 (November/December 1981).

CONTENTS

1. Introduction
2. Mathematical method
3. Space coding
4. Obtaining the transformation parameters
5. Optics for laser beam array generation
6. Hardware for beam array coding
7. Beam array projection onto the scene
8. Image acquisition
9. Further data processing and output
10. Discussion
11. Acknowledgments
12. References

1. INTRODUCTION

Interest in robot vision has greatly increased recently because providing a vision capability to an industrial robot would enhance its versatility and generic utility in a factory/assembly environment. For example, computer-aided manufacturing may be improved if a real-time fully-three-dimensional (3-D) computer-aided inspection system were on-line.

A standard videocamera for robot vision provides a tw dimensional image which usually contains insufficient informatic for a detailed three-dimensional reconstruction of an object. (Th is not always a problem, however, if the objects of interest in tl robot/inspection environment can be mathematically define and/or labeled in advance.)

To obtain the additional information needed for thre dimensional mapping of objects with complex surface shapes, scene can be analyzed passively by stereo photogrammetry or a tively with rangefinders and coded illumination. Passiv stereophotogrammetry generally requires a human operator t determine corresponding scene positions in different photograph

Invited Paper 5058 received Apr. 28, 1980; revised manuscript received Feb. 11, 1981; accepted for publication Feb. 16, 1981; received by Managing Editor Mar. 12, 1981. This paper is a revision of Papers 182-24 and 182-25 which were presented at the SPIE Seminar on Imaging Applications for Automated Industrial Inspection & Assembly, April 9-20, 1979, Washington, D. C. The papers presented there appear (unrefereed) in SPIE Proceedings Vol. 182.
© 1981 Society of Photo-Optical Instrumentation Engineers.

ClearCorrect Exhibit 1002, Page 971 of 3373

and is therefore too ... or real-time applications. Automated passive stereophotogrammetry requires considerable analysis.[1-3] Methods of actively interrogating a scene (by applying various kinds of light to the scene) have been used in recent years. Laser rangefinders[3,4] project one beam onto the scene at any instant; thus there is no difficulty in correlating the illuminated position in the scene with its images in each of two cameras. Although this method requires as many "images" as there are sample points in the scene, very rapid sequential laser rangefinders may soon be possible.[5] Holography requires the interference of phase coherent light beams (one beam scattered off the scene and one reference beam), but the scene must be free of vibrations, and to extract numerical data is often difficult. Three-dimensional information has also been obtained by illuminating the scene from different directions[6-11] and by applying light grids[12,13] and light stripes.[14-17] The light stripe method appears to have been adapted recently for commercial use to create 3-D busts and sculpture.[18]

The system described in this paper analyzes a sequence of laser dot patterns which are rapidly projected onto a surface and viewed from one or more suitable perspectives. An example of a system consists of

(1) a laser beam array generator:
  (a) a single laser,
  (b) a lens and shearing plate assembly that expands and partitions the primary laser beam into a two-dimensional (usually rectangular) array of, say, M × N separate laser beams (where M and N are typically about 128),[19,20]
  (c) a spatially programmable electro-optic light-modulating device to sequence the M × N beams through several (for example) binary-encoded patterns;
(2) an optical image recorder:
  (a) one or more video cameras (with wavelength-specific optical filters), each of which captures in digital form (or transmits in analog form to an A/D converter) the image of each coded pattern as reflected from the surface and seen from the particular camera perspective,
  (b) a device to synchronize all the TV cameras with the patterns generated by the electro-optic device,
  (c) a buffer storage device to hold a sequence of images, and/or a device to rapidly transfer image data to a computer;
(3) software:
  (a) software which rapidly decodes the sequence of TV images and calculates the position (x,y,z) of the surface at each visible dot,
  (b) a software warning capability which can automatically detect inconsistent or incomplete data (e.g., from incorrectly pointed TV cameras) and can suggest corrections to the operator,
  (c) software for image processing and error detection (possibly with an extra parity bit image),
  (d) software for interpolation between surface points to obtain a continuous surface,
  (e) software for fully-three-dimensional pattern recognition, motion detection, etc., depending on application.

An array of laser beams, subsets of which can be turned on and off by an electro-optic shutter under computer control, can be perceived as an "active camera." The present paper then discusses a modified method of stereophotogrammetry using one active camera and at least one "passive camera" rather than two passive cameras as in conventional stereophotogrammetry. (See also the preliminary accounts of this system.[21,22]) More than one passive camera may be used to view the projected patterns from more than one viewing angle if the surface of interest is rough or convoluted. Systems using several active cameras (projectors of laser beam arrays each at a selected wavelength) and several passive cameras can also be used for those applications requiring both low-resolution global mapping of large surfaces and simultaneous high-resolution mapping of selected areas, or where simultaneous viewing of multiple surfaces is desired, or if the surfaces of interest are changing in time.

The active-passive camera system has several advantages over strictly passive camera systems. Industrial parts of varied composition, material reflectivity, material finish, and textural or paint combinations, can produce artifacts or ambiguities when straightforward passive video imaging is used; interpretation difficulties and boundary definition for pattern recognition may become difficult especially when convolutions occur in complex shapes. The projection of discrete beams creates unambiguous reflective peaks (bright dots) on the object surface that are largely independent of surface characteristics, and are detectable despite peak intensity variation between dots on mixed textural surfaces. Natural protective coloration of biological specimens in their natural habitat could mask passive analysis but are clearly measurable using active sensing.

The projection of a laser beam array onto a surface produces a dot pattern image in a viewing camera. With highly convoluted surfaces, the dot images may appear much less ordered than the original beam array. Space coding, however, tags each column in the laser beam array so that the beam array column of each dot seen on the surface is uniquely identified no matter how randomized the dot images may become. Thus the reflected dot pattern (passive image) can be correlated automatically with the original beam array projection pattern (active image) to permit point-by-point triangulation of the sample points on the 3-D surface.

Beam reflections (bright dots) hidden from the passive camera sensor can be "detected" as missing by the software. This is done by taking attendance, that is, by matching the M × N discrete beams projected with those beams whose reflections are imaged. Knowledge of which beams are not imaged provides the feedback information needed to reposition a (passive or active) camera during automatic topographic scanning of a 3-D object.

Various stripe projection methods can also be space coded but require somewhat more analysis to provide information than does the discrete dot (beam array) method described here.

A space code for an array of beams arranged in M rows and N columns reduces the number of images, I, necessary for correlating all light spots seen on the surface to $I = 1 + \log_2 N$ (compared with $I = M \times N$ for a laser scanner), where N is also the number of columns of the electro-optic shutter which can be individually switched. For convenience, the value of N is usually chosen to be a power of two.

2. MATHEMATICAL METHOD

When an array of laser beams illuminates a surface, at least some of the illuminated surface positions can be imaged by an image recording device (e.g., a video camera) at a suitable perspective. The passive image plane then contains a large number of bright dots each caused by a light ray connecting an illuminated position on the surface with the passive camera focus. The information in the passive image plane (that is, the projection of some of the 3-D surface spots onto the 2-D image plane) is by itself insufficient to determine the 3-D positions of the illuminated spots on the surface.

Suppose an array of laser beams diverges from some focal point or laser source and passes through a transparent active image (shutter) plane. If (1) a particular laser beam (identified by its intersection with the transparent active image plane) illuminates a spot on the surface of interest, and (2) the image of that spot can be located in the passive camera plane, then the 3-D spatial position of the surface spot can be determined (just as in stereophotogrammetry) provided the homogeneous 4 × 4 transformation matrices (containing parameters of orientation, displacement, perspectivity, scaling, etc.) are known for the active camera (laser source and shutter) and the passive camera.

The passive camera image (x^*,y^*) of a point (x,y,z) in the scene is given by the perspective transformation[2,24]

$$(T_{11}-T_{14}x^*)x + (T_{21}-T_{24}x^*)y + (T_{31}-T_{34}x^*)z + (T_{41}-T_{44}x^*) = 0 \qquad (1)$$

$$(T_{12}-T_{14}y^*)x + (T_{22}-T_{24}y^*)y + (T_{32}-T_{34}y^*)z + (T_{42}-T_{44}y^*) = 0, \qquad (2)$$

If the scene-to-image transformation matrix T is known, we have for each laser dot visible to the TV camera the known quantities T_{ij}, x^*, y^* and two equations for the three unknowns x, y, z. We need one more equation. Suppose our laser beam array passes through an electro-optic shutter, so that the intersection of a beam with the shutter plane has a unique position (u,w) in that plane. Then the laser beam array can also be described in terms of a perspective transformation

$$(l_{11}-l_{14}u)x + (l_{21}-l_{24}u)y + (l_{31}-l_{34}u)z + (l_{41}-l_{44}u) = 0 \qquad (3)$$

$$(l_{12}-l_{14}w)x + (l_{22}-l_{24}w)y + (l_{32}-l_{34}w)z + (l_{42}-l_{44}w) = 0, \qquad (4)$$

where L is the scene-to-laser transformation matrix, (u,w) identifies the particular beam in the shutter plane, and (x,y,z) is (as before) the (unknown) position on the surface (in the scene) that the laser beam hits.

We apply space coding to associate with each image point (x^*,y^*) the value u of the corresponding laser beam. We then have the given quantities T_{ij}, l_{ij}, x^*, y^*, u and solve Eqs. (1), (2), (3) above for the three unknowns x, y, z provided the equations are nonsingular. Thus for each image point (x^*,y^*) we can obtain the corresponding surface position (x,y,z).

The camera equations by themselves give two equations for three unknowns and thus determine only the ray from the scene to the camera. The first equation for the laser perspective transformation (with u given by the space code) provides the plane which intersects the ray to the camera. Clearly, a well-conditioned solution for x, y, z requires that the laser and camera parameters (in particular, the laser and camera positions and the space coding planes u = const) are such that the solution rays from the camera are not nearly parallel to the mathematical planes determined by L_{ij} and u = constant. Well-conditioned solutions (accurately determined positions) should be obtainable as long as the points in the scene are not extremely distant from the camera laser system (where all distances are measured relative to the camera-laser separation distance). Once we find x, y, z, we can calculate w from the last equation so that we can later determine which laser beams (u,w) have been imaged.

3. SPACE CODING

We now describe the space coding technique. Suppose we have an M × N array of laser beams (M rows, N columns) which pass through an electro-optic shutter plane u,w. Let the centroid of beam (n,m), where $1 \le m \le M$ and $1 \le n \le N$, intersect the shutter plane at some position (u_n, w_m), such that $n-1 \le u_n/a < n$ and $m-1 \le w_m/b < m$, where a is the distance between the midlines of the adjacent columns of the laser beam array and b is the distance between the midlines of the adjacent rows of the laser beam array. With this definition, that beam of the laser beam array which passes through the shutter plane at position (u,w) is identified with the unique integer pair

$$(n,m) = (1 + \mathrm{fir}(u/a), 1 + \mathrm{fir}(w/b)), \qquad (5)$$

where fir(x) = largest integer contained in real number x.

We design the electro-optic shutter to have N separately controllable columns (one for each column of the laser beam array) so that if we apply an electric signal to one of N input wires, say wire n, the domain $\{(u,w): (n-1)a \le u < na\}$ of the laser shutter will become opaque. With such a shutter we can control which beams of the laser beam array are transmitted and which are blocked, and in this way encode patterns in the array of transmitted beams. By projecting a sequence of $I = 1 + \log_2 N$ binary laser beam patterns, we can determine uniquely, for any dot image seen in the passive image plane, the address n of the shutter column of the corresponding laser beam.

As an example, suppose we have a 200 × 16 laser beam array passing through an electro-optic shutter with 16 controllable columns labeled by 1 + fir(u/a). We then sequentially project (and image) the following patterns: (1) the entire laser beam array, (2) the higher-numbered half of the array (columns 16 through 9 transparent; columns 8 through 1 opaque), (3) alternate quarters of the array (columns 16 through 13 and 8 through 5 transparent; all others opaque), (4) alternate eighths of the array (columns 16, 15, 12, 11, 8, 7, 4, 3 transparent; all others opaque), (5) alternate columns of the array (even columns transparent; odd columns opaque). Altogether $I = 1 + \log_2 N$ patterns must be projected and imaged for a binary space code. In the case just illustrated, N = 16, so that $I = 1 + \log_2(16) = 5$. Then for any spot imaged by the camera during the first pattern (all the beams), the value of fir(u/a) of the corresponding beam in the laser beam array is given by the binary number obtained by the appearance or nonappearance of the spot in the images of subsequent patterns. For example, suppose a surface spot appears in the passive camera images of patterns 1, 2, and 4 but not in patterns 3 and 5. Then

$$\mathrm{fir}(u/a) = 1010_2 = 10$$

(corresponding to its appearance or nonappearance in patterns 2, 3, 4, 5) so that

$$n = 1 + \mathrm{fir}(u/a) = 11$$

shutter domain = {(u,w): $10\,a \le u \le 11\,a$}.

The apparatus can be set up and calibrated so that a more precise position value u_n on the shutter plane is known for each column n of the laser beam array. Thus once the shutter column $n = 1 + \mathrm{fir}(u/a)$ is determined, the value of u_n is known for the laser beam.

If the transformation parameters T_{ij} and L_{ij} are known, we can obtain (x,y,z) for each (x^*,y^*,u). Once (x,y,z) is known, w can be found with the last equation. Any beam (u,w) not visible to the camera can be found by listing all the projected beams and then eliminating from the list those that *are* visible.

In Fig. 1 we illustrate the space coding for a 6 × 8 array. Only four spots on the scene are visible to the camera in this example. The laser shutter column corresponding to each image point is found in Table I from the data of Fig. 1.

TABLE I.

Image point	Binary number	fir(u/a)	n
A	000	0	1
B	011	3	4
C	110	6	7
D	010	2	3

The space code method, which allows us to use one passive camera and one active camera, should be compared with the case of stereophotogrammetry in which one must use two cameras and know the corresponding transformation matrices T_{ij}^a, T_{ij}^b and the corresponding image points (x_a^*,y_a^*), (x_b^*,y_b^*) for the same unknown point (x,y,z) of the scene; hence four equations are solved for the three unknowns x, y, z with inconsistencies treated by least squares.[23,24]

4. OBTAINING THE TRANSFORMATION PARAMETERS

In a laboratory the camera and laser beam projector can be fixed and the parameters T_{ij} and L_{ij} measured directly.

In portable operation, as for example a medical or industrial ap-

ClearCorrect Exhibit 1002, Page 972 of 3373

Many shutters as illustrated (Fig. 3) in the laboratory demonstration, even if engineered into a filmstrip mechanical device) would be cumbersome and prone to failure. The optimum method for blocking selected columns (or rows) is to use a fixed, vibrationless, programmable spatial light modulator (PSLM) with exclusively electro-optic components and properties.

A laboratory demonstration model using a 128 (vertical) column electro-optic PSLM is seen in Fig. 5. The PSLM is visible in the center of the figure, just below the videocamera lens and above the top of the laser (Fig. 5). The tooth model and support is to the extreme right in the figure. In this photo, the PSLM has been programmed with four sets of "ON" (transmisive) blocks of columns alternating with four sets of "OFF" (opaque) blocks. Each set has sixteen successive columns "ON" or "OFF." A polarizing plate mounted in a metal frame appears just in front of the shutter. Not visible (hidden by the videocamera) is an interface and microprocessor which controls the PSLM.

Since space coding image conservation made a log-base-2 width system desirable and since standard U.S. videocameras of 480



Fig. 5. Laboratory demonstration breadboard in which an electro-optic programmable spatial light modulator (PSLM) is substituted for manual cards (illustrated in Fig. 3) to provide space coding. The PSLM blocked selected (preprogrammed) columns (or rows depending on orientation) in the projecting beam array path. The PSLM (center of photo below videocamera lens and above laser) is shown with 16 consecutive rows on, 16 off, etc., or 128 columns in which eight sets of 16 columns are alternately on (transmisive) or off (opaque or black). A microprocessor (hidden by videocamera lens) controls the PSLM pattern. Any combination of the 128 individual columns in the PSLM may be selected for transmission or opaqueness. Tooth model is at right center fixed to a magnetic mount.

useful scanned lines were available in the laboratory, a total column number of 128 was chosen for this demonstration. The PSLM module was constructed by Applied Optics Corporation (a division of ITEK Corporation) and mounted on a glass plate with a total optical (light modulating) area of 2 × 2 inches square. The module contained integral (embedded) peripheral electronics to assist in loading the pattern. Each column of electro-optic material in the shutter is individually programmable. When an appropriate voltage signal is applied to this material it will exhibit half-wave plate behavior. Since the beams in the array have definite polarization derived from the laser source, any beam passing through an energized column would be eliminated by an appropriately oriented analyzing polarizer placed beyond the shutter.

An interface was devised by Capt. Michael Tworek, USAF, so that any suitable microprocessor could be used with the PSLM. Moreover, the requirement to load the PSLM with 128 bits of clocked serial data from the microprocessor is avoided. Instead, 16-bit parallel-load-to-serial-data-out capability was created whe eight 16-bit words are loaded into the interface to properly code the 128 columns of a selected configuration. The interface matched an available Intel SBC 80/20 single-board computer to the PSLM liquid crystal materials rise time of 500 ms. Were a faster PSLM to be used, the existing interface could be redesigned with a faster clock to load a pattern in 1 ms. Two PSLM modules and interfaces were assembled in the optical path so that either vertical columns or horizontal rows, or a combination, could be space coded. Since the present PSLM module is too slow for switching between video raster scans, the preprogrammed patterns were loaded into the microprocessor and a manual binary switching method was used to reconfigure the shutter. This was sufficient to demonstrate space coding by a PSLM in an active camera. A second generation PSLM can be constructed to permit reconfiguring the PSLM columns within (and synchronized to) the vertical blanking time of a standard video raster scan, or during the erase/recovery cycle of a solid-state imaging camera. A 100 μs reconfiguration rate could be achieved with little difficulty (well within the 1.4 ms of the vertical blanking time) using PLZT material, and even 1 μs reconfiguration rates are theoretically possible for some candidate methods.[25,26] The limiting factors would then be the videocamera image acquisition and throughput/erase/recovery cycle, and the ability of a suitable device to store or process incoming data.

7. BEAM ARRAY PROJECTION ONTO THE SCENE

The choice of optics required to adjust the total area illuminated by the beam array, as patterned by the coding subsystem, is determined by the relative size and distance of the object from the beam array projector, and the resolution required for mapping the scene or surface of interest. Either a nondiverging, converging, or diverging beam array may be used to suit a particular application. A converging optical arrangement may be used to project a higher spatial frequency array onto a very small object. For example, a 10 dot/mm spatial frequency array (100 μm dot separation) has been projected onto a surface and viewed through a microscope objective. A zoom lens may quickly and conveniently alter the spatial frequency and size of the beam array projected field for multipurpose uses, or for changing from wide area to detailed scanning. Suitable rotatable and gimbal-mounted optical devices may be used to accurately control the direction of beam array projection. The laser beams in the array are focused at infinity by the beam array generating optics. The laser beam array will project through space for a considerable distance until impeded by an object or surface.

8. IMAGE ACQUISITION

A videocamera records from a suitable perspective the images of the sequence of coded beam array patterns reflected off the surface of interest. In Fig. 6, a full (128 × 128) pattern is intercepted by a 2"-diameter plaster premolar model which was bordered by black rubber. A General Electric TE26 videon camera with a CIE f/2.5 to 22 and 20 to 80 mm tele-zoom was used to record the pattern. Illumination of the object was approximately 10 μW/cm² by 514.5 nm laser light. Ambient daylight fluorescent lighting was present. A ± 10Å selective filter was used in front of the telephoto lens. The image was recorded on an IVC 1" reel-to-reel video recorder and played back on a black and white 19" monitor. A 35 mm still camera recorded this photograph (Fig. 6) during playback. A dot in the lower left corner (beyond the model) is an artifact in the monitor. Approximately three thousand sample points are visible.

Figure 7 is photographed in real time in the laboratory. Note ambient lighting levels seen in Figs. 5 and 7. A two "ON," two "OFF" alternating pattern was being projected.

Figure 8 is another image of the object shown in Figs. 6 and 7. In this image the pattern was configured with alternating eight columns on and eight columns off. Variations in dot brightness (intensity) and adjacent dot to dot spacing are caused by surface curvatures of the object.



Fig. 6. Two-inch-diameter bicuspid tooth plaster model illuminated by full beam array pattern (128 × 128). Approximately 3000 dot reflections are visible. Photo was taken of video monitor while videorecording playback. Object was illuminated with a 514.5 nm argon laser in a daylight-fluorescent lighted laboratory. Videocamera had a selective-wavelength filter in front of its lens to remove ambient lighting (black cylinder housing on videocamera lens is seen in top left of Fig. 5).

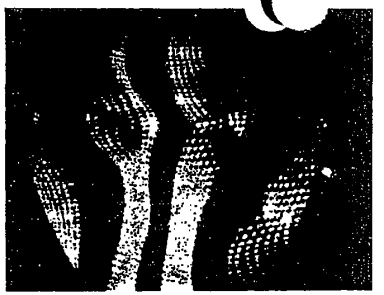


Fig. 8. Photograph of same object as in Fig. 6 but with the beam ray now coded by the PSLM into one of the binary patterns. A of eight different binary patterns are sequentially projected to pletely code a 128 × 128 beam array and tag each array colum identification in the image.



Fig. 7. Photograph of videomonitor viewing in real time a two-on-two-off consecutive pattern projected onto the tooth model. Ambient lighting in laboratory is used for this exposure.

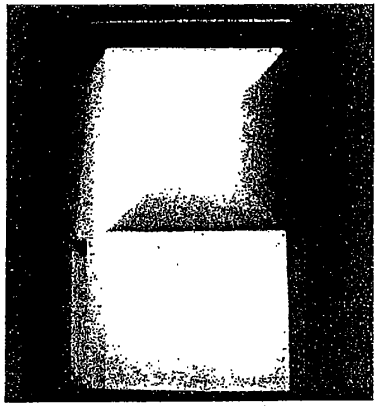


Fig. 9. White-light digitized image of prism block displayed computer graphics terminal after playback from digital (comp tape.

Figures 9 and 10 show digitized images of a prism played back from computer tape onto a Comtal display unit. Figure 10 shows the passive image of a laser beam array pattern coded by a PSLM and reflected off the prism.

For a standard composite video signal, a raster scan of each image is completed in 1/30th second. During the interval between the end of the preceding raster scan and the beginning of a new scan, the electro-optic shutter reconfigures. A microprocessor, minicomputer, or clock synchronizes the videocamera, beam array shutter, and video-recording device. A video recorder or video disk system may be used to initially record the images. An alternative method would be solid-state storage of individual video images on charge-coupled device (CCD) or random access memory (RAM) chips with high speed sequential or parallel analog to digital (A/D) conversion. A 512 × 512 × 8 pixel array from a 1/30th second raster scan may be stored in digital form (using commercially available dev with each point mutually addressable.

For a 16,000 point topographic spatial map, a total of eight coded images is required. Total storage time is thus 8/30th se (≈ 267 ms), and eight images must be stored for processing. W adequate for many applications, faster speeds are often desira If charge-injection device (CID) or CCD direct imag technologies are used, then the speed of total scene capture (the eight views for a 16,000 point 3-D) might be extremely rapid. A millisecond time cycle is reasonable for acquisition of all data re

ClearCorrect Exhibit 1002, Page 973 of 3373

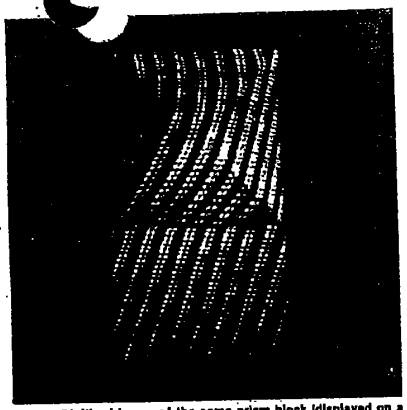


Fig. 10. Digitized image of the same prism block (displayed on a computer graphics terminal) with the 128 × 128 laser beam array shown coded by a pattern of the 128-column PSLM.

ed to define the three-dimensional coordinates (x,y,z) of a beam array projection such as the one on the bicuspid tooth model shown in Fig. 6. A 512 × 512 CID or CCD array matrix would have to be developed for rapid acquisition of data, in which the output would entail simultaneous (parallel) output of rows or blocks of rows of the array (rather than using the RS-170 output rate serial-scan methods presently used to emulate the vidicon camera raster scan). Present commercial devices have designed the imaging array output serially only, unfortunately. A parallel-processing computer, or a hierarchy of serial-processing computers would be needed to absorb data rapidly.

In certain applications pertaining to a rapidly changing environment (e.g., assembly lines, human motion, vision aids for the blind,[29] etc.), all the necessary coded images could be obtained by using a cluster of $1 + \log_2 N$ separate active cameras, each projecting a single beam array pattern at a different laser wavelength and a cluster of $1 + \log_2 N$ separate selectively filtered passive cameras, each receiving the corresponding pattern reflections in the corresponding wavelength. Such a $(1 + \log_2 N)$-fold parallel active-passive camera system would accomplish data collection for an entire topography in one cycle time. The calibration for the cluster cameras would be only slightly more complicated than for the sequential cameras.

Parallel processing of data could result in "almost instantaneous" scene capture and analysis; an updated 3-D map could possibly be calculated every second, or faster. A two millisecond scene capture with one to ten seconds minicomputer processing would be adequate for many medical and industrial applications. A high-speed synchronized cinematic process could be used as an alternative for image acquisition, but it would require a possibly unacceptable postprocessing film development delay.

One or more scene capture devices (e.g., videocameras) may be placed around the scene which is being illuminated by the space coded beam arrays. Gimbal mounts may be used for these cameras, as well as various robot arm mountings, and various electro-optic and/or acoustic aimers can be used to keep the cameras focused and centered on the scene, even if the camera(s) and beam array projector are mobile. Calibration and positioning requirements have already been discussed. Camera-projector angulations can be calculated automatically by the minicomputer dedicated to the 3-D analysis. Suitable lens systems, determined by the user for each application, are mounted on the imaging cameras.

User-defined narrow-bandpass optical filters for each relevant laser wavelength are chosen for viewing in ambient lighting conditions. If eye safety constraints require low levels of laser light for measuring human subjects,[29] image intensification may be required. A beam array pattern illuminating at 1 μW/cm² at 514.5 nm has been detected reflecting off a coarse black cardboard when appropriately selected videocameras or externally mounted image intensifiers were used.

9. FURTHER DATA PROCESSING AND OUTPUT

Data processing is required for (1) hardware control to synchronize the programmable laser-shutter encoder with the image acquisition system, and (2) the calculation of the three-dimensional number maps for the surface topography. The data processor may also verify the accuracy of the camera orientation vis-à-vis the laser surface target and warn of reflected points hidden to the camera by convolutions in the surface topography. Data output may be in the form of digitally stored numerical tables. Numerous applications and postprocessing methods are possible once a numerical table of the 3-D coordinates of sufficient sample points of a surface is available. For example, graphic display output and numerical control of machines are possible. Serial maps may be rapidly updated to discern movements and distortions occurring on a surface being scanned by the topographic system. Straightforward image subtraction techniques using sequentially generated output maps could lead to notification and 3-D vector analysis, in real time, of objects entering or moving within even the most cluttered scene area.

10. DISCUSSION

The objectives of this effort were to define and conceptually create the technological capability: (1) to obtain unambiguously and from a distance the three-dimensional coordinates of a large number of sample points of any open uncovered surface of any object (of any size) and thereby to determine the surface topography of the object, (2) to map a surface rapidly, remotely, nondestructively, and automatically, (3) to obtain, where possible, spatial data from as few as one scene-viewing direction, (4) to generate the topographic data in real time, (5) to design a simple-to-operate, self-contained, portable system whose output requires no human processing and whose setup requires no tedious calibration or excessive expertise, (6) to design a device so that its software determines insofar as possible the geometric transformations among the sensor, emitter, and scene (to enable decoding of the image data), (7) to design a system for maximum versatility and ruggedness for use in hazardous industrial, clean room clinical and surgical, and military environmental conditions, (8) to provide human or machine interactive capability for design fabrication, pattern recognition and scene analysis in three dimensions, and servo-controlled robot-vision-coupled applications.

The specific concept described and demonstrated by laboratory breadboarded means, and outlined mathematically, has certain uniquely interesting features that lend themselves to industrial and medical applications, were the concept developed further.

(1) The same apparatus could map microscopic or large-size objects merely by choosing suitable end objective lenses. The beam array is composed of discrete beams at infinite focus, so that an object intercepting a beam need not be at a predetermined distance from the origin of the array. Pattern array generation is the product of diffraction, so that the array may be enlarged or reduced at will or projected a long distance, avoiding the diffraction-limiting effects that occur when "grids" are produced with limiting apertures or masking slits. No moving parts or mechanical devices are used for array generation or for space coding, and the electro-optic candidate materials appear to have long duty cycles, possibly permitting the active camera optics to be sealed for maintenance-free use. With reasonable selection of optics, the array generation would work with most laser wavelengths or power outputs.

(2) The active (projector) and passive camera(s) can be positioned (moved) independently at arbitrary axes (e.g., on independent robot arms) for observation of the scene from different perspective directions after each set of data is acquired. Thus a fixed rotation axis for the camera system and/or the part to be inspected is not necessary.

(3) The active illumination of medical or industrial parts eliminates ambiguities obtained with passive systems due to (a) natural protective coloration, and (b) variations in reflective properties as a result of mixed textures, machine surface finishings, differing materials, coatings, and clothings. Active beam illumination creates discrete peak reflections (even if of variable amplitude) on the object surface, and a known finite array of ordered beams can be accounted for as either present or missing.

(4) Any suitable recording sensor(s) could be used for the passive camera(s). A videocamera output by whatever means could be rapidly converted to a standard TV broadcast system for remote transmission of image data in very near real time, permitting remote monitoring of automated system 3-D measurement. With lasers of different wavelengths and correspondingly filtered videocameras, more than one beam array pattern may be projected and simultaneously and independently viewed. Thus simultaneous coarse/fine scanning and global/regional scanning of a large object or parts (for positioning or comparative dimensional analysis) is possible.

(5) Gross deformations may be comparatively and accurately measured against a data base. Fully-3-D deformation analysis in gross increments is especially useful for comparison of rough castings or forgings, measurements of bubble expansion, and choosing which of a set of similar large industrial assemblies should be mated to another with the least hand fitting.

11. ACKNOWLEDGMENTS

We would like to thank our colleagues Drs. J. Posdamer and G. Frieder of the Department of Computer Science, SUNY Buffalo, for their comments and suggestions.

The work of Martin D. Altschuler was supported in part by NIH grants HL18968, HL4464, and GM-381. The other authors were supported in part by the United States Air Force School of Aerospace Medicine, Aerospace Medical Division (AFSC), Brooks AFB, Texas; Defense Advanced Research Projects Agency; Integrated Computer Aided Manufacturing (AFWAL) (AFSC); and NASA, Johnson Space Center.

We would further like to thank Capt. M. Twarek, USAF, for programming and constructing an interface for the electro-optic shutter, Col. (Dr.) J. M. Young, and Col DeHart USAFSAM, for tireless administrative ens

This paper is a work of the U.S. Gov... ...ent and may ... reproduced by the U.S. Government for its needs.

12. REFERENCES

1. Sobel, I., 3rd Int. Joint Conf. on Artificial Intelligence, 648 (197...
2. Shapira, R., 5th Int. Joint Conf. on Artificial Intelligence, 628 (197...
3. Gennery, D. B., 5th Int. Joint Conf. on Artificial Intelligence, ... (1977).
4. Moravec, H. P., CMU-RI-TR-3 (Carnegie-Mellon Robot Institute, (1980).
5. Dreyfus, M. G., Dreyfus-Pellman Corp., Contourmate 3000 Syst... (1979).
6. Lewis, R. A., and Johnston, A. R., 5th Int. Joint Conf. on Artifi... Intelligence, 762 (1977).
7. Kaneda, T., Proc. SPIE 283, 48 (1981).
8. Horn, B. K. P., MAC TR-79, MIT Project MAC (Nov. 1970).
9. Horn, B. K. P., Obtaining Shape from Shading Information, in ... *Psychology of Computer Vision* (P. H. Winston, ed.), McGraw-H... New York (1975).
10. Shirai, Y., and Tsuji, S., 2nd Int. Joint Conf. on Artificial ... telligence, 71 (1971).
11. Woodham, R. J., 5th Int. Joint Conf. on Artificial Intelligence, ... (1977).
12. Will, P. M., and Pennington, K. S., 2nd Int. Joint Conf. on Artifi... Intelligence, 66 (1971).
13. Rocker, F., and Kiessling, A., 4th Int. Joint Conf. on Artificial ... telligence, 669 (1975).
14. Sirai, Y., and Suwa, M., 2nd Int. Joint Conf. on Artificial ... telligence, 80 (1971).
15. Agin, G. J., and Binford, T. O., 3rd Int. Joint Conf. on Artificial ... telligence, 629 (1973).
16. Popplestone, R. J., Brown, C. M., Ambler, A. P., and Crawf... G. F., 4th Int. Joint Conf. on Artificial Intelligence, 668 (1975).
17. Tsuway, E. J., Proc. Symp. Comm. V, ISP Biostereometrics, 74-... 147 (1974).
18. Solid Photography advertisement with photograph of subject ... luminated by light stripes.
19. Tabuada, J., and Altschuler, B. R., Appl. Optics, 15, 897 (1976
20. Altschuler, B. R., Tabuada, J., and Segretto, V. A., Proc. SPIE ... 147 (1975).
21. Altschuler, B. R., Tabuada, J., and Altschuler, M. D., Proc. S... 182, 192 (1979).
22. Altschuler, M. D., Altschuler, B. R., and Tabuada, J., Proc. S... 182, 187 (1979).
23. Sutherland, I. E., Proc. IEEE, 62 (2), 453 (1974).
24. Rogers, D. F., and Adams, J. A., *Mathematical Elements for C... puter Graphics*, McGraw-Hill, New York (1976).
25. Land, C. E., Opt. Eng., 17 (4), 317 (1978).
26. Oliver, D. S., Opt. Eng. 17 (3), 288 (1978).
27. Blaha, W. P., Lipton, L. T., Wiener-Avnear, E., Grinberg, J., ... P. G., Casarent, D., Brown, H. B., and Markevitch, B. V., Opt. ... 17 (4), 371 (1978).
28. Crochet, J. L., Harris, D., J. O., and Laguna, G. A., Sc... Laboratories Tech. Report SLA-73-0777 (1973).
29. Altschuler, M. D., Posdamer, J. L., Frieder, G., Manthey, M... Altschuler, B. R., and Taboada, J., Proc. Int. Conf. on Cybern... and Society, ISSN 0360-8913, Cambridge, Massachusetts, p. ... Oct. 1980.

ClearCorrect Exhibit 1002, Page 974 of 3373

Measuring surfaces space-coded by a laser-projected dot matrix

Martin D. Altschuler
Medical Image Processing Group
Department of Computer Science
State University of New York at Buffalo
Amherst, New York 14226

Bruce R. Altschuler
Dental Investigation Service
USAF School of Aerospace Medicine
Brooks AFB, Texas 78235

J. Taboada
Laser Effects Branch
USAF School of Aerospace Medicine
Brooks AFB, Texas 78235

Abstract

We describe a mathematically-rigorous easy-to-use portable topographical mapping technique that within seconds or less can determine the heights of a surface at 16,000 (128x128) distinct sample points. The necessary data derive from (narrow-optical-bandpass) TV images of a surface which has been illuminated and space-coded by a rapid sequence of laser-projected dot patterns.

Introduction

A two-dimensional television or photographic image of a scene usually contains insufficient information for a three-dimensional reconstruction of the scene. To obtain the additional information needed for three-dimensional mapping, a scene can be analyzed passively by stereophotogrammetry or actively by introducing coded illumination. Generally stereophotogrammetry requires a human operator to determine corresponding scene positions in different photographs, and is therefore too slow for real-time applications. Automated stereo methods require considerable analysis[1,2]. Methods of actively interrogating a scene (by applying various kinds of light to the scene) have been used in recent years. Holography requires the interference of phase coherent light beams (one beam scattered off the scene and one reference beam) but post-analysis is often difficult. Three-dimensional information has also been obtained from illumination of the scene from different directions[3,4,5,6] and by the application of light grids[7,8] and light stripes [9,10,11,12]. The light stripe method appears to have been adapted for commercial use to create 3-D busts and sculpture[13]. As far as we can tell, however, none of these methods have been used for portable real-time surface mapping applications.

The system described in this paper analyzes a sequence of laser dot patterns which are rapidly projected onto a surface and viewed from one or more suitable perspectives. An example of a system consists of (1) a laser beam array generator: (a) a single laser, (b) a lens and shearing plate assembly that expands and partitions the primary laser beam into a two-dimensional (usually rectangular) array of say N^2 separate laser beams, (where N typically is 128)[14,15], (c) a special electro-optic device to sequence the N^2 beams through several (for example) binary-encoded patterns; (2) an optical image recorder: (a) one or more narrow bandpass TV cameras each of which captures in digital form the image of each coded pattern as reflected from the surface and seen from the particular camera perspective, (b) a device to synchronize all the TV cameras with the patterns generated by the electro-optic device; (3) software: (a) software which rapidly decodes the sequence of TV images and calculates the position (x, y, z) of the surface at each visible dot, (b) a software warning capability which can automatically detect inconsistent or incomplete data (e.g. from incorrectly pointed TV cameras) and can suggest corrections to the operator. The hardware of the system is discussed in another paper of this conference[14]. Here we describe some of the key concepts of the algorithm. Further mathematical details of this and more complex systems will be published in the literature.

Space Coding

A 2-D TV image of a surface usually does not contain sufficient information to determine the 3-D locations of the surface points. Space coding inserts information into a scene by rapidly projecting a sequence of dot matrix patterns onto the surface of interest. A TV camera records the image (appearance) of the scene for each projected pattern in the coding sequence. The minimum number of patterns (also TV images) required for coding a surface is proportional to the logarithm of the number of columns (more generally, point sets) that must be distinguished in the dot matrix. For a dot matrix with N columns we must project and image $1 + \log_2 N$ coded patterns if we are to determine the (x,y,z) position of each dot appearing on the surface. For an 8 x 8 dot matrix (64 distinct surface sample points), four coded patterns of the matrix must be projected and imaged. For a 128 x 128 dot matrix (16,384 distinct surface sample points), eight coded patterns of the matrix must be projected and imaged. Thus a significant increase in the surface resolution (the number of projected dots) can be achieved with only a small increase in the number of coded patterns

JAN-29-1992 13:55 FROM UofM College Park TO UMHS P.02

ClearCorrect Exhibit 1002, Page 975 of 3373

and images.

In Figure 1 we illustrate the basic idea of our space coding method. The upper left corner shows a 4 x 4 pattern of laser dots viewed from above. Three laser dots A,B, and C are specifically labelled. Suppose we project three patterns ($=1 + \log_2 4$) of laser dots parallel and downward onto the scene of the upper left and then image these patterns from another perspective. The first pattern consists of the entire 4 x 4 matrix array and is observed in image 1. (Only the images of dots A,B,C are shown). Since dots A,B,C are all visible to the camera, there are (in this case) no obstructions of background dots by foreground peaks and rises of the surface. The second pattern projects dots only on columns 11 and 10 of the scene and the third pattern projects dots on columns 11 and 01. Point A of image 1 also appears in image 2 but not in image 3. Point B appears in image 3 but not in image 2, and point C appears in neither image 2 nor image 3. The space code of a laser dot appearing first in image 1 is just the two-bit binary number with the bits corresponding to the appearance (1) or non-appearance (0) of the dot in images 2 and 3 (see lower left of figure 1). The binary number of the space code gives the column of the scene on which the laser dot fell. For N columns of dots, the code would require $\log_2 N$ bits, thus $\log_2 N$ patterns and associated TV images plus an initial full dot pattern and image to identify the visible dots.

The TV image (x^*, y^*) of a point (x,y,z) in the scene is given by the (perspective) transformation[16,17]

$$(T_{11} - T_{14}x^*)x + (T_{21} - T_{24}x^*)y + (T_{31} - T_{34}x^*)z + (T_{41} - T_{44}x^*) = 0$$

$$(T_{12} - T_{14}y^*)x + (T_{22} - T_{24}y^*)y + (T_{32} - T_{34}y^*)z + (T_{42} - T_{44}y^*) = 0$$

In our example of parallel downward beam projection, the space code provides the value of x for each laser dot. If the scene-to-image transformation matrix T is known and the columns are space coded, we have for each laser dot visible to the TV camera the known quantities T_{ij}, x^*, y^*, x and two equations for the two unknowns y and z. For a well-conditioned solution, the camera must be some angle away from the y-z plane and such that the two lines in the y-z plane corresponding to these two equations are not nearly parallel.

We have just discussed the very special case of parallel downward beam array projection. In a more general case, the laser beams can be divergent and need not shine straight down on a surface. We can then conceptualize the laser array of N^2 beams as a "reverse camera" which projects from the "image" (shutter) plane to the scene. Instead of being given the value x (of a point in the scene) by the space code we are now given another "perspective" transformation for the laser beam array

$$(L_{11} - L_{14}u)x + (L_{21} - L_{24}u)y + (L_{31} - L_{34}u)z + (L_{41} - L_{44}u) = 0$$

$$(L_{12} - L_{14}v)x + (L_{22} - L_{24}v)y + (L_{32} - L_{34}v)z + (L_{42} - L_{44}v) = 0$$

where L is the scene-to-laser transformation matrix, (u,v) identifies the particular beam in the projected beam array, and (x,y,z) is (as before) the position on the surface (in the scene) that the laser beam hits. The space coding now associates with each point seen in the camera image the corresponding shutter column u of the laser beam array. Ignoring the second equation (since we do not yet know the shutter row v associated with a given image point) and assuming the matrix L is known, we solve the two equations given earlier for the camera together with the first equation for the laser beam array to obtain the three unknowns x, y, z. That is, we are given T_{ij}, L_{ij}, x^*, y^*, u and solve the first three equations of this section for the three unknowns x, y, z (provided the equations are non-singular). The camera equations by themselves give two equations for three unknowns and thus determine only the ray from the camera to the scene. The first equation for the laser "perspective" transformation (with u given by the space code) provides the plane which intersects the ray from the camera. Clearly, a well-conditioned solution for x, y, z requires that the laser and camera parameters (in particular, the laser and camera positions and the space-coding planes u = const) are such that the solution rays from the camera are not nearly parallel to the mathematical planes determined by L_{ij} and u = constant. Points in the scene very distant from both the camera and the laser source positions will be ill-conditioned (inaccurate). Thus our proposed system has a limited range of accuracy which depends primarily on the camera-laser separation distance. Once we find x, y, z, we can calculate v from the last equation so that we can later determine which laser beams (u,v) have been imaged. The parallel downward beam projection illustrated in Figure 1 is the special case $L_{ij} = 1$ if i = j and $L_{ij} = 0$ if $i \neq j$, so that x = u.

The space code method, which allows us to use only one camera (if all the dots of interest are visible), should be compared with the case of stereophotogrammetry in which one must use two cameras and know the corresponding transformation matrices $T_{ij}^{(1)}$, $T_{ij}^{(2)}$ and the corresponding image points (x_1^*, y_1^*), (x_2^*, y_2^*) for the same unknown point (x, y, z) of the scene; hence four equations are solved for the three unknowns x, y, z with inconsistencies treated by least squares[16,17].

JAN-29-1992 14:00 FROM Lehman College Bank TO UMHS P.03

ClearCorrect Exhibit 1002, Page 976 of 3373

Transformation Parameters

Several methods can be used to obtain the transformation parameters T_{ij} and/or L_{ij}. The transformation matrix L can be assumed known from sensors and measurements of the laser beam or can be found by flashing particular laser beams (u_a, v_a) onto six non-coplanar points of known location (x_a, y_a, z_a) where $a = 1, \ldots, 6$. We then have 12 equations for the 12 unknowns L_{ij}. Similarly to find the transformation matrix T we need to insert six non-coplanar reference points in the scene[16,17], that is, six non-coplanar reference points each of known location (x_a, y_a, z_a) and image position (x_a^*, y_a^*). (The six points can be those just mentioned to find the laser matrix L). We then have 12 equations for the 12 unknowns T_{ij}. If there is a reference region in the scene, the transformation matrices T and L can be found automatically.

It is also possible to find T for the camera given L for the laser without introducing any known points into the scene itself. In this case the unknowns are x, y, z for each point in the scene used for calibration together with the 12 unknown T_{ij}. For each point (x, y, z) we solve the two laser equations and obtain one equation for a ray with a single unknown parameter. The problem then reduces to solving the 12 unknowns T_{ij} and as many unknown parameters as there are rays (dots in the scene) used for calibration. For each calibration ray we introduce one unknown and obtain two equations. With 12 calibration rays we would have 24 unknowns (12 for T_{ij} and 12 unknown parameters) and 24 equations. Although the equations are nonlinear in complete generality, some a priori knowledge can be assumed and iterative methods can be used to find the T_{ij}. This method is being worked out in collaboration with J. Posdamer of SUNY Buffalo.

The easiest situation of all would be to do all calculations relative to a coordinate system fixed to the laser projector and to sense independently the camera orientation and other parameters with respect to this reference frame. Again, no reference points in the scene would be required.

The Algorithm

1. The user selects or fixes the parameters of the dot array to be projected on the scene (assume N columns of dots are chosen).
2. The operator points the laser and the cameras to some area of the scene. (There is no need to predetermine the coordinate transformations by arduous calibration).
3. The operator pushes a button and the computer takes over the rest of the procedure.
4. The computer automatically projects a sequence of $(1 + \log_2 N)$ coded dot patterns for coding by columns.
5. The corresponding TV images of each projected coded dot pattern are obtained.
6. In each image, the brightness peaks (laser dot images) are located.
   The space code of each laser dot is found by comparing brightnesses at corresponding dot locations in consecutive images from a given perspective.
8. The parameters of the scene-to-image and/or laser-to-scene coordinate transformations are calculated automatically either (a) by recognizing reference points in the scene, (b) knowing the laser parameters and solving for the camera parameters without introducing reference points in the scene, or (c) using laser coordinates and being able to determine the camera orientation and parameters with respect to those coordinates.
9. The (x,y,z) location of each visible laser dot and the (u,v) identity of any unseen laser beam are found and recorded.

Error checks are built into every step of the algorithm.

Design Factors

Our primary design factors in developing a 3-D surface-mapping system have been to achieve (1) portability of the entire system (hardware and software), (2) simplicity of use, with automatic determination of the parameters of coordinate transformation, (3) fail-safe operation of the system with regard to spurious data and inconsistencies from one camera to the next, (4) real-time capability, (5) high signal-to-noise ratio under daytime operation and for varied surface textures, (6) adaptability, that is, a system to which can be added additional software related to computer graphics, 3-D pattern recognition, variable spacing of the beam pattern under operator or automatic control, etc., (7) continual monitoring of the quality of the calculation during operation (whenever possible).

The present system for surface mapping is designed to be portable with little or no set-up time. All angles, scale lengths, translations, and other parameters required to transform from the coordinates of the actual surface to the coordinates of the TV image are directly obtainable by computer analysis of the space-coded images of the scene. This means that it is not necessary to fix the laser projector and the cameras and then carry out extensive and careful angle and position calibration prior to use of the system. A user need only point his laser and his cameras and press the button for automatic sequencing of the electro-optic shutter (in less than a second) through the necessary space-coded patterns (with image capture by synchronized TV cameras). The computer then extracts the necessary data from the images and calculates the height of the surface at each observed reflected dot.

JAN-29-1992 14:00 FROM UofM College Park TO UMHS P.04
JAN-29-1992 14:02 FROM UofM College Park TO UMHS P.06

ClearCorrect Exhibit 1002, Page 977 of 3373

fail-safe operation is essential for portable equipment. The software includes a hierarchy of error checks. If there are any inconsistencies in the data, for example, if a camera is pointed away from the space-coded area or sees only a fraction of the space-coded surface, the computer will provide detailed error messages. In fact, the greatest effort in implementing the present system has turned out to be not the mathematics as much as the "idiot-proofing" or the "fail-safing" of the system to ensure that the incoming data is not "garbage" (that is, TV images which are totally uncorrelated to the scene of interest, incomplete in scene coverage, falsified by jamming with stray laser beams, obtained with a poor choice of camera angle so that the analysis is ill-conditioned, incapable of adequately sampling the reflected dot pattern, etc.) This failsafe effort in the software is essential for the reliability of any portable surface mapping device.

Another objective has been to obtain real-time capability, which for a medical/dental clinical application is about a second from the time the laser projector begins its sequencing to the time the analysis of the surface is completed. Applications of real time surface mapping are manifold. A dentist would like to verify the surface mapping of his patient's dentition or oral-facial structures for prosthetic impressionless measurement prior to surgery. A manager would like to inspect an assembly line as various components are added to (say) engine blocks or to inspect molds or mold-injection formed parts. Military aircraft and systems could possibly optically map the surface terrain in 3-D and plot course corrections within fractions of a second if high speed hardware could be devised for this purpose.

The computer program presently operational on a Data General S-200 Eclipse minicomputer is a serial program written in standard Fortran. Thus far it has been tested and debugged only on computer-simulated data, so no time estimates are yet available. (For simple 32x32 simulated raster images, the calculation requires less than a second). The program is expected to be very fast in actual operation because it does not do "scene analysis" on the entire TV image but immediately extracts from the TV scans just the image locations of the laser dots. Analysis on the (say) 128x128 laser dot images is much faster than the analysis of an entire TV raster of (say) 512x512 pixels.

Extremely rapid image analysis is possible with solid state non-raster (no electron beam) video devices. Were the algorithm programmed for parallel processing, the extraction of the image positions of the laser dots would be even faster; we estimate that a 128x128 matrix of laser dots could be analyzed in less than a second with present off-the-shelf hardware. Such hardware designs will be discussed elsewhere.

Because monochromatic laser sources are used together with TV cameras tuned to the same narrow optical bandpass region, a high signal to noise ratio is expected even with daytime operation and textured surfaces. The phase coherence property of the laser beam is not used in the imaging process, so that special vibration-free environments are not needed.

A highly convoluted terrain could well obstruct many of the reflected laser dots from observation by a particular TV camera. In the present program, any beams of the laser-projected pattern that cannot be seen by any of the TV cameras are placed on a list and their (u,v) identities are mapped at the end of the calculation. It is possible to have the computer calculate upper limits on the heights of these hidden dots.

The present program allows the user to preset the dot spacings and other parameters and thereby increase the surface resolution at the expense of the surface area interrogated, or vice versa. Not yet implemented is the automatic adjustment of parameters according to the calculated curvature or convolution of the interrogated surface.

Conclusions

We have described a portable, fast, mathematically-rigorous topographical mapping technique whose design feasibility has been tested with hardware and software. The purpose of the system is to preprocess raw scene data into useful 3-D information for input into pattern (and moving-object) recognition programs and industrial and medical applications.

This effort was sponsored by the USAF School of Aerospace Medicine, Brooks AFB, Texas and the Defense Advanced Research Projects Agency, ARPA Order No. 3639/1. Martin D. Altschuler was supported in part by NIH grants GM-381, HL18968, HL4664 and RR7.

Acknowledgments

We would like to thank Drs. J. Posdamer and G. Frieder of SUNY Buffalo for their comments on this manuscript, and to B. Dane for typing this manuscript.

References

1. Sobel, I., 3rd International Joint Conference on Artificial Intelligence, 648, 1973.
2. Shapira, R., 5th International Joint Conference on Artificial Intelligence, 628, 1977.
3. Horn, B.K.P., "Shape From Shading", MAC TR-79, MIT Project MAC, Nov. 1970.
4. Horn, B.K.P., "Obtaining Shape From Shading Information", in The Psychology of Computer Vision, P.H. Winston (ed.), McGraw-Hill 1975.

JAN-29-1992 14:01 FROM UofM College Park TO UMHS P.05
JAN-29-1992 14:02 FROM UofM College Park TO UMHS P.06

ClearCorrect Exhibit 1002, Page 978 of 3373

5. Shirai, Y. and Tsuji, S., 2nd International Joint Conference on Artificial Intelligence, 71, 1971.
6. Woodham, R.J., 5th International Joint Conference on Artificial Intelligence, 635, 1977.
7. Will, P.M. and Pennington, K.S., 2nd International Joint Conference on Artificial Intelligence, 66, 1971.
8. Bocker, F. and Klessling, A., 4th International Joint Conference on Artificial Intelligence, 669, 1975.
9. Sirat, Y. and Suwa, M., 2nd International Joint Conference on Artificial Intelligence, 80, 1971.
10. Agin, G.J. and Binford, T.O., 3rd International Joint Conference on Artificial Intelligence, 629, 1972.
11. Popplestone, R.J., Brown, C.M., Ambler, A.P. and Crawford, G.F., 4th International Joint Conference on Artificial Intelligence, 668, 1975.
12. Lovesay, E.J., Proc. Symp. Comm. V, ISP Biosteriometrics, 74-311: 147-153, 1974.
13. Solid Photography advertisement with photograph of subject illuminated by light stripes.
14. Altschuler, B.R., Taboada, J. and Altschuler, M.D., SPIE Proceedings 182 (these proceedings).
15. Taboada, J. and Altschuler, B.R., Appl. Optics 15, 597, 1976.
16. Sutherland, I.E., Proc. IEEE, 62, (2), 453, 1974.
17. Rogers, D.F. and Adams, J.A., Mathematical Elements for Computer Graphics, McGraw Hill, 1976.

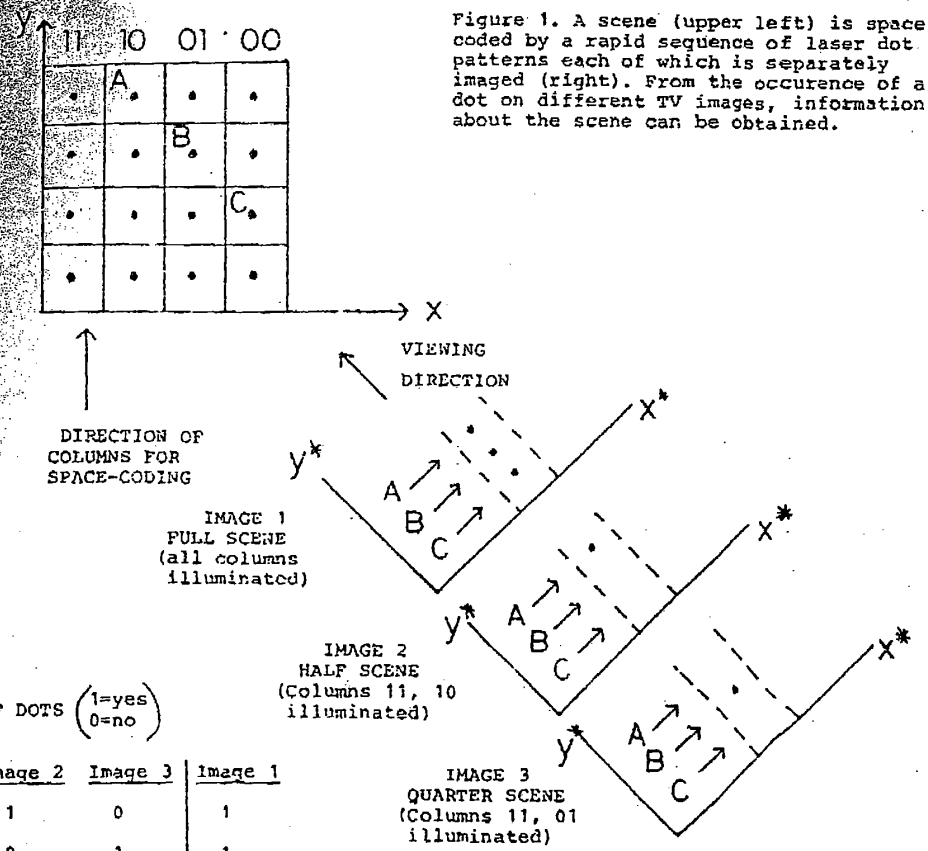


Figure 1. A scene (upper left) is space coded by a rapid sequence of laser dot patterns each of which is separately imaged (right). From the occurence of a dot on different TV images, information about the scene can be obtained.

VISIBILITY OF DOTS (1=yes, 0=no)

Image dot	Image 2	Image 3	Image 1
A	1	0	1
B	0	1	1
C	0	0	1
	Space Code		

ClearCorrect Exhibit 1002, Page 979 of 3373

605

Dental Appointment and Medical Appointment Behaviors of Dentists. E.W. MITCHELL*, A. NOWE, C. MALEWAY, and W.A. AYER. American Dental Association Research Institute, Chicago, IL.

Regular medical and dental checkups are recommended by health professionals as a means of preventing or identifying disease at its initial stages of development. To date, little information exists regarding the extent to which professionals comply with their own recommendations. As part of the 1978 Health Screening Program at the American Dental Association's Annual Meeting, participants were requested to indicate when they had last been to a dentist and a physician and the reasons for their visits. Some 1,160 dentists completed the questionnaire. The mean age of all dentists surveyed was 48.2 years of age and 81.8% were in general practice. Some 59.1% reported going to a physician within the last year, with 74.2% of these going for a routine physical examination. These findings will be discussed in relation to these behaviors in the general public and their implications for general compliance behaviors.

Supported by grants from the S.S. White Company, American Fund for Dental Health and the Warner-Lambert Foundation.

606

Career Satisfaction of Dentists in Relation to their Work Structure. P. YABLON.*School of Dental and Oral Surgery, Columbia University, New York.

This paper is part of a larger research project which examines relationships between career satisfaction of dentists with various factors in their professional and personal lives. The purpose of this part of the study was to look at career satisfaction in relation to the following structure of work variables: 1) Main Activity, 2) Social class of patients treated, 3) Average number of hours worked per week. Work satisfaction was trichotomized into intrinsic satisfaction, extrinsic satisfaction and overall career satisfaction. Indices were then developed for each category.
The data for this research was collected in 1977 by mail survey of Columbia Dental School graduates from 1920-1976. N=1172 for a 53% response rate.
It was found that specialists were significantly more satisfied than general practitioners on all three satisfaction scales, ($P<.01$). Dentists usually treating higher social class patients also were more satisfied on all satisfaction indices, ($P<.01$). Those dentists working more than 40 hours per week were high on the intrinsic satisfaction scale ($P<.001$), as compared to those dentists working less than 40 hours per week. The dentists highest on the overall index were those who worked more than 60 hours per week. One conclusion drawn from this data is that underachieving in the area of work is detrimental to positive career satisfaction. It can also be concluded that greater rewards are perceived by those dentists practicing within a specialty status as well as those who usually treat higher social class patients.

607

3-D Mapping of Maxillo-facial Prostheses. B.R.ALTSCHULER*[1], J.M.YOUNG[1], M.D.ALTSCHULER[2], G.FRIEDER[2]. Dental Investigation Service, USAF School of Aerospace Medicine, Brooks AFB, TX[1], and Medical Image Processing Group, SUNY at Buffalo[2].

Three-dimensional remote mapping of maxillo-facial structures was performed in-vitro on facial casts using a projected laser array and a uniquely programmable electro-optic spatial light modulator system. Scene capture was by still photography. A video digitizer translated image data to computer compatible format. Data processing algorithms calculated maps which contain fully three-dimensional information suitable for numerical controlled fabrication of replicated prostheses and for correlative comparison of paired (left/right)anatomic features.
The electro-optic spatial light modulator was programmed for semi-automatic reconfiguration through manual control of a microprocessor. Completely automated reconfiguration by a host computer permits image capture by video recording means.
A maxillo-facial prostheses and an ear prostheses were topographically mapped. Remote, non-contacting measurement may lead to fabrication techniques for more accurately fitting and esthetic facial prostheses.

608

Comparison of Methods for Measuring Plaque on Dentures. M. GHALICHERAF*, G. N. GRASER, E. SOLOMON and N. A. ZANDER. Eastman Dental Center, Rochester, New York.

Different methods have been used for determining plaque on dentures. The purpose of this study is to compare staining methodology with protein measurements.
Fifteen subjects with a complete maxillary denture were selected. A 1 cm. x 1 cm. piece of the inside surface of the denture was cut out so that removable methylmethacrylate sections could be inserted and removed for evaluation. The dentures were thoroughly cleaned in an L & R ultrasonic cleaner. The subjects wore the dentures for 24 hours with no cleaning allowed. The dentures were then removed and the piece and denture were individually sonicated for 10 minutes in a 0.5N NaOH solution. Plaque determination was assessed by protein analysis (Lowry). The dentures were again cleaned and a new piece placed in the denture and worn for 24 hours. This time the section and denture were stained for plaque using 5% Erythrosine. The piece was then analyzed with step serial sections and the tissue surface of the denture by the percentage of stained plaque. All procedures were repeated using a calgon-chlorox solution and performing both methods of plaque analysis for the denture and the piece. There was a negative correlation between protein and staining ($r=-.693$). A positive relation was found between protein determination on the whole denture and the piece ($r=+.750$) and with staining on the underside of the denture with the percentage of plaque on the sectioned piece ($r=+.584$). All methods showed a significant reduction in plaque after calgon-chlorox soak ($P<.004$).

ClearCorrect Exhibit 1002, Page 980 of 3373

Clinical results with titanium crowns fabricated with machine duplication and spark erosion

Matts Andersson, Bo Bergman, Christer Bessing, Gunnel Ericson, Peter Lundquist and Hans Nilson

Public Dental Health Service, County of Jämtland, and the Department of Prosthetic Dentistry, Faculty of Odontology, University of Umeå, Umeå, Sweden

Andersson M, Bergman B, Bessing C, Ericson G, Lundquist P, Nilson H. Clinical results with titanium crowns fabricated with machine duplication and spark erosion. Acta Odontol Scand 1989;47:279–286. Oslo. ISSN 0001–6357.

A new method for fabrication of metal crowns has been developed by one of the authors (M.A.). There are two principles involved: machine duplication of models and electric discharge machining. The metal used is pure unalloyed titanium, which is processed as a coping and later covered by a composite resin. In 1986, 205 separate titanium crowns were made on 149 patients. One year later 192 crowns on 137 patients could be examined. Five crowns had been replaced by new ones owing to fracture of the composite resin. In accordance with the CDA quality evaluation system the following results were obtained for the remaining 187 crowns: margin integrity, 186 excellent or satisfactory (99.5%); anatomic form, 185 excellent or satisfactory (98.9%); and surface and color, 181 excellent or satisfactory results (96.8%). The 1-year results are promising, and further follow-up studies will be made. □ *Clinical behavior; dental materials; fixed restorations*

Bo Bergman, Faculty of Odontology, University of Umeå, S-90187 Umeå, Sweden

Since the beginning of this century casting by means of the lost-wax technique has been the dominant method when fabricating metal crowns in dentistry. In the field of industrial manufacturing various methods have been developed to increase precision when working with metals. One of these methods is spark erosion, which was introduced in industry more than 30 years ago. Spark erosion has been applied in dentistry for fabrication of attachments and other components of removable prostheses (1, 2) and for inlays, crowns, and bridges (3–6). However, the spark erosion method as used in the above-cited papers utilizes some technical procedures that preserve certain error sources associated with conventional methods and introduce others. Andersson & Andersson (7) have developed a method by which the principles of spark erosion are combined with a method of machine duplication. With these combined techniques several error sources associated with the casting technique when fabricating metal crowns have been eliminated. When introducing a new method for fabrication of crowns, it is necessary to perform an adequate clinical evaluation of the restorations. The aim of the present paper is to describe the new combined technique for fabricating titanium crowns and report on a 1-year longitudinal study of treatment with such crowns.

Materials and methods

Crown fabrication

Titanium is exceptionally well tolerated in biologic environments, where it has a high corrosion resistance (8). Pure titanium is a cheap metal and has been used for a long time in dental implants—for example, in the successful long-term treatment with the Brånemark implants (9). For the present purpose it was decided to try to use the same quality of titanium for crowns as used for dental implants—that is, A TI 24 and A TI 30 (Avesta, Sweden). However, titanium is not easily precision cast, so its use has been

ClearCorrect Exhibit 1002, Page 981 of 3373

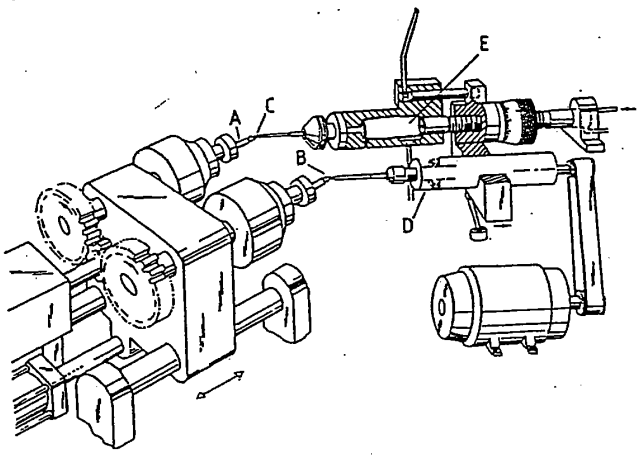


Fig. 1. The coping milling machine with (A) the holder for the stone die. (B) the blank to be produced as a copy of A with the help of the detection needle (C). D is the milling device. and E the hydraulic servo unit.

limited mainly to wrought, rolled. or otherwise fabricated applicances.

Thus with regard to the difficulties in casting titanium, two other methods were applied—machine duplication and spark erosion. In this way a coping was shaped out of a solid piece of titanium. The coping was thereafter veneered with a composite resin. The total process involves a) a tool system that enables the model of the tooth—a stone die—to be repositioned with great precision; b) a coping milling machine, on which the shape of the model can be reproduced with great precision; and c) a spark erosion process with short processing time and low electrode wear (carbon electrode). The tool system will make it possible to copy the position of the tool in the other machines, and the machining of the inner and the outer contour can be made quite independent of each other.

The principal design of the coping milling machine is shown in Fig. 1. There are two corotating elements that hold the stone replica, A, and the blank, B, which is to be machined to become a copy of A. The replica and the blank are mounted on guides enabling simultaneous longitudinal displacement along their axes of rotation. A detection needle, C, interacts with the surface of the replica during its rotation and longitudinal displacement. The movements of the detection needle are transmitted to the milling device. D. by a hydraulic servo. E. This transmission enables a simultaneous processing of the blank, B, to a copy of the replica A.

The accuracy of the servo unit is related to the velocity of the servo, which again depends on the surveying speed and on how complex the form of the item is. When sur-

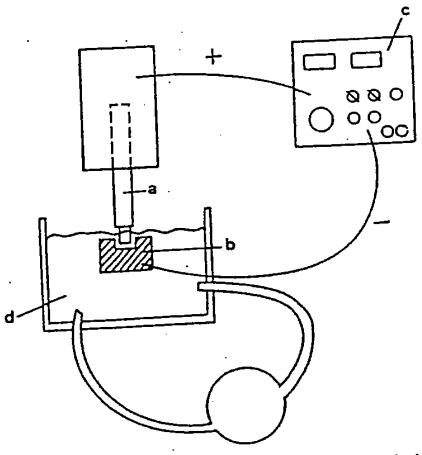


Fig. 2. The electrical discharge machine with (a) the workhead. (b) the table. (c) the generator. and (d) the work tank.

ClearCorrect Exhibit 1002, Page 982 of 3373

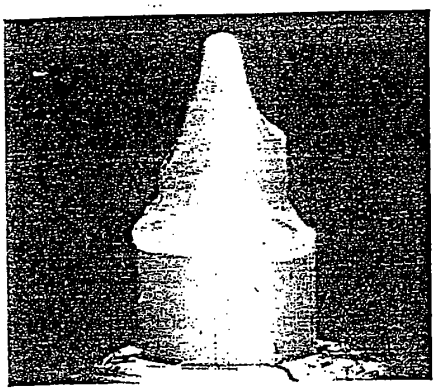


Fig. 3. The titanium copy of the stone die.

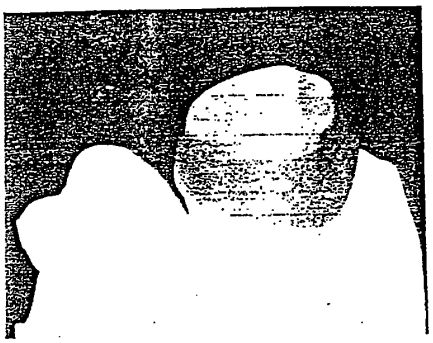


Fig. 5. The titanium coping with its rough surface before the application of the veneering material.

veying, the servo speed should not exceed 5–10% of the maximum servo speed. That gives a surveying time of about 2 min per preparation. When the shape of the stone die is very complex, the surveying speed has to be slowed down to ensure a precise fit.

The die sinking electrical discharge machining (EDM) apparatus has the following principal design (Fig. 2): a) a workhead, which consists of a spindle that is run by a servo, either electric or hydroelectric: b) a table, often a two-coordinate one, where the workpiece can be positioned; c) a generator, which delivers the sparks. Together with the generator there is also a control unit monitoring the movement of the workhead; and d) a work tank in which the process takes place under protection of a dielectric fluid. The control unit ensures that there is always a constant gap between electrode and workpiece. In coordination with the removal of metal from the workpiece, the electrode is progressed forward.

The procedure is in brief as follows. The stone die is placed in a tool. Thereafter the stone is positioned in a profile projector and suitable dimensions of titanium blank and carbon electrode are chosen. In the milling procedure the tools with stone die and titanium blank are placed in a spindle, the

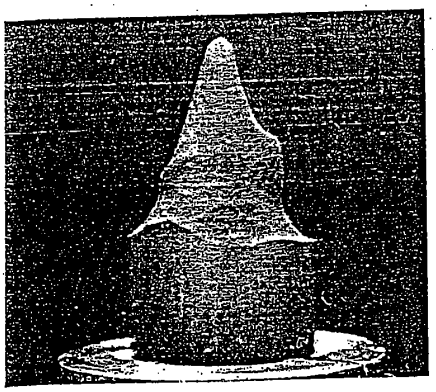


Fig. 4. The carbon blank of the stone die.

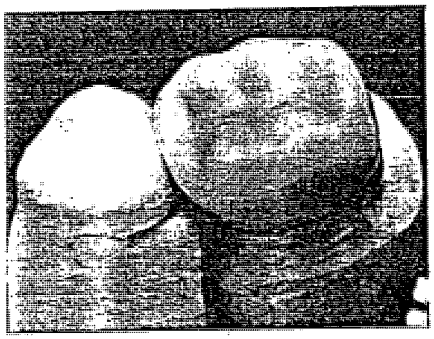


Fig. 6. The completed titanium crown covered with the veneering material Dentacolor®.

ClearCorrect Exhibit 1002, Page 983 of 3373

Table 1. Number of patients treated with titanium crowns and examined in 1986 (= zero) and re-examined in 1987 (= 1 year)

	No. of patients examined	
	Zero	1 year
Male	67	57
Female	82	80
Total	149 (mean age, 47.5 years)	137 (mean age, 48.9 years)

milling machine is started, and the outer form of the die is automatically copied in the titanium. This titanium copy is evenly enlarged, so that the milled surface represents the outer surface of a future cap with adequate wall thickness (Fig. 3). The stone die is transferred to a machine equipped for carbon milling. The carbon blank is mounted, and the carbon electrode is milled to a copy of the stone die. This carbon copy can also be enlarged to give any desirable compensation for the cement layer between the tooth and the titanium coping (Fig. 4).

After being detached the milled titanium blank is mounted in another tool, which is placed in the table of the EDM apparatus. The milled carbon electrode is placed in the spindle of the same machine. The EDM apparatus is started, and the inner cavity of the coping is processed automatically. There is a certain wear of the electrode, so that two or three electrodes are usually needed for each coping to give the accurate shape of the cavity. The total time for the spark erosion process is 8–10 min per coping. When the EDM processing is finished, the coping is checked and thereafter polished on surfaces not to be veenered, using the same methods and materials as for polishing gold castings. Surfaces to be veneered are left rough, to facilitate mechanical retention for the veneering material (Fig. 5). For veneering, two composites have been used. The first 90% of the crowns in the present series were veneered with Isosit®, which is a heat-cured resin bonded mechanically to the rough titanium surface. The remaining 10% were veneered with the light-cured resin Dentacolor®, using the Silicoater® technique to achieve a bond between titanium and the composite resin (Fig. 6).

Clinical study

In the spring of 1986, 205 separate titanium crowns were made in 149 patients. The design of the clinical study had been approved by the Swedish National Board of Health and Welfare and the Ethical Review Committee of the Medical Faculty at the University of Umeå. The treatment was performed by 27 general practitioners in the Public Dental Health Service in the four northernmost counties in Sweden. The patients were volunteers selected among ordinary recall patients in need of crown therapy. They were treated with conventional clinical methods. The same principles as for preparation of teeth for metal–ceramic crowns were followed. Titanium crowns were made on both vital and root-filled teeth. If root-filled, the tooth was provided with a cast post and core in a type 3 gold alloy. After the crowns had been cemented—time zero—they were examined by four licensed specialists in prosthetic dentistry who had undergone calibration with regard to the evaluation methods used (10). The following three characteristics were evaluated in accordance with 'Quality Evaluation for Dental Care' issued by California Dental Association (11): surface and color, anatomic form, and margin integrity. Further-

Table 2. The distribution of crowns examined in 1986 and (in parentheses) in 1987

	Maxilla	Mandible	Total
Incisors and canines	60 (57)	16 (16)	76 (73)
Premolars	64 (55)	32 (30)	96 (85)
Molars	14 (12)	19 (17)	33 (29)
Total	138 (124)	67 (63)	205 (187)

ClearCorrect Exhibit 1002, Page 984 of 3373

Table 3. Judgement of the characteristic 'surface and color' in accordance with the CDA system for the 187 titanium crowns that could be examined both in 1986 (= zero) and in 1987 (= 1 year)

	Zero		1 year	
Satisfactory				
Excellent	156 (83.4%)	98.4%	131 (70.1%)	96.8%
Acceptable	28		50	
Not acceptable				
Replace or correct	3	1.6%	—	3.2%
Replace statim	—		6*	

* Five fractures of the Isosit + one crown with large porosities in the Isosit.

more, Bleeding Index (12) and Margin Index (13) were registered. When judging Bleeding Index, a contralateral tooth or a tooth as close as possible to the contralateral one was chosen as control.

Each crown was examined by any two of the four calibrated specialists independently of each other. Whenever disagreements in rating of a given crown occurred, the two examiners resolved their disagreement by joint examination.

After 1 year, in 1987, the patients were recalled. Of the original 149, 137 could be examined (Table 1). The reasons of the 12 for not attending were as follows: 3, abroad; 3, moved away from the region; 2, ill; 2, deceased; 1, on vacation; and 1, reason unknown.

The re-examined 137 patients had been provided with 192 titanium crowns. However, from the initial examination to the 1-year control, five of these crowns had been replaced owing to extensive fractures of the veneering material, the composite Isosit. The comparisons between zero and 1-year figures are therefore limited to 187 crowns. Of the 187 control teeth 94 were provided with some type of full crown, 87 with fillings, and 6 were intact.

The distribution of titanium crowns made and examined in 1986 and examined in 1987 is shown in Table 2.

Table 4. Judgement of the characteristic 'anatomic form' in accordance with the CDA system for the 187 titanium crowns that could be examined both in 1986 (= zero) and in 1987 (= 1 year)

	Zero		1 year	
Satisfactory				
Excellent	118 (63.1%)	100%	113 (60.4%)	98.9%
Acceptable	69		72	
Not acceptable				
Replace or correct	—		2*	1.1%
Replace statim	—		—	

* Two insufficient occlusal contacts owing to wear.

Table 5. Judgement of the characteristic 'margin integrity' in accordance with the CDA system for the 187 titanium crowns which could be examined both in 1986 (= zero) and in 1987 (= 1 year)

	Zero		1 year	
Satisfactory				
Excellent	166 (88.8%)	100%	161 (86.1%)	99.5%
Acceptable	21		25	
Not acceptable				
Replace or correct	—		—	0.5%
Replace statim	—		1*	

* Caries.

ClearCorrect Exhibit 1002, Page 985 of 3373

Table 6. Bleeding Index in percentage judged in accordance with Lenox & Kopczyk (12) for the 187 teeth with titanium crowns (T) and the control teeth (C) which could be examined both in 1986 (= zero) and in 1987 (= 1 year)

	Mesial		Buccal		Distal		Lingual	
	T	C	T	C	T	C	T	C
Zero	28.3	27.8	11.2	10.2	31.0	32.6	13.9	16.0
1 year	21.9	18.2	23.5	16.6	28.3	31.6	32.6	27.3

Results

CDA ratings

During the follow-up period five crowns had been replaced owing to fractures of the composite resin, thereby reducing the number of crowns to be examined at 1 year to 187. Of these, six crowns were judged not acceptable at the 1-year examination, five because of fractures of the composite (Table 3). Thus the number of fractured veneers during the 1st year amounts to 10 out of 192 (5.2%). The ratings presented refer to 187 crowns.

When the factor surface and color was rated as satisfactory (excellent or acceptable), there was a small decrease between zero and 1 year from 98.4% to 96.8% (Table 3). However, when comparing the rating excellent only, there was an obvious decrease from 83.4% to 70.1%. With regard to anatomic form (Table 4) and margin integrity (Table 5), there were only minor changes between the initial and 1-year ratings, no matter how the comparisons were made.

Bleeding Index

There was a decrease in bleeding approximally and an increase buccally and lingually with regard to teeth provided with titanium crowns (Table 6). The same tendency was found for the control teeth. Comparable bleeding rates were very similar when teeth with titanium crowns were compared with the control teeth.

Margin Index

The initial rating showed that the margins of the titanium crowns approximally to a greater extent were located at or below the gingival margin compared with the buccal and lingual surfaces (Table 7). After 1 year the subgingivally located margins had increased in number approximally, as had both the supragingivally and subgingivally located margins buccally and lingually. The latter observations are in accordance with a substantial decrease of the number of crown margins rated as degree 2 (= level with the gingival margin) at the 1-year control.

Table 7. Number of surfaces with Margin Index judged in accordance with Silness (13) for the 187 titanium crowns that could be examined both in 1986 (= zero) and in 1987 (= 1 year)

Margin Index*	Mesial		Buccal		Distal		Lingual	
	Zero	1 year	Zero	1 year	Zero	1 year	Zero	1 year
0	0	0	4	7	0	0	3	3
1	2	2	13	22	2	5	30	42
2	45	19	107	76	38	20	115	89
3	140	166	63	87	147	162	39	53

* 0 = Restoration margin more than 2 mm above the gingival margin; 1 = restoration margin less than 2 mm above the gingival margin; 2 = restoration margin level with the gingival margin; and 3 = restoration margin below the gingival margin.

ClearCorrect Exhibit 1002, Page 986 of 3373

Discussion

In the present study spark erosion has been combined with a method of machine duplication for fabrication of crowns. With this combined technique the inherent error sources from waxing, investment, and casting procedures are eliminated. These error sources are associated with conventional methods for fabrication of metal crowns and partly also with previous attempts to adapt spark erosion for this purpose (3–6). The present method enables high precision and accuracy because of the possibility of modifying the electrode in relation to the stone die. In this manner both the spark erosion time and the final dimension can be affected. According to preliminary tests (Øilo 1986, personal communication) the resulting gap between the die and the coping is in a range comparable with that of well-made cast conventional gold alloy copings. It also seems reasonable to assume that the fact that the copings are fabricated from one solid piece of titanium, an exceptionally biocompatible metal, without the heat treatments included in conventional casting procedures will create conditions for keeping corrosion at a very low level.

Of the initial 149 patients 137, or 92%, could be examined after 1 year. The reasons for the non-attendance of 12 patients do not indicate any association with factors pertaining to the study. Therefore, there is every reason to believe that the results after 1 year would have been the same if it had been possible to examine all patients.

It can be concluded that the 1-year results with the present 187 titanium crowns are promising. The margin integrity of the crowns had a high rating at both zero and the 1-year control. The veneering material used in the first 90% of the cases was the composite Isosit. During the present 1-year control period this material disclosed some shortcomings, as there were veneer fractures in 10 crowns, of which 5 had been replaced at the 1-year control. This may be due to insufficient reduction of tooth substance especially occlusally/incisally. Furthermore, several changes from excellent to acceptable were noted with regard to surface and color. The observations of fractures and surface and color changes indicate that other veneering materials may be more compatible with titanium copings. The last 19 crowns in the present series were veneered with the composite Dentacolor, using the Silicoater technique. The registered observations with Dentacolor in the present study have not as yet shown any of the above-mentioned disadvantages. The shift to a new veneering material took place during late spring of 1986. Since then a large number of titanium copings veneered with the Dentacolor/Silicoater method have been cemented in patients. A clinical study of this material is in progress (B. Bergman, H. Nilson, M. Andersson. Unpublished observations).

It has recently been reported that the light-cured resin Dentacolor showed a markedly lower substance loss than the heat-cured resin used (14). Although the long-term wear of Dentacolor and of Isosit as veneer materials for titanium copings is a matter of future research, it can be noted that the findings of the present study do not contradict those of Ekfeldt & Øilo (14).

A 1-year observation period with this new type of titanium crown is short. To enable more detailed, long-term comparisons with other clinical studies on various types of crowns the present patient material will be followed up continuously.

Acknowledgement.—This study has been financially supported by the Board for Technical Development (STU), Stockholm, the Development Fund of the County of Jämtland, the Investment Company of the County of Jämtland, the Counties of Jämtland, Norrbotten, Västerbotten and Västernorrland, and the University of Umeå. The following clinicians are acknowledged for their clinical skill and for their participation in this study: C. Adibzadeh, K. Ahlfeldt, S. Bäckman, C. Bäckström, M. Bäckström, L. Enbom, S. Ericson, H. Eriksson, K. Gunnarsson, K. Isaksson, O. Larson, H. Lundström, B. Malm, I. Quick-Nilsson, J.-O. Nordberg, A. Nordin, G. Ramstedt, O. Ramstedt, J. Segerström, A. Sjöblom, L. Sjögren, G. Stroh, K. Sundin, L. Viklund, K. Zachrisson, B. Ödman, and L. Överby.

References

1. Rübeling S. Funkenerosion in der Zahntechnik. Möglichkeiten und Gränzen. Dent Labor 1982;30:1967.

ClearCorrect Exhibit 1002, Page 987 of 3373

1. Rübeling S, Kreyios H. Spark erosion in dental technology: possibilities and limitations. Quintessence Dent Technol 1984;8:649–57.
2. Stachniss V, Zimmer B. Funkenerosion—ein neuer Weg zu passgenauen Gussfüllungen und Kronen aus Edelmetall und edelmetallfreien Legierungen. Dtsch Zahnaerztl Z 1984;39:294.
3. Körber E, Lindemann W, Pielsticker W. Herstellung einer Schwebebrücke mit Hilfe der Funkenerosion. Die Quintessenz 1986; (Heft 10 Referat 6918):1689–94.
4. Körber E, Lindemann W, Pielsticker W. Herstellung einer Metallhülsenkrone aus Vollmaterial mit Hilfe der Funkenerosion. Dtsch Zahnaerztl Z 1986;41:525–6.
5. Lindemann W, Pielsticker W, Schiebel G. Inlayherstellung unter Einsatz der Funkenerosion. Dent Labor 1986;34:949–50.
6. Andersson M. Andersson M. Swedish Patent 8400396-1. 1987.
7. Cranin AN, Silverbrand H, Sher J, Satler N. The requirements and clinical performance of dental implants. In: Smith DS, Williams DF, eds. Biocompatibility of dental materials. Vol. IV. Boca Raton, Fla., USA: CRC Press. 1982; Chapter 10.
8. Albrektsson T, Zarb G, Worthington P, Eriksson AR. The long-term efficacy of currently used dental implants: a review and proposed criteria of success. Int J Oral Maxillofac Implants 1986:1:11–25.
9. Ryge G, Jendresen MD, Glantz P-O, Mjör I. Standardization of clinical investigators for studies of restorative materials. Swed Dent J 1981:5:235–9.
10. California Dental Association. Quality evaluation for dental care. Guidelines for the assessment of clinical quality and professional performance. Los Angeles: California Dental Association. 1977.
11. Lenox JA, Kopczyk RA. A clinical system for scoring a patient's oral hygiene performance. J Am Dent Assoc 1973:86:849–52.
12. Silness J. Periodontal conditions in patients treated with dental bridges. J Periodontol Res 1970:5:60–8.
13. Ekfeldt A, Øilo G. Occlusal contact wear of prosthodontic materials. An in vivo study. Acta Odontol Scand 1988:46:159–69.

Received for publication 30 May 1988

ClearCorrect Exhibit 1002, Page 988 of 3373

Straight Wire

The Concept and Appliance

Lawrence F. Andrews, D.D.S.

L.A. Wells

Chapter 3

The Six Keys to Optimal Occlusion*

The third and—in retrospect—the most important step leading to the development of a fully programmed appliance was the discovery of six characteristics that were consistently present in the collection of 120 casts of naturally optimal occlusion [4]. These qualities will be referred to as the Six Keys to Optimal Occlusion. The individual keys are not entirely new, but together they have special value for the orthodontist, because (1) they are a complete set of indicators of optimal occlusion; (2) they can be judged from tangible landmarks; and (3) they can be judged from the facial and occlusal surfaces of the crowns, reducing the need for a lingual view or for articulating paper to confirm occlusal interfacing.

Many writers have described in detail how the occlusal surfaces of teeth should fit together, but that information has not been adequate for orthodontists, who must work chiefly with the facial surfaces of the teeth. The extent to which the facial surfaces of each tooth type have dependable angular relationships to their occlusal surfaces at all times, and to the occlusal plane when the teeth are optimally positioned, has not been known. Some such correlations have been assumed, but verification and quantitative specifics have been absent. Treatment, therefore, has proceeded by trial and error in some respects. This factor may be partly responsible for disparate treatment results.

The traditional guidelines used by orthodontists to indirectly assess occlusion have been individually inadequate and collectively incomplete. One such guideline is the classic concept of the interarch relationship of the permanent first molars. In 1899 Angle postulated that, as a *sine qua non* of optimal occlusion, the mesiobuccal cusp of the maxillary first molar must occlude in the buccal groove between the mesial and middle buccal cusps of the mandibular first molar [6]. Angle did not contend that this factor alone would yield proper occlusion. Many occlusions, before or after treatment, are inadequate even though Angle's preferred molar relationship is present.

A more recent (1953) guideline for judging

*Called the Six Keys to Normal Occlusion in earlier writings, but *optimal* is more correct.

ClearCorrect Exhibit 1002, Page 990 of 3373

one aspect of occlusion uses roentgenographic cephalometry. The guideline sets forth recommended inclinations of the maxillary and mandibular central incisors for various interjaw relationships [23]. This guideline cannot be applied intraorally or with the cast itself, because it concerns the tooth's long axis, which cannot be seen clinically. For that matter, even when optimal incisor inclinations are attained along with Angle's preferred molar relationship, the total occlusion may still not be optimal.

So the question arose whether a complete set of guidelines for judging occlusal interfacing without articulating paper and without a lingual view could be found. Ideally, this would make it possible to assume an occlusion to be optimal or at least equilibratable if all guidelines were present.

The positions and interarch relationships of all the crowns in the collection of 120 dental casts with optimal occlusion were studied intensively to learn what characteristics, if any, occurred consistently. Angle's insight about the molar cusp-groove relationship was again validated. However, the articulation of the molars in these dental casts exhibited three cardinal elements rather than one, and the other two are just as important as the cusp-groove requirement (see Key I, p.18).

Other characteristic features of optimal occlusion became apparent. For instance, in a dentition with optimal occlusion, nearly every tooth type has its independent amount of crown angulation and inclination; but the amounts for each tooth type are similar for other dentitions that are optimal. The depth of the curve of Spee varied only moderately and was clearly an important attribute of optimal occlusion.

In all, the Six Keys make it possible to assess occlusion from facial and occlusal sites without using measuring devices. Later, for purposes of designing the new appliance, instruments were used to measure angulation, inclination, relative facial prominence of each crown, and other relevant factors.

The following terms (introduced alphabetically through p. 18) are necessary for discussing the Six Keys.

Andrews plane. The surface or plane on which the midtransverse plane of every crown in an arch will fall when the teeth are optimally positioned (Fig. 3.1). If the plane is concave or convex, technically it is a surface; but in all instances it will be referred to here as the Andrews plane.

Clinical crown. Normally, the amount of crown that can be seen intraorally or with a study cast.

In this book *clinical crown* means the amount visible in late mixed dentitions and adult dentitions with gingiva that is healthy and not recessed (Fig. 3.2). Orban has defined the clinical crown as the anatomical crown height minus 1.8 mm [21]. In young patients or those with hypertrophied or receding gingiva, the clinical-crown height can be found by measuring the distance from the incisal edge or cusp tip of the crown to the cemento-enamel junction, and then subtracting 1.8 mm.

Crown angulation. The angle formed by the facial axis of the clinical crown (FACC) and a line perpendicular to the occlusal plane (Fig. 3.3).

Crown angulation is considered positive

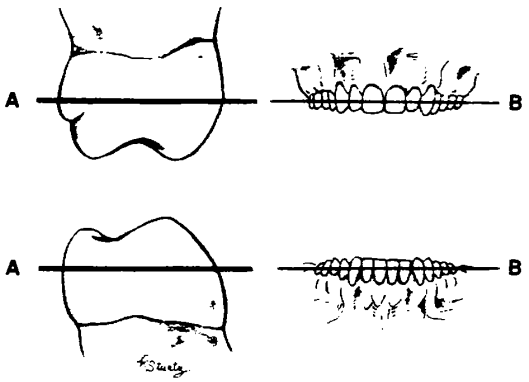


Fig. 3.1. When a crown is optimally positioned, its mid-transverse plane (*A*) falls on the Andrews plane (*B*).

ClearCorrect Exhibit 1002, Page 991 of 3373

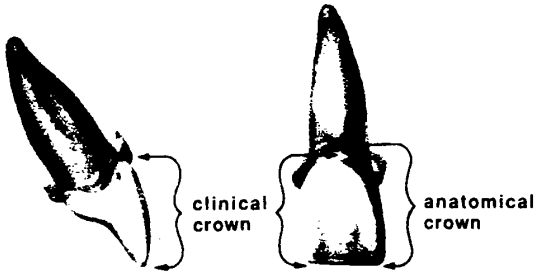


Fig. 3.2. Clinical and anatomical crown.

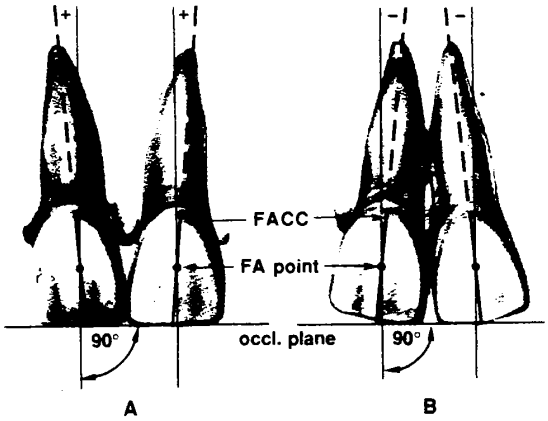
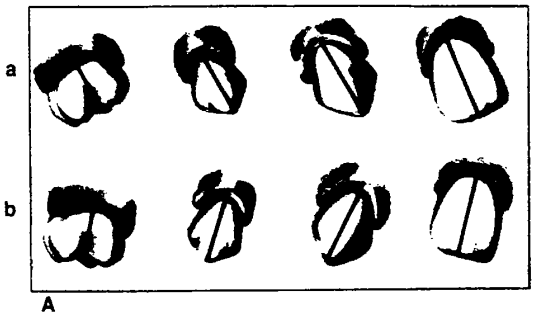


Fig. 3.3. Crown angulation: *A*, positive; *B*, negative.



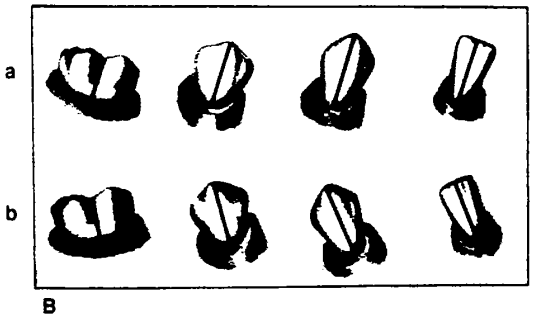


Fig. 3.4. Examples of crown angulation for each tooth class: *A*, maxillary positive *(a)* and negative *(b)*; *B*, mandibular positive *(a)*, and negative *(b)*.

when the occlusal portion of the FACC is mesial to the gingival portion (Fig. 3.3A), negative when distal (Fig. 3.3B).

The exact degree of crown angulation cannot be judged, but the nature of the angulation (positive or negative) and whether it is excessive can be (Fig. 3.4).

Crown inclination. The angle between a line perpendicular to the occlusal plane and a line that is parallel and tangent to the FACC at its midpoint (the FA point). Crown inclination is determined from the mesial or distal perspective. It is sometimes incorrectly called torque, which means a twisting force. "Tangent to" means that the line representing the inclination of the FACC should be equidistant from each end of the clinical crown, while touching the FACC.

Crown inclination is considered positive if the occlusal portion of the crown, tangent line, or FACC is facial to its gingival portion, negative if lingual (Fig. 3.5). The exact degree of crown inclination cannot be judged, but the nature of the inclination (positive or negative) and whether it is excessive can be (Fig. 3.6).

Facial axis of the clinical crown (FACC)*. For all teeth except molars, the most prominent portion of the central lobe on each

*Called the long axis of the clinical crown (LACC) in earlier writings. Anatomically and geometrically, *facial axis* is the more correct term.

ClearCorrect Exhibit 1002, Page 992 of 3373

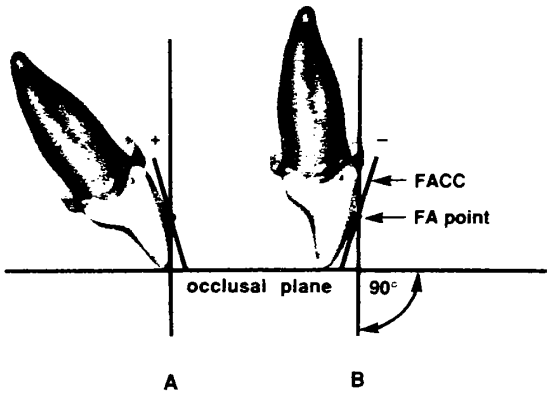


Fig. 3.5. Crown inclination: *A*, positive; *B*, negative.

crown's facial surface (Fig. 3.7); for molars, the buccal groove that separates the two large facial cusps (Fig. 3.8).

Crowns develop from the fusion of embryonic lobes. Upon maturation, these lobes retain their identity with areas of prominence (cusps and ridges) and boundary lines (fissures and grooves) (Fig. 3.9). Clinically, the FACC for all teeth except molars can be highlighted with the side of a pencil lead (Fig. 3.10); for molars, it can be highlighted with the point of a pencil (Fig. 3.11). From the facial perspective, the FACC is observed as a straight line (Figs. 3.7 and 3.8). From the mesial or distal perspective this landmark is used to judge inclination by visualizing a straight line that is parallel to the FACC and tangent to a point on the FACC that separates the gingival half of the crown from the occlusal half (Fig. 3.12).

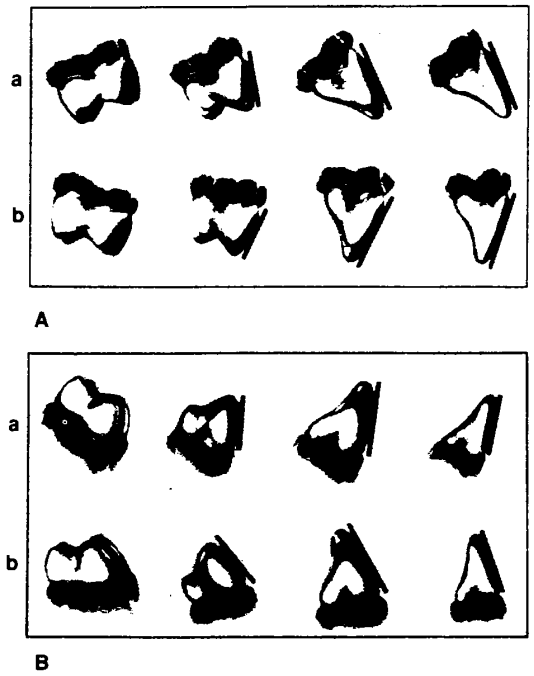


Fig. 3.6. Examples of crown inclination for each tooth class: *A*, maxillary positive *(a)* and negative *(b)*; *B*, mandibular positive *(a)* and negative *(b)*.

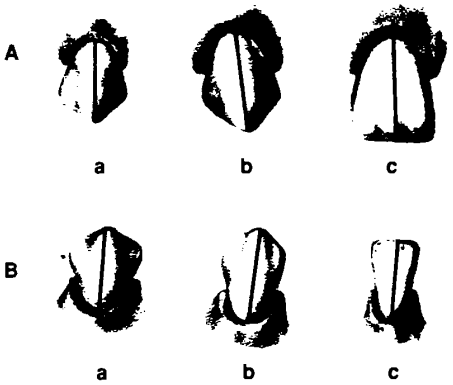
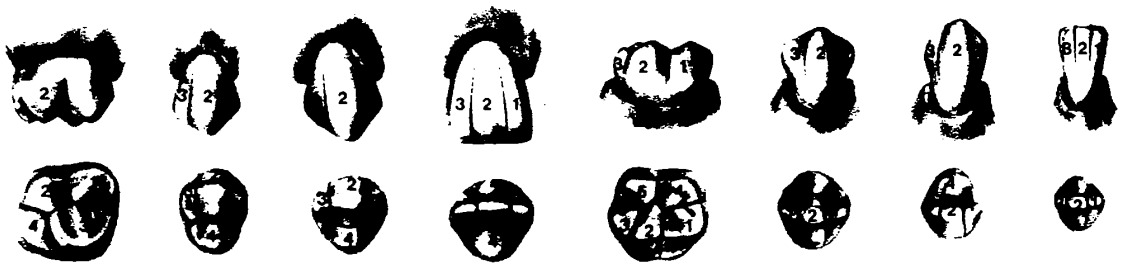


Fig. 3.7. Facial axes of premolars *(a)*, canines *(b)*, and incisors *(c)*: *A*, maxillary; *B*, mandibular.



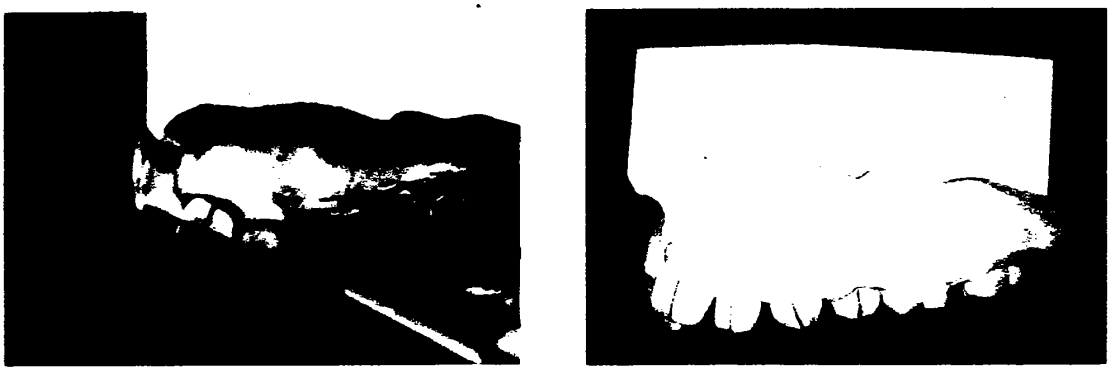
Fig. 3.8. Facial axes of molars: *A*, maxillary; *B*, mandibular.

ClearCorrect Exhibit 1002, Page 993 of 3373



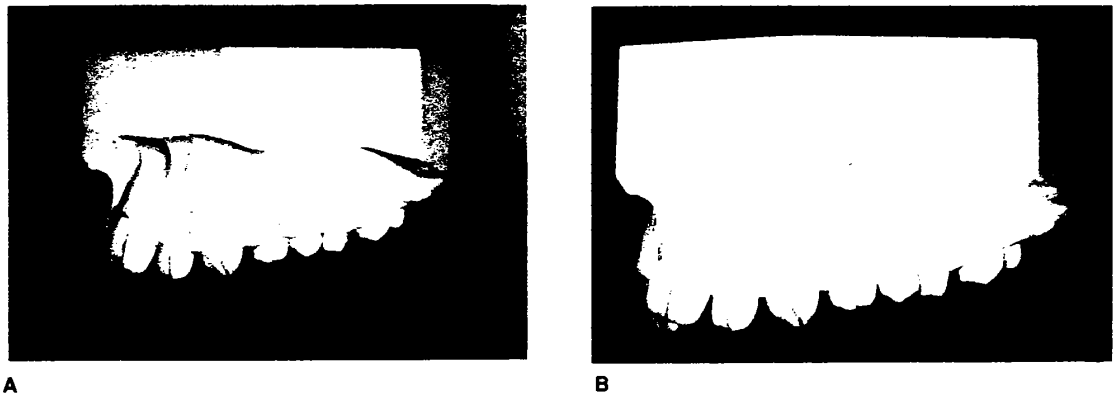
A B

Fig. 3.9. Facial and occlusal views of each tooth class with their lobes numbered: *A*, maxillary teeth; *B*, mandibular teeth.



A B

Fig. 3.10. *A*, Highlighting a central incisor's FACC (the prominent ridge of the crown's central lobe) with the side of a pencil. *B*, FACC marked on each maxillary crown except molars.



A B

Fig. 3.11. *A*, Highlighting the first molar's FACC with the point of a pencil. *B*, FACC marked on all maxillary crowns.

ClearCorrect Exhibit 1002, Page 994 of 3373



Fig. 3.12. From the mesial or distal perspective, the facial axis is an imaginary line tangent to the FA point. Examples are for each maxillary (*A*) and mandibular (*B*) tooth class.



Fig. 3.13. The facial-axis point (FA point) is the point on the FACC that separates the gingival half of the clinical crown from the occlusal half. Examples are for each maxillary (*A*) and mandibular (*B*) tooth class.

It should be noted that the FACC differs from conventional referents (the long axis of the crown or tooth, contact points, marginal ridges, incisal edges) for judging angulation and inclination. These traditional referents are impractical for reasons that will be explained in detail in Chapter 7.

Facial-axis point (FA point)*. The point on the facial axis that separates the gingival half of the clinical crown from the occlusal half (Fig. 3.13).

The distances between the occlusal and gingival extremities of the facial surfaces are not equal for all crowns within an arch, but

*Called the long axis point (LA-point) in earlier writings. Anatomically and geometrically, *facial-axis point* is the more correct term.

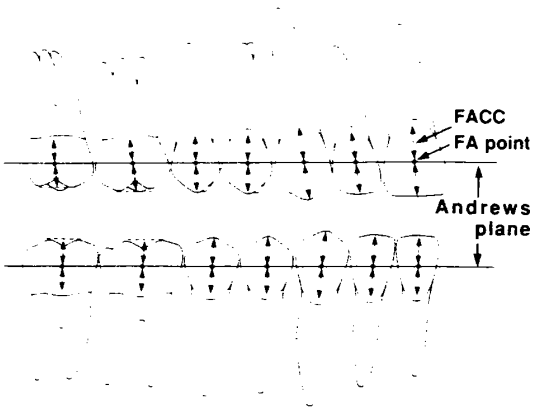


Fig. 3.14. The distance between the occlusal and gingival borders varies for each crown in an arch. However, the borders are equidistant from the crown's FA point at all times, and equidistant from the Andrews plane when the teeth are optimally positioned.

for each crown they are equidistant from the FA point (Fig. 3.14).

Tooth class. A group of teeth having similar shape and function. Classes are incisors, canines, premolars, and molars.

Tooth type. A subordinate category within a class of teeth. Premolars are a class of teeth and are similar; a mandibular first premolar is a type and is different from any other tooth type, such as a mandibular second premolar.

Key I: Interarch Relationships

Key I is the first of the six significant characteristics that were consistently present in the sample of 120 dental casts with optimal occlusion. Key I pertains to the occlusion and the interarch relationships of the teeth. This key consists of seven parts.

1. The mesiobuccal cusp of the permanent maxillary first molar occludes in the groove between the mesial and middle buccal cusps of the permanent mandibular first molar (Fig. 3.15Ab), as explained by Angle [6].

ClearCorrect Exhibit 1002, Page 995 of 3373

2. The distal marginal ridge of the maxillary first molar occludes with the mesial marginal ridge of the mandibular second molar (Fig. 3.15Aa).
3. The mesiolingual cusp of the maxillary first molar occludes in the central fossa of the mandibular first molar (Fig. 3.15Bd, Ce).
4. The buccal cusps of the maxillary premolars have a cusp-embrasure relationship with the mandibular premolars (Fig. 3.15Ac, D).
5. The lingual cusps of the maxillary premolars have a cusp-fossa relationship with the mandibular premolars (Fig. 3.15Cf).
6. The maxillary canine has a cusp-embrasure relationship with the mandibular canine and first premolar. The tip of its cusp is slightly mesial to the embrasure (Fig. 3.15D).
7. The maxillary incisors overlap the mandibular incisors (Fig. 3.15D), and the midlines of the arches match.

The cusp-groove and the marginal-ridge conditions of the molars, the cusp-embrasure relationship of the premolars and canines, and incisor overjet can be observed directly from the buccal perspective (Fig. 3.15). The FACC permits assessment of the lingual-cusp occlusion of the molars and premolars when these teeth are viewed from their mesiobuccal aspect, as explained below.

Interarch relationship of the posterior teeth of two dentitions can be the same, but the interfacing of the occlusal surfaces of the two dentitions may differ because of differing crown inclinations. Judging crown inclination (and therefore occlusal interfacing) is ineffective from the buccal perspective. It can be compared to attempting to learn whether the flanges of a hinge are together or apart by looking only at its joint (Fig. 3.16).

Correct occlusal interfacing depends on correct interarch relationship, angulation, and crown inclination. Interarch relationship and angulation are best judged from the buccal perspective (Fig. 3.16); crown inclination for

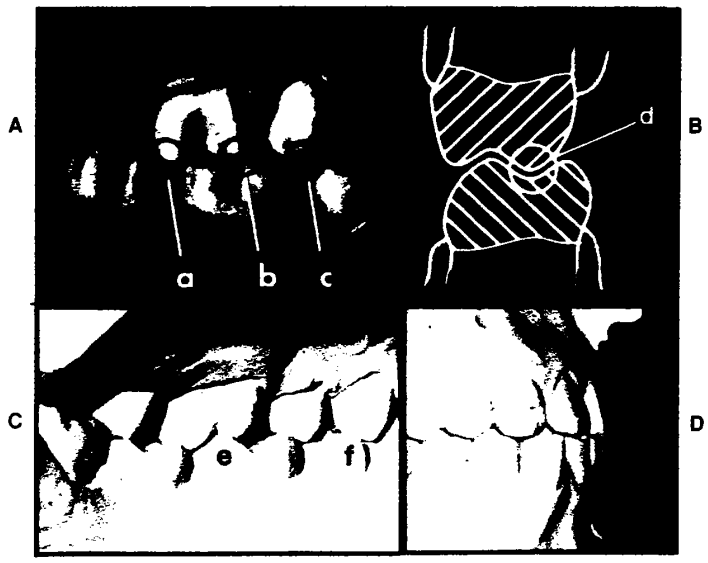


Fig. 3.15. Key I: Optimal interarch relationships and occlusal interfacing. *A*, Interarch relationships of molars and premolars: *a*, marginal-ridge occlusion; *b*, molar cusp-groove relationship; *c*, premolar cusp-embrasure relationship. *B*, Mesial perspective of occlusal interfacing of molar or premolar: *d*, cusp-fossa relationship. *C*, Lingual perspective of occlusal interfacing: *e*, cusp-fossa occlusion of molars; *f*, cusp-fossa occlusion of premolars. *D*, Interarch relationships of canines and incisors.

ClearCorrect Exhibit 1002, Page 996 of 3373

posterior teeth is best judged from the dentition's mesiobuccal perspective (Fig. 3.17). Judging posterior occlusion first from the buccal (for angulation and interarch relationship) then from the mesiobuccal aspect (for inclination) provides a perspective that can be systematically described and quantified. Such information, along with other nonocclusal guidelines, provides a set of standards against which occlusal deviations can be identified.

Key II: Crown Angulation

Essentially all crowns in the sample have a positive angulation* (Fig. 3.18). All crowns of each tooth type are similar in the amount of angulation (Chapter 2). (Wheeler [29] notes the similarity of contact-area position for each tooth type, which supports the optimal sample findings.)

*Maxillary second molars are positive in angulation only if they have completed their eruption. Third molars were not present often enough to be evaluated.

Key III: Crown Inclination

As they do in angulation, consistent patterns also prevail in crown inclination, with the following characteristics for individual teeth.

1. Most maxillary incisors (81.5%) have a positive inclination (Fig. 3.19A,B); mandibular incisors have a slightly negative inclination (Fig. 3.19A,C). In most of the optimal sample, the interincisal crown angle is less than 180°. The crowns of maxillary incisors are more positively inclined, relative to a line 90° to the occlusal plane, than the mandibular incisors are negatively inclined to the same line (Fig. 3.20).
2. The inclinations of the maxillary incisor crowns are generally positive—the centrals more positive than the laterals. Canines and

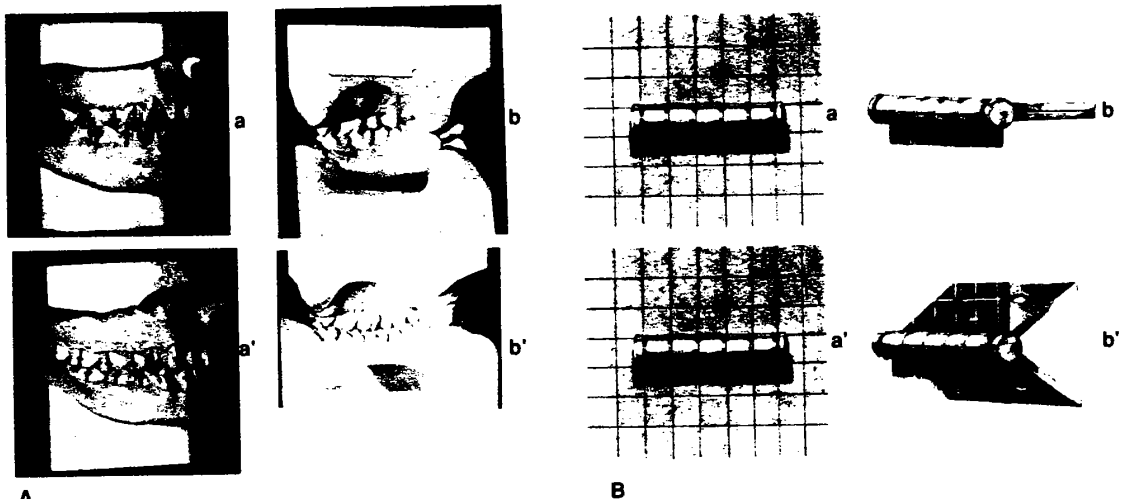


Fig. 3.16. Interarch relationship of two dentitions can be the same (*Aa and Aa'*). However, their occlusal interfacing can differ (*Ab and Ab'*). Similarly, the joint portions of two hinges (*Ba and Ba'*) look the same whether the flanges are together (*Bb*) or apart (*Bb'*). Vertical lines on crowns indicate facial axes; junctions of horizontal and vertical lines indicate FA points.

ClearCorrect Exhibit 1002, Page 997 of 3373

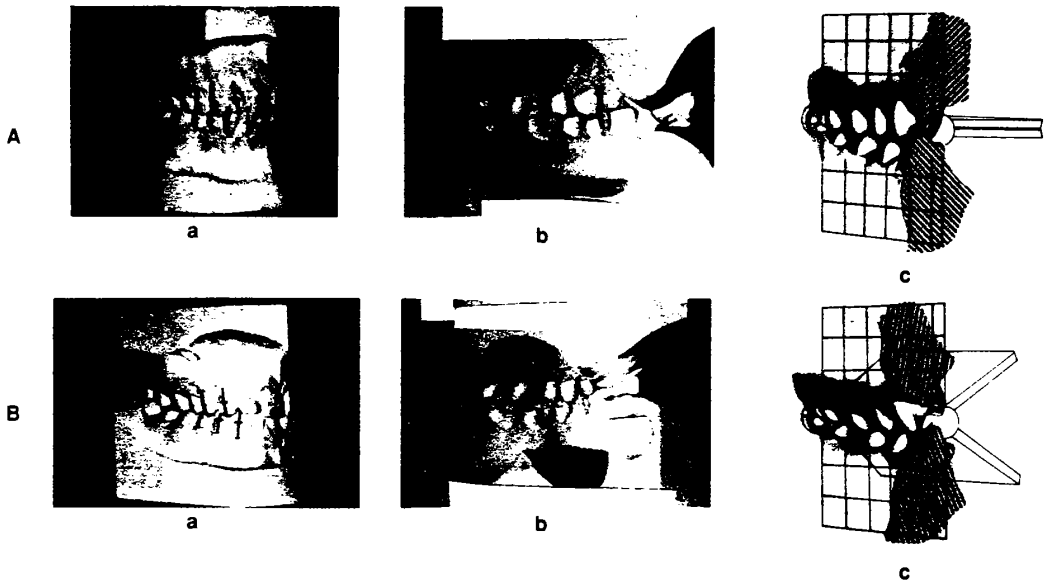


Fig. 3.17. From the mesiobuccal perspective the inclination of the crowns permits indirect judging of occlusal interfacing. *A*, Correct inclination and correct occlusal interfacing: *a*, mesiobuccal perspective; *b*, lingual perspective; *c*, inclination correlated with occlusal interfacing. *B*, Incorrect inclination and incorrect occlusal interfacing: *a*, mesiobuccal perspective; *b*, lingual perspective; *c*, inclination correlated with occlusal interfacing. Vertical lines on crowns indicate facial axes; junctions of vertical and horizontal lines indicate FA points.

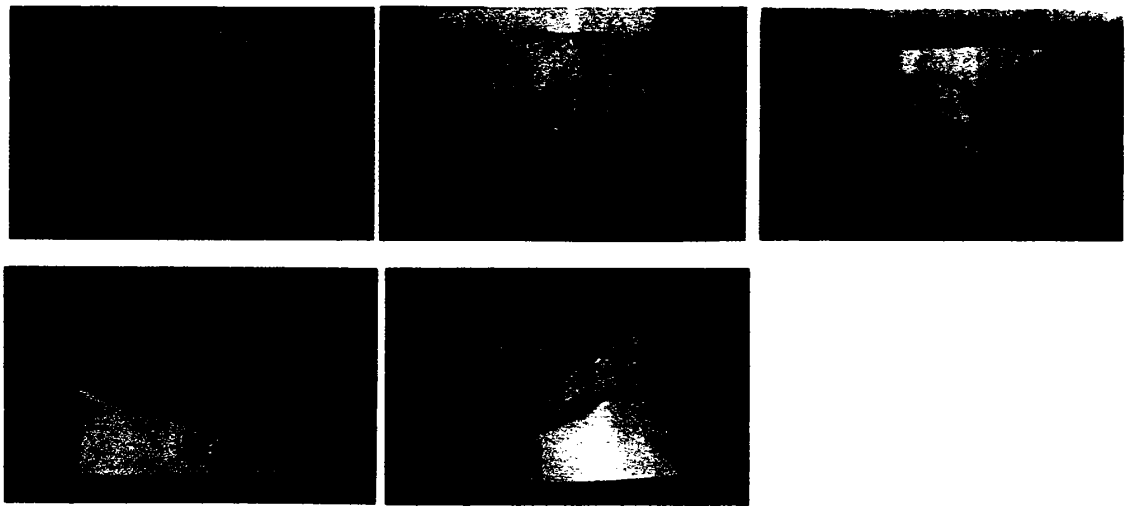


Fig. 3.18. Positive FACC angulation for each tooth type in the optimal sample. Wires are glued at the FA points, parallel to each crown's FACC.

ClearCorrect Exhibit 1002, Page 998 of 3373

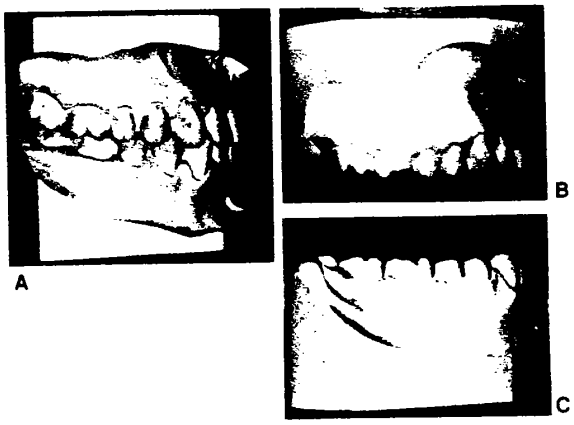


Fig. 3.19. Incisor inclination. Maxillary incisor inclination is consistently positive (*A, B*); mandibular incisor inclination is consistently negative (*A, C*).

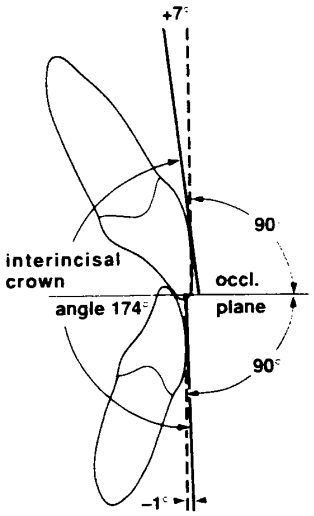
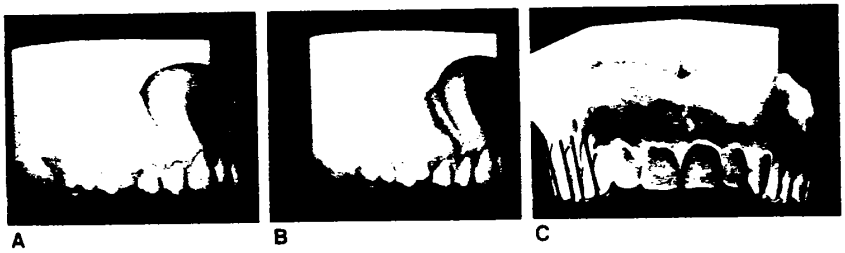


Fig. 3.20. Interincisal crown angle for the majority of the optimal sample was less than 180°.

Fig. 3.21. Maxillary crown inclinations. Central incisors (*A*) are more positive than lateral incisors (*B*); posterior teeth are negative (*C*). Wires are glued at the FA points, parallel to each crown's FACC.



premolars are negative and quite similar. The inclinations of the maxillary first and second molars are also similar and negative, but slightly more negative than those of the canines and premolars (Fig. 3.21). The molars are more negative because they are measured from the groove instead of from the prominent facial ridge, from which the canines and premolars are measured.

3. The inclinations of the mandibular crowns are progressively more negative from the incisors through the second molars (Fig. 3.22).

Key IV: Rotations

The fourth key to optimal occlusion is an absence of tooth rotations (Fig. 3.23).

Key V: Tight Contacts

Contact points should abut unless a discrepancy exists in mesiodistal crown diameter (Fig. 3.23).

ClearCorrect Exhibit 1002, Page 999 of 3373

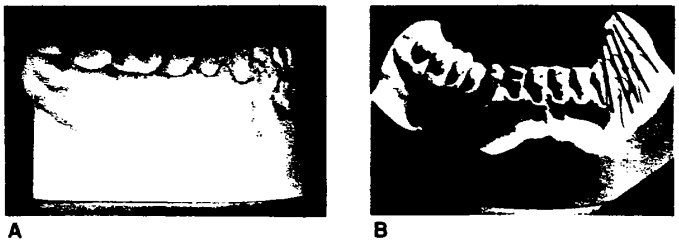


Fig. 3.22. Mandibular crown inclinations. Central and lateral incisors *(A)* have the same inclination (generally slightly negative). The posterior teeth are increasingly negative from the canines through the molars *(B)*. Wires are glued at the FA points, parallel to each crown's FACC.

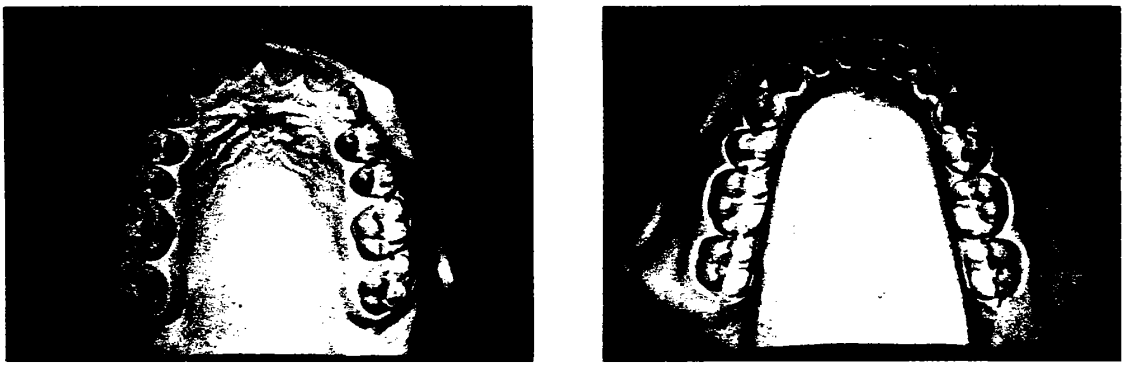


Fig. 3.23. Maxillary arch *(A)* and mandibular arch *(B)* showing no rotations and no interdental spacing. Dots indicate contact points.

Key VI: Curve of Spee

The depth of the curve of Spee ranges from a flat plane to a slightly concave surface (Fig. 3.24).

Discussion

Although the 120 dentitions with naturally occurring optimal occlusion show individual differences in arch form and size of teeth, they generally possess the Six Key characteristics described above. Absence of any of the six qualities results in an occlusion that is proportionally inferior to the naturally optimal sample.

The Six Keys are interdependent elements of the structural system of optimal occlusion. As such, they serve as a base for evaluating occlusion. More important, the Six Keys can be used as treatment objectives for most patients. In 1974 at the seventeenth annual meeting of the Saint Louis University Orthodontic Education and Research Foundation, Ronald H. Roth reported his experience with the Six Key guidelines: ". . . if I were to define very simply the requirements of an ideal occlusion, both anatomically and functionally, for the natural dentition, I would have to say: 'It would incorporate the Six Keys . . . with mandible in gnathologic centric relation.' " To achieve these goals may not be feasible in all instances, but to stop short when they are attainable may be unacceptable.

ClearCorrect Exhibit 1002, Page 1000 of 3373

The optimal sample revealed similarities in the patterns of angulation, inclination, shape, and relative size (facial prominence) of tooth types. It appeared that these characteristics could be incorporated into an orthodontic appliance to enhance precision and consistency in treatment results. But this was not enough for appliance design. The next steps were to explore and quantify the extent to which position, shape, and relative size were, within each tooth type, shared. This information was vital for determining the extent to which an appliance could be programmed and yet be suitable for most patients.

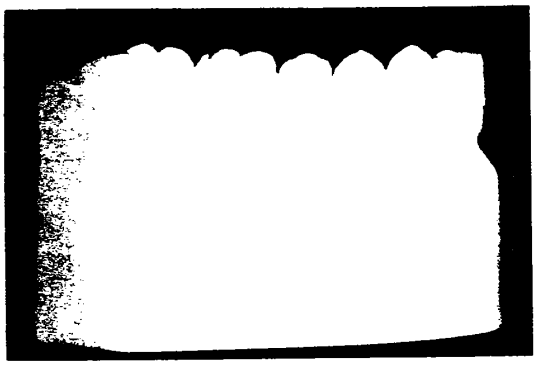
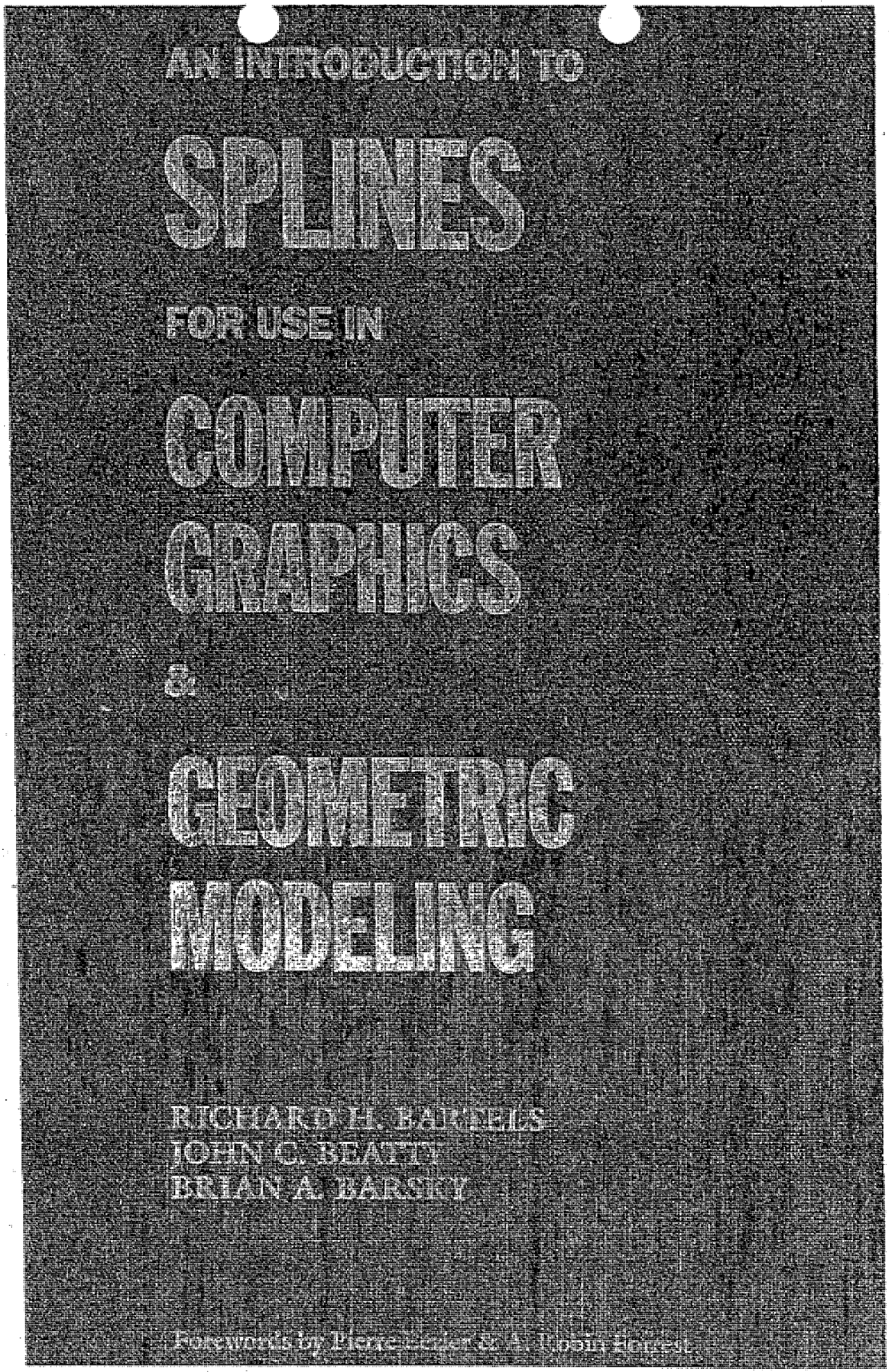


Fig. 3.24. Mandibular arch with a curve of Spee within the 0–2.5-mm depth range.

ClearCorrect Exhibit 1002, Page 1001 of 3373


AN INTRODUCTION TO
SPLINES
FOR USE IN
COMPUTER
GRAPHICS
&
GEOMETRIC
MODELING
RICHARD H. BARTELS
JOHN C. BEATTY
BRIAN A. BARSKY

An Introduction to Splines for use in Computer Graphics and Geometric Modeling

By

Richard H. Bartels
John C. Beatty
UNIVERSITY OF WATERLOO

Brian A. Barsky
UNIVERSITY OF CALIFORNIA, BERKELEY

Forewords by

Pierre Bézier

A. Robin Forrest
UNIVERSITY OF EAST ANGLIA

MORGAN KAUFMANN PUBLISHERS, INC.
LOS ALTOS, CALIFORNIA 94022

ClearCorrect Exhibit 1002, Page 1003 of 3373

Editor and President *Michael B. Morgan*
Production Manager *Jennifer M. Ballentine*
Production Assistant *Todd R. Armstrong*
Copyediting *Lee Ballentine*
Book Design *Beverly Kennon-Kelley*
Cover Design *Irene Imfeld*
Composition *ETP Services Company*

Library of Congress Cataloging-in-Publication Data

Bartels, Richard H.
An introduction to splines for use in computer graphics and geometric modeling.

Includes index.
1. Computer graphics. 2. Spline theory. I. Beatty, John C. II. Barsky, Brian A., 1954-
T385.B365 1986 006.6 86-27650
ISBN 0-934613-27-3

Copyright © 1987
Morgan Kaufmann Publishers, Inc.
95 First Street, Los Altos, California 94022

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, recording, or otherwise, without the prior written permission of the publisher.

ISBN 0-934613-27-3
Printed in the United States of America

91 90 89 88 87 5 4 3 2 1

Finally, Section 21.5 will illustrate the use of B-splines in another form of control vertex approximation: least squares fitting. We will present an application of this form of approximation to the job of capturing and editing gestures made with a tablet or mouse.

A point we would like to emphasize is that different spline representations are suitable for different tasks: B-splines and Beta-splines are not *always* the representation of choice. Then, too, it is useful to distinguish between the representation used to interface with the user and the representation used computationally, inside a program.

In any given situation the choice between techniques might be based on some combination of convenience, ease of use, efficiency, numerical accuracy, or compactness of storage. Thus, for example, one might design a surface using a Beta-spline representation for ease of use, but convert to a Bézier representation for output because it provides more efficient rendering via subdivision [Barsky/et al.87].

That any given spline can be represented in many ways is illustrated by the cover of the January, 1985 issue of *Computer Graphics* [Stone85], reproduced in this volume as Plate XIV. In this image the outline of a flamingo is defined in three equivalent ways: one (designated as "interpolating") uses what is essentially a segment-polynomial representation; one (labeled "B-spline") shows the B-spline control graph defining the same piecewise curve; and the third (labeled "Bézier") shows the equivalent Bézier polygon for the curve. A discussion of the practical ramifications of converting between spline representations can be found in [Barsky/Thomas81].

21.1 The Hermite Basis and C^1 Key-Frame Inbetweening

Material in this section derives from [Kochanek/et al.82] and [Kochanek/Bartels84].

One of the oldest techniques used in computer animation is the automatic generation of *inbetweens* (intermediate frames) based on a set of *key frames* supplied by the animator. This same method is frequently used in computer assisted special effects where camera and positions of objects are defined only at key points in the action, leaving the calculation of intermediate positions to the computer.

Linear interpolation has been used in many such systems, but it produces undesirable side effects that give the animation a mechanical look, often referred to as the "computer signature." The most objectionable characteristic of this type of animation is a lack of smoothness in the motion. The key frames may be clearly visible in the animation because of sudden changes in the direction of motion (Figure 21.1). Discontinuities in the speed of motion may also be visible with linear interpolation, for example when the animator requests a different number of frames between successive keys (Figure 21.2). A third common problem is distortion, which may occur whenever the movement has a rotational component (Figure 21.3).

ClearCorrect Exhibit 1002, Page 1005 of 3373

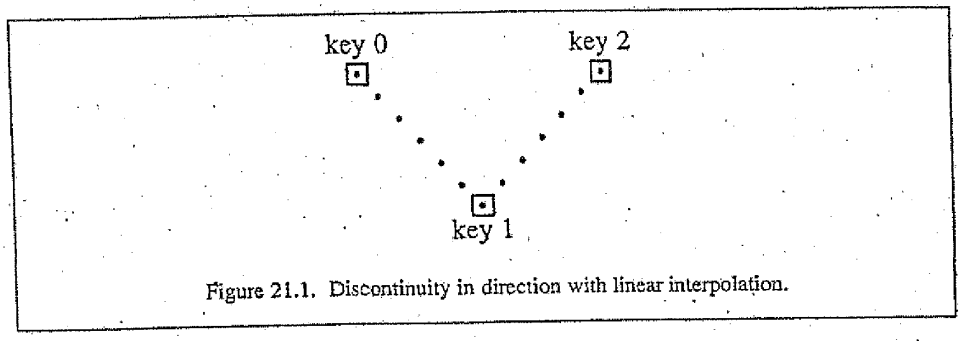


Figure 21.1. Discontinuity in direction with linear interpolation.

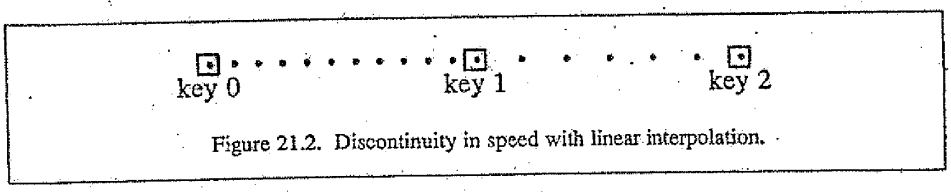


Figure 21.2. Discontinuity in speed with linear interpolation.

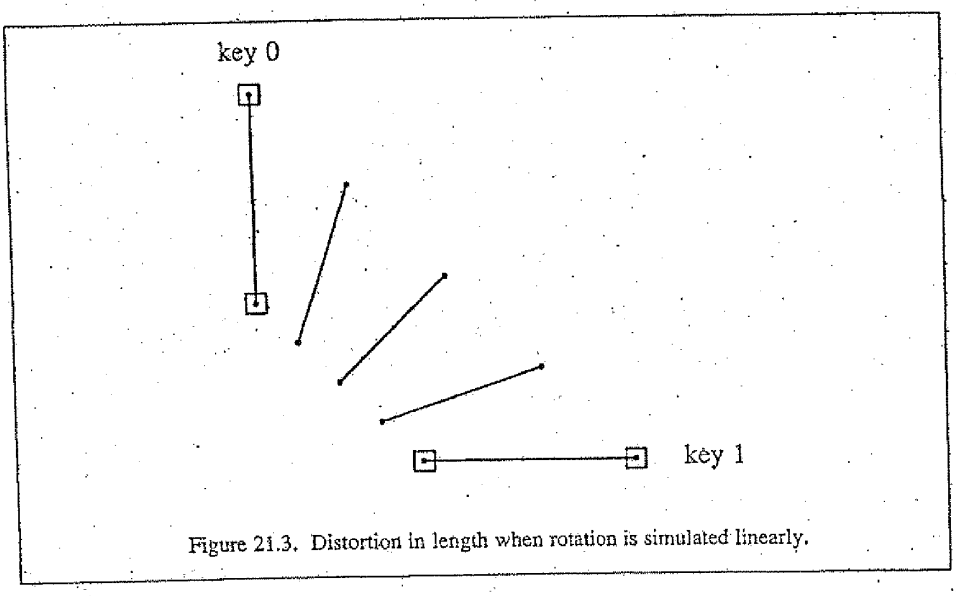


Figure 21.3. Distortion in length when rotation is simulated linearly.

Inbetweening systems usually begin with the assumption that each of the objects in the ith key frame in a sequence can be described by a collection of *key points* (e.g., the two designated endpoints of the line segment in key 0 shown in Figure 21.3, which completely define the segment) and that to each such point in one key frame there will be a corresponding point in all the other key frames of a

ClearCorrect Exhibit 1002, Page 1006 of 3373

motion sequence (e.g., the same two endpoints which reappear in key 1 of Figure 21.3 to specify a later position of the line segment.) If we choose one such point at the ith key frame,

$$\mathbf{P}_i = (x_i, y_i, z_i),$$

called the ith *key position*, then the corresponding points in all the key frames constitute a sequence of key positions

$$\cdots, \mathbf{P}_{i-1}, \mathbf{P}_i, \mathbf{P}_{i+1}, \cdots,$$

that we want to interpolate using a simple smooth curve to ameliorate the problems described above. In Figure 21.3, for example, the top endpoint of the line segment in key 0 could be the chosen key position, $\mathbf{P}_0$; hence, the key position, $\mathbf{P}_1$, would be the right-hand endpoint of the line segment in key 1, and the sequence we must interpolate is merely

$$\mathbf{P}_0, \mathbf{P}_1.$$

The result of the interpolation should be a parametric curve $\mathbf{Q}(\overline{u})$ with segments

$$\mathbf{Q}_i(u) = (X_i(u), Y_i(u), Z_i(u)) \quad \text{for } 0 \le u \le 1,$$

where

$$\mathbf{Q}_i(0) = (X_i(0), Y_i(0), Z_i(0)) = (x_i, y_i, z_i) = \mathbf{P}_i$$

and

$$\mathbf{Q}_i(1) = (X_i(1), Y_i(1), Z_i(1)) = (x_{i+1}, y_{i+1}, z_{i+1}) = \mathbf{P}_{i+1}.$$

The positions in the inbetween frames on each such segment will be given by $\mathbf{Q}_i(u)$ for some sequence of u-values between 0 and 1. The entire curve $\mathbf{Q}(\overline{u})$ defines the *trajectory* followed by the point whose key positions we have interpolated. The *motion dynamics* of the the point's transit over this trajectory will be determined by the sequence of $\overline{u}$-values chosen. The discussion given here covers only the trajectory aspects of inbetweening; there is much work left to be done on the motion dynamics.

If we decide to use cubic splines with C^1 continuity at each joint, and we consider each of the segments in turn, we recall from Chapter 3 that each of the component polynomials $X_i(u)$, $Y_i(u)$, and $Z_i(u)$ can be defined uniquely by Hermite interpolation. Two constraints are given directly by the interpolation conditions and the other two constraints are given by specifying derivatives at $u = 0$ and $u = 1$. Thus, $\mathbf{Q}_i(u)$ is completely determined by

ClearCorrect Exhibit 1002, Page 1007 of 3373

$$\mathbf{P}_i \quad \text{and} \quad \mathbf{D}_i = \left[\frac{dX_i(0)}{du}, \frac{dY_i(0)}{du}, \frac{dZ_i(0)}{du} \right]$$

and

$$\mathbf{P}_{i+1} \quad \text{and} \quad \mathbf{D}_{i+1} = \left[\frac{dX_i(1)}{du}, \frac{dY_i(1)}{du}, \frac{dZ_i(1)}{du} \right].$$

This is shown in Figure 21.4.

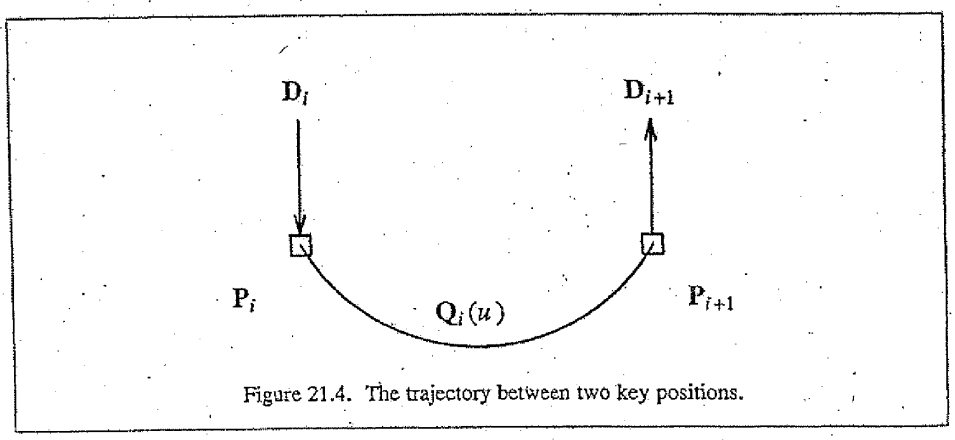


Figure 21.4. The trajectory between two key positions.

An automatic inbetweening system may choose $\mathbf{D}_i$ and $\mathbf{D}_{i+1}$ using some geometric information derived from the surrounding keys, or by human input, or by some combination of both.

The specification of $X_i(u)$, $Y_i(u)$, and $Z_i(u)$ is most conveniently made in terms of the *Hermite interpolation basis functions*, which are shown in Figure 21.5. These functions have the following properties.

	h_{00}	h_{10}	h_{01}	h_{11}
function value at $u = 0$	1	0	0	0
function value at $u = 1$	0	1	0	0
derivative at $u = 0$	0	0	1	0
derivative at $u = 1$	0	0	0	1

Consider any expression of the form

$$p(u) = a\,h_{00}(u) + b\,h_{10}(u) + c\,h_{01}(u) + d\,h_{11}(u),$$

ClearCorrect Exhibit 1002, Page 1008 of 3373

SPIE Volume 166

NATO Symposium on APPLICATIONS OF HUMAN BIOSTEREOMETRICS

Sponsored by The Special Programme Panel on Human Factors

A. M. Coblentz, R. E. Herron
Editors

July 9–13 Juillet
1978
Paris, France

Symposium OTAN sur

LES APPLICATIONS DE LA STEREOMETRIE A LA BIOMETRIE HUMAINE

Published and distributed worldwide by the
Society of Photo-Optical Instrumentation Engineers
P.O. Box 10, Bellingham, Washington 98225 USA
206/676-3290

ClearCorrect Exhibit 1002, Page 1009 of 3373

A STEREOPHOTOGRAMMETRIC SYSTEM FOR THE DETECTION OF PROSTHESIS LOOSENING IN TOTAL HIP ARTHROPLASTY

UNE MÉTHODE STÉREOPHOTOGRAMMÉTRIQUE POUR LA DÉTECTION DU DÉCOLLEMENT DE LA PROTHESE DANS L'ARTHROPLASTIE TOTALE DE LA HANCHE

Sheldon Baumrind, Harry K. Genant, John Hunter, David Miller
Francis Moffitt, William R. Murray, Steven E. Ross
University of California — School of Medicine
University of California — School of Dentistry
San Francisco, California 94143
University of California — Department of Civil Engineering
Berkeley, California 94720 (U.S.A.)

Abstract

Loosening of the prosthetic device occurs in about 5% of cases following placement of total hip prostheses (THP). Early detection of loosening is much desired but is difficult to achieve using conventional methods. Due to errors of projection, it is quite possible to fail to detect mobility of even as much as 5 mm on single x-ray films.

We are attempting to develop a simplified photogrammetric system suitable for general hospital use which could detect loosening of 0.8 mm at the 95 % level of confidence without use of complex stereoplotting equipment. Metal reference markers are placed in the shaft of the femur and in the acetabular region of the pelvis at the time of surgery. The distances between these reference markers and certain unambiguous points on the prostheses are computed analytically using an X—Y acoustical digitizer (accuracy ± 0.1 mm) and software developed previously for craniofacial measurement. Separate stereopairs of the joint region are taken under «weight-bearing» and «nonweight-bearing» conditions. Differences in the measured distances between the bone markers and the prosthetic components on the two stereopairs are taken as indicators of prosthesis loosening.

Measurements on a phantom using ten different x-ray stereopairs taken from as many different perspectives have established that true linear distances between reference points and prostheses can be measured at the desired reliability with the present low precision system. Preliminary *in vivo* measurements indicate that the main unresolved problem is the movement of the subject between the two exposures of each single stereopair. Two possible solutions to this problem are discussed.

Résumé

Le desserrement de l'appareil de prothèse se produit dans environ 5 % des cas après le placement de prothèses totales de la hanche (THP, Total Hip Prostheses). Une détection rapide du desserrement dès le début est hautement souhaitable, mais n'est guère facile en suivant les méthodes classiques. A cause des erreurs de projection, la mobilité d'une prothèse, même seulement de l'ordre de 5 mm, peut parfaitement passer inaperçue sur des radiographies simples.

Nous essayons de développer un système photogrammétrique simplifié propre à être utilisé dans les hôpitaux et qui puisse détecter un desserrement de 0,8 mm, pratiquement sans risque d'erreur, sans qu'il faille recourir à un matériel de repérage compliqué. Des marqueurs de référence métalliques sont placés dans le corps du fémur et dans la région de la cavité cotyloïde du pelvis au moment de l'opération chirurgicale. Les distances entre ces marqueurs de référence et certains points précis des prothèses sont calculées analytiquement à l'aide d'un digitizer acoustique x-y (de l'ordre de précision de ± 0.1 mm) et du logiciel développé antérieurement pour les mensurations crâniofaciales. Des couples d'images distincts de l'ensemble de la région sont pris, le sujet portant le poids du corps sur sa jambe à prothèse puis sur l'autre. Les différences dans les distances mesurées entre les marqueurs et les composants prothésiques sur les deux stéréopairs indiquent le degré de desserrement de la prothèse.

Les mesures effectuées sur une silhouette à l'aide de 11 différents «stéréopairs» radiographiques pris à partir d'autant de perspectives différentes, ont établi que même avec le système actuel imparfait, les distances linéaires réelles entre les points de référence et les prothèses peuvent se mesurer avec le degré de précision voulu. Des mensurations préliminaires *in vivo* chez 18 patients opérés, indiquent que le principal problème restant à résoudre est l'estimation du mouvement du sujet entre les deux poses de chaque «stéréopair». Deux solutions possibles au problème sont proposées.

ClearCorrect Exhibit 1002, Page 1010 of 3373

A STEREOPHOTOGRAMMETRIC SYSTEM FOR THE DETECTION OF PROSTHESIS LOOSENING IN TOTAL HIP ARTHROPLASTY

Introduction

Total hip arthroplasty is a surgical procedure in which severe disease of the hip joint is treated by extirpation of the affected parts and their replacement by a prosthesis. The site of the operation is shown in Figure 1.

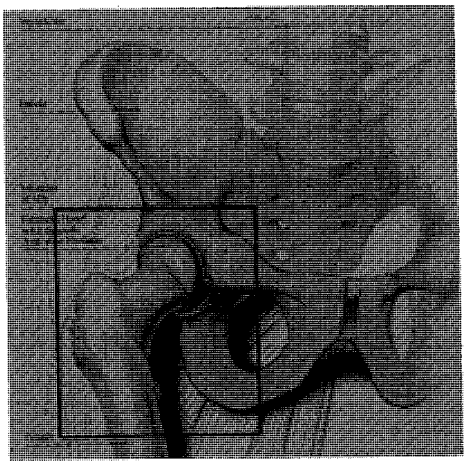


Figure 1

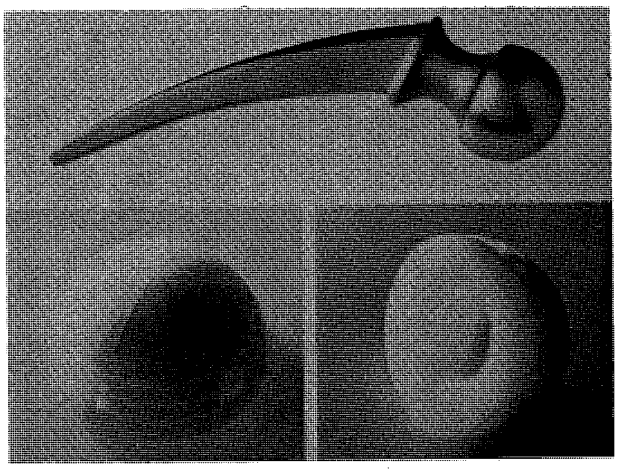


Figure 2

The prosthesis consists of two parts. These are a femoral component, which is made of cobalt-chromium-molybdenum alloy, and an acetabular (or pelvic) part, which is made of high-density propylethylene. The plastic acetabular component usually contains metal reinforcing wires. (See Figure 2). After suitable surgical preparation, the two parts of the prothesis are cemented into their respective bony housings with surgical bone cement (an acrylic polymer).

While the procedure is usually highly successful and is an important addition to modern orthopedic surgery's operational repertoire, the prosthesis is subjected to heavy functional stresses by the very fact of its physical location. Hence, loosening, particularly of the femoral component, occurs through time in a clinically consequential number of cases. The early detection of prosthetic loosening is therapeutically desirable in order to abort or minimize harmful secondary effects. Also, the ability to measure accurately the spartial relationships between the two components of the prosthesis and/or between each component and the bone into which it is cemented is crucial to the development of improved appliance designs and placement procedures.

Conventional roentgenographic methods using single films are inadequate for the making of linear measurements in three dimensional space because of inherent projection errors. These errors are particularly important in the present case because the neck of the femur does not lie parallel to either the frontal plane or the sagittal plane. Arthrography, a technique involving the introduction of contrast medium into the joint capsule prior to taking the x-ray film, also tends to be inconclusive for the present purposes, as well as being invasive.

An alternative approach to the problem is quantitative stereoroentgenology, a procedure which analogizes the classical methods of aerial mapping (1). A considerable number of x-ray variants of this method have been attempted by ourselves and others (2, 3), and there is little doubt that satisfactory results can be obtained at high levels of precision and accuracy if sophisticated stereoplotting instruments are used under ideal or nearly ideal conditions (4,5). Our own present attempt, however, has a somewhat different thrust. We desire to develop a simplified photogrammetric system suitable for general hospital use which is capable of detecting linear displacements of 0.8 mm or greater at the 95 % confidence level *without the use of complex stereoplotting equipement*. In lieu of conventional stereophotographic techniques which employ glass diapositives and stereoplotters, we employ direct digitization of x-ray films and/or acetate overlays using an X—Y accoustical digitizer (accuracy ± 0.1 mm) and software developed previously for craniofacial measurement (6,7). X-ray stereopairs are taken both with the subject at rest and with the leg under load. Between-stereopair differences in the measured distances from the prosthetic components to certain unambiguous points on the bone are taken as indicators of prosthesis loosening.

Materiels and Methods

The measurement task involves three quantitative determinations : 1) the determination of the spatial relastionship between the femoral component of the prosthesis and the shaft of the femoral bone; 2) the determination of the spatial relationship between the acetabular component of the prosthesis and the structure of the pelvic bone (more properly termed «innominate bone»); and, 3) the determination of the spatial relationship between the two components of the prosthesis.

In each determination, one desires to define the relative positions in three dimensional space of two assumedly rigid bodies. Such an operation requires the location of three unambiguous landmarks on each of the two objects involved in each determination with sufficient precision and accuracy as to yield useful information. Successful solution of the problem involves not only developing a sufficiently accurate measuring system, but also obtaining sufficiently unambiguous landmarks on each bone and on each component of the prosthesis.

ClearCorrect Exhibit 1002, Page 1011 of 3373

With regard to the acetabular component of the prosthesis, adequate unambiguous reference landmarks appear to exist in the form of the ends of the metal reinforcement wires shown in Figure 2, but with respect to the femoral component and the two bones, the situation is less favorable. On the femoral component of the prosthesis, one can locate the center of the sphere and the end of the prosthesis with sufficient reliability, but no third point is uniquely identifiable in appliances of current design. This means that one can define an axis between the two points on the prosthesis, but that one cannot, in fact, detect pure rotation around that axis. However, given the curvature of the appliance shaft, it is highly improbable that the shaft could rotate without discernable translatory movement of the two identifiable reference points.

As far as the two bones are concerned, the task of landmark location is considerably more difficult, since anatomical structures in general tend to be rounded and to have little edge strength on x-ray films. We have therefore generated artificial landmarks by placing a number of 0.8 mm or 1.0 mm metal spheres in each of the two bones at the time of surgery. In order to minimize galvanic effects, these spheres are made of the same alloy as that from which the femoral component of the prosthesis is constructed. The metal spheres are implanted into the bones using the instrument shown in Figure 3. It is modified from that of Lipper (8) in such a way as to make it «cartridge loading» rather than « ball loading», in order to reduce fatigue to the surgical team. The instrument consists of a 13 gauge hypodermic needle approximately 65 mm in length through which is fitted a somewhat longer pointed stylet. The outer end of the stylet is reinforced to provide a malleting platform. The stylet is inserted into the needle and the assembly is malleted into place in the bone, after which the stylet is withdrawn leaving the needle in position. A one-harf inch cartridge of 13 gauge tubing containing a single metal sphere is inserted into the breech of the needle and a slightly longer, blunt ended stylet is used to tap the sphere into position in the bone.

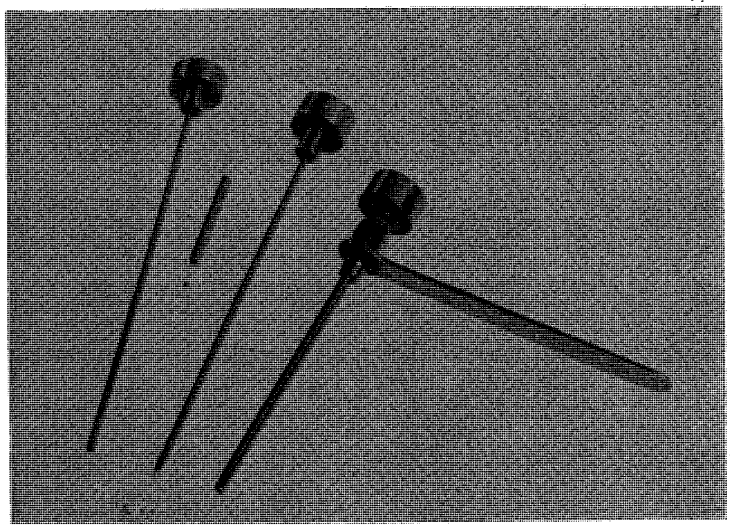


Figure 3

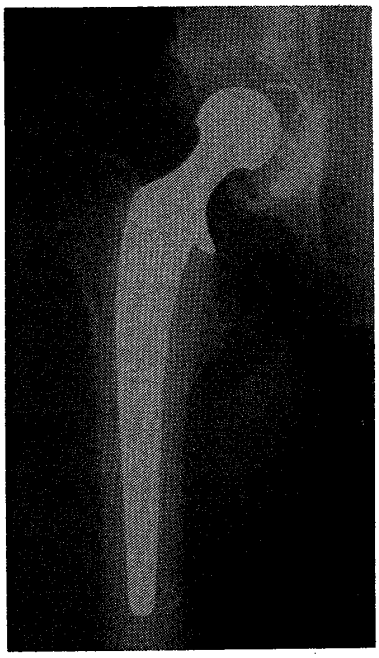


Figure 4

Ideally, four metal reference spheres are positioned in the femoral shaft and four others are placed in the innominate bone. The minimum number required to define uniquely the position of a three dimensional rigid body is, of course, three, but some redundancy helps to minimize measurement error. On the other hand, we have found that when more than five reference points are used in either bone, it becomes a practical problem to identify the same point uniquely on both films of a stereopair. As an additional aid to measurement accuracy, one would also wish that the reference points within each bone be as widely spaced as possible, but in practice questions of surgical accessibility constitute a limiting factor with respect to this goal. A representative x-ray of an early case showing the prosthetic components and the reference spheres in position *in vivo* is shown in Figure 4. (We have been able to obtain wider spacing of the reference markers in some of our more recently treated patients).

In addition to having unambiguously identifying points within and upon the object being measured, it is required that one know the geometry of the region in space in which the object lies. In order to define this object space, a «calibration cage» of known configuration has been constructed (See Figure 5). This cage, which mounts on the x-ray cassette holder, has four unambiguously identifiable metal points mounted in known positions on its front surface (between the patient and the x-ray source), and a similar array of four points between the patient and the cassette. This arrangement effectively «boxes in » the subject so that measurements of subject dimensions based upon them are computed by interpolation rather than by extrapolation.

ClearCorrect Exhibit 1002, Page 1012 of 3373

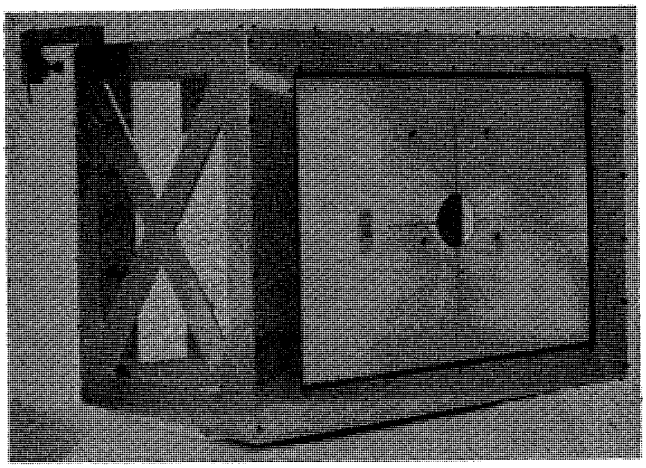


Figure 5

The x-ray exposures are made with the subject standing on paired support blocks within the calibration cage (See Figure 6). For one stereopair he is instructed to shift his weight entirely onto the leg which contains the prosthesis. The two exposures of this pair differ only in that the x-ray source is displaced vertically between them. For the second stereopair, the subject is instructed to shift his weight entirely onto the *non*prosthesis bearing leg. One of the support blocks is removed and the prosthesis bearing leg is allowed to hang free. Lanex rare earth screens are used with Ortho-G film. Exposure factors are 105 kVp, 500 mA and .035 seconds for a subject of average build.

All exposures are made with a nominal Focus Film Distance (FFD) of 72 inches (approximately 183 cm). The tube shift (or base displacement) is in the vertical direction and is approximately 14.5 inches (around 36 cm). Precise Focus Film Distances and base distances are computed by the system software for each stereopair, based on the configuration of reference markers in the calibration cage. Using the same reference, the software also computes the principal point for each film (i.e., the point of contact on the film plane of the normal ray from the x-ray source). Cassettes are conventionally changed after each exposure or each stereopair, so that there are two separate physical films for each stereopair. However, since the cassette position is the same for both film of each stereopair, the two films are coplanar and normal case stereometric equations can be used, considerably simplifying data reduction. Alternatively, both exposures of each stereopair can be made on the same film surface, at the cost of somewhat increased problems in landmark identification (See Figure 7).

Primary data acquisition in our system has, to date, been accomplished by trans-illuminating each x-ray film and then marking the locations of the points of interest on a .005 matte acetate overlay with a 0.5 mm lead pencil! (See Figure 8). Up to 27 points are located on each x-ray film. These include four points on the calibration cage between the cassette and the subject, termed REG points, four points on the calibration cage between the subject and the x-ray source, termed ROD points, three to five femoral shaft reference points (designated FTIP1 through FTIP5), two to four femoral prosthesis reference points (designated CENTPROS, ENDPROS, CAVCOL and VEXCOL), three to five innominate bone reference points (designated ATIP1 through ATIP5), and three to five acetabular prosthesis reference points (designated AWIRE1 through AWIRE5). These landmarks are illustrated on Figure 10. Three replicate «tracings» are made of each film — thus far without the aid of magnification or of variable illumination. In fact, the act of «tracing» is by far the crudest part of our system at this stage of its development.

Landmark locations from the tracings are encoded in digital form using a Science Accessories Corporation GP/3 Acoustical digitizer linked to the IBM 370/148 computer at the University of California, San Francisco (See Figure 9). In the mode in which it is employed, this digitizer has a rated machine accuracy of ± 0.1 mm in the X *or* Y direction (9). The three tracing values for each point are automatically averaged and outlying values are automatically detected and cast out by the software. By means of a least squares best fit, the two two-dimensional arrays of values for the two films of each stereopair are superimposed on the values of the four registration points on the calibration cage which are located between the patient and the cassette. The FFD and the principal point for each film are computed. The base distance is then calculated as the distance between the two principal points on the datum plane. All points on both films are now re-expressed in terms of a common coordinate system whose origin is the principal point of one film and whose X axis passes through the principal point of the other film. In this coordinate system, displacements between the conjugate images of the same point on the two films is a measure of Z (the height above the reference plane defined by the REG points), while Y displacements are a measure of error due either to failure to identify the same point uniquely on both films or to subject movement between films. A table is routinely generated showing the two dimensional coordinate values for all points on each film, as well as the parallax of each point in both X and Y). Excessive errors in Y are flagged as an assurance that undue confidence will not be placed in flawed output (See Figure 11).

The X parallax of each point is now used to generate a three dimensional coordinate map using standard photogrammetric equations. Three versions of the digital map are which differ only with respect to their coordinate systems. For determinations fo the spatial relationships between the femoral component of the prosthesis and the femoral bone, a coordinate system is used in which the X, Y, and Z axes are defined in terms of the femoral shaft reference points and measurements are made to the femoral prosthesis points. For determination of the spatial relationships between the acetabular component of the prosthesis and the innominate bone, the axes are defined in terms of the innominate bone reference points and measurements are made to the acetabular reference points. For determination of the spatial relationships

ClearCorrect Exhibit 1002, Page 1013 of 3373

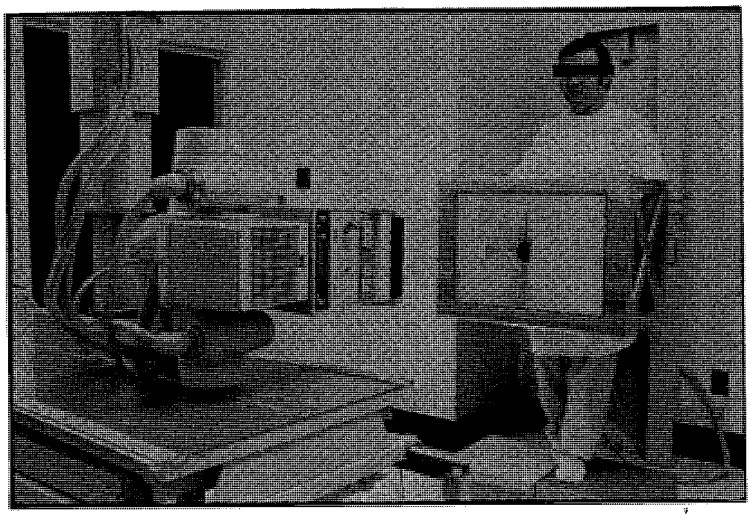


Figure 6A - Subject and X-ray source positioned for a «normal» exposure.

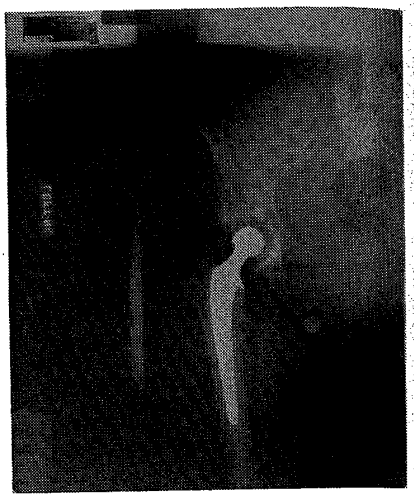


Figure 6B - A film taken from the perspective shown in Figure 6A.

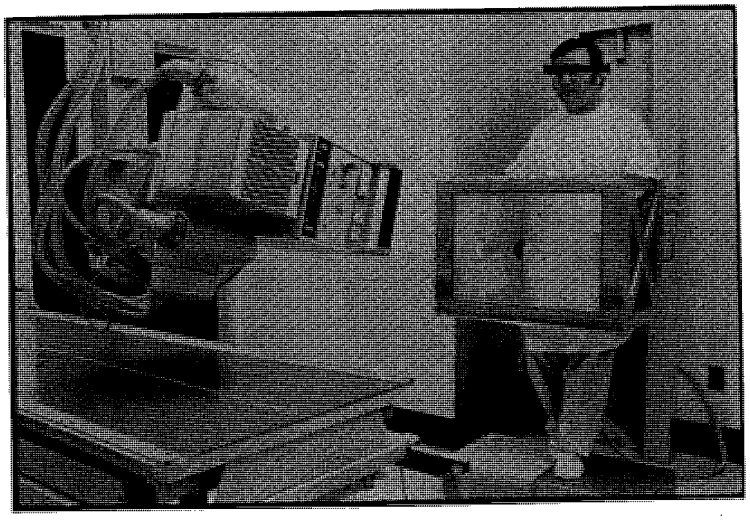


Figure 6C - Subject and X-ray source positioned for an «oblique» exposure.

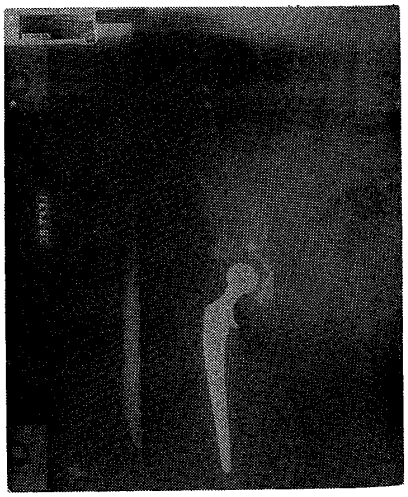


Figure 6D - A film taken from the perspective shown in Figure 6C.

Note : The films shown in Figures 6B and 6D constitute a stereopair.

ClearCorrect Exhibit 1002, Page 1014 of 3373

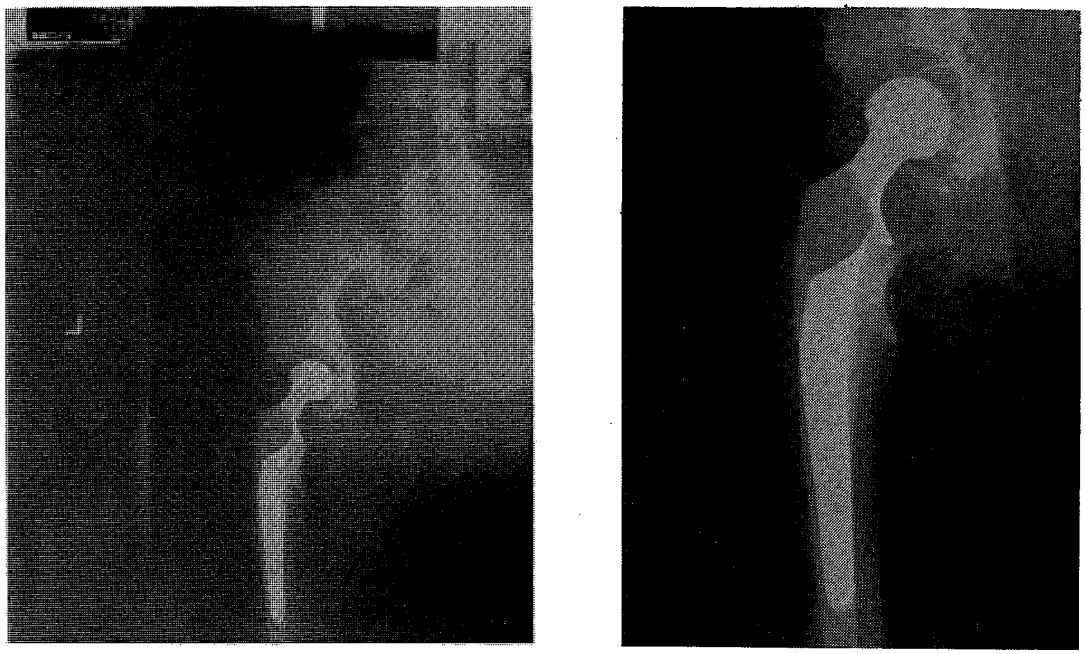


Figure 7 - A «double exposure» stereopair; both projections on a single film.



Figure 8 - Tracing a film.

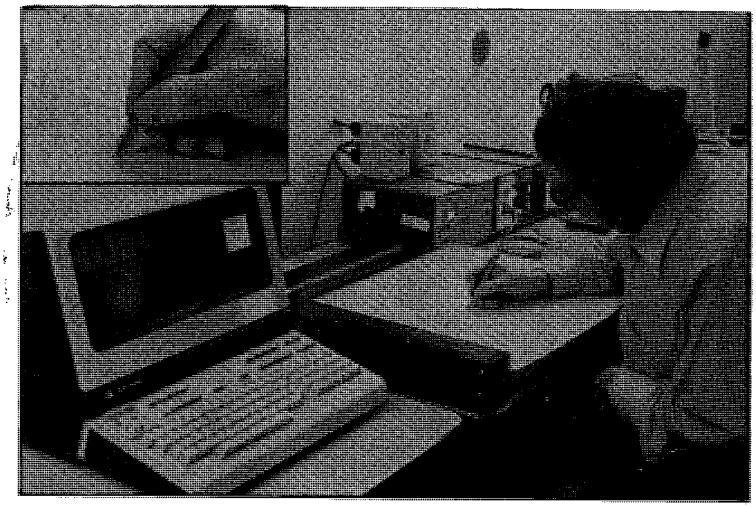


Figure 9 - Digitizing a tracing.

ClearCorrect Exhibit 1002, Page 1015 of 3373

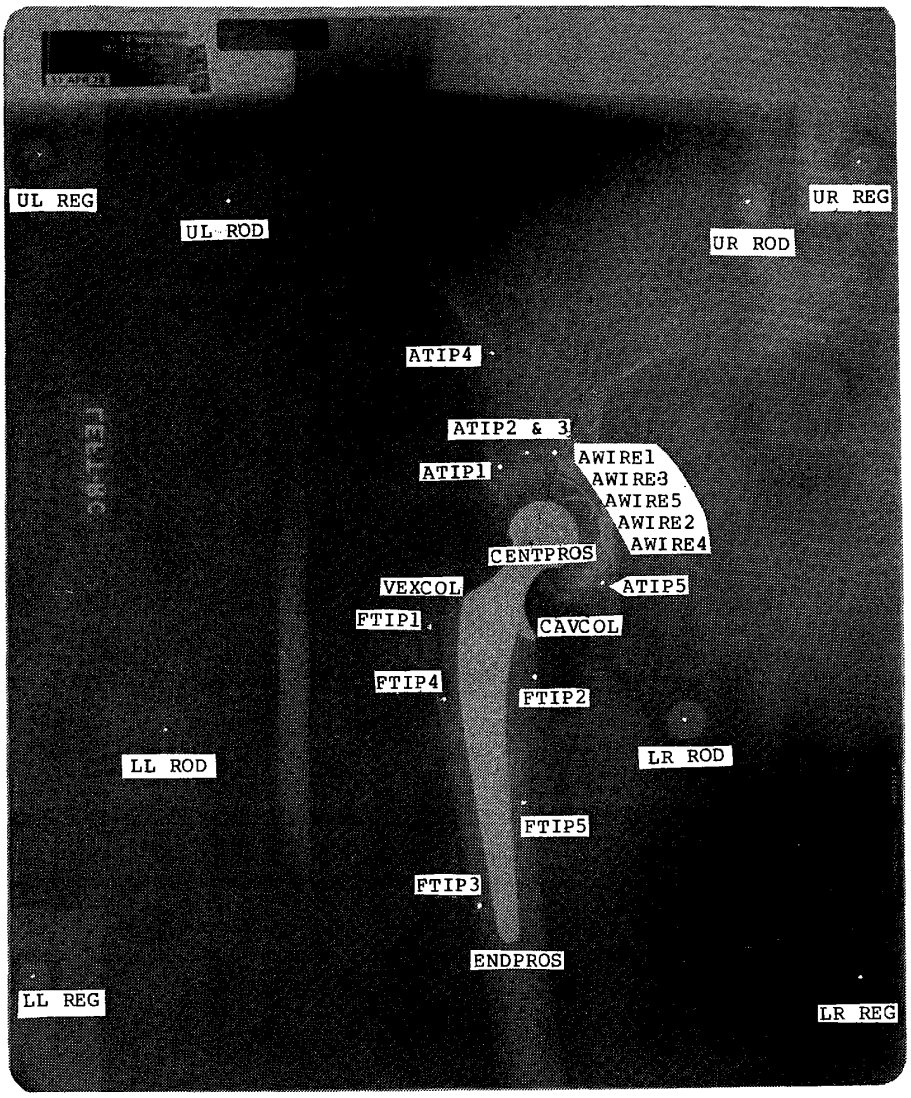


Figure 10 - A semi-schematic and somewhat idealized representation fo the twenty-seven landmarks employed as see on a «normal» projection. (See Figures 6A & 6B).

Points LL REG, UL REG, UR REG and LR REG are located on the back plane of the calibration cage between the subject and the film surface.
Points LL ROD, UL ROD, UR ROD, and LR ROD are located on the front surface of the calibration cage between the subject and the X-ray source.
Landmarks FTIP1, FTIP2, FTIP3, FTIP4 and FTIP5 are located on the shaft of the femur.
Landmarks ATIP1, ATIP2, ATIP3, ATIP4 and ATIP5 are located in the acetabular region of the innominate bone (pelvis).
Landmarks AWIRE1, AWIRE2, AWIRE3 and AWIRE4 are the ends of the two crossed re-inforcing wires in the acetabular component of the prosthesis. (See Figure 2). AWIRE5 is the intersection between the two crossed wires.
CENTPROS is the center of the sphere of the femoral component of the prosthesis.
ENDPROS is the tip end of the femoral component.
CAVCOL is the outermost point of the femoral component on its concave surface while VEXCOL is the outermost point on its convex surface.

ClearCorrect Exhibit 1002, Page 1016 of 3373

between the two prosthetic components, the axes are defined in terms of the acetabular component landmarks and measurements are made to the center of the femoral component.

POINT CO-ORDINATES AND PARALLAXES IN PRINCIPAL POINT CO-ORDINATE SYSTEM:
(REPORTED AT THE SCALE OF THE ORIGINAL PHYSICAL RECORD)

NORMAL FILM			OBLIQUE FILM			PARALLAX		
PT NAME	X	Y	PT NAME	X	Y	X	Y	
LL REG	-304.13	161.80	LL REG	-304.21	161.66	0.08	0.13	
UL REG	13.60	164.00	UL REG	14.00	164.03	-0.39	-0.04	
UR REG	16.43	-153.51	UR REG	16.14	-153.23	0.29	-0.28	
LR REG	-300.75	-155.02	LR REG	-300.77	-155.20	0.02	0.18	
LL ROD	-222.55	92.52	LL ROD	-316.07	93.46	93.52	-0.94	
UL ROD	-21.31	118.43	UL ROD	-115.41	118.76	94.10	-0.33	
UR ROD	-20.92	-82.79	UR ROD	-114.49	-82.30	93.58	-0.49	
LR ROD	-225.68	-107.48	LR ROD	-318.66	-106.36	92.99	-1.11	*** EXCESSIVE Y PARALLAX
FTIP1	-204.50	-17.27	FTIP1	-221.23	-17.46	16.73	0.19	
FTIP2	-205.24	-22.19	FTIP2	-223.10	-22.36	17.87	0.17	
FTIP3	-221.95	-12.88	FTIP3	-240.76	-13.03	18.82	0.15	
FTIP4	-214.89	-18.14	FTIP4	-233.36	-18.59	18.46	0.46	
FTIP5	-214.15	-19.52	FTIP5	-232.73	-20.01	18.58	0.49	
CENTPROS	-175.94	30.28	CENTPROS	-194.83	29.57	18.89	0.71	
ENDPROS	-334.11	3.43	ENDPROS	-303.86	162.15	-30.25	-158.71	*** EXCESSIVE Y PARALLAX
CAVCOL	-216.36	24.03	CAVCOL	-236.41	23.00	20.05	1.03	*** EXCESSIVE Y PARALLAX
VEXCOL	-196.58	-1.69	VEXCOL	-215.31	-2.51	18.74	0.82	
ATIP1	-149.60	13.04	ATIP1	-166.49	12.41	16.90	0.63	
ATIP2	-150.13	9.76	ATIP2	-168.81	8.86	18.68	0.90	
ATIP3	-151.96	28.19	ATIP3	-167.05	27.52	15.08	0.67	
ATIP4	-303.84	162.13	ATIP4	-303.96	162.15	0.12	-0.02	
ATIP5	-303.91	162.16	ATIP5	-303.89	162.18	-0.02	-0.02	
AWIRE1	-176.91	52.52	AWIRE1	-195.89	52.22	18.98	0.29	
AWIRE2	-151.79	31.10	AWIRE2	-169.37	29.85	17.58	1.25	*** EXCESSIVE Y PARALLAX
AWIRE3	-169.28	46.59	AWIRE3	-190.44	45.78	21.16	0.81	
AWIRE4	-159.74	36.93	AWIRE4	-175.53	35.94	15.79	0.99	
AWIRE5	-160.50	47.26	AWIRE5	-178.24	45.62	17.74	1.64	*** EXCESSIVE Y PARALLAX

Figure 11

Results

We report at this time comparisons of two groups of preliminary findings on the performance of the system. The first group is from a series of tests on a phantom consisting of a femoral prosthetic component cemented into a dried specimen femur. Ten stereopairs were made of a single, suitably prepared specimen (Figure 12). After each stereopair was taken, the specimen was translated and/or rotated within the object space by adjusting the tripod on which it was mounted. There was no movement of the specimen between the films of each stereopair, and the position of the calibration cage was held constant throughout the entire series.

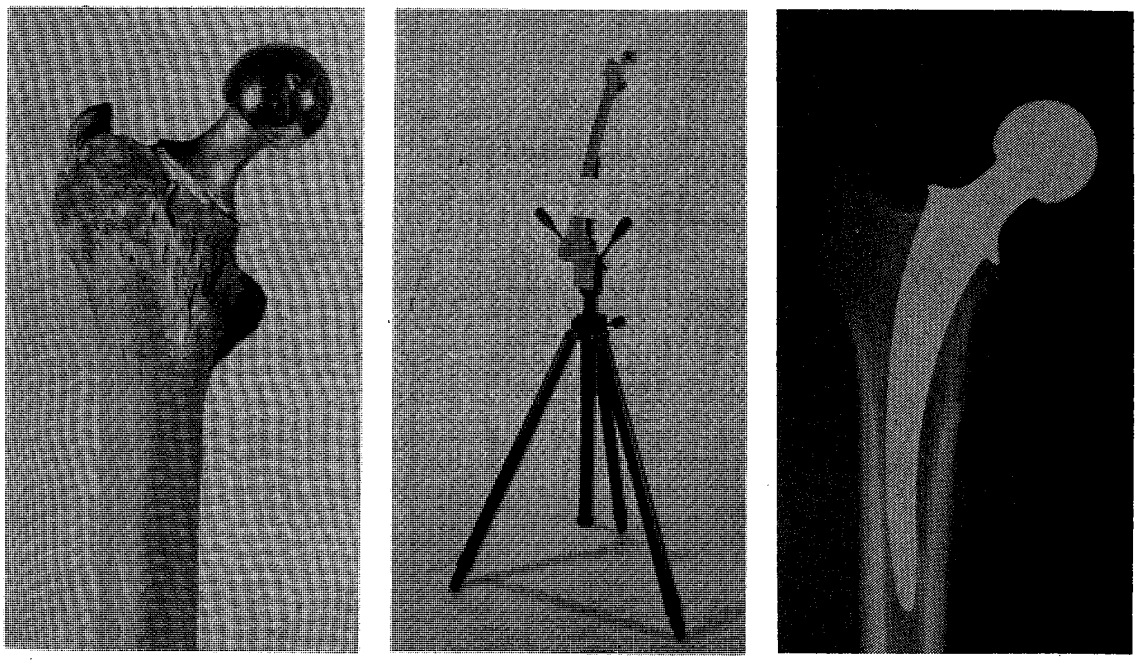


Figure 12

ClearCorrect Exhibit 1002, Page 1017 of 3373

The second group of findings is from sets of stereopairs taken for a single clinical patient on each of three occasions (ten days, six weeks and three months postoperative). At each time point, both a weight-bearing and a nonweight-bearing stereopair were obtained. Thus, six stereopairs are available in this group. A problem in the evaluation of this second group of data consists in the fact that no means of external validation is available since no other extant measurement system approaches the degree of accuracy we desire to achieve. For this reason, we have as yet no way of knowing whether small changes normally occur *in vivo* in the measured parameters between the weight-bearing and nonweight-bearing stereopairs at a single time point due to elastic changes in the anatomical structures under load. Similarly, we have as yet no way of knowing whether small dimensional changes normally occur through time in the distances between the metal markers within each single bone (from bone remodeling), or between the prosthetic components and their respective bones (from cement flow), or between the two prosthetic components (from appliance wear). Since the time interval between the first and the third sets of films in this group is relatively brief (i.e., three months), we have made the working assumption that none of these sorts of changes has occurred and that all measured differences between stereopairs in this group are due to measurement error.

Table 1 lists simple statistics comparing the reliability of location of the control points of the calibration cage for the two groups. This table and the ones which follow it permit inferences concerning three questions. 1. How reliably is each landmark estimated on each trancing ? 2. For each given landmark, is the same physical point located on both films of each stereopair ? 3. Does the goodness of the answers to questions # 1 and # 2 vary between the dried specimen and the clinical subject data sets ?

Columns # 1 and # 2 of Table 1 list the standard deviations for the location of each landmark for the three tracings of each films, summed through films. Column # 1 lists the standard deviation for the first films of all stereopairs; Column # 2 lists the standard deviation of the second films of all stereopairs. One would wish these values to be as small as possible, since if all three tracings for each film identified precisely the same physical point, the standard deviation would be zero.

Table 1 - Reliability of Measurement of Calibration Cage Points
(All Values Are Standard Deviations Units in mm)

	Group	N	Tracing Errors Film 1	Tracing Errors Film 2	Y-Parallax Error
LL REG	1	10	0.13	0.16	0.17
	2	6	0.14	0.16	0.12
UL REG	1	10	0.13	0.18	0.21
	2	6	0.15	0.18	0.14
UR REG	1	10	0.17	0.17	0.25
	2	6	0.16	0.15	0.15
LR REG	1	10	0.17	0.18	0.20
	2	6	0.15	0.12	0.10
LL ROD	1	10	0.21	0.25	0.28
	2	6	0.20	0.22	0.24
UL ROD	1	10	0.22	0.18	0.21
	2	6	0.29	0.17	0.15
UR ROD	1	10	0.27	0.23	0.27
	2	6	0.18	0.23	0.20
LR ROD	1	10	0.24	0.25	0.10
	2	6	0.14	0.20	0.24

The observed values are, in fact, small by clinical standards, and F tests indicate that there are no significant differences in reliability of location between the dried specimen group and the clinical patient group for any point in either film projection. This implies that the movement of the calibration cage does not consequentially affect the reliability of location of the landmarks on it. On the other hand, the data do imply that the reliability of locating the ROD points between the focal spot and the patient is significantly less good than that for locating the REG points between the subject and the cassette ($p < .002$ on the F test). This finding is consistent with the empirical observation that ROD points are relatively blurred on the films as the result of increased projection distance and greater enlargement.

Column # 3 reports for each landmark the standard deviation of Y parallax between the two films of each stereopair. These data are summed from tables of the type shown in Figure 10. As has been stated, there are two possible causes of Y parallax other than measurement error in landmark location. These are : 1) movement of the subject between the films of the same stereopair; and, 2) failure to locate the same physical point on both films of each given stereopair. Neither of these conditions should occur with any landmark on the calibration cage itself and no differences were, in fact, found beyond the reasonable expectations of system measurement error.

We conclude from the examination of Table 1 that the calibration cage landmarks are identifiable with an accuracy which is sufficient to meet the requirements of the system as specified, particularly when one considers the system redundancy and recognizes that the errors in estimation of ROD point altitudes introduce only fractional errors in the measurements of the test objects themselves.

Table 2 is analogous to Table 1 and reports findings concerning the first of the measurement tasks alluded to in Materials and Methods; the determination of the spatial relationship between the femoral prosthetic component and the shaft of the femoral bone. As in Table 1, comparisons are possible between the output from the group of ten stereopairs of the dried specimen and the group of six stereopairs from the same clinical subject. Column # 1 and # 2 reveal that the reliability of landmark location on the several tracings of the films of the dried specimen and treatment groups are, in the main, quite similar for each given landmark, but that some landmarks are more difficult to locate than are others. Specifically, the metal spheres in the femoral shaft (FTIP1, FTIP2, and FTIP3) are almost as readily located as are the REG points in Table 1, but the four points on the femoral prosthesis component itself are somewhat more variably located. These findings reflect real ambiguities in landmark identification which, however, we feel could be somewhat reduced by the use of slightly more so-

ClearCorrect Exhibit 1002, Page 1018 of 3373

phisticated landmark locating equipment (i.e., a better digitizing cursor and a low-power magnifying glass). Notwithstanding, it seems clear that even the present apparatus performs fairly satisfactorily for clinical measurement at the level of accuracy we have set ourselves.

Table 2 - Reliability of Measurement of Femur Bone and Femoral Component Prosthetic Component Points (All Values Are Standard Deviations, Units in mm)

	Group	N	Tracing Errors Film 1	Tracing Errors Film 2	Y-Parallax Errors	HYP (Linear) Errors
FTIP1	1	10	0.18	0.19	0.29	0.0
	2	6	0.17	0.16	2.04	0.0
FTIP2	1	10	0.17	0.17	0.21	0.70
	2	6	0.16	0.14	2.07	1.04
FTIP3	1	10	0.19	0.23	0.24	0.25
	2	6	0.22	0.16	1.98	0.34
CENTPROS	1	10	0.21	0.28	0.22	0.20
	2	6	0.22	0.17	1.93	0.33
ENDPROS	1	10	0.29	0.26	0.25	0.42
	2	6	0.24	0.28	83.68	94.03
CAVCOL	1	10	0.20	0.18	0.64	0.29
	2	6	0.34	0.34	2.10	0.40
VEXCOL	1	10	0.22	0.26	0.41	0.78
	2	6	0.18	0.33	2.15	0.52

Column # 3 reports Y parallax, a measure of the degree to which the same physical point was located on both films of each given stereopair. The Y parallaxes for the metal sphere in the dried specimen group are not markedly different from the analogous values in the calibration cage data of Table 1, but the values for the prosthesis points tend to be higher, again reflecting the ambiguity in landmark identification. More importantly, the Y parallax errors of the clinical subject group are systematically ten times higher than those for the dried specimen group, clearly reflecting the movement of the subject between the two films of each stereopair. In statistical terms, these differences are highly significant, the probability of chance differences of this magnitude being p is less than .0005 on the f test. (The single enormously elevated value for the landmark, ENDPROS, stems from the fact that this structure falls off the surface of some of the films in this group, completely precluding valid measurement).

Column # 4 lists the standard deviation for the computed distances between the origin (FTIP1) and each other landmark in the table. The calculations are made from the equation :

$$HYP = \sqrt{X^2 + Y^2 + Z^2}$$

where X, Y and Z are the coordinates of the given landmark in an orthogonal system in which FTIP1 is the origin and in which FTIP2 and FTIP3 define the axes. It is important to recognize that the HYP distance to each landmark on the femoral shaft is unaffected by errors in location of FTIP2 and FTIP3, whereas coordinate values for these landmarks would not be unaffected.

We conclude from Table 2 that the system can withstand slight movements of the subject between films of the same stereopair while still giving *linear* measurements of sufficient accuracy to be clinically useful. However, measurement accuracy is not great enough at present to permit generation of meaningful output in coordinate form.

Table 3 - Reliability of Measurement of Innominate Bone and Acetabular Prosthetic Component Points (All Values Are Standard Deviations, Units in mm)

	Group	N	Tracing Errors Film 1	Tracing Errors Film 2	Y-Parallax Errors	HYP (Linear) Errors
ATIP1	2	6	0.15	0.18	2.12	0.0
ATIP2	2	6	0.19	0.21	2.13	1.31
ATIP3	2	6	0.18	0.18	2.08	0.63
AWIRE1	2	6	0.18	0.51	1.99	0.64
AWIRE2	2	6	0.18	0.17	2.02	0.83
AWIRE3	2	6	0.20	0.20	1.89	1.44
AWIRE4	2	6	0.18	0.16	1.98	0.18
AWIRE5	2	6	0.24	0.22	1.94	1.15

ClearCorrect Exhibit 1002, Page 1019 of 3373

Table 3 reports findings relevant to the second measurement task; the determination of the spatial relationships between the acetabular prosthetic component and the innominate bone. Between group comparisons are not possible here since no information on the acetabular portion of the prosthesis is available in the dried specimen group. The values of this table confirm those of Table 2 – that there are consequential and statistically highly significant parallax errors associated with patient movement between films and that these affect the linear determinations of the distances between the origin (ATIP1) and the other landmarks. However, the effect on the HYP measurements is only a fraction of the actual parallax error itself. The variability among the findings for the several AWIRE points in the treated groups is mildly disappointing and we believe it may be due to the fact that the wire reinforcements in the prosthesis are thin and relatively radiolucent and are indistinct on some films.

Table 4 - Reliability of Measurements Acetabular Component Points and Center of Femoral Component

	Group	N	Tracing Errors Film 1	Tracing Errors Film 2	X-Parallax Errors	HYP (Linear) Errors
AWIRE1	2	6	0.18	0.51	1.99	0.0
AWIRE2	2	6	0.19	0.17	2.02	0.21
AWIRE3	2	6	0.20	0.20	1.89	1.09
CENTPROS	2	6	0.21	0.17	1.99	0.22

Table 4 is analogous to Table 3 for the third determination, that between the two components of the prosthesis. Linear distances between the origin of the coordinate system (AWIRE1) and the center of the femoral component seem to have been measured with sufficient reliability to detect looseness of the femoral component within the acetabular component, but not probably with sufficient accuracy to measure prosthesis wear through time.

Discussion

We believe that the data warrant the assertion that the system approaches clinical utility in its present form. The two major sources of error, given satisfactory placement of the metal reference markers, are : 1) Adequacy of the landmark locating and digitizing procedures; and, 2) control of the effects of subject movement between the two films of each stereopair.

It is a relatively simple task to reduce the errors of the landmark locating operation by direct digitization of the x-ray film while it is mounted on a light table and under suitable low-power optical magnification and we are currently making such a modification. The control of movement of the object between films is a more challenging problem. Two kinds of approach to the solution of this problem present themselves. The first is a physical solution, based on simultaneous exposure of both films of the stereopair from two x-ray sources as has been done, for example, by Selvik (6). Two variants of this approach are possible : a) One could simultaneoulsly double expose a single x-ray film. This approach would permit reduction of patient exposure (since the dose for each projection could be reduced by approximately 50%). It also has the advantage of reducing the total number of film generated, thus saving in film costs and storage space. Its liabilities are that the tasks of landmark identification is made considerably more difficult and that the resultant film is not useable for any other diagnostic purposes. (We have done some preliminary work with this approach and a representative early image of this type has been shown in Figure 7). b) One could alter the geometry of the system by holding the films further back behind the subject while protecting each film from stray emissions from the other energy source through the use of suitable baffles. This method has the advantage of producing discreet films less ambiguous than those of method «a», but it would involve either the use of oversized films and cassettes with attendant increased problems in film processing and storage, or of more expensive alternative image capturing systems.

The second general approach to the problem of patient movement between films involves mathematical corrections based on the known configuration of the metal reference spheres embedded in the femoral shaft and the innominate bone. In this approach, the weight-bearing stereopair would be taken with the patient physically immobilized. Baseline computations would be made establishing the true relationships between the several metal markers on each bone. These data would be used for rectification of the data from the nonweight-bearing stereopair by computation. An analogous problem involving head movement during craniofacial stereorentgenography has been under development by our group for some time.

The test of the clinical utility of this system is not solely a question of quantitating accuracy and precision, but also involves questions of costs and of facility of application. Conversion of the information from the x-ray film to digital form by this method can be satisfactorily accomplished by a semi-skilled medical technician after no more than three hours of training. Digitizing time does not exceed 1 1/2 hours per two stereopairs including triple determinations of all landmark locations as a control for operator reliability. Total processing time on our IBM 370/148 is approximately 12 seconds for two stereopairs.

This study has been supported in part by NIH—NIDR Grant Number DE03703.

ClearCorrect Exhibit 1002, Page 1020 of 3373

References

1 - Moffitt F.H., *Photogrammetry*, International Textbook Company, 1967.

2 - Hallert B., *X-Ray Photogrammetry*, Elsevier, Amsterdam, 1970.

3 - Herron R., *Biostereometric Measurement of Body Form*, In Yearbook of Physical Anthropology, 16 : 80–120, 1972.

4 - Varess S.F., Lippert F.G., Takomoto T., *An Analytical Approach to X-Ray Photogrammetry*, Photogrammetric Engineering and Remote Sensing, 43 : 1503–1510, 1977.

5 - Rune B., Jacobsson S., Sarnas K.V., Selvik G., *Roentgen Stereophotography Applied to the Cleft Maxilla of Infants*, Scand. J. Plastic Reconstructr. Surg., 11 : 131–137, 1977.

6 - Baumrind S., Moffitt F., Miller D., *Computer-Aided Three-Dimensional Mapping of the Skull from Stereo Head Films*, J. Dent. Res. (Spec. Issue), 53 : 274, 1974.

7 - Baumrind S., *A System for Craniofacial Mapping Through the Integration of Data from Stereo X-Ray Films and Stereophotographs*, in Technical Papers from the Symposium on Close Range Photogrammetric Systems, Am, Soc. Photogrammetry, 1975.

8 - Lippert F.G., Varess S.A., Takomoto T., Skolek M.S., *Experimental Studies in Patellar Motion Using X-Ray Photogrammetry*, in Technical Papers from the Symposium on Close Range Photogrammetric Systems, Am. Soc. Photogrammetry, 1975.

9 - Moritz W.E., Shreve P.L., Mace L.E., *Analysis of an Ultrasound Spatial Locating System*, IEEE Trans. Instr. and Meas. IM–25 : 43, 1976.

ClearCorrect Exhibit 1002, Page 1021 of 3373

MAPPING THE SKULL IN 3-D

Sheldon Baumrind, D.D.S.
Berkeley
Francis Moffitt, M.C.E.
Berkeley

ALN122594

Reprinted from **The Journal,**
California Dental Association
1972 Fall Issue, Volume 48, No. 2

MAPPING THE SKULL IN 3-D

Sheldon Baumrind, D.D.S.*
Berkeley
Francis Moffitt, M.C.E.**
Berkeley

What do grandmothers's old stereoscope, aerial map making, and dental research have in common? You may remember the stereoscope. It was an odd glass and wood gadget frequently used by kids on rainy afternoons before TV to look at faded sepia-toned cardboard-backed double pictures of the Palace of the Medici and the Leaning Tower of Pisa.

Strangely enough, the principles of parallax by which that old stereoscope worked are now widely used in aerial map making. And the same principles are beginning to be used by dental researchers and clinicians interested in measuring craniofacial growth and in assessing the effects of orthodontic treatment.

This article is a discussion of the principles involved in using parallax to make measurements on photographs and x-ray films of the face, jaws and teeth. A study aimed at developing simplified methods and equipment for making such measurements is currently being conducted by the authors. The study is aided in part by funds from the Research Council of the California Dental Association and the Computer Center of the University of California, San Francisco.

The characteristic of the stereoscope which is useful in both aerial mapping and dental research is its ability to produce a three dimensional effect from two simultaneously viewed pictures. The two pictures are termed a stereopair. They must overlap and must have been taken with a common film plane but from different camera positions. Figure 1 shows a typical aerial photographic stereopair while Figure 2 shows a pair of stereo x-ray films of the skull. A careful examination of these two figures using a small lens stereoscope will reveal a surprising similarity in three-dimensional effect.†

Fgure 2. A pair of stereoscopic x-ray films of the skull taken with the apparatus described in this article.

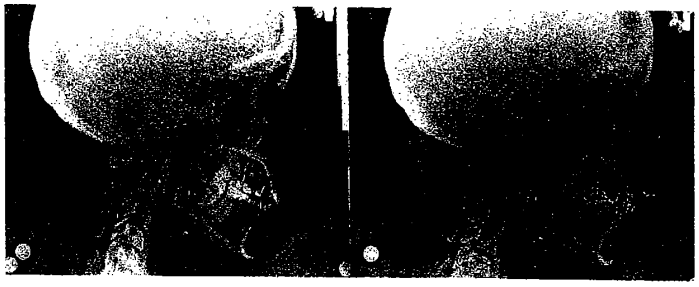
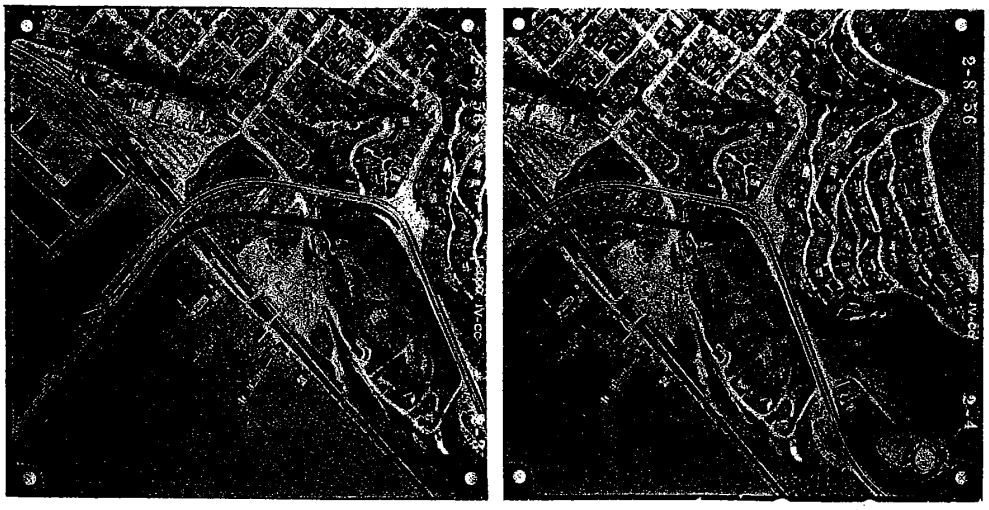


Figure 1. This typical pair of overlapping photographs shows the old Carquinez bridge prior to construction of the parallel span.



ALN122595

*Assistant Professor of Orthodontics, University of California, San Francisco

**Professor of Civil Engineering, University of California, Berkeley

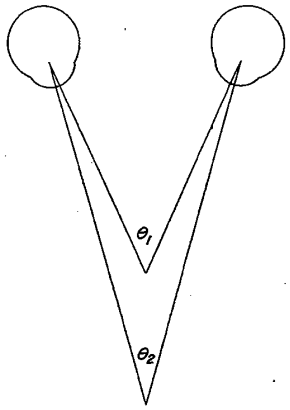
†While this article is written so that it can be followed reasonably well without a stereoscope, its illustrations will be more dramatic and its ideas more readily apparent if such an instrument is available. If reader will fill out and return the detachable envelope attached to page 31, a suitable lens stereoscope will be mailed to him.

Lay the Journal flat on a well-illuminated surface. Hold the stereoscope against the eyes with its handle in your right hand. The plane of the stereoscope should be aligned parallel to the plane of the Journal and about six inches above its surface. The imaginary line joining the centers of your eyes (termed the eye base) should be parallel to the upper and lower edges of the illustration. Move the head slowly toward and then away from the printed page until you get precisely the right distance for your own eyes. It is sometimes helpful to blink occasionally. After a few moments of accommodation, you should see a three dimensional "stereoscopic" image. Figure 1 will probably be a bit easier to view stereoscopically than Figure 2 because even to us dentists the idea of viewing x-ray films in three dimensions is more foreign than is the idea of a three dimensional aerial view. Also, as will be explained later, the principle of stereoscopic viewing depends upon binocular vision. This implies that your eyes need be reasonably well balanced in viewing ability in order for the demonstration to work satisfactorally.

"Well," you may say, "those may be dramatic pictures but what do they have to do with measurement?" The answer is not completely simple but is well worth the trouble of a brief exploration.

When we view a point at some distance from us, the eyes converge slightly to focus on the point. Figure 3 represents schematically the act of viewing such a point. Line segments can readily be drawn

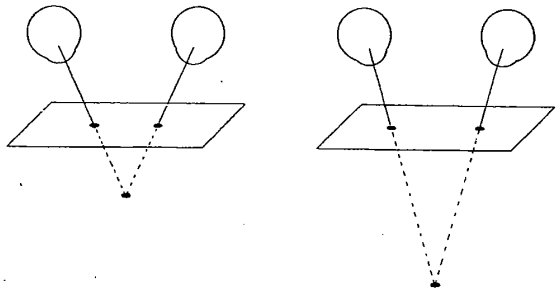
Figure 3. The relationship between binocular depth perception and parallactic angle. As the perceived point gets farther away, the parallactic angle gets smaller.



from the point through the center of the lens of each eye. The included angle between the two line segments is known as the parallactic angle of the point. Points at different distances from an observer will obviously have different parallactic angles. These differences in parallactic angle are automatically interpreted by the brain as differences in distance. The smaller the parallactic angle, the more distant from the observer the point is perceived to be.

Suppose we now conduct a demonstration experiment. On a piece of blank white paper, mark two pencil points about one inch apart. Hold this slip of paper ten to twelve inches in front of your face with the dots aligned horizontally and the plane of the paper perpendicular to the floor. Now force yourself to view the dots simultaneously, viewing each dot with only one eye. This procedure involves a bit of eye strain but if you are successful your brain will be fooled and will tell you that you are viewing but a single dot positioned behind the plane of the paper. Try the procedure again with a new piece of paper the same distance in front of your face but this time with the two dots positioned a quarter of an inch further apart. Now the two dots will appear to merge at a single point somewhat further behind the paper.

Figure 4. Parallactic angle as a function of the separation of a pair of dots. As the distance between the pair of dots increases, the resultant fused dot appears to recede from the viewer.



What you have done is depicted schematically in Figure 4. Actually, the operation carried out in this little demonstration is remarkably similar in principle to the act of viewing with a stereoscope. In grandma's old version, the two pictures of the stereopair were taken from camera positions separated from each other by approximately an average person's interpupilary distance. Each photograph of the stereopair can properly be considered as an infinite set of dots similar to those viewed by one eye in Figure 4. Each point in one picture is related uniquely to one point in the other picture, i.e. the point which represents the same physical object. We call these "conjugate points." The stereoscope itself is conceptually nothing more than an optical crutch which allows one eye to observe one picture while the other eye views the other picture, avoiding the eyestrain involved in our demonstration experiment. The distance between the two dots of each conjugate pair varies as a function of the distance between the camera and the physical object which the conjugate points represent.

It may thus be seen that with the aid of a stereoscope the eyes receive information separately, one eye receiving each picture in the stereopair. The

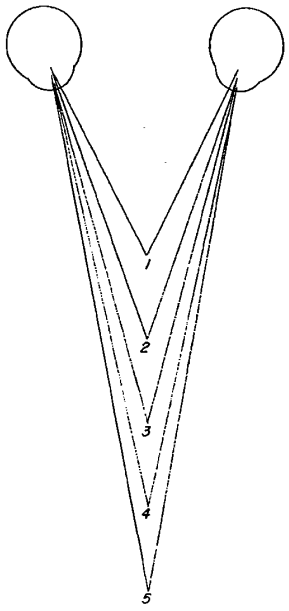
ALN122506

brain integrates the information contained in the two pictures. For each physical object depicted in the stereopair, the brain automatically measures the distance between the conjugate points. This distance between the two conjugate points is of course a measure of the parallactic angle as was shown in Figure 4. It defines what is termed the parallax of the point. For different structures in the visual field, differences in parallax are automatically interpreted by the brain as differences in distance.

The mechanism by which a human being estimates distances binocularly in normal viewing of the external physical world (without photographs or stereoscope) is precisely similar in principle. Each eye sees the external physical world independently. The brain integrates the two retinal "pictures" and measures the displacements of conjugate points between them. But the closeness together of a man's eyes is a limiting factor in his ability to estimate distances binocularly. For as the objects observed get further from us, the changes in parallax and in parallactic angle become progressively smaller for incremental increases in distance of the same magnitude, as may be seen in Figure 5.

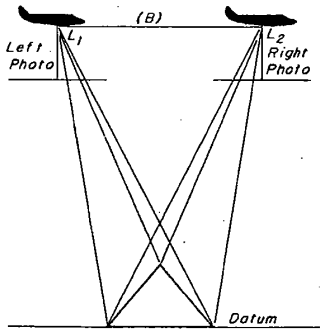
This explains why the more distant an object is from us, the more difficult it is to estimate its distance precisely. One way to minimize this problem of estimating how far we are from distant objects is to increase the effective distance between the eyes.

Figure 5. Reduction in the rate of change of parallactic angle as distance increases. Points 1 through 5 are equally spaced. (Check them with a Boley gauge!) Yet the size difference between the angle at 4 and the angle at 5 is much smaller than that between the angles at 1 and 2. The decrease in the rate of change of parallactic angle as distance increases is a limiting factor in binocular depth perception.



This principle is widely employed in the field of aerial photogrammetry. Photogrammetry is the science of measuring photographs and aerial photogrammetry is a branch of civil engineering concerned, among other matters, with the making of precise contour maps from aerial photographs.

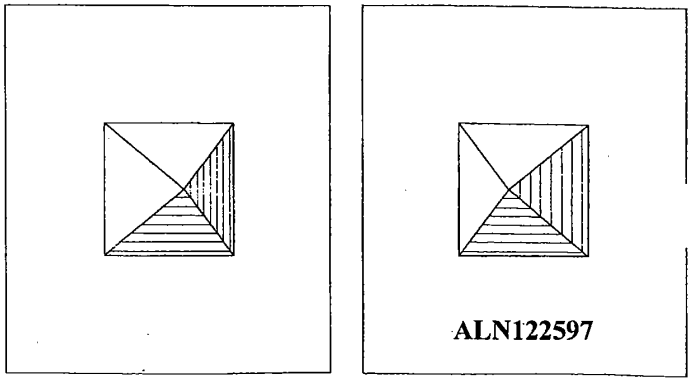
Figure 6. Schematic diagram of an airplane taking a pair of overlapping photographs. The object on the ground is an idealized pyramid.



Almost all modern maps are made from overlapping aerial photographs (see Fig. 6). An airplane flies over the terrain to be mapped. At camera station L1, a photograph is taken with a vertically oriented camera. The plane then flies onward a pre-determined distance (B), analogous to the interpupillary distance in Figures 3, 4 and 5 above, at a constant altitude. When the plane reaches camera station L2, another vertical photograph is taken. The distance (B) is called the air base.

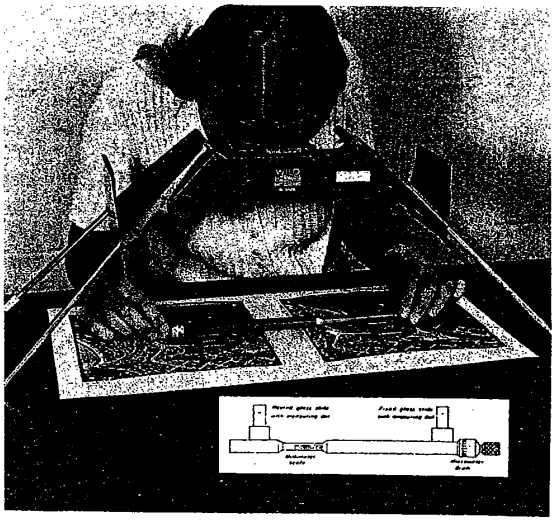
Figure 7 is a schematic stereopair showing how the two photographs taken in Figure 6 would actually

Figure 7. The two overlapping "photographs" which were "taken" in Fig. 6. Careful measurement of the distance between the points representing the pyramid top shows it to be just a bit over 50 mm while measurement between the conjugate images of any of the corners at the pyramid base yields a value of 55 mm. Thus the difference in parallax between top and base is just under 5 mm.



look. If you view Figure 7 through the stereoscope, you will in fact find that the two points representing the top of the pyramid fuse and appear through the instrument as a single point nearer to you than is the single fused point from the conjugate pair at say the lower left corner of the base of the pyramid. If you now put aside the stereoscope and measure the length of the horizontal line segment connecting the two points of each conjugate pair directly upon the Journal page, you will find that the line segment connecting the pyramid top points differs in length from that connecting the pyramid base points. A Boley gauge is a good instrument for making these measurements. Once they are made you will have acquired the only remaining piece of information needed in order to duplicate physically the previously discussed operation of the brain in measuring distances on retinal images. This is to say that if height of the aircraft above the ground, the distance between the camera stations (B), and the camera characteristics are all known, the actual altitudes of the base and top of the pyramid can be computed simply from the measurements of parallactic distance. Of course the height of the aircraft above the ground and the base distance (B) must be known with great accuracy. In aerial photogrammetry, information about aircraft altitude and the distance traveled between camera exposures is computed very precisely by reference to three or more "ground control points" whose positions are known from previous measurement. The process of determining the locations of these control points prior to the flight mission is known as establishing ground control. The principle of the use of ground control can also be utilized in dental stereo measurement as will be developed later.

Figure 8. Use of a mirror stereoscope and parallax bar in measuring the stereopair from Figure 1. The insert details the parallax bar. See text for a description of its essential components.



The system we have outlined in fact represents the classical measuring method of modern aerial map making. In Figure 8, a young lady is shown actually measuring, with the aid of a stereoscope, the same stereopair which you have already seen in Figure 1.

In her hand may be seen a specialized measuring micrometer known as a parallax bar. It is a more precise tool for carrying out the same measuring process for which you used a Boley gauge on Figure 7. The terrain features of real stereopairs are usually not so easily identified as are those of the schematic Figure 7. The parallax bar is therefore so constructed as to facilitate the process of precise landmark identification. It consists of a micrometer with glass slides at each end. On each slide a black dot is inscribed. Viewed through the stereoscope, these two dots merge into a single dot which appears to rise and fall in the visual field as the two glass slides are brought closer together or moved further apart by turning the micrometer thumbscrew. When the two dots are aligned on the stereopair precisely on the conjugate images of a given physical point, the single dot viewed through the stereoscope appears to lie at the same height as does the image of the point in question. The operator now reads the micrometer measurement to determine the parallax of the point. The height of the point is then computed using standard equations.

If, like the girl in Figure 8, you examine Figure 1 with your stereoscope again, you will observe a peculiar sort of elongation in the height direction. The bridge structure, the buildings, and even the hills all seem to be too tall. This phenomenon is known as vertical exaggeration. It occurs because you are viewing pictures taken at increased between-camera distance using eyes with a normal interpupillary distance. Vertical exaggeration can be

Figure 9. Schematic diagram of three overlapping photographs being taken sequentially along a flight line. Note that the difference in parallactic angles between the top and bottom of the tower is greater for the photo pair a,c than for the photo pairs a,b or b,c.

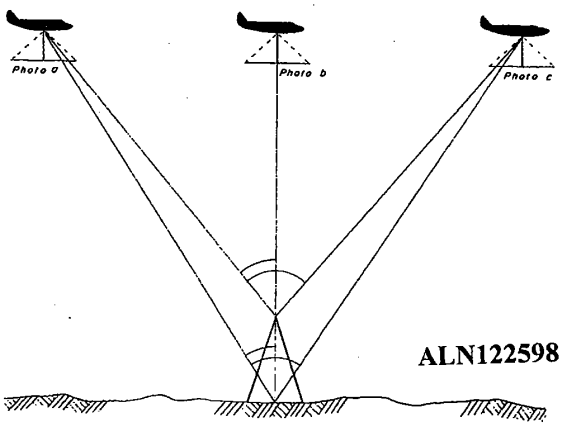
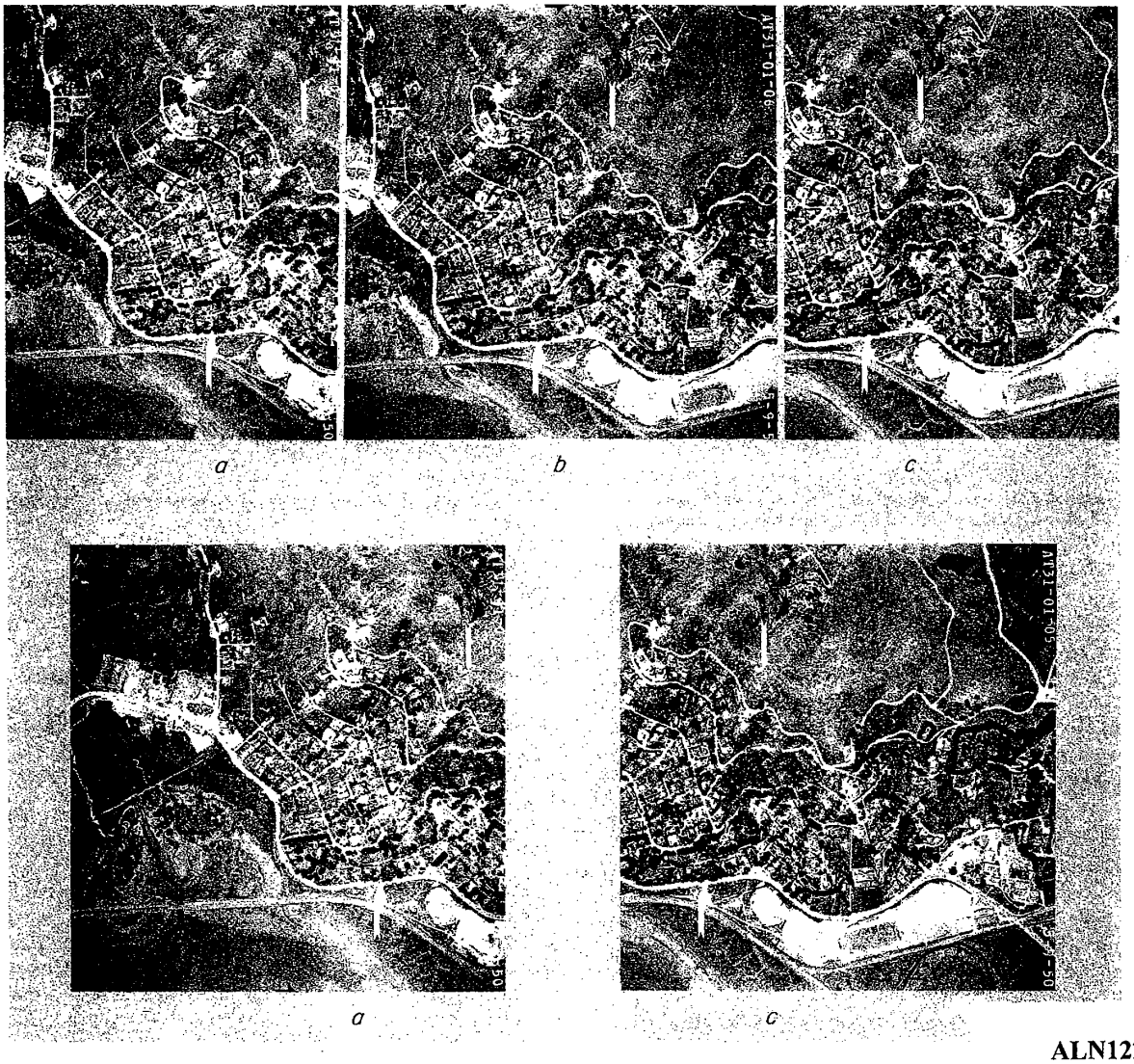


Figure 10. A sequence of three overlapping aerial photographs taken over Marin County iust north of San Francisco. These photographs are precisely analogous to those "being taken" in Figure 9. If the reader views pairs a,b or b,c with his sterescope, he will get the same impression of height from each. However in pair a,c the hills look twice as high because the "vertical exaggeration" has been enhanced by increasing the distance between exposure stations. The same principle may be used to increase precision in measuring cusp heights on dental casts. Refer to the text for the significance of the arrows. (Photographs courtesy of Pacific Resources Inc., Oakland, California.)

used as a powerful tool for measuring height with great precision in the following way.

Consider an aircraft photographing a tower from three camera stations so as to yield three overlapping photographs. Such a situation is depicted schematically in Figure 9. Measurements of the height of the top and bottom of the tower could

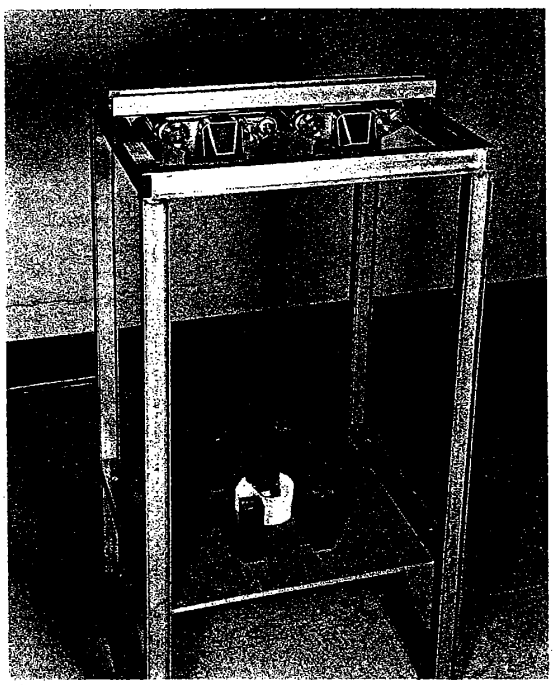


ALN122599

obviously be made using photographs a and b, or b and c, or a and c. It is intuitively apparent however that the most powerful solution would be that involving the use of photographs a and c, since the difference in parallactic angle from the top to the bottom of the tower is greatest in this stereopair. This is precisely equivalent to saying that the photo pair a,c gives the greatest vertical exaggeration when viewed stereoscopically. You may confirm this fact yourself by viewing Figure 10. On the top row of this figure are three actual aerial photos taken from three camera stations analogous to those in Figure 9. Photos a and b may be viewed as a stereopair (preferably by covering photo c with a sheet of blank paper). Photos b and c may similarly be viewed as a stereopair by covering photo a. On the second row of Figure 10, photos a and c are repeated. If you view them as a stereopair, you will note an increase in vertical exaggeration. If you now use your Boley gauge or a millimeter rule to measure the distance between the conjugate points at the top of the hill as indicated by an arrow on each photograph, and between the conjugate points on the flat land indicated by another pair of arrows, it will be noted that the difference in the length of the line segments connecting conjugate points for these two physical locations is greater for stereopair a,c than for either stereopair a,b or stereopair b,c. This fact of course permits more precise measurement of the altitudes of these two physical locations. It is thus a reasonable conclusion that the operation of increasing the distance between camera stations which produces an apparent visual distortion in the vertical direction also yields the conditions for increased precision of measurement.

You have now learned enough about the general principles of stereoscopy and aerial map making to permit consideration of the authors' application of these principles to the general problem of dental measurement. We have in essence constructed several x-ray and camera configurations each of which operates as an analog of the aerial system depicted in Figure 6. Figure 11 shows the first such terrestrial camera system. In place of a single aircraft photo-

Figure 11. A camera system for stereophotography of study casts. This system is a conceptual analog of Figure 6.



graphing successively from two camera stations, two separate fixed cameras are used. The cusps and fossae of a conventional lower study model replace the top and bottom of the pyramid in Figure 6. The four vertical posts surrounding the study cast as well as the grid pattern on the supporting surface constitute a special kind of dental ground control which acts to increase measurement precision.

AJ N122600

Figure 12. Stereopair of a lower study cast taken with the camera system shown in Figure 11. Be sure to note the increased vertical exaggeration when viewed through your stereoscope. Note in addition the acrylic appliance with embedded metal "ground control" pins. These pins may also be seen in Figure 2.

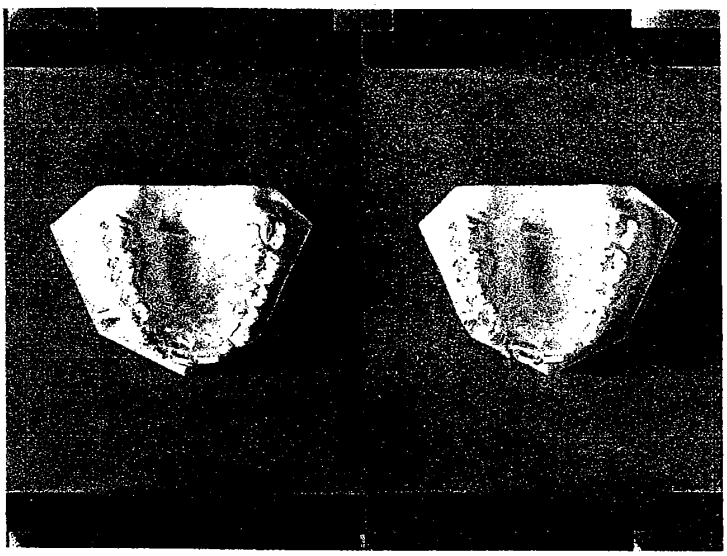
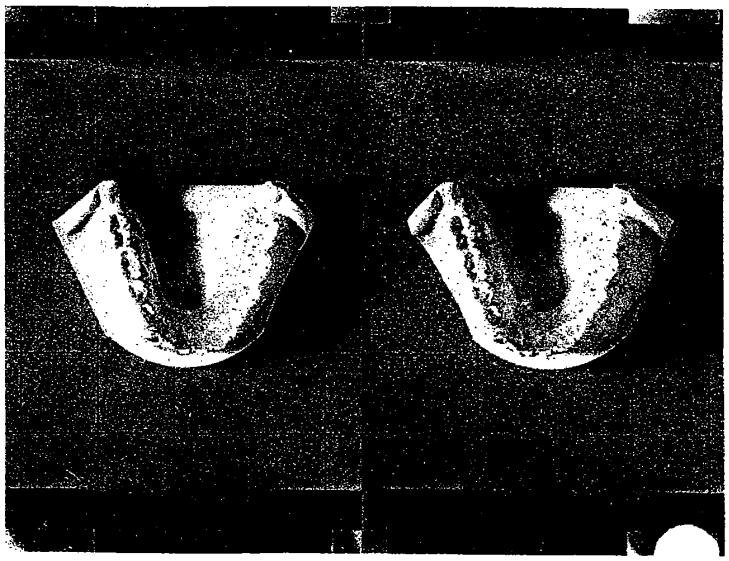


Figure 12 shows the stereopair produced by the two cameras of Figure 11. The cusps and fossae whose height we are interested in measuring have been marked on the model prior to taking the photographs. Careful use of the Boley gauge will permit you to note that the distance between conjugate points for different structures is different and in particular that the conjugate points for fossae tend to have a greater separation than do those for adjacent cusps. You can also observe that a clear acrylic appliance has been constructed and fitted to the model. This appliance has been made in such a way as not to interfere with the occlusion of the teeth when the mouth is closed. Its function is to carry the three radiopaque metal pins which may be seen mounted on its surface. These pins constitute a different type of dental "control point" which is used to orient the model relative to the headfilms and facial photographs in a manner to be described later.

A similar model of the upper dentition with a similar acrylic appliance is constructed and photographed using the same camera system. The stereopair for the upper model is shown in Figure 13.

The upper and lower acrylic appliances are removed from the models and placed in the patient's mouth. A set of stereo lateral skull x-ray films is now

Figure 13. Stereopair of an upper study cast similar to Figure 12.



taken using a specially constructed stereo x-ray apparatus. The patient is seen positioned in this apparatus in Figure 14. The device is again a precise analog of the aerial map making model, this time with the whole system rotated ninety degrees. In Figure

ALN122601

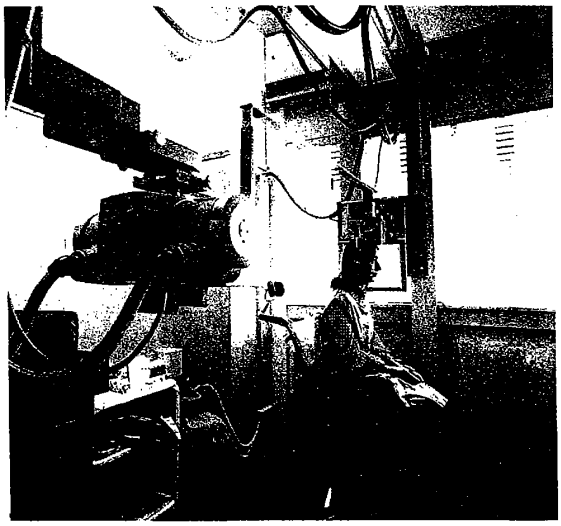


Figure 14. View of the authors' stereo x-ray system. Note the control rod arrangement behind the patients head. The control rods are shown in greater detail in Figure 16.

15a, the x-ray tube may be seen positioned at one end of a traveling track. In this position, the film it takes will have perspective characteristics identical to those of standard orthodontic lateral skull head films. In figure 15b, the x-ray tube has traveled to a new camera station, moving as did the airborne camera in Figure 6, but oriented, of course, in a horizontal direction. As the x-ray tube shifts, a new film cassette is automatically moved into position behind the patient's head. You may note a configuration of four horizontal rods surrounding the patient's head. These rods, shown in detail in Figure 16, are equivalent to the vertical ground control posts in Figure 11.

The stereopair being produced by this x-ray system is in fact the very one you saw in Figure 2 at the beginning of this paper. If you examine Figure 2 again carefully, you will be able to discern the same sets of three metal control points which were seen on the acrylic appliances in Figures 12 and 13. These control points will be used to relate the upper and lower models to the stereo x-rays films. You can also make out in Figures 2 and 16b an additional set of radiopaque metal pins pasted to the surface of the patient's face. This surface mounted set of control points is used to relate the stereo x-ray head films to a stereopair of facial photographs. The stereo camera configuration in which the profile photographs are taken is conceptually identical to the model-photographing apparatus of Figure 11,

Figures 15a, 15b. The horizontal "flight" of the x-ray emitter is demonstrated. A separate head film is taken with the emitter in each position.

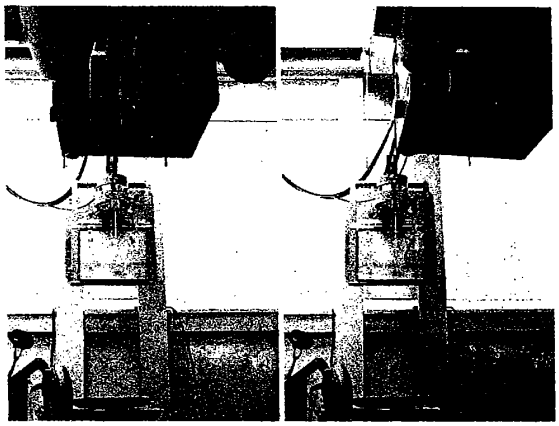


Figure 16a. Close-up of the control rods in front of and normal to the plane of the x-ray film.

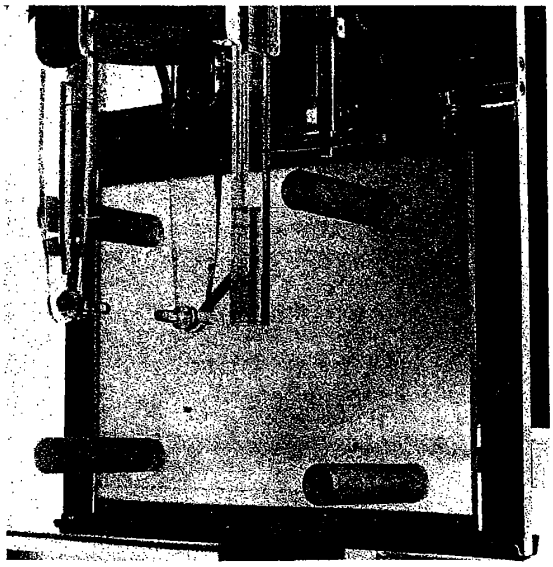
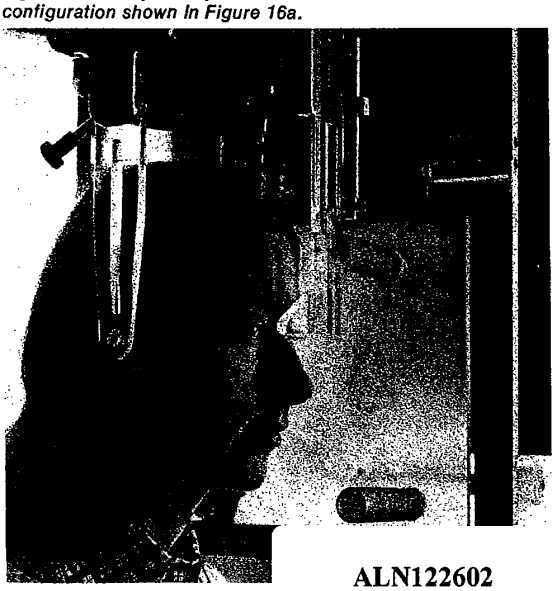


Figure 16b. The patient positioned in the control configuration shown in Figure 16a.



ALN122602

but is larger in size and is rotated ninety degrees. The patient is shown in this facial photographic unit in Figure 17. The resulting stereopair is shown in Figure 18.

A basic pool of information has now been acquired from which we can proceed to construct an integrated three dimensional map of face, skull, and teeth. This information pool consists of the following sub-systems:

a. A lateral skull stereo x-ray pair (Fig. 2).

b. A pair of stereo photographs of the lower study model (Fig. 12).

c. A pair of stereo photographs of the upper study model (Fig. 13).

d. A pair of profile stereo photographs of the face (Fig. 18).

In addition, if more information or more precise information is desired, the following fully compatible sub-systems could be added using our already available physical apparatus.

e. A frontal skull stereo x-ray pair.

f. A pair of frontal stereo photographs of the face.

g. An x-ray stereopair of the upper and lower study models related to each other by means of a conventional centric wax check bite taken with the acrylic appliances in place. This final stereopair would constitute a control for checking the relationship of the upper and lower jaws in the lateral and frontal stereo x-ray films.

Figure 17. Camera system for stereo photography of the patient's facial contours. Note the three radiopaque pins on the face also seen in Figures 2 and 16b. The purpose of these pins is explained in the text.

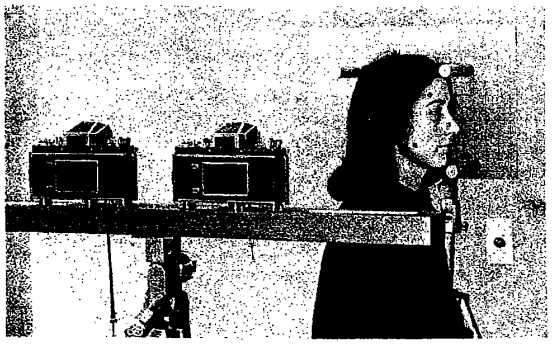
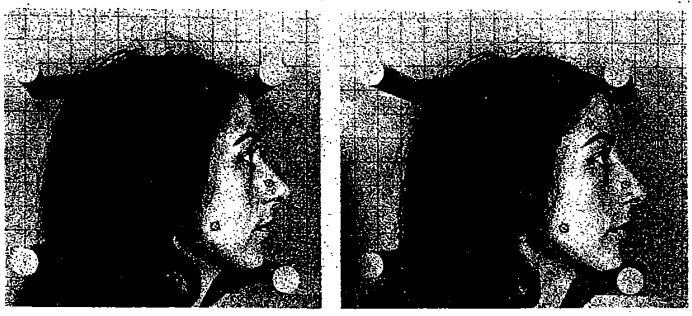


Figure 18. Photographic stereopair of the patient's profile. The contours of the face may be viewed quite easily using the stereoscope.



We can now consider the use of the triads of control point pins on the face and the two acrylic appliances. As has been noted, these control points are to be used to relate the various photographic and roentgenographic stereopairs to each other. Two classical problems of clinical dentistry (particularly in prosthetics and gnathology) are how to relate the upper jaw to the skull and how to relate the upper and lower jaws and teeth to each other. We approximate the solution of the first of these problems in clinical practice by making face bow mountings. We attempt to solve the second by making hinge axis registrations, wax check bites, and gothic arch tracings. An analogous problem exists in quantitative dental research where the question is how to orient study models, facial photographs and x-ray head films precisely with respect to each other. Stated in mapping terms, the problem is how to express landmark locations on models, headfilms and facial photographs in terms of the same three dimensional coordinate system.

In the authors' system, the triads of control points provide a precise quantitative answer. This is the case because the radiopaque pins mounted on the appliances and pasted to the face are unambiguously identifiable and measureable on both the photographs and the x-ray films. This makes the task of orienting the stereo photographs of the models and face to the stereo x-ray films of the skull operationally identical to another problem which aerial photogrammetrists first faced many years ago. That problem was the integration of information from two overlapping maps having three common control points whose positions are known on both maps. The photogrammetric problem has long since been completely solved by the recognition that the three points known in both systems uniquely determine a plane common to the two maps. Given modern computer technology, it is a relatively straightforward matter to rotate, translate and rescale one of the maps so that the corresponding control points on the two maps are superimposed. Once this has been done, all other points on the two maps are automatically in correct relationship to each other. The authors have adapted th' classical photogrammetric solution to dental u: using the triads of control points on the face an the acrylic appliances to produce a single integrated three dimensional map of the face and skull.

ALN122603

We have outlined the principles underlying a new method for integrated three-dimensional cranio-

facial mapping. A possible disadvantage of the method might be thought to be the fact that a considerable amount of stereoscopic measurement would be required to reduce the data from the several photographic and x-ray sub-systems to useable form. The seriousness of this problem would appear the greater when one recognizes that a great deal of time and effort would be required before dentists and dental researchers could be taught to use sophisticated stereoscopes properly. But fortunately, once one understands the principles of stereoscopic measurement, it is possible to utilize those principles without physically using the stereoscope itself at all! For if you think about it, you yourself actually measured the parallax of the points in Figures 7 and 10 directly with a Boley gauge or millimeter rule. Such a procedure is called a monocular or analytic photogrammetric method.

Both analytic and stereoscopic methods are conventionally used in applied photogrammetry. Analytic methods tend to be faster and simpler for the operator. On the other hand, direct stereoscopy has the advantage in most applications of permitting reduction in the error with which ambiguous or indistinct landmarks are identified. One might think that this error reducing potential of direct stereoscopy would be of great advantage in interpreting skull x-rays, where landmark identification errors present a serious problem. However, preliminary investigations by our associate, Dr. Robert Conner, have established that these advantages do not in fact accrue. In addition, the dentist's lack of familiarity with stereo projection and the absence of normal shadow clues make quantitative direct stereo x-ray measurement very difficult and very taxing to the eyes. For these reasons, the authors have chosen to employ an analytic rather than a stereoscopic method. In the authors' procedure, the dentist/researcher examines the two pictures of each stereopair separately and identifies the same prescribed set of landmarks on each. The landmarks located on the x-ray film stereopair include all the control points and approximately sixteen skull landmarks. The landmarks located on the facial stereo photographs include all the visible control points and approximately fifteen soft tissue landmarks. The landmarks located on the stereo photographs of each dental cast include all the visible control points and approximately twenty representative cusps and fossae.

Once these landmarks have been located by the dentist, his part of the work is ended. The entire subsequent process of reducing the x-ray and photograph data to numerical form, integrating data from the several sources, and calculating three dimensional coordinates for all landmarks is done by semi-skilled personnel using semi-automatic plotting equipment and a specially written set of computer programs.

But the manner in which that data reduction process is actually carried out is properly the subject of a different article.

(75-309)

A SYSTEM FOR CRANIOFACIAL MAPPING THROUGH THE INTEGRATION OF DATA FROM STEREO X-RAY FILMS AND STEREO PHOTOGRAPHS

Sheldon Baumrind, D.D.S., M.S.
Associate Professor of Orthodontics
University of California
San Francisco, California
94143

BIOGRAPHICAL SKETCH

Sheldon Baumrind is Associate Professor of Orthodontics at the University of California, San Francisco, where he is in charge of research activities in the Division of Orthodontics. He received his BS and DDS degrees from New York University and his MS degree from the University of Oregon. His primary interest is in the development and application of new instrumentation for craniofacial measurement and in the quantitative evaluation of the effects of orthodontic treatment. Since 1968 he has been involved in studies on the reliability of measurement on skull X-ray films, on the development of computer-aided methods for analysing craniofacial data and, (in association with F. H. Moffitt, Professor of Engineering, University of California, Berkeley), on the development of quantitative stereo-radiographic and stereo-photographic techniques for use in craniofacial research. These studies are supported by Grants #DE03598 and #DE03703 from the National Institute for Dental Research, N.I.H.

ABSTRACT

A system is described for integrated three dimensional craniofacial mapping. This system consists of three geometrically similar sub-systems:

1. A stereo X-ray system, by means of which the positions of relevant internal structures of the skull and face are located by normal case, analytical, (monocular) techniques.

2. A stereo camera system, by means of which the postions of tooth cusps, fossae, and grooves are located on photographic stereopairs by similar techniques.

3. Another stereo camera system, by means of which the positions of relevant structures of the face are located by methods identical to those used in 2. above.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1033 of 3373

Radiopaque and photographable "control points" are utilized common to the first and second, and to the first and third subsystems. Using the control points as reference points, data from the three subsystems are integrated by computer conducted three dimensional matrix transformations in which the dental cast and facial photograph coordinates are rotated and translated into appropriate positions with respect to the stereo-X-ray system. In this way, the positions of all internal and external anatomical structures of the skull are expressible rigorously in terms of the same three-dimensional coordinate system.

INTRODUCTION

The human head is a region of great structural and functional complexity in which relatively small dimensional changes in one region can have consequential ramifying effects in other regions. The general scientific discipline which deals with the development, anatomy, function and pathology of the head is called "craniofacial biology." Craniofacial biology represents an intersection of interest of practitioners of several biological specialties. Among these specialties are anatomy, physical anthropology, maxillofacial surgery, speech pathology and orthodontics.

Orthodontics is a specialty of dentistry which is concerned with the correction of malrelationships of the teeth and jaws through the controlled application of low levels of force to the teeth over a period of time, primarily through the use of wire springs and elastic bands. The effect of these forces is to cause rotational and translatory changes in the positions of the teeth within the jaws. Orthodontic treatment is usually administered during childhood and early adolescence--that is, during periods of relatively rapid growth and development of the head and face. Active treatment characteristically lasts from one to three years and the doctor usually continues to monitor the patient's development during a post-treatment period of two to ten years. The absolute distances through which teeth are moved during treatment are characteristically quite small, and the difference between success and failure in treatment is always a matter of millimeters.

Given these considerations, it is easy to see that critical evaluation of treatment-associated and growth-associated changes in the craniofacial region requires the development of rather accurate measurement techniques. Orthodontists and other craniofacial biologists have traditionally monitored dimensional changes by analysis of data reduced from three types of physical record. These are: (1) X-ray films of the skull and teeth; (2) study casts (plaster molds) of the teeth; and (3) photographs of the face and mouth. It would be desirable to develop a system for integrating measurements made on these different types of physical record in such a way as to form a single three dimensional map of the skull

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1034 of 3373

and face. Indeed, the problem of mapping skull changes through time in three dimensions has concerned and intrigued craniofacial biologists for many years. Heretofore, however, no simple system for making three dimensional measurements of the skull routinely from X-ray films has been developed, and it has previously been impossible to orient the dentition and the overlying soft tissues of the face to the boney structures of the skull with quantitative accuracy. This paper reports on a system currently in development at the Division of Orthodontics, University of California, San Francisco and the Department of Civil Engineering, University of California, Berkeley which attempts to achieve these ends.

BACKGROUND

Craniofacial biologists have made numerous attempts to measure the spatial relationships of the jaws, teeth and cranium. Photogrammetric methods have been employed in intra-oral photography by Zander and Gruner [1], in photography of the face by Sassouni [2] and Dixon [3], and on study casts by Berkowitz [4] and Biggerstaff [5]. Non-photogrammetric quantitative methods have also been used to reduce study cast data to coordinate form by Van Der Linden [6] and Savara [7]. In general, those photogrammetric procedures designed to produce three dimensional output have utilized convergent photography and have required the use of relatively sophisticated stereo plotting instruments. Such approaches make it mandatory that either the biologist, or the photogrammetrist or both, learn to operate in a mode markedly different from that of their prior professional experience. Notwithstanding this disadvantage, the investigations cited have clearly established that the problems of photogrammetric mapping of dental study casts and of the face are solvable in a conceptually straightforward fashion at the present state of the art.

The crucial difficulty in craniofacial mapping is not therefore in the field of visible light photography of the face and of study casts. It is rather the fact that there has been no satisfactory solution to the problem of producing a three dimensional X-ray map of the skull into which the smaller detail maps of the teeth and soft tissues could be integrated. In 1931, Broadbent [8] introduced a method for making three dimensional X-ray maps by integrating information from pairs of X-ray films exposed almost simultaneously from camera stations oriented at right angles to each other so as to yield a lateral and a frontal view of the skull. A schematic diagram of the Broadbent system may be seen in Figure 1.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1035 of 3373

FIGURE 1

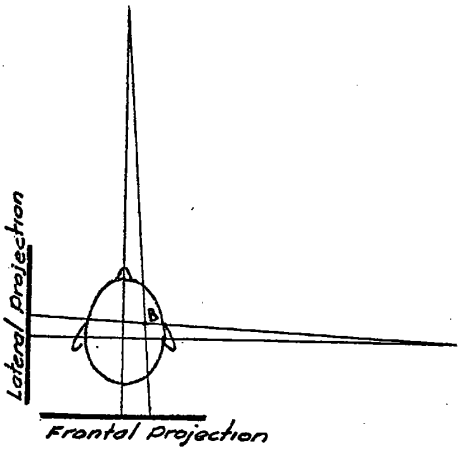


Figure 1

While conceptually quite straightforward, the Broadbent principles proved quite difficult to apply and the method was never widely used. The main problems stemmed from the fact that great difficulty was encountered in identifying the image of the same anatomical structure reliably on two such dissimilar projections. This problem was compounded by the fact that the method provided no possibility of correction or control of these errors in the integration of information from the two projections since the image of any landmark could be expected to be in a different position with respect to both the X and Y axes on the two films of each pair. Nonetheless, the conceptual correctness of the Broadbent approach was so intuitively obvious to craniofacial biologists and clinicians that they continued to attempt to refine it for many years rather than to attempt to develop sharply different methods [9,10,11].* To our knowledge, our own project is the

*Parenthetically it may be noted that the same method continues to be employed in medicine in the "stereotactic" X-ray systems of the specialty of neurology. Here, tables of average correction factors are employed and a relatively low level of accuracy is accepted.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1036 of 3373

first to attempt to develop a general system for measuring quantitatively from stereopairs of the skull, rather than from right angle projections.

In terms of geometry, an X-ray film may be likened to a photograph taken with a camera of long focal length. (See Figure 2.)

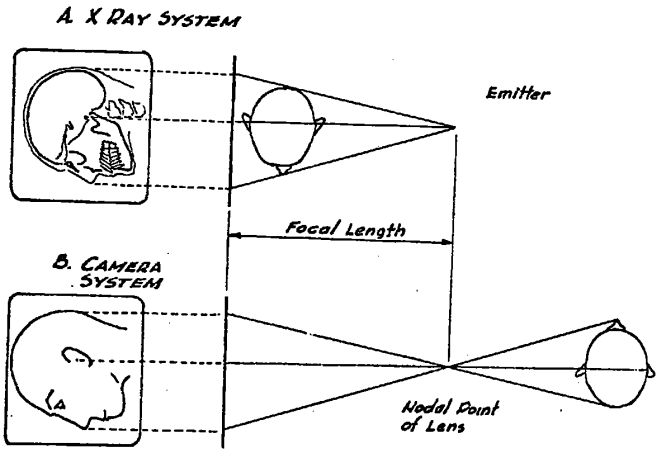


Figure 2

The emitter may for these purposes be considered as a point source located at the nodal point but with the subject interposed between the nodal point and the film plane rather than being located beyond the nodal point as in the conventional case. Thus, if one merely defines f as being equal to H, standard photogrammetric equations should hold. But while the geometry of the head film presents no special problems, the operational process of landmark location on X-ray films confronts the user with several sources of error not encountered in most photogrammetric applications. These include the following:

1. In X-ray photogrammetry, the images of many structures lying at different depths within the specimen are projected in such a way as to be superimposed upon each other on the film plane yielding a noisy and ambiguous film. (See Figure 3.)

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1037 of 3373

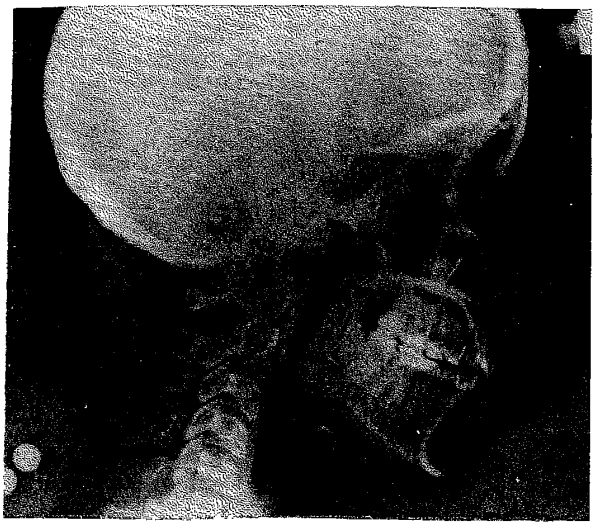


Figure 3

This layering of structures also causes greatly increased eyestrain if one attempts to view X-ray stereopairs through a stereoscope.

2. In X-ray photogrammetry, there are no shadows to place high points in relief. This makes the mapping of contour lines difficult and unreliable. [7]

3. In X-ray photogrammetry no control points are available within the subject (although reference control points may be placed within the object space with relative freedom).

4. In X-ray studies of human subjects, there is no opportunity to check on ambiguous landmarks by retrospective ground survey since the analog of rechecking on the ground would be the quite impermissible operation of dissecting the patient. This problem is compounded by the fact that the structures which medical clinicians and craniofacial biologists X-ray are not structures which fall within the range of normal sensory experience. Not even the most experienced orthodontist or craniofacial biologist has as much experience examining X-ray projections of the face from different angles as has the average ten year old child in examining visible

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1038 of 3373

light representations of the face from different perspectives. As a result, even the experienced craniofacial biologist will routinely have difficulty in the precise integration of information from two different projections of the face.

5. In X-ray photogrammetry of live subjects, there is a greater likelihood of the subject moving within the object space during the time interval between the exposure of the two films of a stereopair than exists in most photogrammetric applications.

On the other hand, it should be noted that there are some advantages of the X-ray case over the conventional aerial photogrammetric situation. These include the following:

1. There is no problem analogous to that of the tilted photograph. Since the emitter is effectively a point source, there will always be some ray normal to the film plane (though, to be sure, the principal point may lie beyond the edges of the film and its location may require some ingenuity).

2. The X-ray photogrammetrist may define the position of his "camera" more electively than can the aerial photogrammetrist.

3. The X-ray photogrammetrist has an enormous advantage in terms of scale. He is characteristically working at a scale of between 1:0.5 to 1:2 rather than at the 1:5000 to 1:25,000 scales typical of aerial photogrammetry.

4. The X-ray photogrammetrist can usually position reference control points within the object space more feely than can the aerial photogrammetrist.

In consideration of the above listed advantages and constraints and based on the prior experience of other investigators, our group, in 1970, decided to design and construct an integrated system for craniofacial measurement. The general idea was to produce a large scale map from stereo X-ray films of the skull, into which could be keyed supplementary detail maps of the teeth and soft tissues of the face. Such maps were to be constructed for different time points for the same patient. The changes in position of given landmarks between time points would constitute an accurate record of the effects of growth and/or treatment.

At the outset we decided that a successful system should have the following properties:

a. The system should be capable of accurate measurement in three dimensions and should permit precise integration of

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1039 of 3373

data obtained from different primary sources. (These primary sources would include X-ray films, facial photographs and plaster study casts of the teeth.)

b. The craniofacial biologist or orthodontic clinician should be able to identify each landmark on the primary data source upon which it appears least ambiguous. Thus tooth cusps should be identified in dental study casts, soft tissue structures should be identified on photographs, and deep structures of the skull should be identified on head X-ray films.

c. The physical apparatus used should be contemporary off-the-shelf standard equipment minimally modified. It should be robust in construction and sufficiently reliable mechanically so that it can be used in a production mode in order to obtain samples of sufficient size to permit biologically consequential research. (In this context, it should be noted that variability in biologic systems is probably greater than usually encountered in industrial quality-control situations and that fairly large samples are therefore required in order to do biologically meaningful research.)

d. The electromechanical precision and reliability of the measurement system should be on the order of ± 0.05 to ± 0.1 mm (± 0.002 to ± 0.004 inches). Greater precision would of course not be unwelcome, but the point is that since the major sources of error are inherent in the act of landmark identification, it would be inappropriate to increase the complexity of the system in order to reduce the machine error beyond the stated values.

e. The physical equipment should be simple to operate and should require the minimum departure from the technician's usual procedures. Internal controls should signal the event of operator error.

f. The primary user of the system, the clinician or biological researcher, should be required to alter his procedures as little as possible from previous techniques. He should be required only to identify and locate landmarks, and should be able to delegate all other procedures to auxiliary personnel. All measurements, computations, and integrations of data from different primary sources should be made semi-automatically or automatically by computers and computer-aided technicians.

g. Provision should be made for improving precision in locating inherently ambiguous landmarks through automatic averaging of replicate unbiased estimates.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1040 of 3373

h. The system should permit all measurements to be made in such a way as to leave the primary data sources unmarked. Only in this way can the primary records remain available for later unbiased remeasurement by other methods or other investigators.

i. The physical design of the subsystems used for measuring the different types of physical record should be sufficiently similar so as to allow the use of uniform data reduction techniques and to permit the same software to be used in the reduction of data from all types of physical record.

The remainder of this paper describes the design, fabrication, and operation of the present operating version of the system.

REDUCTION OF DATA FROM STEREO X-RAY FILMS

Figure 4 diagrams schematically the method employed to obtain lateral and frontal stereo X-ray films of the skull. In the case shown, a lateral stereopair is being taken. This figure is generally representative of the geometry for stereophotography of all types of physical record in our system.

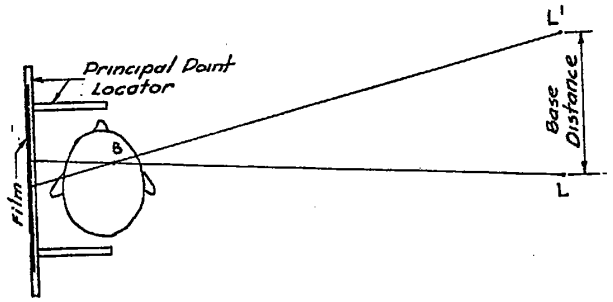


Figure 4

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1041 of 3373

As may be seen, our measuring system is an analog of the aerial normal photogrammetric case, rotated 90° in space. The physical apparatus (not shown) is a rigid rectangular structure with twin HRT1 General Electric S-ray emitters mounted at one end. These are the two "cameras" of a stereo system. The points L and L' in Figure 4 designate the position of the anodes of the two emitters and are, as noted above, located by definition at the nodal points. At the opposite end of the apparatus, beyond the patient's head is a machined plate defining the datum plane. (See Figure 5.)

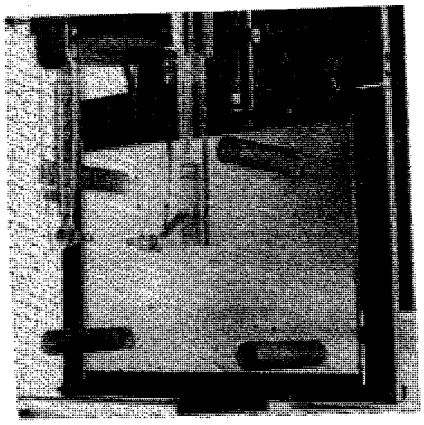


Figure 5

This plate is vertical in orientation and its surface is equidistant from points L and L' (that is to say, H is identical for both "camera stations," and is, in fact, 66 inches, a previously defined orthodontic standard). Projecting from the datum plane, that is, in a horizontal direction, is a set of four plexiglass rods. Each of these rods contains a pair of built in radiopaque control points, one at the datum plane and one at the opposite end of the rod. For convenience, we will refer hereafter to the end of the rod on the datum plane as the "lower" or "base" point and the end nearest the camera station as the "upper" or "top" point. The points of each rod are so aligned that the line connecting them is perpendicular to the datum plane.

The machined datum plane plate with the four projecting rods is termed the "principal point locater." It performs a number of functions:

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1042 of 3373

1. Perhaps most important, as its name would imply, it constitutes a device for locating the principal point on each film. Since each rod is perpendicular to the datum plane, its shadow will be displaced radially from the principal point. Therefore, a line on the datum plane determined by the projected image of the upper rod point with its associated lower point and bottom of each rod will also pass through the principal point and the intersection of the two such lines from any pair of rods will locate the principal point. Error is minimized through redundancy with four rods yielding 3 independent solutions.

Immediately behind the principal point locator lies a cassette changing mechanism, the details of which do not concern us here, it being sufficient to indicate that it constitutes a device for positioning a photographic film parallel to the datum plane and at a known (and small) distance from it.

The sequence of steps in the operation of the stereoscopic X-ray system is as follows:

1. The subject's head is positioned within the object space, secured in a head holder or cephalostat to minimize movement between exposures. (See Figure 6.)

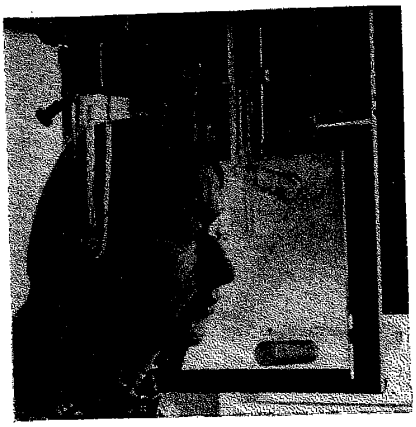


Figure 6

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1043 of 3373

2. A cassette containing an unexposed X-ray film is positioned behind the principal point locator.

3. The X-ray emitter located at station L is fired, exposing the film.

4. The first cassette is removed and replaced with a new cassette containing a new unexposed film.

5. The X-ray emitter located at station L' is fired exposing the film.

A stereopair of lateral skull films has now been produced. The subject and the cephalostat are next rotated 90 degrees such that the patient is now facing the emitter. Two more films are exposed from stations L and L'. These constitute a frontal X-ray stereopair.

It should be noted at this point that the head films conventionally used by orthodontists are standardized lateral and frontal projections of the skull. In the present method a lateral stereopair and a frontal stereopair are employed. In the present method, the lateral and frontal films taken from station L conform to the standards of the respective conventional projections. The lateral and frontal films taken from station L' are lateral oblique and frontal oblique projections. See Figure 7. We have adopted the convention of referring to the films taken from camera station L as normal lateral and normal frontal. The films from station L' are referred to as oblique lateral and oblique frontal.

The films pairs are processed and examined by a monocular analytic method as follows.

The two films of each stereopair are mounted side by side on a light table. A piece of .003 matte acetate is overlayed upon each film and fastened to it along the top edge with masking tape. A biologically trained judge now examines the two films individually. He marks upon each acetate sheet the locations of the four rod top registration points, the four rod bottom registration points, and a set of anatomical landmarks in which we are interested. Clearly, the landmarks must be located in the same numerical sequence on both films of each stereopair. The use of a light table sufficiently large to enable the examination of both films of a given stereopair at the same time is employed as a device to aid the judge in locating the same point on both films. On the other hand, we do not desire that the judge use any physical measuring aid based on the principle of minimizing Y parallax, since we wish to use this measuring principle later as a control on the reliability of the biological estimate.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1044 of 3373

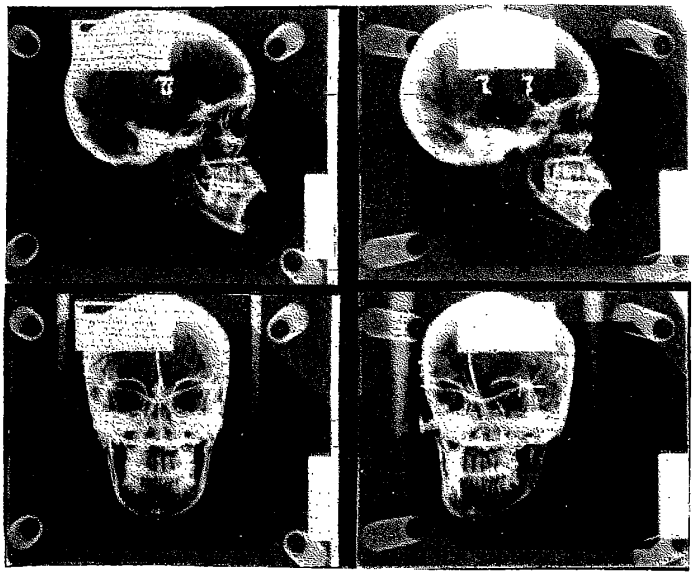


Figure 7

It is to be expected that the eight rod registration points will be located with great reliability upon the X-ray film but that the anatomical landmarks will be considerably more ambiguous and hence considerably less reliably located. For this reason the process of examining each pair of X-ray films is repeated independently by several equally well trained judges. (It is our convention to use four tracings made by four different judges for each film of each stereopair.)

The process of integrating the information from the four judges is accomplished as follows. Each tracing is digitized (that is, reduced to coordinate form) using a semi-automatic digitizer, the output of which is in machine readable form. (Our group employs either its own Oscar E or the LARR-M of the data reduction group at

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1045 of 3373

Stanford Research Institute). The digitized output is processed on an IBM 360/50 computer at University of California, San Francisco, using a PL/1 program known as ORTHO which was previously developed by us for the analysis of conventional lateral skull head films. This program examines the group of four tracings for each film as a unit of information. The first subroutine rotates, translates and rescales the four tracings to a least squares best fit upon the directly measured known X and Y coordinates of the four rod bottom registration points upon the datum plane. The goodness of fit of these four points is then examined and any unsatisfactory tracing is discarded. The computer program then automatically shifts the coordinate system to a standard anatomical coordinate system known as the "sella-nasion" or "SN" coordinate system. This is done because previous investigations have established specific criteria for the reliability of location of each cranial landmark we employ referred to this coordinate system. [12,13] (A standard coordinate system is required because the envelopes of error for most skull landmarks are eliptical rather than circular. The long axis of the envelope for each landmark has a characteristic angle of orientation to the axes of the SN coordinate system.) The program now examines the set of four individual tracing estimate for each landmark for each X-ray film in the knowledge of the general character of the errors involved in locating that landmark. [12] Outliers are deleted and a best estimate for each landmark on each film is produced, referenced to the SN coordinate system. The set of coordinate values for all landmarks of each film is stored as a block. Also stored are the two dimensional coordinates of the four rod bottom and the four rod top registration points.

Next, the principal point for each film is located as a machine operation by means of an iterative procedure which computes the best estimate of the intersection of the four lines determined by the projections upon the tracing surface of top and bottom registration points of each rod. The coordinates of the principal point of each film are added to the set of coordinate values for the film. The entire set of coordinate values for each film containing landmark coordinates, registration point coordinates and principal point coordinates is termed an "Avpic file."

The Avpic files for the two films of each stereopair are passed to the program STEREO which uses them to produce a three-dimensional map in the following manner. The Avpic file for the film from camera station L' (the oblique film) is rotated and translated such that its four bottom registration points are best fit upon the rod bottom registration points of the film from station L (the normal film). At this stage the locations of all points from both films will be expressed in terms of the SN coordinate system of the L (normal) film. A change in coordinate system is now effected such that the principal point of

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1046 of 3373

the L (normal) film is taken as the origin and the principal point of the L' (oblique) film lies upon the X axis. The distance between these two points is the photo base which should (since this is the normal photogrammetric case) equal the camera base distance L-L'. The X parallax of each point in the system may now readily be computed as the ΔX between any landmark on the "normal" film and its conjugate on the "oblique" film, and the altitude of the landmark is computed automatically using standard photogrammetric equations. As control, computed values are compared with the previously directly measured values for the four rod top registration points and for the camera base distance. In addition, the Y parallax for each landmark and registration point is computed as a measure of the degree to which the same physical structure was actually identified on both films of the stereopair. Where the Y parallax is excessive for one or a few landmarks, the conclusion may reasonably be drawn that those landmarks were not measured validly on both films of the stereopair. (That is, that the same anatomical structure was not in fact identified on both films.) Where the Y parallax is excessive systematically for all anatomical landmarks, the conclusion may reasonably be drawn that the subject moved between the taking of the two films of the stereopair.

If the data is considered satisfactory according to the built-in criteria of the program, the final step of the system software is to re-express the location of all landmarks in terms of an anatomically meaningful coordinate system. This is defined as a three dimensional orthogonal system whose origin is at Sella, whose X axis contains the line SN and whose Y axis lies in the plane determined by the points S, N, and ANS (all these being standard structures familiar to the craniofacial biologist). The new three dimensional "Avpic" file is automatically printed as hard copy and also stored on magnetic tape. Angular, linear, area and volumetric relationships between and among sets of landmarks at the same time point may be computed as needed from the stored values as a machine operation. In addition, separate maps made at different time points may be machine compared.

REDUCTION OF DATA FROM STEREO PHOTOGRAPHS

We will now briefly consider the reduction of three dimensional data from stereo photographs of the face and from study casts. The physical apparatus for making the stereopairs used for these purposes is so designed that data can be reduced using the same tracing method and the same software package employed for the X-ray stereopairs.

Figure 8 shows the apparatus employed for photographing study casts.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1047 of 3373

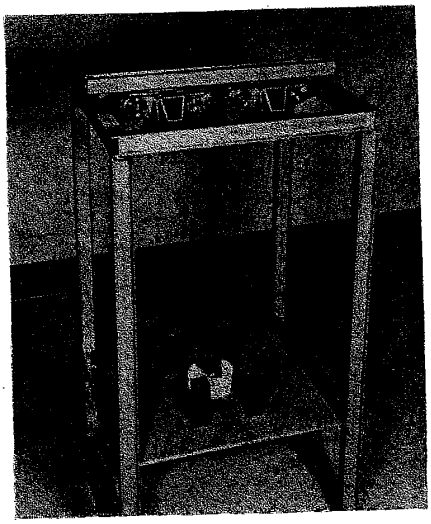


Figure 8

This consists of a rigid rectangular frame at the top of which a pair of Exacta IIB cameras with matched Tessar f2.8 lenses are mounted with a photo base distance of 6.5 inches in such a way that their film planes are coplanar. Eighteen inches below the nodal points of the lens is a machined aluminum plate oriented parallel to the film plane. This machined surface is defined as datum. A one inch grid is scribed upon it as an aid in calibration and as a control for the vertical orientation of the principal rays of the cameras. Upon the datum are mounted four carefully machined perpendicular steel rods which surround the space in which the study cast we wish to photograph is placed. The registration points in this system (analogous to those on the plexiglas rods of the X-ray system) are the tops and bottoms of the inner edges of each of the four rectangular rods.

The study cast photographic system is employed as follows. The cast to be photographed is oriented on the surface of the principal point locator such that the plane of the biting surfaces of the teeth (termed the occlusal plane) is oriented

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1048 of 3373

generally parallel to the datum. The set of landmarks in which we are interested has been previously marked upon the surface of each cast by a biologically trained investigator using # zero Rapidograph pen with washable black transparent ink. Lighting and exposure factors are standardized and the two photographs of each stereopair are taken simultaneously. Positive paper prints are made from each negative such that the object size on the print is approximately 2X natural size. Figures 9a and 9b show reductions of such prints for an upper and a lower stereopair.

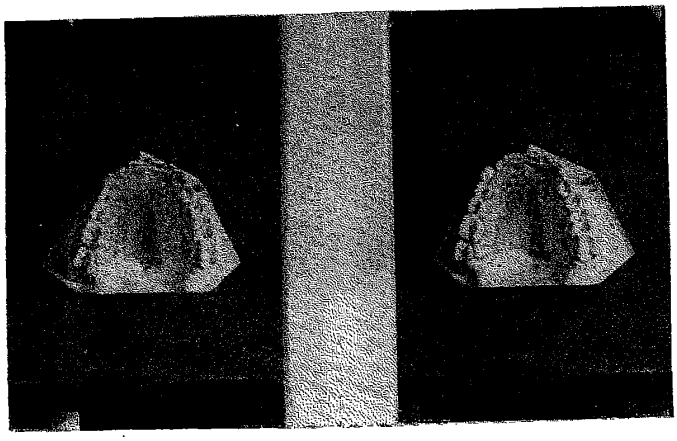


Figure 9a

Note: Figures 9a, 9b and 11 may be viewed stereoscopically.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1049 of 3373

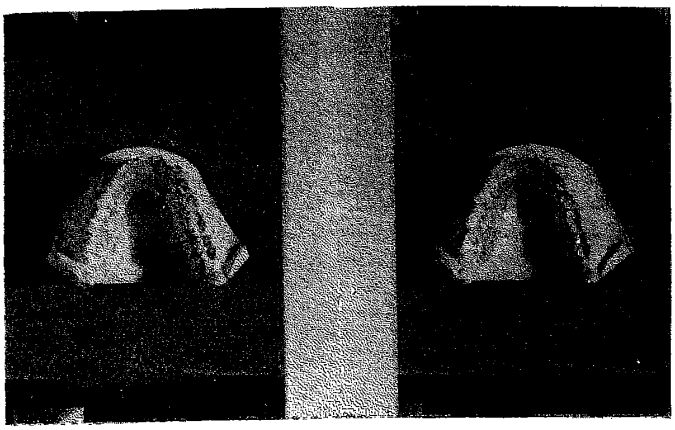


Figure 9b

The positive prints for each stereopair are overlaid with .003 matte acetate (Kodak) and the locations of the desired dental landmarks and of the 8 registration points are recorded. The washable ink markings are then removed from the study cast using a suitable bleach and remarked by another biologically trained investigator. Duplicate stereopairs are made, traced and digitized and the resulting coordinate information is processed by the same software which was employed in the X-ray system.

It is interesting to note that the photographic enlargements used can actually be at any convenient scale, since the software automatically rescales all points on the tracing in the process of best fitting the tracing values for the four rod bottom registration points to the previously determined correct values for the physical system which are written into the computer program. However, it needs to be noted that this solution assumes that the rod bottom registration points are unambiguously locatable on the paper print and that the paper print undergoes no consequential distortions in processing.

It is also interesting to note that, given that the distance between the nodal point and the datum plane for each of the two cameras is constant and that vertical (normal case) photographic

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1050 of 3373

conditions are assured, the focal length of the lens is not critical and does not need to enter into the computations.

The apparatus for obtaining stereophotographs of the face is analogous to that for study casts. It also consists of a pair of Exacta IIB cameras arranged so that their film planes are coplanar and parallel to a four rod principal point locating apparatus. However, the base distance is increased to ten inches and the nodal point to datum distance is increased to 48 inches. An early version of this subsystem is illustrated in Figure 10 and a resulting stereopair is shown in Figure 11.

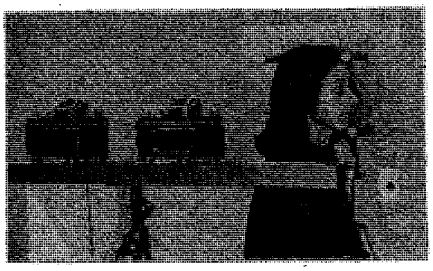


Figure 10

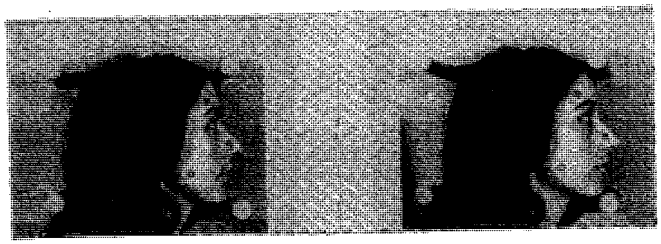


Figure 11

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1051 of 3373

It may be seen that in this apparatus the subject's hair may tend to obscure the bases of the rods of the principal point locator. For this reason four substitute points on the datum plane located at known distances from the rod bases are used as proxies for the rod bottom registration points. The computer software is so configured that upon receiving the coordinates of a proxy point, it automatically makes the appropriate X and Y translations to move the point to its appropriate position at the base of the rod. After this has been done, the computation of the principal point is performed in the manner previously described.

INTEGRATION OF DATA REDUCED FROM DIFFERENT SOURCES

We have outlined the procedures by which three dimensional data from each of the three types of physical record conventionally utilized by craniofacial biologists can be encoded. We will now briefly describe the method by which precise integration of the numerical data from the several sources is possible. The principle is taken from the standard technique by which photogrammetrists integrate information from pairs of overlapping maps which have three or more control points in common. Under these conditions the coordinates of all landmarks known on one map may be rotated and translated into appropriate relationship with respect to the other map as a computer operation by superimposing the appropriate control points mathematically.

In order to take advantage of this principle, conventional plastic appliances of a type well known to all practicing dentists, are fabricated upon the study casts of the upper and lower dental arches in such a manner that the teeth can occlude freely and without interference with the appliances in place. Such appliances may be seen in position on the study casts of Figures 9a and 9b. Separate appliances are constructed for each jaw. Each appliance has fastened to its surface three or more radiopaque metal pins. It is, of course, a relatively simple task to identify the metal pins on each properly enlarged paper print of the study cast stereopair, as may be seen by again looking at figures. These reference points are identified on the tracings at the same time the cusps and grooves of the teeth are identified. The same technique may be used on the facial stereophotos to define a known plane in the face by the expedient of placing three or more radiopaque and photographable control points on its exterior surface. (See Figures 10 and 11.) The stereo X-rays of the skull are made with the acrylic appliances in place in the mouth and with the facial control points in position. (See Figure 6.) Because of the radiopaque property of the metal control points, they will also be unambiguously identifiable in the stereo X-rays of the skull. (See Figure 3.)

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1052 of 3373

The three dimensional maps made for each of the subsystems (frontal X-ray stereopair, frontal and lateral facial photographic stereopairs and upper and lower study cast stereopairs), can now be unambiguously integrated into the major system (lateral skull X-ray stereopair) by means of a set of computer conducted three-dimensional matrix rotations which superimposes appropriate sets of control points. A single integrated three dimensional craniofacial map can thus be constructed.

The actual sequence of procedures for the entire mapping operation may now be listed:

(1) Conventional upper and lower impressions are taken and conventional dental casts are poured and trimmed.

(2) Without damaging the casts, thin cold cure acrylic upper and lower appliances are fabricated in such a way as to be stably positionable in the mouth without occlusal interference.

(3) Three or more radiopaque points are imbedded into each acrylic appliance with the point tops visible at the surface. These are the cast control points.

(Note: Steps (4) through (7) inclusive must be performed at the same visit.)

(4) The acrylic appliances are placed in the subject's mouth.

(5) Three or more radiopaque points are fixed to the lateral and frontal aspects of the patient's face. These are the facial control points.

(6) The patient is positioned in the object space of the X-ray system as described above and the lateral and frontal X-ray stereopairs are taken as described.

(7) The patient is positioned in the object space of the facial photographic system and lateral and frontal photographic stereopairs are taken.

(8) The upper and lower acrylic appliances are returned to their respective casts and the casts are individually stereophotographed in appropriate positions.

(9) (Optional) If checks on bite relationship are desired, the appliances may be returned to the mouth and a wax check bite registration may be made. The appliances and the wax bite are removed from the mouth, fastened together and stereo X-rayed.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1053 of 3373

The relationship of the pins on this X-ray pair constitutes a mathematically applicable control on the correctness of the bite relationship during the taking of the lateral and frontal stereo X-ray pairs.

(10) Appropriate tracings are made of the X-ray and photographic stereopair. It is of course of paramount importance that each control point be located both on the photograph and on the X-ray film.

(11) The tracing data is reduced to coordinate form by the Oscar E, LARR M, or other A to D converter.

(12) The two dimensional coordinates of all points are passed to the programs "ORTHO" and "STEREO" which use them to produce a single integrated dimensional craniofacial map. This map is stored on tape or disc.

(13) Tape stored maps from different time points or different subjects are compared as desired as a machine operation.

LIMITATIONS OF THE SYSTEM

We believe that the system outlined above is the best available solution thus far to the practical problems of integrated three dimensional craniofacial mapping but feel that it is necessary to note the existence of several unsolved or incompletely solved problems.

1. The problem of patient movement in the time interval between the taking of the two films of each X-ray stereopair has not been completely solved. For technical reasons, it is not likely that it will ever be possible or desirable to take both these films simultaneously. Three approaches are possible to the problem of minimizing errors from this source.

a) One might increase the physical constraints upon the movement of the patient's head. This course of action is deemed undesirable for psychological and emotional reasons.

b) One could seek to reduce the time interval between film exposures through the use of more rapid cassette changing apparatus. This course of action would be quite expensive. X-ray cassettes are heavy and apparatus to accelerate and decelerate them with precision would be about double the total cost of the X-ray taking system. Also, the addition of such apparatus would require a considerable increase in the size of the room needed to house the X-ray facility.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1054 of 3373

c) One could attempt a mathematical solution by having the subject wear a helmet with an additional set of control points in known configuration. The translation of these points between the two films could be used to rectify the relationship of the oblique film in x, y, z. We consider this approach quite interesting and have been conducting preliminary investigations directed towards achieving this type of solution.

2. The idea of using acrylic appliances bearing radiopaque control points as a method of locating the study casts in the X-ray map involves the assumption that these appliances can be reliably transferred between the study cast and the subject's mouth. The validity of this assumption has yet to be tested critically.

3. The optimum base distance for the production of X-ray stereopairs of the skull has not yet been determined. If we increase the base, we achieve a stronger photogrammetric solution but we also increase the problem of uniquely identifying the same landmark on both films of any given stereopair. Here again further empirical investigation is needed.

4. The question of optimum base distance and of optimum base-height ratio in the photographic subsystems also requires further study. In this area there even remains the possibility that we might be better off using some form of convergent photography. We have rejected this solution thus far for two reasons. First, it would considerably complicate the task of data analysis, moving us toward the use of stereoscopic instruments or more complicated computer programs. Second, the individual photographs produced in convergent photography would, when viewed singly by the biologist, have a disturbing foreshortened and "distorted" appearance. However, it is quite premature to reject the possibility that convergent photography may be desirable particularly in the development of supplementary intra-oral systems [1].

5. The system in its present form provides no method for locating the roots of the teeth. Several possible solutions are available, the most interesting being the addition of a subsystem of stereo-panoramic X-rays. This is indeed a promising area for future investigation.

6. There is also need for development of a compatible intra-oral system with which to interpolate data from time points between full records surveys. Full records surveys are not likely ever to be practical more frequently than on an annual basis.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1055 of 3373

7. Finally, there is need to develop simple and efficient systems for the dynamic analysis of the functioning of the jaws, teeth, and musculature in real time. We believe that the static analysis we are developing is a necessary prerequistie to such dynamic analyses, but that the dynamic analyses are not likely to be primarily photogrammetric in nature.

REFERENCES

1. Gruner, H. et al.: A Short Range Camera System for Dental Surgery, Photogrammetric Engineering, 33:1240, 1967.

2. Sassouni, V.: Palatoprint, Physioprint, and Roentgenographic Cephalometry as New Methods of Human Identification, Journal of Forensic Science, 2:429, 1957.

3. Dixon, D. A. and Newton, L.: Minimal Forms of the Cleft Syndrome Demonstrated by Stereo-Photogrammetric Surveys of the Face, Brit. Dent. Journal, 132:183, 1972.

4. Berkowitz, S.: Stereo-Photogrammetric Analysis of Casts of Normal and Abnormal Palates. Am. J. Orthod., 60:1, 1971.

5. Biggerstaff, R. H.: The Basal Area of Posterior Tooth Crown Components: The Assessment of Within Tooth Variations of Premolars and Molars, American Journal of Physical Anthropology, 31:163, 1969.

6. Van Der Linden: Quality Control of Digitized Data and Inclusion of Essential and Meaningful Checkpoints, J. Dent. Res., 50:982, 1971.

7. Savara, B.: A Method of Measuring Facial Bone Growth in Three Dimensions, Human Biology, Vol. 37, No. 3, 1965.

8. Broadbent, B. H.: A New X-ray Technique and Its Application to Orthodontia, Angle Orthodontist, 1:45, 1931.

9. Wylie, W. H. and Elasser, W. A.: Understated Vertical Projections of the Head from Lateral and Posterioanterior Roentgenograms, Am. J. Roentgenol., 60:414, 1948.

10. Vogel, C. J.: Correction of Frontal Dimensions from Head X-rays, Angle Orthodontist, 37:1, 1967.

11. Adams, J. W.: Corrections of Error in Cephalometric Roentgenograms, Angle Orthodontist, 10:3, 1940.

Supplied by the British Library - "The world's knowledge" www.bl.uk

ClearCorrect Exhibit 1002, Page 1056 of 3373

12. Baumrind, S. and Frantz, R.: The Reliability of Head Film Measurements 1 Landmark Identification, Amer. J. of Orthodontics, 60:111, 1971.

13. Baumrind, S. and Frantz, R.: The Reliability of Head Film Measurements 2 Conventional Angular and Linear Measures, Amer. J. of Orthodontics, 60:505, 1971.

Supplied by the British Library - "The world's knowledge" www.bl.uk

Integrated Three-Dimensional Craniofacial Mapping: Background, Principles, and Perspectives

Sheldon Baumrind

This article reviews the origins and history of three-dimensional (3D) measurement in orthodontics. Some principles of integrated 3D craniofacial measurement are discussed and illustrated. Present and future perspectives of 3D measurement in orthodontics are examined through the prism of the author's experience at the Craniofacial Research Instrumentation Laboratory (CRIL) of the University of the Pacific School of Dentistry.(Semin Orthod 2001;7:223-232.) ***Copyright © 2001 by W.B. Saunders Company***

This issue of *Seminars in Orthodontics* contains several studies generated in different laboratory and clinical settings. Each author tells the reader about his own experiences in the field. The purpose of this review is to point to some general considerations involved in three-dimensional (3D) mapping of the human head and to highlight for the reader several crucial issues that will be discussed in the studies that follow. The review deals with several separate but overlapping subjects:

- Why do we need 3D Imaging in orthodontics?
- Historical antecedents.
- How does one measure in 3D?—Some basic principles.
- The requirement for calibration.
- Recent advances—3D quantitative measurement of study casts and the face.
- Merging 3D maps from different sources: the requirement for tie points.
- What's ahead in craniofacial measurement?

From the Craniofacial Research Instrumentation Laboratory, University of Pacific School of Dentistry, and the University of Medicine and Dentistry of New Jersey, NJ.

Address correspondence to Sheldon Baumrind, DDS, MS, University of the Pacific School of Dentistry, 2155 Webster St, San Francisco, CA 94115.

Copyright © 2001 by W.B. Saunders Company

1073-8746/01/0704-0001$35.00/0

doi:10.1053/sodo.2001.25424

Why Do We Need Three-Dimensional Imaging in Orthodontics?

Orthodontics and dentofacial orthopedics deal primarily with the physical relationships among the parts of the human head. These physical relationships exist in a usually asymmetric 3D structure that changes through time in the course of growth, development, and treatment. Our interest is in the totality of craniofacial anatomy and in the interactions among the parts.

The human head is a concentration of sensory functions—it contains competing end organs of all five senses, sight, hearing, smell, taste, touch. As part of the heritage of our quadruped past, the head goes first (literally, "ahead"), so it is the first part of the body to need and acquire the sensory information for attack, defense, and interaction with others of like and different species. Not only does the head receive information, but it also puts out information for other members of the species to see, react to, and be guided by. Facial conformation is extremely important to our peers. Whole social structures are based on facial adornment and responses to different facial configurations.[1-3]

In addition to its information processing functions, the head must perform such bread-and-butter physical functions as breathing, mastication, and deglutition. Evolution has solved the problem of packing so many disparate functions into so small a volume by developing a structure of great physical complexity. It is this

ClearCorrect Exhibit 1002, Page 1058 of 3373

complex environment that the orthodontist seeks to understand and modify (according to type). To treat effectively, clinicians need to understand not only how the teeth relate to and interact with each other, but also how they are mounted in the bony armature of the skull and how they affect and are affected by the soft tissue covering of the face.

The complexity of this system is sufficiently great that we cannot understand it well without decomposing the whole into a set of component parts. Therefore, our specialty has developed a set of standard transforms, each of which enables us to understand better the functioning of part of the system by shedding confounding information about the whole. Thus we generate plaster study casts that permit us to examine the teeth of both jaws separately and in occlusion but that lose all information about the skeletal armature and the facial soft tissues. We generate x-ray cephalograms to help us understand the relationships between the jaws and the skull—but despite their great advantages, they lose almost all information about arch form and about the facial soft tissues. We generate photographs of the face—but despite their unique information content, they lose all information about structures below the facial surface.

Each kind of transform provides much valuable information, but each loses much more. Even all of them taken together lose important information about the head and teeth in motion; about chewing, swallowing, speech and nonverbal communication. In addition, only the study casts retain information about all three spatial dimensions. Both conventional skull x-ray images and conventional facial photographs are two-dimensional (2D). Standard 2D x-ray images project information from all layers of the skull upon the single plane of the film, considerably complicating the process of interpretation. Except for a few structures of interest which lie in the mid-sagittal plane, it is impossible to make accurate 2D measurements on lateral cephalograms, because structures in planes lying at different distances from the film plane are enlarged differentially. Conventional facial photographs, even when standardized, also lose depth information by projecting images of structures at different heights upon a single plane.

Perhaps more important than the loss of information within the individual facial transforms is the fact that, even taken all together, the conventional physical transforms of orthodontics preserve no information that can allow us to reassemble an integrated picture of the whole head. Because there is no way of accurately relating information from 2D lateral cephalograms to information from 3D study casts, there is no satisfactory way to measure true distances between cranial structures and the teeth. Because there is no satisfactory way of orienting 3D study casts to 2D facial photographs, there is no satisfactory method for measuring the thickness of the soft tissues covering jaws. For this reason, accurate measurements of the relationships between different physical transforms are not possible in contemporary orthodontic practice. Instead, such relationships can only be estimated or inferred by the clinician as a conceptual operation.

The long-time dream of the orthodontist, to achieve the ability to reintegrate information from different craniofacial transforms in a manner that is clinically useful, is represented schematically in Figure 1. As several authors will demonstrate later in this issue, newly available techniques now make it possible to improve upon this dream; to merge information from different physical records with greater accuracy,

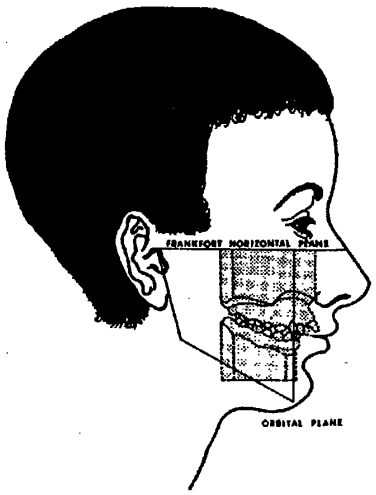


Figure 1. The early 20th century orthodontists' dream: putting the study casts into the facial picture.

ClearCorrect Exhibit 1002, Page 1059 of 3373

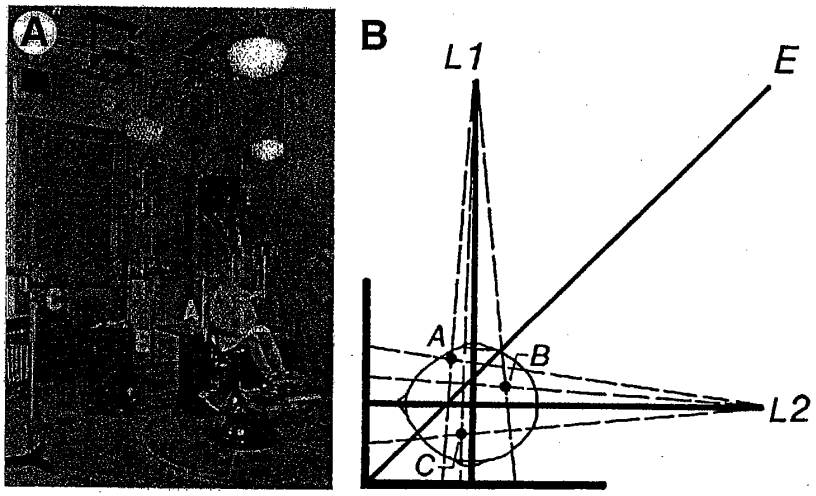


Figure 2. The original Broadbent cephalometer. Patient positioned for exposures in the Bolton room at Case-Western (A). The geometry of the Broadbent Cephalometer (not to scale). The frontal cephalogram is generated from the position L1 while the lateral cephalogram is generated from position L2. The two film planes are perpendicular to each other. Note that the three schematic anatomical points in the head are each at different distances from the lateral and frontal film surfaces. For this reason, they are magnified differently on the two films causing the image of each point to fall at different heights on the frontal and lateral cephalograms. This dissimilarity in y coordinate complicates landmark location when this "bi-planar" geometry is employed. Only the images of landmarks falling on line E (the diagonal line bisecting the angle between the two film planes) will have the same y location on both the frontal and lateral cephalogram (B).

smaller measurement errors, and greater information content than was even thought possible 20 years ago.

Historical Antecedents

This section begins with a caveat. The present author has been an active participant in this research area since 1968. Although he will attempt to avoid the biases of his personal experience, success in that venture cannot be guaranteed. The reader is accordingly forewarned.

The earliest 3D measurements of the skull were made by anatomists and physical anthropologists in the late 19th century. The reference planes of Frankfort, His and Camper, and most of the skeletal landmarks we now use were defined and measured directly on dried skulls before 1900.[4]

Among the earliest systems of measuring the spatial relationships between the teeth and the skull in living subjects were Van Loon[5] and Simon.[6] Simon's apparatus included a maxillary clutch and frame that resembled and foreshadowed the later facebows of Hanau, McCollum, and all their modern variants. Indeed, Simon's apparatus and his system of "gnathostatic measurement" were used by some conscientious orthodontists as late as the 1970s. The contributions of Van Loon and Simon are especially important to us, because they were among the first to focus sharply on the location with respect to the skull of the anatomical structures that interest dentists most—the teeth and their supporting alveolar structures.

By 1925, x-ray cephalometry had become feasible and the stage was set for the classic work of Broadbent (Fig 2).[8] The Broadbent method, presented in its modern form in this issue by Hans et al, involves the integration of data from two head films taken nearly simultaneously from a pair of x-ray tubes so oriented that (1) the angle of intersection between their central rays is 90 degrees, (2) the point of intersection between the central rays is 60 inches from the focal spot of each emitter, and (3) the two cassettes are oriented perpendicular to each other and

ClearCorrect Exhibit 1002, Page 1060 of 3373

each is perpendicular to the central ray of one emitter. The subject was placed at the point of intersection between the central rays in such a position that one film captured a norma lateralis projection and the other a norma frontalis projection. In principle, the user would identify the same landmark on each image and the three-space position of the point would later be derived from a knowledge of the system geometry. In practice, it was extremely difficult to locate the same anatomical feature on two such different projections and the true 3D properties of the system were not heavily pursued until the recent development of computer-aided digital variants. The Broadbent method in its original form did not contemplate the quantitative integration of information from study casts and photographs.

In the 1960s and 1970s, a number of investigators sought to implement the use of stereophotogrammetric methods, originally developed for aerial mapping to measure the skull and other anatomical systems. Prominent among these investigators were Rune, Sarnas, and Sevik.[8-11] Also during this period, the present author's laboratory proposed the use of coplanar geometry and conceptualized the use of tie points for merging data from different skull transforms.[12-15] However, in general, the engineering and medical communities were more receptive to the new geometry than our own.[16-22]

In the late 1970s, computerized axial tomography (first referred to as CAT and later as CT) became available. For a brief period it was thought by many that CT and the magnetic resonance imaging modality that followed soon afterward (first referred to as NMR and later as MRI) would replace conventional projection radiology. Although both technologies have an enormously important role in medicine, they have not proved useful for routine diagnosis and treatment planning in orthodontics. So far as CT is concerned, orthodontic applications have been impractical or inappropriate because of the following:

1. The dose of ionizing radiation has been prohibitively high. The conventional fan-geometry CT scanners of earlier years had radiation doses several hundred times that of a conventional skull series.
2. The economic cost of CT scans for routine diagnostic purposes has remained prohibitive.
3. As an consequence of (1) and (2), the spatial resolution of CT images in the long axis of the body (the one which is most important to those of us who treat vertically positioned teeth), has been extremely poor. Radiation and economic costs have made it impractical to reduce slice thickness below 5 mm in routine use even though spatial resolutions of 1 mm^2 on the surface of the slice have become routinely available. Because the slices are relatively thick, the visualization of tissue detail in vertically oriented teeth has remained quite poor.

The limiting factor in the use of MRI in orthodontics (aside from the question of economic cost) has been that this modality depends for its functionality on the presence of large numbers of hydrogen nuclei in the tissues being imaged. Because hard tissues such as bone, enamel, and dentin contain few if any free hydrogen nuclei, the use of this powerful diagnostic tool is restricted in orthodontics to the visualization of the cartilaginous components of the temporomandibular joint (TMJ).

Very recently, at least one new CT-like system that uses a different optimization strategy and is specialized for craniofacial applications has made an appearance. This device is called the Newtom.[23] Radiation doses associated with its use are said to have been reduced to approximately one and a half times the level of a single panoramic image by three strategies: (1) the use of cone, rather than fan geometry, (2) optimization on hard tissue visualization by de-emphasizing the acquisition of subtle differences in the gray scale resolution of soft tissues, and (3) the use of advanced image intensifying algorithms and hardware. This device has recently received the Food and Drug Administration (FDA) approval and tests of its clinical usefulness by several of the investigators represented in this issue are now in progress.

How Does One Measure in Three Dimensions?—Some Basic Principles

There are two main geometrical strategies for measuring in three dimensions. They are 1) or-

ClearCorrect Exhibit 1002, Page 1061 of 3373

thogonal measurement and 2) measurement by triangulation.

The general characteristic of orthogonal (ie, "right-angular") systems is that they locate the third dimension (usually designated "z") by a technique separate from that used to measure the other two dimensions (usually designated x and y). In most orthogonal measurement, the object to be measured is sliced into layers, either physically or optically. An example of physically slicing a biological system is the well-known serial section of histology and pathology. Here, the specimen is sliced into a number of layers of known thickness. The x and y dimensions are measured on the slice surface and the z dimension is measured by tallying how many slices into the specimen the feature of interest lies. An example of optical slicing in medicine is the already mentioned CT scan. In systems of this sort, the subject lies on a gantry and is moved further into the imaging device a known distance between the exposure of successive slices. Here too the x and y dimensions are measured on the slice surface and the z dimension is measured by counting slices. The common feature of all orthogonal measuring systems is that x and y distances are captured by some method other than that used for capturing z.

Systems that measure by triangulation analogize the geometry of mammalian stereoscopic vision (Fig 3A). Typically, such systems view the object to be measured from two positions in space and capture images from both positions on film or some digital medium either simultaneously or in rapid succession. Both the biplanar and coplanar stereo xray systems described above are examples of triangulation geometry. For a somewhat more extensive treatment of this subject, see the CRIL website, www.cril.org.

All 3D measuring systems share a requirement that seem so self-evident as to appear trivial but that in practice can present formable problems. Simply put, the measurement process must be able to identify the same anatomical structure in all three dimensions. To meet this obvious requirement is frequently not as easy as it sounds, especially in stereoscopic x-ray systems. The greater the separation between the x-ray

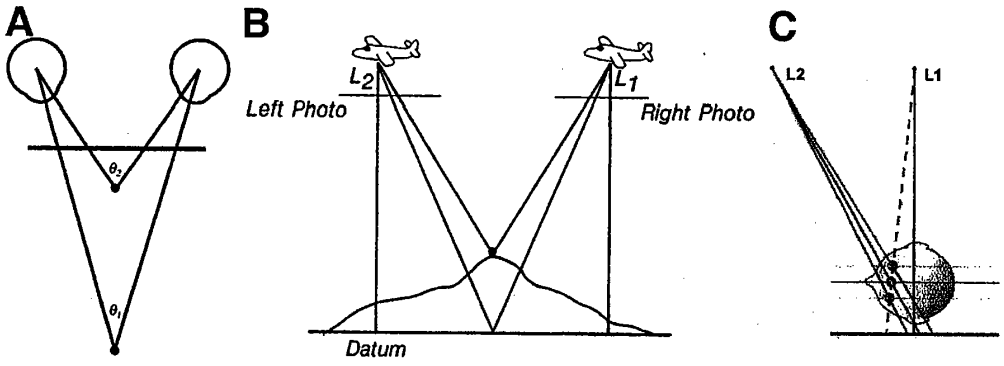


Figure 3. Three applications of stereo measurement. The geometry of human vision. When we view a point at some distance from us, our eyes converge to focus on the point. Line segments can conceptually be drawn from the point to each eye. The included angle between the two line segments is known as the parallactic angle of the point. Points at different distances from the observer have different parallactic angles. The smaller the parallactic angle, the more distant from the observer the point is perceived to be. Similarly, for any plane parallel to a plane between the eyes and a known distance from it, the lengths of the horizontal line segments connecting the two rays of either angle will be proportional to the height. The brain uses this information to compute the 3D location of the point (A). An application of the same principle to aerial photography. If the distance an aircraft or satellite flies between taking two photographs is known, the distance between the two images of any point which can be seen in both photographs can be used to measure the 3D location of that point (B). The same principle applied to a pair of cephalometric x-ray sources. Notice that here, unlike Figure 2B, each anatomical feature is the same distance from the film plane for each image of the stereo pair. For that reason, the vertical (y) dimension for any landmark will be the same on both films of the stereo pair. This correspondence simplifies the unique location of any landmark on both films (C).

ClearCorrect Exhibit 1002, Page 1062 of 3373

sources for two of the images of any stereopair, the more difficult it is to identify the same landmark in both images.

When other factors are equal, the most powerful geometrical solution for any stereoscopic measurement occurs when the angle between the two emitters and the object being imaged approximates 90 degrees. However, most skull structures of orthodontic interest look very different, indeed *are* different when viewed from the lateral and frontal projections. Hence the tradeoff between the coplanar and biplanar methods. In effect, the coplanar method sacrifices some of the mathematical power of the 90-degree ray intersection of the biplanar system to obtain a pair of images on which it is possible to locate the same physical point on both images with reduced error. Much empirical testing still needs to be done before we establish the optimum separation between emitters in x-ray stereocephalometry.

The Requirement for Calibration

Most contemporary x-ray cephalometers, unlike the earlier instruments of Broadbent and Hofrath, are of relatively flimsy construction. In particular, the cassette carriers are nonrigid and the ear rods are usually poorly aligned. It seems self-evident, however, that if accurate physical measurements are to be made, the dimensional relationships between the emitter(s) and the film plane(s) must be known with very high accuracy. In reality, the geometry of any single xray emitter is essentially identical with that of a single camera and no careful worker would consider making critical measurements on photographs taken with an out-of-focus camera.

If accurate measurements are to be made, the physical relationships between the component parts of any optical or x-ray system used must be known with even greater accuracy. The process of determining the relationships among the system components is called calibration. In x-ray stereoscopy, one needs to calibrate the spatial relationships between the two x-ray emitters and between each emitter and the film plane.

Stereo x-ray systems are usually calibrated by projecting upon the film plane a 3D array of radiopaque points whose true positional relationships with respect to each other are known with great accuracy and precision based on previous measurement. Another part of the calibration process involves building into the cassette holder a number of radiopaque points called fiducials whose images are projected onto the film plane at exposure. These fiducials facilitate accurate and precise identification of the position of the cassette at the time of exposure, providing information that is necessary for subsequent analytic processing. Calibration of the system geometry is important in all x-ray cephalometry but becomes particularly critical when one attempts to merge two or more 3D craniofacial maps from different sources.

Recent Advances: Three-Dimensional Quantitative Measurement of Study Casts and the Face

Underpinning all recent developments in 3D craniofacial mapping has been an exponential increase in the availability of high-speed high-capacity low-cost digital computers over the past two decades. Without this increase in computational power, 3D x-ray mapping of the sort discussed in this issue could never have become practical. Using this increased computational power, several recent technical advances have now made it practical to generate accurate 3D digital maps of the teeth and the facial surface.

Locating the same structure in 3D in facial and study cast mapping involves different problems from locating the same structure on stereo x-rays. Special problems are associated with each task. The main problem in 3D photography of the face is that the facial surface inherently contains little fine detail. This increases the difficulty in identifying the set of discrete points on the facial surface needed to construct a useful map. Most attempts to solve this problem have involved the projection of an array of "pseudopoints" on the face. Some investigators have approached this problem by using laser ranging techniques.[24] These methods usually involve rotating the subject around a vertical axis in a series of very small steps. At each rotational step, a laser projects a thin vertical line upon the face and ranges the distance to that line. Such solutions are in fact variants of the orthogonal geometry described earlier.

Other investigators, including ourselves, have

ClearCorrect Exhibit 1002, Page 1063 of 3373

chosen to use what are called "structured light" methods.[25] It has long been understood that it is possible to project a grid on a subject being measured in such a way as to generate artificial discrete points that can be readily measured.[26] Indeed, if the system is well calibrated, the projected grid can itself constitute one image of a triangulation-type stereo pair, because the image of a properly projected grid will retain its shape regardless of the shape of the object upon which it is projected, thus reducing the amount of measurement that needs to be done. The traditional problem with this approach had been that the higher the resolution desired by the user, the closer together the grid lines needed to be. When the desired resolution approached 1 mm^2, the density of the grid on the surface made it difficult to illuminate and hence difficult to measure. In the past decade, several manufacturers have implemented computerized applications of this principle in which a semitransparent vertical "rainbow" spectrum is projected on the surface of the face from one location and photographed by a digital camera positioned a known distance from the projector. A system of this type, developed by the 3DMetrics Corp. (Petaloma, CA), is in use in our laboratory. This system is described and illustrated in the accompanying paper by Curry et al (see page 258).

The main problem in creating 3D maps of the teeth also is the problem of locating all points of interest without ambiguity. Here the problem is not lack of texture but rather the existence of undercuts, which make it impossible to see all points of interest from any single viewing plane. A number of investigators have attempted to solve this problem by mounting arrays of cameras surrounding the study casts or by rotating the casts between images. But thus far, the very wide variations in patterns of tooth irregularity between subjects have kept such solutions from being practical.

Fortunately, in recent years an industrial process known as destructive scanning[27] has been used to map study casts successfully for different purpose by two major orthodontic corporations, Align Technology (Santa Clara, CA) and OrthoCad (Fairview, NJ). Destructive scanning is a variant of the orthogonal slicing method of 3D mapping described above. Typically a study cast is invested in a solid matrix of contrasting color, just as one would invest a histology or pathology specimen in a block of paraffin or epoxy. The surface of the block is then sliced or ground parallel to the occlusal plane until the first trace of the study cast becomes apparent. At this point, a laser scan of the 2D surface is made and stored as a layer in a computer file. An additional 0.003-inch layer of the block is now ground away and another laser scan is made and stored. This process is repeated until the entire erupted dentition has been mapped in a series of successive layers. Thus, a 3D map consisting of stacked 2D layers has been generated using a variant of the orthogonal method described above.

Merging Different Three-Dimensional Craniofacial Maps: The Role of Tie Points

At this point we have demonstrated methods for constructing individual 3D maps from lateral x-ray cephalograms, frontal x-ray cephalograms, study casts, and the facial surface, that is to say, from each of the component layers of the head that were discussed in the first part of this essay. The question now arises as to how we can merge the 3D digital data representing these several transforms into a single reintegrated 3D craniofacial map. The paradigm for answering this question is again to be found in the experience of terrestrial mapping from aircraft and satellites.

The merging of two aerial maps through the use of tie points is discussed in the additional materials provided on our website, www.cril.org. In topographic mapping situations in which it is desired to integrate different 3D maps made from different perspectives or at different scales, one takes advantage of the fact that any two overlapping 3D maps can be merged accurately (within the limits of measurement error) by computer-conducted rotations, translations, and rescaling of landmark coordinate values provided that the coordinates of three or more landmarks common to the two maps are known on each of the two maps. To generate such unambiguously identifiable landmarks, appropriate markers are typically located or placed in the region to be mapped prior to imaging. Such

ClearCorrect Exhibit 1002, Page 1064 of 3373

markers are called tie points. Unlike fiducials, there is no need for the spatial locations of the tie points to be known precisely before the generation of the 3D maps to be merged. The only requirements are (1) that there be at least three clearly identifiable tie points in the region of overlap of any pair of 3D maps to be merged and (2) that the tie points remain fixed in position during the acquisition of the images of both maps.

In our own craniofacial application of this principle, triads or tetrads of small radiopaque and photographable metal markers mounted on paper or plastic labels are attached temporarily to the surface of the face. Other groups of markers, mounted on separate upper and lower plastic overlays provided to us by the Align Corporation are secured to the upper and lower teeth just before imaging. After all images have been collected, the facial tie points are located on the 3D facial surface using software provided by the manufacturer of the facial camera. The locations of the study cast tie points with relation to the teeth are known from prior destructive scanning mapping at Align. The 3D locations of both the facial and tooth tie points with respect to the anatomy of the skull are captured from frontal and lateral x-ray stereopairs using software developed at CRIL. Using the tie point information from all sources, the 3D maps of the study casts and the 3D maps of the facial surface are now merged into the 3D x-ray map of the skull. The resulting integrated craniofacial model may be rotated, translated, or segmented as desired using the Align Corporation TREAT software or other available systems for viewing computer illustrated in Figure 4 and displayed interactively on our laboratory website (www.cril.org).

What's Ahead in Craniofacial Measurement?

In the very near future, orthodontists and maxillofacial surgeons will have at their disposal an array of information-acquisition tools to match the complexity of the clinical problem at hand. For some simple problems, the use of the current nonintegrated 2D physical records may suffice. For more complex situations, a graduated series of responses will be available. At moderate levels of complexity, existing cephalometers in clinicians' offices can be calibrated on site, making possible 3D reconstructions of acceptable accuracy from a single conventional emitter. The information source could be limited to a single lateral cephalometric head film plus a single frontal cephalometric head film, provided that the x-ray system used is calibrated and that the same set of tie-points can be located without ambiguity on both films. Where 3D information about the locations of discrete anatomical features lying off the mid-sagittal plane is needed, stereo x-ray systems equivalent to the present one at CRIL would have to be available. Where more extensive 3D information about cranial surfaces and skeletal contours is needed, low-

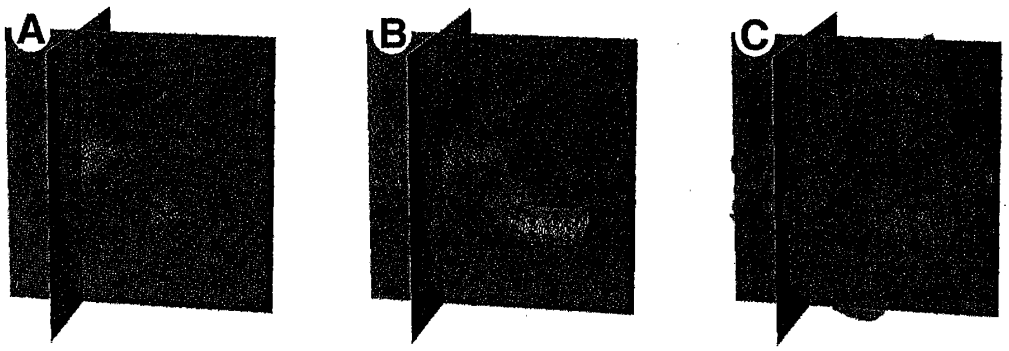


Figure 4. Achieving the dream of Figure 1. Intersecting lateral and frontal cephs (A). Hanging the dentition in its proper orientation on the xray scaffold (B). Adding the facial soft tissue in accurate registration to the xray images and the dentition (C).

ClearCorrect Exhibit 1002, Page 1065 of 3373

emission CT scanners, such as the Newtom,[23] will become available. These will probably best be used synergistically with tie-point–based high-resolution systems, such as that described here.

Almost certainly, clinicians will wish to add to their armamentarium high-resolution information about the head in motion. Recent developments in computer robotics make it certain that such information will become available. For information about changes in the contours of the facial surface during speech, mastication, and deglutition, high-speed variants of the structured light camera used in our present system will soon be here. For studies of the changing relationships between the jaws and teeth during function, apparatus that automatically tracks active targets like light-emitting diodes attached to the face have already been built and will become increasingly practical.[28-30] The use of tie points to facilitate automatic merging of information from different sources will become progressive and more widely applied.

Finally, our specialty will gain from a vast increase in our ability to share information over distance. Tele-orthodontics (the simultaneous viewing at distance by two or more clinicians of relevant information on individual patients) will be greatly facilitated, hopefully with due regard for patient privacy. Clinical and research databases containing linked 2D and 3D images, data, and written information on growth, development, and treatment will soon become widely available through the Internet. Indeed, several of the groups represented in this issue, including our own, have made significant progress in that direction. Page 294 of this issue contains a list of relevant website addresses, many of which are directly related to articles in this issue of *Seminars in Orthodontics*. Truly, a new day is dawning for orthodontics!

References

1. Bull R, Rumsey N. The Social Psychology of Facial Appearance. New York: Springer-Verlag, 1988.
2. Phillips C, Tulloch C, Dann C. Rating of facial attractiveness. Community Dent Oral Epidemiol 1992;4:214-220.
3. Meyer E. Psychiatric aspect of plastic surgery, in Converse JM (ed): Reconstructive Plastic Surgery, 1964.
4. Krogman WM, Sassouni V. A Syllabus in Roentgenographic Cephalometry. Graduate School of Medicine, University of Pennsylvania and Philadelphia Center for Research in Child Growth, Philadelphia, PA, 1957.
5. Van Loon C. Neue Method zur Festellung normaler Bezehungen der Zahne zu den gesichtslinien. Z Zahnheilkd. 1916;18:18-39.
6. Simon P. Fundamental proncples of a systematic diagnosis of dental anomalies (Translated by BF Lischer). Boston, The Stratford Company, 1926.
7. Broadbent BH Sr. A new x-ray technique and its application to orthodontia. Angle Orthod 1931;1:45, (Reprinted in the Angle Orthod 1981;51:93).
8. Rune B, Sarnas KV, Selvik G, et al. Posteroanterior traction in maxillo-nasal dysplasia (Binder's syndrome): a roentgen stereometric study with the aid of metallic implants. Am J Orthod 1982;81:65-70.
9. Rune B, Jacobson S, Sarnas KV, et al. Roentgen stereophotogrammetry applied to the cleft maxilla of infants. I Implant technique. Scand J Plast Reconstr Surg 1997;11: 131.
10. Selvik G. A roengenographic sterophotogrammetric method for the study of kinematics of the skeletal system. Thesis, AV-Centralen, University of Lund, 1974.
11. Selvik G. Roentgen stereophotogrammetry in Lund, Sweden: applications of human biostereometrics. Proceedings, Society of Phot-Opt Instr Eng 1978;166:184-191.
12. Baumrind S, Moffitt FH. Mapping the skull in 3D. J Calif Dental Assoc 1972;48:22.
13. Baumrind S. A System for Craniofacial Mapping Through the Integration of Data from Stereo X-Ray Films and Stereophotographs. Technical Papers from the Symposium on Close Range Photgrammetric System, American Society of Photogrammetry, University of Illinois, Urbana 1975;142-66.
14. Baumrind S, Moffitt FH, Curry S. Three-dimensional X-ray stereometry from paired coplanar images: a progress report. Am J Orthod 1983;84:292-312.
15. Baumrind S, Moffitt FH, Curry S. The geometry of three-dimensional measurement from paired coplanar X-ray images. Am J Orthod 1983;84:313-322.
16. Moffitt FH. Stereo x-ray photogrammetry applied to orthodontic measurements. Proceedings of the 12th Congress of the International Society of Photogrammetry, Ottawa, Canada 1971.
17. Curry S, Anderson JM, Moffitt F. Calibration of a Close-Range Stereometric Camera System. Proceedings, American Society of Photogrammetry Annual Convention, Washington, DC 1981.
18. Curry S, Moffitt F, Symes D, et al. A Family of Calibrated Stereometric Cameras for Direct Intraoral Use. Proceedings, Biostereometrics '82 (SPIE), San Diego, California 1982;7-14.
19. Curry S, Baumrind S, Anderson JM. Calibration of an Array Camera. Photogrammetric Eng Remote Sensing 1986;52:627-636.
20. Murray WR, Baumrind S, Hunter J, et al. The detection of loosening in total hip arthroplasty: A computer-assisted stereophotogrammetric method. Proceedings of the 46th annual meeting of the American Academy of Orthopedic Surgeons, 1979.
21. Chafetz N, Baumrind S, Murray W, et al. Subsidence of the Femoral Prosthesis: A stereophotogrammetric evaluation. Clin Orthoped Rel Res 1985;201:60-67.

ClearCorrect Exhibit 1002, Page 1066 of 3373

22. Chafetz N, Baumrind S, Morris JE, et al. Stereophotogrammetry of the lumbar spine. Spine 1985;10:368-375.
23. Mozzo P, Procacci C, Tacconi A, et al. A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results. Eur Radiol 1998;8:1558-1564.
24. Moss JP, Linney AD, Grindrod SR, et al. A laser scanning system for the measurement of facial surface morphology. Optics Lasers Engineering 1989;10:179-190.
25. Image-Based Rendering: Structured Light. The Graphics and Visualization Center, National Science Foundation Science and Technology Centers. Available at: http://www.cs.brown.edu/stc/resea/rendering/research_R6.html.
26. Symes D, Baumrind S, Jendresen M. Three-dimensional mapping of study casts from a single photographic image. J Dent Res (Special Issue) 61:300 (abstr 1099).
27. Destructive Physical Analysis, ORS Labs. Available at: http://www.ors-labs.com/DPA.html.
28. Curry S, Baumrind S. Real Time Monitoring of the Movement of the Mandible. Proceedings, American Society of Photogrammetry 1986;92-100.
29. Curry S, Baumrind S. Realtime Mandibular Motion Measurement. Proceedings IEEE/Ninth Annual Conference of the Engineering in Medicine and Biology Society, Boston 1987;721-722.
30. Miyawaki S, Tanimoto Y, Inoue M, et al. Condylar motion in patients with reduced anterior disc displacement. Dent Res 2001;80:1430-1435.

ClearCorrect Exhibit 1002, Page 1067 of 3373

A Computer System for the Analysis of Dental Casts

ELLEN A. BEGOLE, JOHN F. CLEALL, AND HARRIET C. GORNY

Dr. BeGole is Associate Professor in the Department of Orthodontics at the University of Illinois. She is a graduate of the University of Michigan, with an M.S. degree from Columbia and Ph.D. from the University of Pittsburgh.

Dr. Cleall is Professor and Head of the Department of Orthodontics at the University of Illinois. He holds B.D.S., M.D.S. and D.D.S. degrees from the University of Otago, New Zealand.

Harriet Gorny is Data Processing Analyst in the Department of Orthodontics at the University of Illinois. She holds a B.S. from DePaul University.

Address:

Dr. Ellen A. BeGole
Department of Orthodontics
University of Illinois
College of Dentistry
801 South Paulina St.
Chicago, IL 60612

Computing services used in this research were provided by the Computer Center, University of Illinois Chicago Circle Campus.

Photographs of Dental casts provide the basis for digitization of major dental landmarks, enabling computerization of such descriptive parameters of occlusion as symmetry, mesiodistal relationships, overbite, overjet, curve of Spee, tooth/arch discrepancies, Bolton ratios, and rotations.

In the practice of orthodontics as well as in the teaching clinic, dental cast analysis is frequently an integral part of the diagnostic work-up and continual treatment monitoring. Over the years, certain standard analyses have evolved, and with the introduction of computer technology into the clinical setting at the University of Illinois Department of Orthodontics, a computerized analysis for the casts was deemed appropriate.

A substantial Fortran computer program has been developed to carry out routine analysis of dental casts for all patients who are treated in the orthodontic clinic. In addition, the program is used in various research studies related to assessing changes in the dentition arising from orthodontic treatment. The program is implemented on an IBM 370 computer. It is presently run in batch mode, whereby a set of punched cards containing the data is submitted to the computer center for subsequent processing. Thus, the user is required only to provide a set of 118 data points from a pair of dental casts. Because the casts are three-dimensional,

photography is used to obtain two-dimensional data for the program.

Photographic Procedure

Prior to photographing the casts, two orientation points on the midline of the maxillary cast are marked with a pencil. These are the dorsal aspect of the incisive papilla and a point on the posterior part of the raphé near the fovea centralis. This establishes the raphé as a reproducible anatomic midline. These points are then transferred to the mandibular cast using a mechanical transfer device described in detail by Hechter.[9] The device (Fig. 1) consists of a hollow metal sleeve that projects upward from a wooden platform to receive an oblong metal post that is free to travel up and down. A horizontal metal rod with a long vertical pin at the end is fitted to the post. The casts are placed on the wooden platform and positioned in such a way that a pin is lined up directly under one of the points on the maxillary cast which is to be transferred. The vertical post is subsequently lowered so that the pin makes a small indentation in the mandibular cast. This depression is then marked with a pencil. The process is then repeated to transfer the remaining point on the midpalatal raphé to the mandibular cast.

The models are photographed utilizing a standardized photographic setup consisting of a 35 mm camera equipped with a 200 mm telephoto lens. This enables the use of a long



Fig. 1 Mechanical reference point transfer device, showing position of casts.

ClearCorrect Exhibit 1002, Page 1068 of 3373

object-film distance (132.6 cm) to minimize photographic distortion. Five views of each pair of dental models are photographed and, for each view, the occlusal plane is maintained either in a parallel or perpendicular orientation to the film. The views are maxillary and mandibular occlusal, left and right lateral occluded, and right lateral unoccluded, as shown in Figure 2.

Digitizing the Data

After processing, the film strips are projected at about 2× magnification and a set of 118 points, illustrated in Figure 2, is digitized frame-by-frame, using a sonic instrument to record X-Y coordinates of each landmark. This instrument is interfaced to a computer so that coordinates of the landmarks are recorded directly.

Program Description

Since the views of the models as projected are approximately two times larger than life-size, the program first applies a magnification correction factor of 0.4947 to the coordinates so that they correspond to the actual plaster casts. The data are then standardized by rotation along the midpalatal raphé for the maxilla and its analog in the mandible constructed from the transferred points on the lower cast. Computations are then completed and a report printed.

A plotting routine can also provide a graphic display showing lines connecting the most mesial and distal points on individual teeth (Fig. 3). The printed report and plot become a permanent part of the patient's clinic chart. A complete description of the computer program used for the model analysis has been published by BeGole, Cleall, and Gorny.[3]

The program used for these computations utilizes much of the methodology of Cleall and Chebib[6] to process linear distances, projections, and perpendicular distance from a point to a line. In addition, the program is designed to handle as many as five different sets of records for a given patient, and may be used in conjunction with the cephalometric analysis described by Chebib, Cleall, and Carpenter.[5] The records are labeled A for pretreatment, P for progress records, B for the record taken at the end of active treatment, C for the

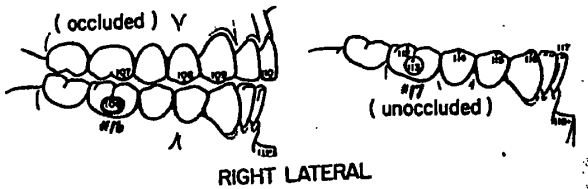


Fig. 2 Standardized views of a set of models showing 118 landmarks to be digitized (101-105 are left-side points comparable to 110-106). *Continued on next page.*

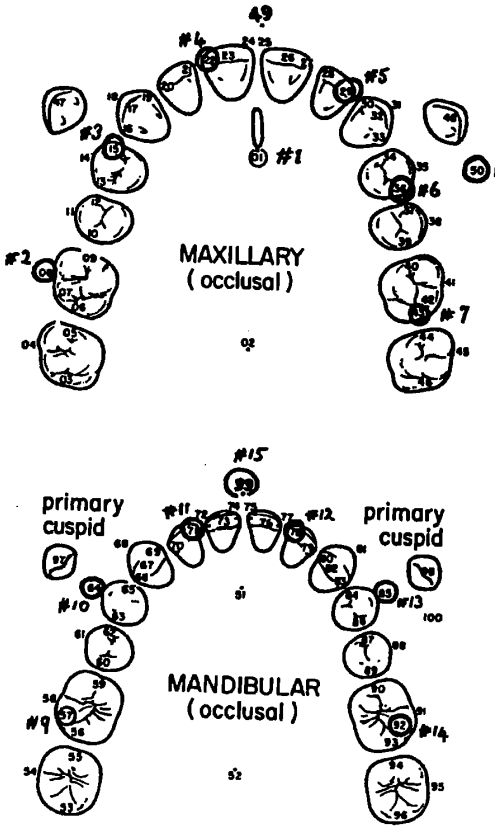


Fig. 2 *Continued*

ClearCorrect Exhibit 1002, Page 1069 of 3373

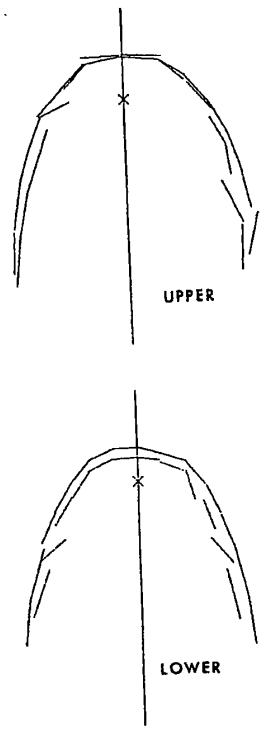


Fig. 3 Plotter output from model analysis program, showing two different records superimposed.

models taken at the end of retention, and D for those taken two or more years postretention.

Printed Report

A sample printed report is shown in table I. In order of the listing, the entries are:

Arch relationship measures the amount of mesial deviation in millimeters of the mesiobuccal cusp of the maxillary first molar from a point representing the buccal groove of the mandibular first molar, as described by Fisk.[7] A class II molar relation is indicated by a positive figure and a Class III relationship by a negative figure.

Overjet, is a measure of the relationship between the maxillary and mandibular central incisor teeth in a horizontal direction as described by Walter.[11] A positive value indicates maxillary overjet, a negative value represents underjet.

Overbite, described by Walter,[11] is used to measure the relationship between the maxillary and mandibular central incisor teeth in a vertical direction. It represents the vertical overlap of the maxillary incisors over the mandibular incisors in mm. A positive value indicates an overbite, a negative value an open bite.

Curve of Spee is measured on the right lateral unoccluded view of the models. The line of occlusion used in the computation is a line connecting the incisal edge of the lower right central incisor to the distobuccal cusp of the lower right first permanent molar. Utilizing the computer routine of Cleall and Chebib,[8] the Curve of Spee is computed as the average of the perpendicular distances to the line of occlusion from the cusp tips of the lower right cuspid and bicuspids.

Compensating Curve is measured on the right lateral view of the upper model. The line of occlusion is formed by connecting the mesiobuccal cusp tip of the upper first permanent molar with a line to the incisal edge of the central incisor. The average of the perpendicular distances to the line of occlusion from the cusp tips of the cuspid and first bicuspid is taken to represent the measurement of compensating curve.

Midlines, utilized by many orthodontists including Walter,[11] is carried out in order to assess deviation of the dental midline from the skeletal midline as determined by the midpalatal raphé in the maxilla or the midline constructed in the mandible by transfer of maxillary landmarks. Midline discrepancy, expressed in millimeters, shows a positive value if the dental deviation is to the left, negative if to the right.

Cuspid Arch Width, suggested by Lundstrom,[10] is expressed as the linear distance between cusp tips of right and left cuspids.

Molar Arch Width expresses the linear distance between distobuccal cusp tips of the first permanent molars.

Arch Length, described in detail by Burke[4] and Hechter,[9] is expressed for both right and left sides, along with the average value for the two sides. It is the distance from the incisal edge of the central incisor to the distobuccal cusp tip of the first molar as measured along the midsagittal plane.

Arch Asymmetry is described by Hechter[9] and is used to provide an indication of overall symmetry of the dental arches. Perpendicular distances from the most buccal or labial point on bicuspids and cuspids are computed to the midline and summed for both right and left sides. The left side total minus the right side total is squared, and the index of symmetry is the squared value. Resulting values of 0-3 suggest a reasonably symmetrical arch form, with larger values indicating asymmetry.

Total dental width is the sum of mesiodistal widths of the teeth lying anterior to the first molars.

Tooth Size/Arch Size analysis is described by many authors, including Fisk[7] and Beazley.[1] The analysis is, in general, based on two measurements, one of which is the total tooth width.

TABLE I
Printed report of a cast analysis. Values (except Bolton ratio) are in mm.

Measure	*A*	*B*
Arch Relationship		
Left	0.4	0.5
Right	2.9	1.5
Overjet	1.3	1.6
Overbite	3.2	0.9
Curve of Spee	0.5	0.1
Compensating Curve	—0.7	—1.1
Midlines		
Maxilla	L 0.7	L 0.2
Mandible	L 0.5	R 1.0
Arch Width Cuspid		
Maxilla	30.6	33.1
Mandible	23.8	25.9
Arch width Molar		
Maxilla	50.3	51.4
Mandible	44.0	45.0
Arch Length Maxilla		
Left	27.9	32.8
Right	26.2	32.0
Mean	27.1	32.4
Arch Length Mandible		
Left	24.0	27.4
Right	25.3	31.0
Mean	24.6	29.2
Arch Asymmetry		
Maxilla	0.0	0.1
Mandible	0.0	0.0
Total Tooth Width		
Maxilla	82.2	87.6
Mandible	75.8	78.6
Arch Size—Tooth Size (Space Available—Tooth Width)		
Maxilla	6.4	6.9
Mandible	—1.5	7.7
Bolton Ratio		
Overall	92.2	89.8
Anterior	76.2	76.1

ClearCorrect Exhibit 1002, Page 1070 of 3373

The second measurement is based on arch perimeter, which is often taken as the sum of various connecting line segments drawn around the dental arch. The analysis, which is the result of subtracting the sum of tooth widths from the perimeter, provides an indication of spacing or crowding of teeth in the dental arch. Perimeter in the analysis used at the University of Illinois is taken as the sum of distances between the mesial surface of the first molar to the distal of the lateral incisor, to the mesial of the central incisor on the opposite side, to the distal of the lateral incisor, to the mesial surface of the first molar. A negative value resulting from the subtraction suggests crowding, whereas a positive value is indicative of spacing of teeth in the dental arch.

Bolton Ratios[3] were devised as a diagnostic aid to gain insight into the functional and esthetic outcome of a case. The anterior ratio gives the percentage relationship of the mandibular anterior tooth widths to the corresponding value for the maxilla. The overall ratio is the percentage relationship of mandibular tooth width for all teeth lying anterior to the second molars to the corresponding maxillary tooth width.

Graphic Display from the Model Analysis

Figure 3 shows a photograph of the plotter output from the model analysis program. The midline with the point of registration marked is shown for both maxilla and mandible, along with straight-line representations of the teeth. For the test subject, two sets of records have been superimposed for the graphics.

The computer system relieves the clinician of carrying out time-consuming hand measurement of dental casts, and is especially useful in universities or clinics where a large number of patients are treated. In using the system, one must keep in mind that a three-dimensional object has been reduced to a set of two-dimensional views through the photographic procedure, much as is done in cephalometrics. A two-dimensional system can never be expected to replace the three-dimensional view of the clinician, but may readily be used to supplement other information the diagnostician draws from the plaster casts and the patient under orthodontic care.

References

1. Beasley, W. W.: Assessment of mandibular arch length discrepancy utilizing an individualized arch form. *Angle Orthod.* 41:45-54, 1971.
2. BeGole, E. A., Cleall, J. F., and Gorny, H. C.: A computer program for the analysis of dental models. *Comput. Program Biomed.* 10:261-270, 1979.
3. Bolton, W. A.: The clinical application of a tooth-size analysis. *Am. J. Orthod.* 48:504-529, 1962.
4. Burke, T. A.: A comparison of maxillary arch dimensions in sibling and non-related pairs. Master of Science Thesis, University of Illinois, Department of Orthodontics, 1979.
5. Chebib, F. S., Cleall, J. F., and Carpenter, J. K.: On-line computer system for the analysis of cephalometric radiographs. *Angle Orthod.* 46:305-311, 1976.
6. Cleall, J. F., and Chebib, F. S.: Coordinate analysis applied to orthodontic studies. *Angle Orthod.* 41:214-218, 1971.
7. Fisk, R. O.: Normal mandibular arch changes between ages 9-16. *J. Can. Dent. Assn.* 32:652-658, 1966.
8. Hechter, F. J.: Symmetry and dental arch form of orthodontically treated patients. *J. Can. Dent. Assn.* 44:179-184, 1978.
9. Hechter, F. J.: Symmetry, form and dimension of the dental arches of orthodontically treated patients. Master of Science Thesis, University of Manitoba, 1976.
10. Lundstrom, A.: An investigation of 202 pairs of twins regarding fundamental factors in the aetiology of malocclusion. *Dent. Rec.* 69:251-264, 1949.
11. Walter, D. C.: Changes in the form and dimensions of dental arches resulting from orthodontic treatment. *Angle Orthod.* 23: 9-18, 1953.

The Angle Orthodontist

October 1981

Volume 51, Number 4 ISSN 0003-3219

CONTENTS

261 • Good, Better, Best for What?
Editorial

263 • The Ribbon Arch Appliance, Its Influence on the Development of Orthodontic Appliances
B. F. Dewel

269 • Influence of Respiratory Pattern on Craniofacial Growth
James A. McNamara, Jr.

301 • Bilateral Buccolingual Forces Produced By Extraoral Traction
Giancarlo Baldini, Donald C. Haack and Sam Weinstein

319 • Surface Corrosion of Nitinol and Stainless Steel Under Clinical Conditions
John W. Edie, George F. Andreasen and Mary P. Zaytoun

325 • Effects of Composition and Cross Section on the Elastic Properties of Orthodontic Archwires
Robert P. Kusy and Alan R. Greenberg

342 • Subject Index, Volume 51

344 • Author Index, Volume 51

ClearCorrect Exhibit 1002, Page 1071 of 3373

URRENT
NLS
opy 1
8K

Journal of Dental Research
UCSF LIBRARY
Received on: 02-12-88

Volume 67
Special Issue

JOURNAL OF Dental Research

Abstracts of Papers

66th General Session
International Association for Dental Research

17th Annual Session
American Association for Dental Research

12th Annual Meeting
Canadian Association for Dental Research

March 9-13, 1988
Montréal, PQ, Canada

UCSF Library
Serials Department
Sciences Bldg.
San Francisco, CA 94143

ClearCorrect Exhibit 1002, Page 1072 of 3373

448 M. Samson*, D. Poussart, D. Laurendeau, C. Bernard (Université Laval, Québec, Canada): Acquisition of the 3D Profile of Dental Imprints by Means of Computer Vision Techniques.

Presently, orthodontics diagnosis is based in part on parameters measured on costly plaster models and X-Rays of the patient's jaw. This work presents a computer vision system designed to automatically extract some of these parameters from measurements performed on a less expensive wax dental imprint. The 3D profile of the imprint is obtained by a method based on light absorption.

The imprint is immersed in a liquid colorant. Each facet of the imprint is illuminated by a light source and its grey-level image is captured by a solid-state camera. When passing through a colorant, a ray of light of a given wavelength is absorbed due to the density and thickness of the medium as stated by Lambert's law. Two points of the imprint surface located at different depths will show a corresponding difference in their grey-levels on the image. A 3D profile of the imprint can be obtained by suitable computer processing of the data recorded at two different wavelengths. Experiments performed on a wide set of imprints have shown that reliable 3D profile data can be obtained. Furthermore, measurements on both sides of the imprint are in perfect registration.

These results indicate that the system is appropriate in terms of overall accuracy cost and ease of utilization. It could be used in population studies since wax dental imprints are easier to obtain than plaster models.

This work was supported in part by the Ministère de la santé et des affaires sociales, FCAR grant EQ-2830 and NSCERC grant A-5274.

449 C. BERNARD*, J.M. BRODEUR, A. FOURNIER, D. POUSSART, D. LAURENDEAU, R. GUAY, M. OLIVIER and P. RETROUVEY (The Dental School, LAVAL University, Ste-Foy, QUEBEC, CANADA): Computerized diagnosis in Orthodontics for Epidemiological studies; a progress report.

Most of the previously reported methods used to computerize diagnosis in Orthodontics are mainly based on a statistical approach where patient's cephalometric measurements are compared to means obtained from a population where he originates from. The purpose of this study was to design and evaluate a computer assisted instrument able, from a limited number of measurements, to classify skeletal and dental malocclusions then rate their severity.

Records of seventy one patients have been independently examined by two orthodontists and two general practitioners. The formers had to diagnose malocclusions according to ANGLE's and DEWEY-ANDERSON's modified classifications using clinical examination, cephalometric analysis and study models then rate the severity of occlusal problems with a scale expressing the need for treatment. The laters had only to measure on study models twelve parameters which were entered in the computer program. Outputs from both orthodontists were paired with those of both general practitioners (via the computer) and compared according to the agreement or desagreement upon severity of malocclusion. A matrix was built for each skeletal (in sagittal, frontal and vertical planes) and dental (DEWEY's types 1, 2, 3, 4 and 5) problem, then for the total malocclusion. According to dentist/orthodontist combination and kind of malocclusion, the sensitivity value was seen to vary from 87.3% to 98.6% for squelettal problems and from 70% to 98.3% for dental problems.

This study was supported by Ministry of Social Affairs.

450 Computer-Assisted Diagnosis of Drug Interactions. R. Caine*, R. JOHANSEN, and M. GELB, UMDNJ-New Jersey Dental School. Newark, New Jersey.

The objective of the study was to determine the effectiveness of DRUG MASTER, a software program, for drug interactions. Drug interactions between two or more drugs may be therapeutic, antagonistic, idiosyncratic or a potentialization. DRUG MASTER was a computer-assisted program designed for the diagnosis of drug interactions. It was developed for an I.B.M. microcomputer. The experimental design was an after only with one experimental group and one control group. The sample of the experimental group was comprised of eighty-five drugs of interest to dentistry. These four major areas included the following: (a) non narcotic and narcotic analgesics, (b) minor tranquilizers and sedative-hypnotics, and (c) antibiotics, and (d) sympathomimetics amines. Each drug was analyzed with another drug that had produced an established interaction. The sample of the control group was comprised of drugs that produced an established interaction with the experimental group. The major source of information was a drug interaction form. DRUG MASTER was evaluated in terms of the accuracy of its knowledge base and the ease of use. The results indicated that it was a valid and reliable computer program. Also, it was user friendly. In conclusion, DRUG MASTER was effective in the determination of drug interactions.

451 G. FELDMAN* and D. STEVENS (University of Pennsylvania, Philadelphia, PA).
The Feasibility of a Computerized Voice Recognition Charting System.

The object of this study was to determine the feasibility of developing and using a voice recognition computerized charting system which allows the examiner to directly store clinical examination data in a computer using voice recognition technology. More specifically, the study was designed to analyze the time and error differential between the traditional examiner/recorder method (ERM) and computerized voice recognition method (VRM).

DMFS examinations were performed twice on twenty patients using first the traditional ERM and then the VRM charting system. The voice recognition DMFS system operated on an IBM PC with a KEY TRONIC'S KB 5152V voice recognition keyboard. The time necessary to complete each examination and number of errors per examination were recorded. Questionnaires were then given to each patient to determine acceptance of the VRM charting system.

Mean time for the ERM was 2.69 minutes compared to the VRM examination of 3.72 minutes. There was a mean of 1 recording errors for each ERM examination compared to 6 uncorrected voice recognition errors. Thus the VRM examination took 1/3 more time and produced a data set with additional errors. 90% of the patients indicated that they felt comfortable with the dentist talking to a computer and only 1 patient, or 5% of the population indicated that they opposed the VRM. During the study it became evident that both the time and accuracy of the VRM charting system could be improved by changing the vocabulary used. Thus, in the near future, voice recognition technology should be a viable alternative to traditional examiner/recorder methods of clinical charting. The paper presented will discuss the statistical significance of the data along with the problems and possible solutions of using current voice recognition technology.

This research was supported by NIH grant #2-S07-RR-05337-26 and the GCRC program DRR grant #5-M01-RR01224.

452 **Prevalence of Dental Fear. P. Milgrom,* L. Fiset, S. Melnick. Dental Fears Research Clinic, University of Washington, Seattle, Washington, USA.**

Adult residents of metropolitan Seattle were surveyed in 1986 by telephone or by mail to determine the prevalence of dental fears. A total of 1019 subjects were interviewed. Respondents were 43.5% male with a mean age of 42.7 yrs. (SD = 17.0) Nearly one-half of respondents were married. Whites, Asians, Blacks, Hispanics and Native Americans were represented. Forty-one percent of respondents had received post-graduate education. Family income ranged from under $10,000 to more than $35,000 per year. Fifty-two percent reported dental insurance. Demographic characteristics did not differ significantly from those of the Seattle SMSA. The prevalence of high dental fear in Seattle for 1986 was 204 people per 1000 population. Among those reporting high fear, 137/204 reported acquiring fear in early childhood, 36/204 during adolescence and 31/204 as adults. Women were 1.8 times more likely to report fear than males ($p = .000$). Individuals with family incomes below $20,000 were 1.3 times more likely to report fears than those with higher incomes ($p = .105$). High fear levels are remarkably constant over decades (19-25%) but drop slightly after age 50 (14%). Fear groups did not differ significantly by race, education, marital status or the availability of insurance. High fear respondents were less likely than low fear subjects to have visited the dentist in the last 12 months (59 vs. 77%, $\chi 2 = 36.7$, $p = .000$). Twenty-four percent had not seen a dentist in over 2 years. Fifty-one percent of high fear subjects delayed making appointments and 9.1% failed to appear for scheduled appointments, often or nearly every time. Fear of the dentist thus remains a common fear with important effects on dental utilization.

Supported by Grant No. 6950 from NIDR, NIH.

453 **Identification of the Relationship between Dental and Non-Dental Fears. L. Fiset,* P. Milgrom, S. Melnick. Dental Fears Research Clinic, University of Washington, Seattle, WA., U.S.A.**

Several recent clinical studies in the U.S. and Sweden suggest a relationship between dental and non-dental fears. To explore these relationships 1019 adult residents of Seattle were surveyed by mail or telephone during 1986. Demographic characteristics of the sample differed insignificantly from those of the Seattle SMSA. Respondents were 43.5% male and mean age of 42.7 yrs (SD = 17.0). Whites, Asians, Blacks, Hispanics, and Native Americans were represented. Forty-one percent had received post-graduate education. Family income ranged from below $10,000 to more than $35,000 per year. Nearly half were married, and 52% reported having dental insurance. Fear items were adapted from the Geer Fear Survey and represent the 9 most common fears. The prevalence of moderate to high fear per 1000 population is: Heights (357), Injury (263), Death (236), Illness (195), Enclosures (170), Traveling alone (91), Storms (91), and Being alone (79). Fear of dentist (204) ranked 4th among all fears. Among respondents reporting intense fear ("terrified"), Dental fear ranked second (30) behind Heights (52). High dental fear respondents were more likely than low fear individuals to fear Flying ($X^2 = 15.7$, $p = .004$), Enclosures ($X^2 = 14.4$, $p = .006$), Illness ($X^2 = 8.4$, $p = .079$), Traveling alone ($X^2 = 15.8$, $p = .003$), and Being alone ($X^2 = 15.4$, $p = .004$). High dental fear subjects were also more likely to report high fear in multiple (3 or more) non-dental situations (54.7% vs. 38.1%, $X^2 = 38.9$, $p = .000$). **Results from this representative survey confirm the relationship between dental and non-dental fears, as observed in clinical populations.**

Supported by Grant No. DE6950 from NIDR, NIH.

454 T. SMITH*, A. KAPLAN, P. WEINSTEIN, P. MILGROM, and T. GETZ. (Univ. of Kentucky, Lexington, and Univ. of Washington, Seattle): Factor Structure of a Dental Fear Survey in Three Patient Groups.

Kleinknecht and others factor analyzed a dental fear survey (1984) for typical dental patients and college undergraduates of both sexes. Three reliable and consistent factors; avoidance and anticipatory anxiety, fear of specific dental stimuli, and felt physiologic arousal, were found. This study replicates this work for 3 groups of fearful patients. The same survey was administered before treatment to 142 fearful patients in a university-based dental fears clinic (Smith et al., 1986), and to a separate sample of 95 similar patients. In addition, fear survey responses of 74 fearful patients treated by 11 private dental practices were collected. Since sex differences in the 20 item means and variances were few, the responses of the total groups were analyzed using the method of principal factors with squared multiple correlations as prior communality estimates. For both university-based groups, 4 eigenvalues exceeded 1.0, while for the private practice patients 3 eigenvalues were greater than 1.0. Sets of 4, 5, and 6 factors were rotated by the varimax method. All correlations between rotated factor pattern loadings of the 3 groups were significant beyond the .005 significance level for the 4 factor solution. The added factors in the 5 and 6 factor rotated patterns did not consistently correlate between groups. Four replicable factors, felt physiologic arousal, individual factors for dental stimuli needle and drill, and avoidance and anticipatory anxiety were found. This is one more factor than reported by Kleinknecht (1984), but two less than originally found by Smith et al. (1986).

455 F.D. MCGLYNN, L.E. GASKINS, M.K. WRUBLE, P.H. FEIL* (University of Missouri-Kansas City and University of Florida, Gainesville, FL): Factor Structure of the Dental Fear Survey.

The Dental Fear Survey has a demonstrably stable factor structure that represents the three-channel construction of anxiety. However six of eight factor analytic demonstrations have used college respondents. Here the survey responses of two very different groups of dental patients were factor analyzed to evaluate factor-structure generality more rigorously.

Eight-hundred-twenty-five respondents took the survey before treatment. Four-hundred-fifty were participants in a comprehensive dentistry program requiring regular appointment keeping. Three-hundred-seventy-five presented to an emergency dental clinic for toothache unrelated to accident. Data from the groups were analyzed separately using orthodox procedures for principal components analysis and axis factoring. Responses from the comprehensive and emergency clinic patients yielded the same three orthogonal factors that also were those reported consistently in eight previous studies: dental avoidance and anticipatory fear; anxious reactions to routine events in restorative dentistry; and physiological arousal during dental treatment. These factors accounted for 60% of the survey variance among comprehensive dental patients and 66% among emergency patients. There were differences in the hierarchical rank of the three factors across the two groups but these were differences in factor order not factor content. Hence the results attest to broad generality for the factor structure of the instrument.

ClearCorrect Exhibit 1002, Page 1073 of 3373

British Journal of Oral and Maxillofacial Surgery (1984) 22, 237–253
© 1984 The British Association of Oral and Maxillofacial Surgeons

A COMPUTER-AIDED DESIGN FOR ORTHOGNATHIC SURGERY

S. N. BHATIA, B.Sc., F.D.S., D.Orth.R.C.S., M.D.S. and
J. H. SOWRAY, B.D.S, F.D.S., M.R.C.S., L.R.C.P.

King's College Hospital, Dental School, London

Summary. An interactive on-line computer system is described with application in orthognathic surgery. Both the hardware and software of the system are discussed. The application of the system is outlined under the various features of the system's software. The general software collects, stores and analyses graphic data such as from cephalometric radiographs and facial and dental photographs. The specific software handles the planning requirements of orthognathic surgery—diagnosis, treatment planning and prediction of post-operative soft-tissue profile.

Introduction

The use of computers in the measurement and analysis of skull radiographs is not new; in orthodontics it has been advocated and practised for many years (Solow, 1970; Walker, 1972; Savara, 1972; Ricketts 1960: Chebib *et al.*, 1976; Houston, 1979). In orthognathic surgery, however, the awareness of their application is recent. Schendel *et al.* (1976) appear to be the first to employ a computer system, a modified version of Walker's craniofacial model, for the analysis of pre- and post-operative soft tissue profiles. Eisenfeld and Mishelevich (1980) in a more comprehensive paper sketched the future role of computers in the diagnosis and treatment of dentofacial deformities, emphasising in particular the contribution of computer graphics. They drew attention to the usefulness of mathematical and multivariate statistical models in the diagnosis of dento-facial deformities and prediction of soft tissue profile. Ricketts' extensive pioneering work (1970–80) on computerised cephalometrics covering orthodonitc diagnosis, treatment and growth prediction, also embraced orthognathic surgery but in a much less exhaustive way. Schulof (1979) amplified the work of Ricketts and discussed in detail the application of computers in orthognathic diagnosis—considering skeletal, dental and soft tissue factors and treatment planning. The visual treatment objectives (VTO) were defined and followed in the same manner as for orthodontic diagnosis and treatment planning. A strong plea was made for the creation of a large central data bank (Rocky Mountain Data Systems—RMDS-Oral Surgery Data Bank) which could provide a frame of reference for the diagnosis and treatment of individual cases.

There are several aspects to the understanding of the use of computers in orthognathic surgery; those relating to the computers themselves and their systems of hardware and software; and those concerned with their applications—in general, the collection, storage and analysis of clinical information, and, in particular, the diagnosis and treatment planning for the correction of jaw deformities.

With regard to hardware, the systems described so far have mainly consisted of a centrally placed computer with local access through a terminal (Solow, 1970; Walker, 1972; Schendel *et al.*, 1976). The feeding of information into the computer is achieved either along a telephone line (Chebib *et al.*, 1976) or on punch cards.

(*Received* 7 February 1983; *accepted* 2 August 1983)

ALN116340

ClearCorrect Exhibit 1002, Page 1074 of 3373

These installations have little independent status and processing of information is carried out in a sharing or 'batch' (queue) fashion. Eisenfeld and Mishelevich (1980) provide the first reference to a system with locally organised facilities including computer graphics. Unfortunately, only a limited allusion is made to programs (software) which harness the hardware and turn it into a workable unit.

In terms of application, though mention has been made of general collection and storage of data, diagnosis and treatment planning, much of the involvement of computers appears to have been in the running of small research projects, particularly in the analysis of pre- and post-operative clinical records. Some of these projects have also attempted prediction of post-operative soft tissue profile.

In this paper a computer-aided design for diagnosis and treatment planning for correction of jaw deformities and prediction of post-operative soft tissue profile is described. The design is an extension of the application of the interactive on-line computer system developed at King's College Hospital, Dental School, London, for measurement of cephalometric radiographs (Bhatia, 1977; 1983).

The following is a brief account of the hardware (equipment) and software (programs) of the system.

THE KING'S COLLEGE HOSPITAL COMPUTER SYSTEM

Hardware

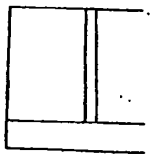
Central to any computer-aided system for measurement of radiographs is a digitiser. A digitiser is a flat tablet fitted with a movable cursor or pen. When the cursor is placed on the surface of the tablet, its position is resolved into two coordinates, the 'X' coordinate on the horizontal axis, and the 'Y' coordinate on the vertical axis. By moving the cursor to various positions or points for example radiographic landmarks on the tablet, a series of 'X' and 'Y' coordinates are obtained, and from these linear, angular and area measurements between the points can be calculated by simple trigonometric functions. The above principle is utilised in the measurement of graphic material such as radiographs, photographs and charts.

In the present system, the digitiser is linked to an LSI–11 microcomputer (belonging to the PDP–11 series of computers made by Digital Equipment Corporation Ltd, and with 32K of 16-bit word of internal memory), and coordinates are fed directly into the computer memory. The back-up store or secondary memory is provided by two interchangeable floppy disks with combined capacity of two million bytes of data. The computer is accessed and controlled by a graphics terminal, the Tektronix 4006–1. It is the master teminal (console) and its keyboard that permits development and running of programmes, direct entry of data, and control of the other devices linked to the computer. The screen of the terminal echos the above keyboard operations and displays the computer response to the programmes in textual, numerical and graphical forms. Also linked to the computer are a printer and a plotter, for providing textual and graphic hard copies of the computer analysis respectively, and two slave terminals for multi-user operations (Figs. 1 & 2).

Software

Extensive software has been developed to harness the above described hardware





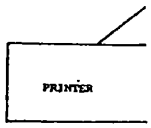


Figure 1—The hard
system. 2. The Tekt
(multibuttoned) cur
2—Dia;

and make it virtu
much training. T
are best describ

The software i
answer style whi
software collects.
the radiographs c
of *specially* writ

ALN116341

ClearCorrect Exhibit 1002, Page 1075 of 3373

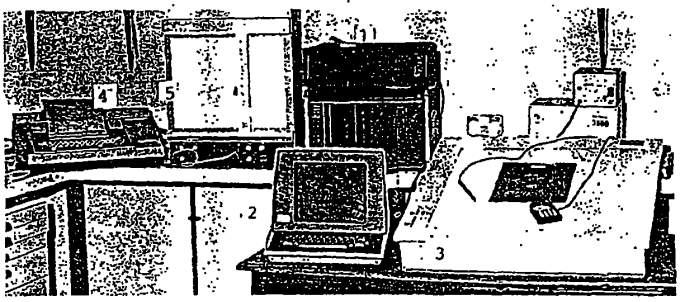


Fig. 1

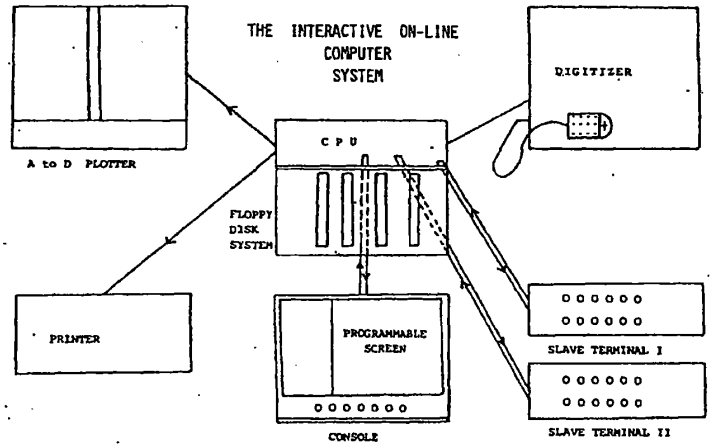


Fig. 2

Figure 1—The hardware of the K.C.H. system. 1. The central processor and the dual floppy disk system. 2. The Tektronix V.D.U. with a keyboard. 3. The Perex 3,600 digitizer with pen and cross-wire (multibuttoned) cursors. 4. The printer. 5. The Bryans instruments hard copy plotter. Figure 2—Diagrammatic representation of the overall configuration of the system.

and make it virtually a 'turn-key' system, so that a novice could operate it without much training. The system has many research and clinical applications and these are best described under the various features of the software.

The software is written in BASIC, and follows an interactive or question-and-answer style which simplifies the system's operational procedures. The *general* software collects, stores, and analyses information from graphic material, such as the radiographs of the skull and photographs of the face and dentition, while a suite of *specially* written programmes handles, within the environs of the general

ALN116342

ClearCorrect Exhibit 1002, Page 1076 of 3373

software, the specific requirements of diagnosis and treatment planning for orthognathic surgery.

The General Software

Initially a MENU programme directs the operator to the appropriate procedure, whether for collection, storage or analysis of data.

The collection programmes are concerned with two types of information, general and specific or graphic. The general information is typed in through the master terminal or console, and comprises of such items as the place or centre of treatment, consultant in charge, patients' personal details (name, age, sex), clinical condition (malocclusion, dental and skeletal characteristics) and treatment provided (orthodonitc and surgical procedures). This information can later be incorporated into the general patients' data base.

The graphic information on the other hand is recorded on the digitiser from radiographs and photographs in the form of cartesian coordinates, and directly fed into the computer store. This information is of two kinds, of discrete points and of

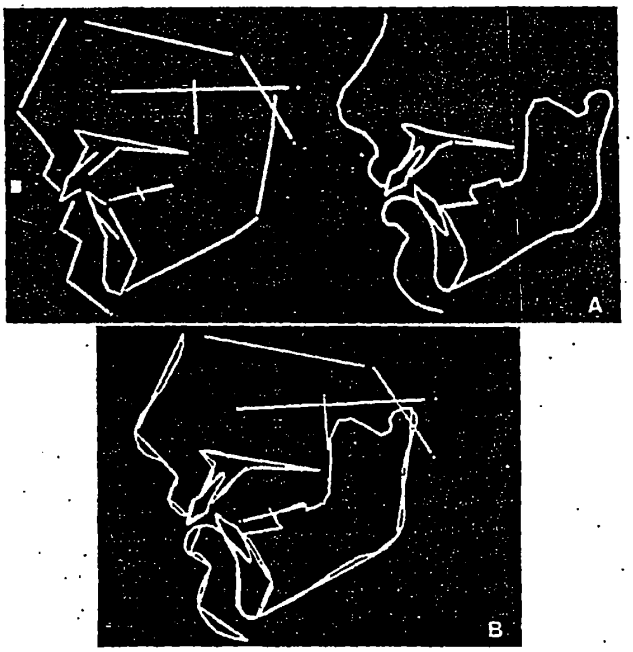


Fig. 3

Figure 3 (A)—Graphic display of discrete and continuous point tracings on the Tektronix screen: (B) The continuous point tracing correctly superimposed on the discrete point tracing.

ALN116343

ClearCorrect Exhibit 1002, Page 1077 of 3373

continuous points (Figs. 3A & 3B). The discrete points refer to specific indentifiable anatomical landmarks which can be reproduced with a reasonable accuracy. Their number is determined before-hand and they are carefully recorded. The continuous points represent shapes such as curves, outlines or areas (such as the cranial base, mandibular canal, soft tissue outline and nasopharyngeal area). Here individual points have no independent significance except in the context of the adjoining points. The number of continuous points recorded, whether from a curve or an area, is not fixed and varies from recording to recording.

The programmes for collection of information, whether general or specific, are structured in such a way that they allow for a great deal of flexibility. The items of general information, number of discrete points and number of curves or areas recorded can all differ from project to project, or centre to centre, yet they can be collated, summarised and analysed by a single, fixed format programme. (Note: Walker employed 289 points, Eisenfeld and Mishelvich 220 points, and Schendel *et al.* 180 points. Most of these points are derived points and have doubtful scientific usefulness as they cannot be used in computation of measurements. They do, however, help complete the drawing). In the projects run at the K.C.H. system to date, the number of discrete or measurable points have varied between 10 and 100. The continuous points from areas and outlines are not always recorded (Fig. 4). This flexibility produces considerable saving of time and effort as unwanted information, whether items of general information or anatomical landmarks, need not be supplied or 'digitised'. In practice this flexibility has resulted in the creation of

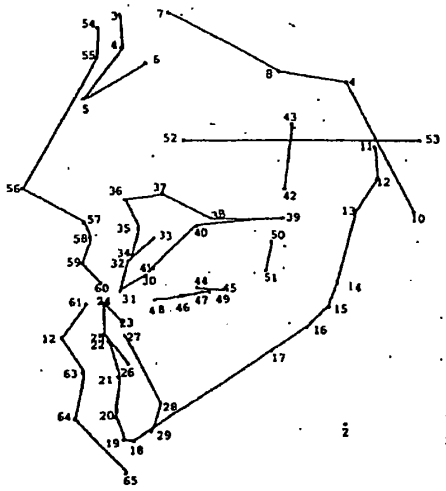


Fig. 4

Figure 4—Discrete point tracing based on 67 hard and soft tissue landmarks. Points 1 and 2 are arbitrary reference (fiducial) points which are used if any later addition is made to the recorded points.

ALN116344

ClearCorrect Exhibit 1002, Page 1078 of 3373

various types of files (in computer language a 'file' refers to a specially designated storage area on a floppy disk)—routine, special project, longitudinal or growth, all with differing natures and amounts of information yet suitably structured to be combined into a single master file, and analysed as such.

Once created these files can be inspected for error, and any editing—deletions or additions—can be easily carried out. The files may be examined numerically or graphically; in the latter case the tracings of the radiographs appear on the screen in sequential order. After inspection the files may be combined into bigger files to create master files. For a research project usually one master file is sufficient, but for routine storage of records with a much larger data base several master files need to be created.

In the K.C.H. system these files are organised alphabetically, but they can be organised on any other basis such as sex, type of surgery, malocclusion group and consultant in charge. Alternatively, and this is a better approach, large alphabetically arranged files can be reorganised or broken down into smaller files on any of the above listed criteria, with the help of a series of SELECT programmes. Cephalometric parameters, that is computed measurements, may also be used for this selection.

Computation of Measurements and Statistical Analysis

A number of programmes can handle the final coordinate files for computation of measurements and statistical analysis. These programmes, apart from minor variations designed for specific requirements, have the same basic format. Programme COMPUT is a general purpose programme with subroutines for most types of measurements including linear (distances and perpendiculars), angular (angles between two points and two lines), projected measurements, and areas built into it. It also has the option for further manipulating the measurements by addition, subtraction, division or multiplication to create new measurements. A list of measurements to be computed is prepared first. This list is used by programme COMPUT and applied to the master file of coordinates of the recorded radiographs. The measurements are computed radiograph by radiograph and stored as a data file. This data file forms the basis for the various statistical analyses. Means and standard deviations are always printed out when the measurements of a sample are computed; in addition a histogram, cumulative frequency curve and range (minimum and maximum values) of one or more measurements can also be obtained (Fig. 5).

Programme CORREL examines the relationship between variables by calculating the correlation coefficient between them while programme REGRES provides the regression of one variable on the other with graphical display of the scattergram.

When comparing two groups such as before and after treatment groups, a whole battery of T-tests on group measurements may be carried out; alternatively in the case of more than two groups, for example pre-operative, post-operative and follow-up, an analysis of variance test may be used.

The above listed statistical procedures, descriptive and inferential, are the commonly used procedures in research projects and these have been incorporated into some SELECT programmes to speed up data analysis. Initially one such SELECT programme breaks up the master coordinate file into smaller units or groups. It then computes the required measurements for each group separately, providing means and standard deviations for each measurement (Fig. 6). It finally



Figure 5— His

carries out a
of variance.
summation o
be displayed
or places for
especially of
areas of po
regression an
Special pro
orthognathic
post-operativ

Diagnosis

The diagnosis
In the num
of the popula
chosen variabl
noting the va
population an
standard devia
in this way. T
clinician has th
wished.

ALN116345

ClearCorrect Exhibit 1002, Page 1079 of 3373

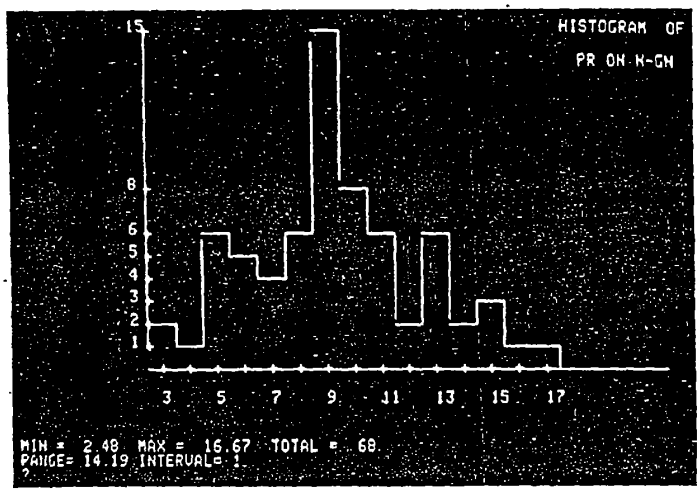


Fig. 5

Figure 5— Histogram of a variable (PR on N–GN) together with the minimum, maximum, range and interval values.

carries out a statistical comparison between the groups either by a t-test or analysis of variance. Each group may also be represented by a mean tracing which is a summation of tracings of all members in the group. These mean group tracings may be displayed on the screen or plotted on paper and superimposed on various areas or places for visual comparison (Fig. 7). These numerical and visual comparisons, especially of the post-operative and follow-up groups, help in the identification of areas of post-operative relapse and, when combined with correlation and regression analyses, in the elucidation of factors which may influence this relapse.

Special programmes have been written to meet the particular requirements of orthognathic surgery—for diagnosis, treatment planning and predicition of post-operative soft tissue profiles.

Diagnosis

The diagnosis of a facial deformity may be carried out numerically and graphically.

In the numerical analysis the values of the deformity are adjudged against those of the population parameters, that is, the means and standard deviations of the chosen variables. The region of discrepancy and its extent are established first by noting the variables which show significantly different values from that of the population and then, by calibrating these differences in terms of the respective standard deviations. All skeletal, dental and soft tissue variables can be considered in this way. There is no restriction as to the number of variables examined, the clinician has the choice of making these variables as comprehensive or limited as is wished.

ALN116346

ClearCorrect Exhibit 1002, Page 1080 of 3373

PROJECT===MAXLLARY ADVANCEMENT IN CLEFTS

*****S-N-A
*****-----

***		PREOP	POSTOP	FOLLOW-UP
		-----	------	---------
****	1	70.11	78.23	73.43
****	2	68.99	74.61	74.49
****	3	61.87	68.99	66.89
****	4	70.56	74.04	73.28
****	5	56.76	64.3	62.34
****	6	68.56	77.35	69.47
****	7	66.54	77.07	77.11
****	8	73.12	76.61	74.58
****	9	68.29	73.08	72.85
****	10	64.36	65.8	69.33
****	11	76.18	82.11	81.3
****	12	72.06	79.74	77.94
****	13	64.92	70.12	68.11
**** MEAN		67.87	74	72.39
**** S.D.		4.88	5.16	4.89
**** S.E.		1.35	1.43	1.35

*****S-N-B
*****-----

***		PREOP	POSTOP	FOLLOW-UP
		-----	------	---------
****	1	75.69	75.46	72.69
****	2	79.58	80.03	80.56
****	3	73.33	72.18	72.62
****	4	72.44	69.53	71.43
****	5	71.58	64.51	69.83
****	6	76.08	74.01	73.33
****	7	72.43	71.98	73.01
****	8	74.94	75.55	73.78
****	9	73.57	73.44	74.48
****	10	63.57	63.9	64.05
****	11	77.8	79.21	79.37
****	12	77.93	80.3	78.23
****	13	70.01	69.93	70.51
**** MEAN		73.76	73.07	73.37
**** S.D.		3.96	5.06	4.16
**** S.E.		1.09	1.4	1.15

Fig. 6

Figure 6—Print-out of a numerical analysis of three groups taken from a research project (Ward-Booth *et al.*, 1983).

A number of clinical analyses have been described in the literature and these are based on either cephalometric or photographic data (Burstone, 1978; Worms *et al.*, 1975; Legan & Burstone, 1980). These analyses may all be built into the system very simply. Alternatively, a personalised analysis may be constructed based on variables found most useful clinically. Programme INDIAN prepares this analysis. The chosen variables may be grouped together in several ways, as soft tissue,

Figure 7—S
surgery

skeletal.
variables.
make it c
chosen va
derived fr
out agains
Figure 8
67 cephal
the list of
shown. Th
deviation
The gr
deformity.
the numer
soft tissue
points. Th
previously
from a san
occlusion,
The tracin

ALN116347

ClearCorrect Exhibit 1002, Page 1081 of 3373

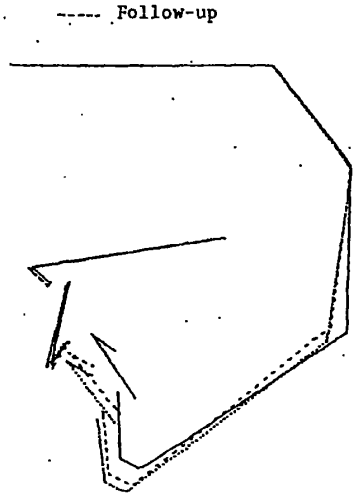


Fig. 7

Figure 7—Superimposition of mean group tracings on the S-N plane showing mean change due to surgery and mean post-operative relapse taken from a research project (Bhatia *et al*, 1983).

skeletal, and dental variables or, as anteroposterior, vertical and transverse variables. The print out of the analysis may be suitably formatted and titled to make it comprehensible at a glance. The means and standard deviations of the chosen variables for the population may be previously fed into the system, either derived from the 'resident' data or taken from the published literature, and printed out against the individual variable values.

Figure 8 demonstrates the format of an analysis based on 27 variables. Initially, 67 cephalometric landmarks were recorded from a radiograph. INDIAN prepared the list of 27 variables and calculated the variable values which were printed out as shown. These were contrasted with the previously obtained mean and standard deviation values for a sample of normal occlusion.

The graphical analysis provides a quick, overall visual assessment of the deformity, and is particularly useful if the clinician is either, not fully familiar with the numerical forms, or has doubts about their clinical significance. Both hard and soft tissues are drawn on the screen using the digitised discrete and/or continuous points. The resultant tracing may either be studied on its own or against a previously prepared template. A template is a mean or composite tracing prepared from a sample of cases. The reference sample may be made up of cases with good occlusion, or good profile, or simply of cases drawn from the population at large. The tracing may be superimposed on the template using various planes to highlight

ALN116348

```
***** MARK PEYTON *****

  SEX  M
  AGE   20 YRS 5 MNTHS
  MALOCCLUSION  3

SIZE
  ANT:CRANIAL BASE ( 75.5 , 3 )          77.3        O.K.
  TOTAL CRANIAL BASE ( 112.4 , 4.2 )     114.8       O.K.
  MAXLLARY BASE ( 56.7 , 3.7 )           54.1        O.K.
  MANDBLAR BASE ( 80.2 , 4.5 )           81.1        O.K.
  TOTAL MANDBLAR LNGTH ( 127.7 , 5.4 )   133.4       INCREASED
  ANT.UPPER FACE HGT ( 58.2 , 4.2 )      51.6        DECREASED
  ANT.LOWER FACE HGT ( 68.5 , 4.4 )      83.5        INCREASED
  ANT.TOTAL FACE HGT ( 126.7 , 6.9 )     135.1       INCREASED
  POST.UPPER FACE HGT ( 48.2 , 2.3 )     48.5        O.K.
  POST.LOWER FACE HGT ( 39.7 , 3.9 )     28.9        DECREASED
  POST.TOTAL FACE HGT ( 87.9 , 4.1 )     77.5        DECREASED

ANT/POST RLTNSHIP
  SNA ( 82.4 , 3.7 )          75.9       DECREASED
  SNB ( 81.3 , 3.9 )          81.6       O.K.
  ANB ( 1.1 , 2.3 )           -5.7       DECREASED
  WITS APPRAISAL (-4.7 , 0 )             -15.8       DECREASED
  MAX/N-S RATIO ( .73 , .05 )            .7          O.K.
  MAND/N-S RATIO ( 1.06 , .05 )          1           DECREASED
  MAX/MAND RATIO ( .7 , .03 )            .6          DECREASED

VERTICAL RLTNSHIP
  ANT.LOWER/TOTAL FACE HGT ( .54 , .02 )  .6         INCREASED
  POST.LOWER/TOTAL FACE HGT ( .42 , .03 ) .3         DECREASED
  MAX/MAND PLANE ANGLE ( 21 , 6.2 )       42.2       INCREASED
  GONIAL ANGLE ( 124 , 5.4 )              147.1      INCREASED

DENTURE
  UPPER INCISOR ( 115.2 , 7.4 )          115.8       O.K.
  LOWER INCISOR ( 93.7 , 5.6 )           75.8        DECREASED
  INTERINCISOR ( 127.2 , 9.4 )           126.1       O.K.
  OVERJET ( 2 , 0 )           -5.6       DECREASED
  OVERBITE ( 2 , 0 )          -3.3       DECREASED
```

Fig. 8

Figure 8—Print-out format of an analysis based on 27 variables. The values in parenthesis represent the mean and standard deviation of the variable obtained from a sample of 7 males with normal occlusion. The case values are evaluated in terms of 1 S.D. departure from the mean values.

overall (for example superimposition on S–N or Frankfort plane) (Figs. 9A & B) or localised areas of discrepancy (for example superimposition on ANS–PNS plane for maxillary, and mandibular axis for mandibular discrepancies). It should be understood that this comparison with the template is primarily intended to identify disproportion in the facial complex, but this identification may become confused if there is a discrepancy in the overall size between the tracing and the template. For this reason, Jacobson (1979) has suggested the use of proportional templates, of differing sizes: small, medium and large. In our system the problem is overcome very simply. The tracing is fitted to the template size by altering the enlargement factor (Figs. 11A & B). A provision for altering the enlargement has been built into some programmes to compensate for the variation in the radiographic or photographic enlargement. Anterior cranial base (sellanasion distance) or total cranial base (nasion-basion distance) values may be used to match up the tracing and template size. It should be appreciated that these corrections though providing a better assessment of differences in proportionality, will conceal true size differences.



Figure 9 (A)—
using S–N plan



Figure 10 (A)—T
registration on mi
similar superimpos

ALN116349

ClearCorrect Exhibit 1002, Page 1083 of 3373

O.K.
O.K.
O.K.
O.K.
INCREASED
DECREASED
INCREASED
INCREASED
O.K.
DECREASED
DECREASED

DECREASED
O.K.
DECREASED
DECREASED

INCREASED
DECREASED
INCREASED
INCREASED

O.K.
DECREASED
K

hesis represent the
normal occlusion.
n values.

gs. 9A & B) or
-PNS plane for
It should be
ded to identify
me confused if
template. For
templates, of
n is overcome
e enlargement
been built into
diographic or
ance) or total
up the tracing
ugh providing
eal true size

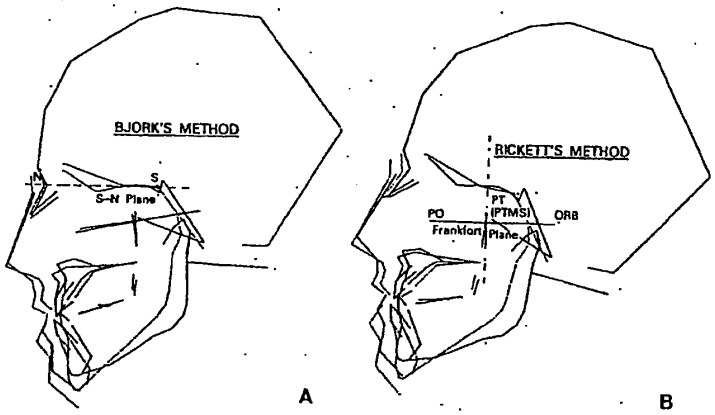


Fig. 9

Figure 9 (A)—Superimposition of a case tracing on a template based on 7 males with normal occlusion using S–N plane. (B) A similar superimposition using Frankfort plane with registration on PT(pterygoid) point. (—— template, – – – – case tracing).

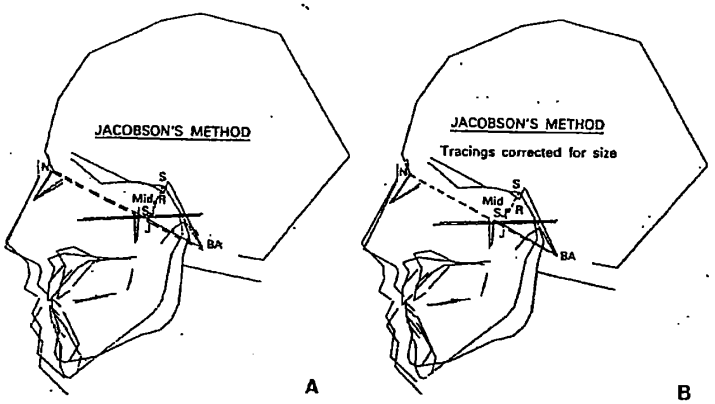


Fig. 10

Figure 10 (A)—The Jacobson's method of superimposition with orientation on N–BA plane and registration on mid point (R point) on the perpendicular S–J from sella (S) to N–BA plane: (B) A similar superimposition as above but the case tracing is corrected to the template size (——— template, – – – – case tracing).

ALN116350

ClearCorrect Exhibit 1002, Page 1084 of 3373

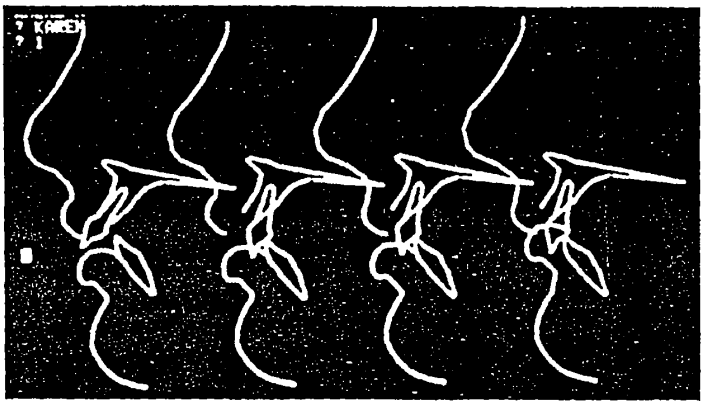


Fig. 11

Figure 11—Graphic display of the correction of incisor angulation to their mean values. The shape and position of the upper and lower lips have been arbitrarily corrected corresponding to the change in the incisor position.

The use of separate templates is recommended for the two sexes. Age is also an important consideration if the patient has not reached maturity. Although the facial growth almost completely ceases in girls by the age of 16 years, it continues in boys till after. 20 years.

Programme AGETMP prepares templates for the two sexes separately, year by year, from either a cross-sectional or longitudinal data base. In the present system the longitudinal growth records collected at the K.C.H. Dental School by Professor B. C. Leighton in the last 30 years are used for the purpose.

Treatment Planning

After the diagnosis of a deformity is made and regions of discrepancy identified, its treatment is planned. A number of programmes are written for this purpose.

There are basically three considerations in the treatment planning: dental, skeletal and soft tissue. The dental considerations involve deciding upon the need and type of pre-surgical orthodontic treatment; the skeletal considerations the choice of surgical procedure: and the soft tissue considerations, the prediction of soft tissue profile following hard tissue surgery.

Pre-Surgical Orthodontic Treatment

The pre-surgical orthodontic treatment, apart from the mandatory alignment of teeth, is generally directed towards altering the inclincation of incisors to their average values. The existing inclination of the incisors may be masking the skeletal discrepancy (dentoalveolar compensation) or exaggerating it. Programme SURGE1 first computes the inclincations of the upper and lower incisors to their respective jaw bases and then corrects them to their average values (109° for the

maxillary and
corrected incis
discrepancies,
either by depr
level could be
The above s
result of orthoc
It also reveals
extent of the

Planning of Su

The resultant t
for planning su
Initially the cl
treatment of the
procedures for
displayed as line
programme to
segments (Fig. 1
bodily—horizont
screen. The prc
clinician to try m
is achieved (Fig.
is within the reali
drawn on the pl
segments numeri
prediction of the

Prediction of Pos

A number of autl
surgery and some
1958; Bell & Daw
Worms *et al.*, 197
chin are the soft tis
unaffected, except
accepted that this
to differing extents
tissue change exte
commented that wi
advancement at th
around the alar
advancement is use
of the nose. The Le
to tip forwards and
lenghtened. Further
bone grafts which
In predicting soft
a number of points a
soft tissue which m

ALN116351

ClearCorrect Exhibit 1002, Page 1085 of 3373

maxillary and 90° for the mandibular incisors), or any other prestated values. The corrected incisors are drawn on the screen and if required on the plotter. Vertical discrepancies, such as of over-bite, may also be considered and can be corrected either by depressing or, less likely, by elevating the incisors. The occlusal plane level could be used as a guide for the vertical adjustment (Fig. 11).

The above simulated tooth movement serves several purposes. It examines the result of orthodontic treatment and helps clarify orthodontic treatment objectives. It also reveals the underlying skeletal discrepancy and, therefore, the nature and extent of the surgical problem.

Planning of Surgical Procedure

The resultant tracing with incisors drawn in their correct position forms the basis for planning surgical procedures (Programme SURGE2).

Initially the clinician indicates the surgical cuts which are to be considered in the treatment of the deformity; a version of SURGE2 has most of the common surgical procedures for the maxilla and mandible included in it. These surgical cuts are displayed as lines across the discrete and continuous point tracings and used by the programme to split the constellation of recorded co-ordinates into separate segments (Fig. 12). These segments can now be separately manipulated, moved bodily—horizontally or vertically—or rotated on any point or axis, on the console screen. The programme follows a question-and-answer style and permits the clinician to try numerous combinations till a satisfactory arrangements of segments is achieved (Fig. 13). It is for the clinician to decide whether the simulated surgery is within the realms of realistic surgical procedures or not. The final arrangement is drawn on the plotter and the extent and direction of movement of the affected segments numerically expressed. This numerical expression is utilised in making a prediction of the soft tissue position subsequent to surgery.

Prediction of Post-operative Soft-tissue Profile

A number of authors have investigated soft-tissue change following orthognathic surgery and some guide-lines have been put forward for its estimation. (Burstone, 1958; Bell & Dawn, 1973; Lines & Steinhauser, 1974; Chaconas & Bartoff, 1975; Worms *et al.*, 1975; Schendel *et al.*, 1976). It is generally agreed that the lips and chin are the soft tissues which display most change while the nose remains relatively unaffected, except in the case of ostectomies of the LeFort II and III types. It is also accepted that this change is not uniform and that different components are affected to differing extents. With the LeFort I advancement, it has been shown that the soft tissue change extends as far as the tip of the nose. Henderson (1980), has commented that with the cleft palate type of nasomaxillary hypoplastic deformity, advancement at the LeFort I level with bone grafting will eliminate the flattening around the alar bases but accentuate the nasal recession. The LeFort II advancement is useful where there is marked recession of the nasal base and bridge of the nose. The LeFort III advancement usually brings the entire nose from bridge to tip forwards and if also the maxilla is brought downwards then the nose will be lenghtened. Further modification of the shape of the nose will occur from any onlay bone grafts which are inserted at the time of the ostectomy.

In predicting soft tissue change and incorporating it into a computer programme, a number of points are to be considered. Firstly, the simple bodily movement of the soft tissue which may be expressed as a ratio of the hard tissue movement.

ALN116352

ClearCorrect Exhibit 1002, Page 1086 of 3373

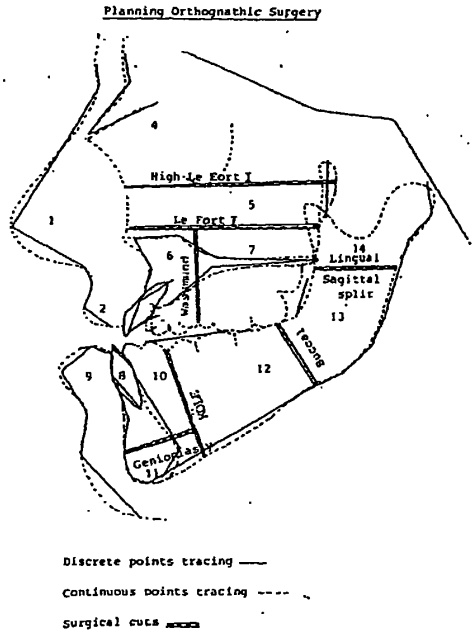


Fig. 12

Figure 12—Superimposed continuous and discrete point tracings of the case for othognathic surgery with lines indicating the likely 'surgical cuts'. These cuts divide the constellation of coordinates into 14 segments.

Secondly, the more complex change in soft tissue shape which is difficult to express mathematically and which may be a function of such undefinable factors as the internal tonicity and posture of the soft tissues. Our observations have shown that, in addition, the presence or absence of intervening incisors and pre- and post-operative vertical dimensions may also influence this shape.

Needless to say that the information on these points to date is not precise. The simplest movement to incorporate into a computer programme is the bodily movement of the soft tissues and this could be varied from region to region: for example in a one-to-one ratio to the hard tissues for the chin and some parts of the lower lip, and in a less than one-to-one ratio (60 per cent. to 90 per cent.) for the upper lip. Where incisor tooth movement is envisaged, a corresponding adjustment in the soft tissue position could be made prior to planning the surgical procedure. Programme PREPRO (predict profile) effects this change with the option for controlling the percentage change.



Figure 13—This s
surgical correctior
indicating some li
incisors to 109° a
mandibular segme
The dotted line in
Shows the distal r
indicating the lingı
to achieve a satisfi
has been placed in
has been placed ir
slightly but this is

ALN116353

ClearCorrect Exhibit 1002, Page 1087 of 3373

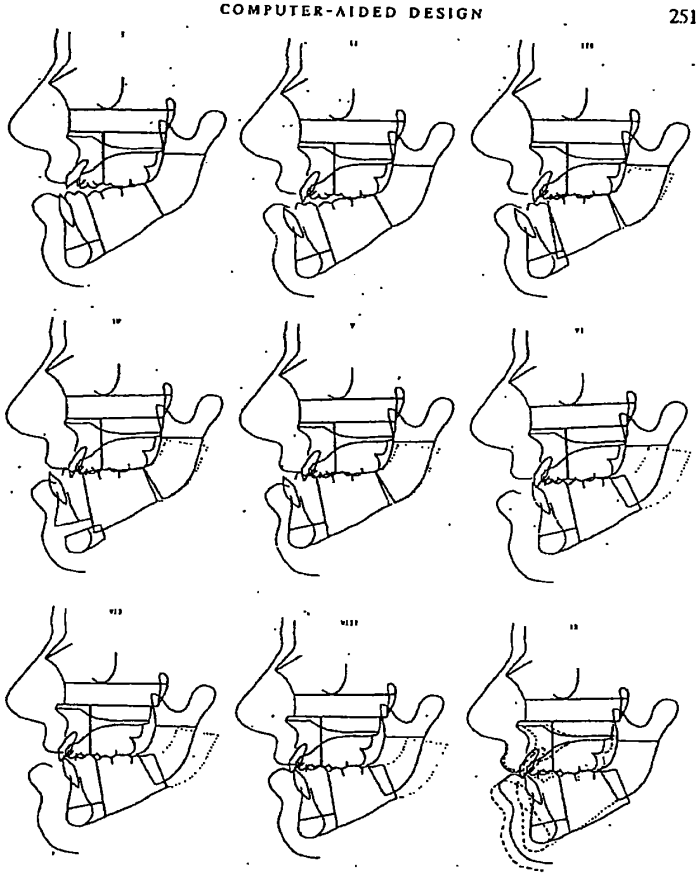


Fig. 13

Figure 13—This shows an example of the step-by-step computer simulation of the planning of the surgical correction of a jaw deformity. (I) Computer tracing of preoperative hard and soft tissue profiles indicating some likely 'surgical cuts'. (II) The incisors are corrected to the normal values with upper incisors to 109° and lower incisors to 92°. (III)–(V) Show the rotational movement upwards of the mandibular segments anterior to the line of the sagittal split in order to correct the anterior open bite. The dotted line indicates the position assumed by the lingual part of the angle of the mandible. (VI) Shows the distal movement of the whole of the anterior part of the mandible, the dotted line again indicating the lingual part of the angle. (VII) The maxilla has been moved anteriorly at a LeFort I level to achieve a satisfactory incisal relationship. (VIII) The soft tissue profile of the lower third of the face has been placed in the post-operative position. (IX) The soft tissue profile of the middle third of the face has been placed in the post-operative position. It is possible that the tip of the nose is also advanced slightly but this is not shown. The dotted lines show the preoperative hard and soft tissue profiles.

thognathic surgery
coordinates into 14

icult to express
factors as the
ve shown that,
and pre- and

ot precise. The
is the bodily
to region: for
me parts of the
r cent.) for the
ing adjustment
cal procedure.
he option for

ALN116354

Regarding the change in shape and its prediction, even less information is available. In programme PREPRO there is a subroutine which alters the shape of the lip by manipulating the successive 'X' and 'Y' coordinates describing the shape. The lips can be lengthened or shortened or narrowed or widened and the outer profile correspondingly made shallow or deep. However, the operator needs to decide on the change that is to be aimed for, or likely to be achieved. The programme first produces a bodily change in the soft tissue position corresponding to the hard tissue change and then effects a change in the soft tissue shape.

The above alteration in the soft tissue position and shape is made, for the upper lip from the junction of the lower border of the nose and beginning of the upper lip (point NOS3) and, for the lower lip, from the point of deepest concavity of the sublabial groove (point LLIP3). The nasal profile depends upon the type of maxillary ostectomy.

Engel *et al.* (1979) describes a multiple regression method for predicting the post-operative soft tissue profile point by point, from the hard tissue profile. Each soft tissue point is considered as a function of several hard tissue points and is predicted from them. This statistical method is shown to give more accurate assessment of the post-operative soft tissue position than the 'non-surgical' prediction method of using the various 'soft-tissue-to-hard-tissue ratios'. In theory, the regression coefficients as obtained by them, could be employed to predict the soft tissue position in new cases, provided the coefficients were derived from a much bigger sample than theirs (N=19). These coefficients could be incorporated into a multiple regression programme and the predicted profile expressed numerically or plotted either on the console screen or plotter.

The prediction of soft tissue profile in the above manner and its graphical display against the hard tissue profile on the screen or plotter—though not necessarily precise, assists in evaluating the eventual effect of surgery on facial aesthetics and, therefore, the suitability of the surgical procedure chosen. If the outcome is unsatisfactory, a different surgical procedure may be simulated and the predicted soft tissue profile evaluated.

Conclusion

The above description briefly outlines some of the possible applications of a digitiser linked computer system with graphic display facilities in the diagnosis and treatment planning for orthognathic surgery. The programmes mentioned are linked in such a way that any procedure, whether routine collection, edition or storage of data, or carrying out of a research project or diagnosis and treatment planning of a case of deformity, follows a natural step-by-step sequence. The applications described are by no means comprehensive and it is felt that with further inevitable spread of computer technology and wider usage of such computer systems, new applications will be found and old ones stringently tested and refined.

The usefulness of computers in collection, storage and analysis of cephalometric data is fully established and this usefulness may be exploited to find answers to the many problems in orthognathic surgery, some of which have been referred to in this paper. This will necessitate examination of a large data base collected from numerous centres. It appears that the plea made by Schulof (1980) on behalf of the Rocky Mountain Data System could be revived in this country too, and an attempt made to centralise past, present and future jaw osteotomy data. Such data should be a source of innumerable research projects and help set up more precise guide-lines for diagnosis and treatment planning of jaw deformities.

Bhatia, S. N. (
paper pres
Dundee, S
Bhatia, S. N. (
practice in
Bhatia, S. N.,
advanceme
Bell, W. H. &
part of the j
12.
Burstone, C. J.
Burstone, C. J.
Chaconas, S. J.,
Orthodontic
Chebib, F. S., (
cephalomet
Engel, G. A., Oı
A prelimina
Eisenfeld, J. &
dentofacial
Proffitt and
Henderson, D. (
Dentofacial I
Philadelphia.
Houston, W. J. I
European Jo.
Jacobson, A. (197
75, 156.
Legan, H. L. & I
Journal of Or
Lines, P. A. & Si
structures in
Ricketts, R. M. (1
of Othodontic
Ricketts, R. M.,
cephalometric
Ricketts, R. M. (19
115.
Savara, B. S. (1972
aids. *American*
Schendel, S. A., E
maxilla. Stabili
Schulof, R. S. (19
Therapy by R.
Solow, B. (1970). (
Walker, G. F. (1972
Journal of Orth.
Ward-Booth, R. P.,
and palate pati
Worms, F. W., Isaac
analysis and ma

ALN116355

ClearCorrect Exhibit 1002, Page 1089 of 3373

References

Bhatia, S. N. (1977). A simple, flexible and automated method of measuring skull radiographs. A paper presented to the Country meeting of the British Society for the study of orthodontics held at Dundee, Scotland.

Bhatia, S. N. (1983). A comprehensive interactive on-line computer system for research and clinical practice in orthodontics. In press.

Bhatia, S. N., Harris, M. & Yan, S. W. (1983). Nature of relapse after surgical mandibular advancement. In press.

Bell, W. H. & Dann, J. J. III (1973). Correction of dentofacial deformities by surgery in the anterior part of the jaws: A study of stability and soft-tissue changes. *American Journal of Orthodontics*, 45, 12.

Burstone, C. J. (1958). The integumental profile. *American Journal of Orthodontics*, 44, 1.

Burstone, C. J. (1978). Cephalometrics for orthognathic surgery. *Journal of Oral Surgery*, 36, 269.

Chaconas, S. J. & Bartroff, J. D. (1975). Prediction of normal soft tissue changes. *American Journal of Orthodontics*, 45, 12.

Chebib, F. S., Cleall, J. F. & Carpenter, K. J. (1976). On-line computer system for the analysis of cephalometric radiographs. *Angle Orthodontist*, 46, 305.

Engel, G. A., Quan, R. E. & Chaconas, S. J. (1979). Soft tissue change as a result of maxillary surgery. A preliminary study. *American Journal of Orthodontics*, 75, 291.

Eisenfeld, J. & Mischelevich, D. J. (1980). Computer-based research studies on the correction of dentofacial deformities. in *Surgical Correction of Dentofacial Deformities* by W. H. Bell, W. R. Proffitt and R. P. White. W. B. Saunders Company. Philadelphia.

Henderson, D. (1980). Nasomaxillary Hypoplasia. Part B of Chapter 9 in *Surgical Correction of Dentofacial Deformities* by W. H. Bell, W. R. Proffit and R. P. White; W. B. Saunders Company, Philadelphia.

Houston, W. J. B. (1979). The application of computer-aided digital analysis to orthodontic records. *European Journal of Orthodontics*, 1, 71.

Jacobson, A. (1979). The proportional template as a diagnostic aid. *American Journal of Orthodontics*, 75, 156.

Legan, H. L. & Burstone, C. J. (1980). Soft tissue cephalometric analysis for orthognathic surgery. *Journal of Oral Surgery*, 38, 744.

Lines, P. A. & Steinhauser, E. W. (1974). Soft tissue changes in relationship to movement of hard structures in orthognathic surgery: A preliminary report. *Journal of Oral Surgery*, 32, 891.

Ricketts, R. M. (1969). The evolution of diagnosis to computerized cephalometrics. *American Journal of Orthodontics*, 55, 795.

Ricketts, R. M., Bench, R., Hilgers, J. J., & Schulhof, R. (1972). An overview of computerized cephalometrics. *American Journal of Orthodontics*, 61, 1.

Ricketts, R. M. (1981). Perspective in the clinical application of cephalometrics. *Angle Orthodontist*, 51, 115.

Savara, B. S. (1972). The role of computers in dentofacial research and the development of diagnostic aids. *American Journal of Orthodontics*, 61, 231.

Schendel, S. A., Eisenfeld, J., Bell, W. H., & Epker, B. N. (1976). Superior repositioning of the maxilla. Stability and soft tissue osseous relations. *American Journal of Orthodontics*, 70, 663.

Schulof, R. S. (1980). Planning oral surgery. New methods of communication. In *Bioprogressive Therapy* by R. M. Ricketts and others. Rocky mountain orthodontics.

Solow, B. (1970). Computers in cephalometric research. *Computers in biological medicine*, 1, 41.

Walker, G. F. (1972). A new approach to the analysis of craniofacial morphology and growth. *American Journal of Orthodontics*, 61, 221.

Ward-Booth, R. P., Bhatia, S. N., & Moos. (1983). The stability of Le Fort II osteotomies in cleft lip and palate patients. In press.

Worms, F. W., Isaacson, R. J. & Spidel, T. M. (1975). Surgical orthodontic treatment planning: profile analysis and mandibular surgery. *Angle Orthodontist*, 46, 1.

ALN116356

ClearCorrect Exhibit 1002, Page 1090 of 3373

15. Savara, B. S., and Sanin, C.: A new data acquisition method for measuring dentition and tests for accuracy, Am. J. Phys. Anthropol. 30: 315-318, 1969.
16. Savara, B. S., and Singh, I. J.: Norms of size and increments of seven anatomical measures of maxillae in boys from three to sixteen years of age, Angle Orthod. 38: 104-120, 1968.
17. Savara, B. S., and Tracy, W. E.: Norms of size and annual increments for five anatomical measures of the mandible in boys from three to sixteen years of age, Arch. Oral Biol. 12: 469-486, 1967.
18. Savara, B. S., Tracy, W. E., and Miller, P. A.: Analysis of errors in cephalometric measurements of three dimensional distances of the human mandible, Arch. Oral Biol. 11: 209-217, 1966.
19. Sekiguchi, T., and Savara, B. S.: Unpublished data.
20. Singh, I. J., and Savara, B. S.: Norms of size and annual increments of seven anatomical measures of maxilla in girls from three to sixteen years of age, Angle Orthod. 36: 312-324, 1966.
21. Singh, I. J., Savara, B. S., and Miller, P. A.: Interrelations of selected measurements of the face and body in preadolescent and adolescent girls, Growth 31: 119-131, 1967.
22. Tracy, W. E., and Savara, B. S.: Norms of size and annual increments of five anatomical measures of the mandible in girls from 3 to 16 years of age, Arch. Oral Biol. 11: 587-598, 1966.
23. Tracy, W. E., Savara, B. S., and Brant, J. W. A.: Relation of height, width and depth of the mandible, Angle Orthod. 35: 269-277, 1965.

611 S.W. Campus Dr.

Computerized analysis of occlusion in the postcanine dentition

Robert H. Biggerstaff, D.D.S., Ph.D., and James A. Wells, D.D.S.
Lexington, Ky., and Madisonville, Ky.

The computer may be used to determine the statistical range of variation for a particular "type" of occlusion.[1] In this study, X and Y coordinate data derived from photographed dental casts are used to develop a two-dimensional mathematical model for determining the magnitude and direction of defined occluding anatomic landmarks. Hopefully, in the future, this model can be incorporated into a more complex three-dimensional model which would include data describing all dental, skeletal, and soft-tissue factors that influence occlusion.

From the University of Kentucky College of Dentistry, Department of Orthodontics. Based on a thesis submitted by Dr. Wells in partial fulfillment of the requirements for a certificate in orthodontics, University of Kentucky.

ClearCorrect Exhibit 1002, Page 1091 of 3373

In the past, occlusion has usually been analyzed and classified on the basis of the observed interdigitation when the teeth of the opposing jaws (dental casts) are closed. However, occlusion results from the synthesis of many interacting factors during the period of growth and development. These factors encompass all dental, skeletal, and soft-tissue variations, whether they be genetic and/or environmental. The composite of these interactions during the dynamic stages of growth and development probably accounts for the normal distribution of occluding relationships observed in a population.

Early scholars of occlusion were unable to devise an acceptable method for segregating occlusion types. Order was brought from chaos when Angle[2] submitted an acceptable classification of occlusion to the dental profession. He considered that an "ideal" occlusion occurred when the mesiobuccal cusp of the maxillary first molar rested in the buccal groove of the mandibular first molar with the other teeth being in good alignment. Malocclusions were grouped into three classes according to molar deviations in an anteroposterior direction. In effect, Angle made an attempt to describe a normally distributed biologic entity in terms of discrete classes.

Angle's classification was readily accepted by the majority of the dental profession; however, there were those who immediately recognized deficiencies in the Angle classification. For example, Calvin Case[3] charged that Angle's system disregarded the relationship of the teeth to the face. Others[4-8] have claimed that only the anteriorposterior relationship was considered, in spite of the fact that malocclusion is a three-dimensional phenomenon, and that Angle's classification did not recognize those wide differences in the character of certain malocclusions which have the same distal or mesial occlusion of the buccal teeth.

These students[4-8] of occlusion and malocclusion, by stating their objections to the deficiencies of the Angle scheme, have, in many instances, offered substitute classification systems which were presumed to be based on criteria that included dental and skeletal variations in the three planes of space. The Angle classification retains its popularity, and its versatility has been enhanced by several modifications which are essential in planning the treatment of malocclusion. Apparently, then, this system suffices for describing occlusal relationships.

Hellman[9] has shown that occlusion, like many other biologic phenomena, may be treated in accordance with the laws of biometrics. He concluded that occlusion occurs "when the jaws are closed" and that the system of discrete anatomic relationships can be observed to estimate the degree of perfection in an individual's occlusion. As a biometrician, he assumed occlusion to be a normally distributed biologic phenomenon.

To discuss a normal distribution intelligently, one needs "numbers." Therefore, this article will describe the mensurational variation in the occlusion of the postcanine dentition, using the "cusp point contact with a fossa or ridge" model, as defined by Hellman[9, 10] and later modified by Friel,[11, 12] as the major criterion. The work reported here utilizes a two-dimensional mathematical model to determine the magnitude and direction in the variation of defined anatomic landmark relationships on the occluding surfaces of the deciduous and permanent molars and premolars in the sagittal and transverse planes of space.

ClearCorrect Exhibit 1002, Page 1092 of 3373

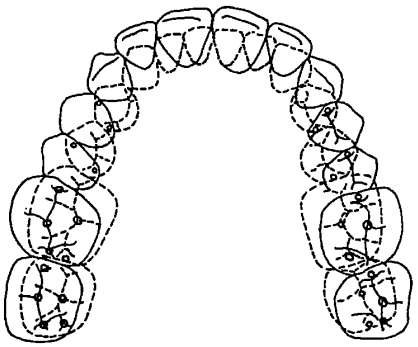


Fig. 1. The major occluding contacts of the permanent postcanine dentition are represented as small circles. Solid line outlines maxillary teeth; broken line outlines mandibular teeth.

Materials and methods

The data utilized in this experiment were recorded X and Y coordinates[13] which represented defined anatomic landmarks located on the occlusal surfaces of the postcanine dentition of monozygotic (100 pairs) and dizygotic (99 pairs) twins with an age range from 4 to 12 years. The coordinate data were derived from dental casts duplicated from the records of an ongoing semilongitudinal twin study at the Forsyth Dental Center. The casts were made available to Robert H. Biggerstaff through the courtesy of C.F.A. Moorrees. The total sample consisted of 199 cases, using the duplicate casts of one individual from each pair of twins. From the duplicate casts, forty-seven with a "socked-in" good occlusion and thirteen with a full-cusp Class II malocclusion were selected. The raw coordinate data associated with these sets of dental casts, respectively, formed the good occlusion and malocclusion data.

The methods for reducing the postcanine anatomic occlusal landmarks to a two-dimensional mathematical model have been described elsewhere[1, 13-15] and need not be repeated in detail here. In summary, photogrammetric data representing defined anatomic occlusal landmarks were converted to X and Y coordinates and stored on data cards. The raw coordinate data were then transformed, by computer, to a system of computed common coordinates, so that the usual occluding relationships of the postcanine dentition were preserved.

These data were used to make comparisons of the cusp-fossa or cusp-ridge relationships for the postcanine deciduous and permanent dentitons. The occluding relationships were selected, using the model proposed by Hellman[9] as modified by Friel.[11] In selecting these occluding relationships, due consideration was given to the variations in occlusal morphology of the mandibular permanent first and second molars and the mandibular deciduous second molars[16] (Fig. 1).

ClearCorrect Exhibit 1002, Page 1093 of 3373

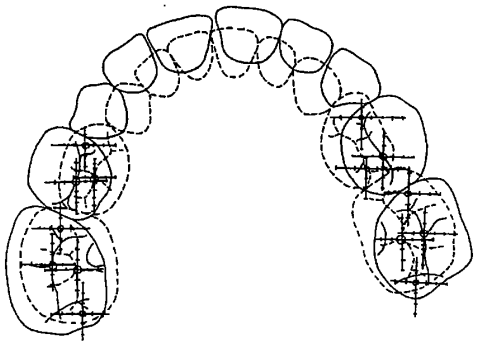


Fig. 2. The variation observed in the occlusal contacts of the total-population deciduous postcanine dentition. The magnitude and direction of the mean values are scaled in millimeters.

The computer programs, containing the mathematics necessary to compute the magnitude and direction of the variations between a landmark, "point zero," on a maxillary tooth and its antagonist were simplified because the data had been transformed into a system of coordinates common to the maxilla and mandible. From "point zero," angular and linear measurements were computed, by quadrants, to describe the variation of each cusp–fossa or cusp–ridge relationship. While the angular dimensions were computed in a counterclockwise direction using abscissa of the first quadrant as the point of origin, the data are presented in the usual way using the ordinate of the first quadrant as the point of origin. These variations were grouped into anterior (mesial), posterior (distal), buccal, or lingual categories. Therefore, the data are arbitrarily separated into buccal (45 to 135 degrees), lingual (225 to 315 degrees), mesial (315 to 45 degrees) and distal (135 to 225 degrees) groups on the right side. The buccal deviations representing the analogous structures on the corresponding left side are displayed between 225 and 315 degrees, whereas the lingual deviations are presented between 45 and 135 degrees. For each group, statistical descriptions were generated for a combined population of males and females.

The computer programs were again modified to provide the instructions necessary to identify the individual data sets for the "good" occlusion and malocclusion groups. The linear and angular variations for the two populations were then computed along with the statistical descriptions to determine the range of variation between the cusp–fossa and cusp–ridge relationships. Tests of significance are not reported in detail because the subsample sizes were small.

Results

Our basic hypothesis assumes that no deviations will exist between the point representing the maxillary cusp-tip, ridge, or fossa, "point zero," and the corres-

Fig. 3. The
postcanine
millimeters.

ponding o
cause of t
the magni
grammatic
populatior
defined oc
buccally,
given dire
between 0

The ra
populatio
Fig. 3. Th
and bucca
in any di
among th
observed
which occ

In the
was relate
and the a
there are
highly co
usually lo
alternativ
and fovea
tributed t

The ta

ClearCorrect Exhibit 1002, Page 1094 of 3373

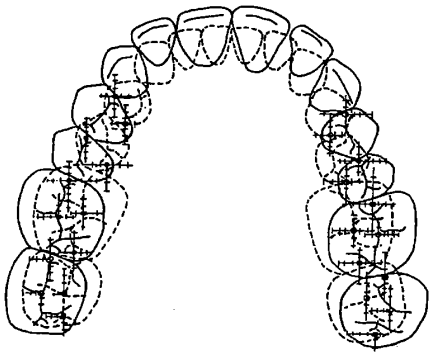


Fig. 3. The variation observed in the occlusal contacts of the total-population permanent postcanine dentition. The magnitude and direction of the mean values are scaled in millimeters.

ponding occluding anatomic landmark on the opposing mandibular tooth. Because of the vast amount of tabular data, only the mean values, which represent the magnitude and direction of the observed variations, will be presented diagrammatically. Fig. 2 shows the magnitude and direction of the observed total population mean values. These represent a part of the variation for each of the defined occluding relationships in the deciduous dentition. The variations occur buccally, lingually, mesially, and distally, and they approximate 3 mm. in any given direction. Although the standard deviations are not presented, they range between 0.72 and 2.39 mm.

The range of variations for the individual occluding relationships in the total population's permanent posteanine dentition is presented diagrammatically in Fig. 3. The continuous nature of the distribution between the mesial and distal and buccal and lingual vectors is apparent. The magnitudes of the mean values in any direction range between 2 and 4 mm. The largest variations appear among the occluding contacts of the premolars. The smallest mean values are observed for the mesiolingual cusp of the maxillary first permanent molar which occludes in the central fossa of the mandibular first permanent molar.

In the tabular data some interesting relationships were observed. One such was related to the position of the distal cusp on the mandibular permanent molar and the area of contact on the opposing maxillary tooth. The data suggest that there are two primary areas of contact on the maxillary tooth and that these are highly correlated to the position of the distal cusp, that is, the distal cusp is usually located buccally if the tooth has a distal marginal ridge and distal fovea; alternatively, the cusp is located distally on teeth without a distal marginal ridge and fovea. The premolar data also indicated that variations in morphology contributed to the observed magnitude of the mean values and standard deviations.

The tabular data for the total population suggested, in many instances, that

ClearCorrect Exhibit 1002, Page 1095 of 3373

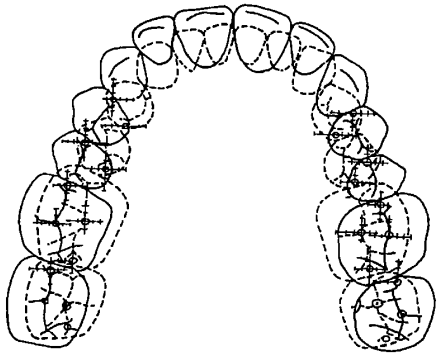


Fig. 4. The variation observed in the occlusal contacts of the population with a good occlusion (Class I) and permanent dentition. The magnitude and direction of the mean values are scaled in millimeters.

sidedness is a factor to be considered in occlusion. Most frequently the contacts were buccal and distal to the ideal location on the right side and mesial and lingual on the left side. These findings are not observable in our diagrammatic presentation because the frequency of occurrence is not presented.

The variations in the population with good occlusion, Class I, are presented in Fig. 4 for the permanent dentition. Generally, the magnitude of the mean values is less than those in the total population. Yet, the directional variation is similar. The molar mean values for the occluding contacts were less than those for the premolars. The over-all variations for the standard deviations were large, probably because of the small sample size.

The malocclusion population (Class II, Division 1), although small, gave clear indications of the trend toward a distal occlusion. Without exception, the occluding contacts were distal and/or buccal to the ideal. More important, the magnitude of the mean values (range, 3.42 to 7.43 mm.) exceeded the distal values of the total population and the good occlusion population. The malocclusion data can suggest only a trend because of the small sample size.

Discussion

In this study, the relationships of defined anatomic landmarks on the occlusal surfaces of the maxillary and mandibular postcanine deciduous and permanent dentitions have been examined by a two-dimensional mathematical model to determine the amount of variation between occluding contacts. The data indicate a normal distribution in both magnitude and direction of the cusp-fossa and cusp-ridge relationships.

The Angle[2] classification, which describes occlusions in discrete categories,

ClearCorrect Exhibit 1002, Page 1096 of 3373

was used to select two experimental groups, that is, a "good" occlusion group and a malocclusion group. In a large population, the Angle classification should produce a three-component system with a trimodal distribution, each class possessing its own peculiar set of descriptive statistics. Although we were unable to characterize the distribution of each class, the data suggest that our malocclusion group (Class II) possesses characteristics that would tend to distinguish it from the good occlusion group and from a normal population. These data must be interpreted with caution because one must consider the transitional nature of the dentitions in the stated age range (or the small sample). However, the data suggest that the magnitude and direction of the variations in occlusion tend to grade insensibly from one class into another anteroposteriorly. How does one incorporate the normal distribution of the buccal and lingual variations into the Angle scheme?

Another interesting observation suggests that there is sidedness to occlusion. The data of the total population suggested that the left side had a slight Class III tendency, and the right side a slight Class II tendency. Even the Class II group, which appeared to be equally "socked in" on both sides, showed the right side to be more inclined to Class II. It would appear that either the maxillary components are more anteriorly placed or the mandibular components are more posteriorly positioned on the right side or that a combination of both exists. How does one account for this biologic phenomenon? Observed differences in morphologic tooth size and shape[18] have been shown from side to side, and asymmetric lateral tongue pressures[19] have been demonstrated; but the answer is not known at present.

Thus, this study establishes as a fact that dental occlusions are normally distributed. This model is not practical, that is, there are no clinical applications in its present form; however, it can be used as a building block for a more complex model in the future. Moreover, we are still unable to look at a population and answer our primary question: "Where on the scale of normal distribution does a good occlusion end and a malocclusion begin?"

Third-party payment for orthodontic treatment seems to be a reality for the future, either by private insurance coverage, labor unions, or federal government programs. With the onset of these programs, the necessity for methods of screening potential orthodontic patients will become crucial to the profession. In the past, occlusal indexes and handicapping malocclusions have been used without a great deal of satisfaction, basically because the examiner has to make several judgments which incorporated his own personal bias.[19-23]

It appears that the proposed occluding landmarks, as used in this research, could be utilized in a model to which the anterior teeth and the vertical plane of space were added. This would result in a workable three-dimensional model, including all dental components in a static computerized analysis. Required is a simple, easy method of taking an occlusal record with the teeth in centric occlusion.

Previously, wax bites have been used to examine masticating efficiency by having the patient bite into a thin piece of wax in centric occlusion. Light transilluminated the wax, allowing a gradient for evaluation. A positive photograph

ClearCorrect Exhibit 1002, Page 1097 of 3373

of the bite and a judgment of good or poor was made from the amount of light in the contact area.[25] Later a planimeter was used to measure the area of the light that was transilluminated.[26]

Yurkstas and Manly[26] improved upon previous techniques by having the patient bite into wax with the proper opacity, transilluminating the wax bite impression and measuring the transmitted light by means of a photoelectric cell to measure the contact area.

Contour mapping by means of stereophotogrammetry has been used for a quantitative, three-dimensional description of tooth morphology on dental casts.[27] These methods are, at present, time consuming and expensive.

Moire topography of soft tissue and underlying bone also has been described.[28] It would seem feasible that a three-dimensional dental model could be constructed utilizing an imprint of occluding contacts made by the patient biting into centric occlusion. Moire topography would be the logical choice of methods to analyze all three planes of space.

On the other hand, occlusion must be considered as a dynamic phenomenon, whereby the upper and the lower teeth contact when the jaws are closed. To be fully aware of the problems associated with analyzing occluding contacts, one must have an understanding of the developmental biology of occlusion. Craniofacial growth, dentition development, and neuromuscular maturation are the primary correlates of an occlusion which are interrelated in function but develop on different time schedules.[29]

An exhaustive model must, therefore, incorporate dynamic relationships of the above correlates to provide the best possible diagnosis, treatment, planning capability, and prognosis. We foresee, in the future, a computerized approach to orthodontic diagnosis that will utilize information derived from oriented dental casts, oriented radiographs, photographs, and electromyographic data to evaluate occlusion fully in relationship to the craniofacial complex. The model will provide data on the relationship of the maxilla and the mandible to the cranial base and the maxilla to the mandible, as well as the teeth to each other and to their respective bases. The skeletal maturational level and a prediction of the direction and amount of growth forthcoming will allow treatment to coincide with the largest increments of growth.

Electromyographs and pressure reading will be used to examine the neuromuscular system to distinguish etiologic factors and functional influences which are unclear at this time.

The proposed model using the centric registration would include alignment, tooth size discrepancies, morphologic variation, transitional stages of the dentition with such variations as the inherent mesial shift, and the occluding relationships in all three planes of space. Although it might have limitations in relating the teeth to their bases, this would be included with data from radiographs of the craniofacial complex. The two-dimensional model presented here is hopefully a small step toward the ultimate model.

Summary and conclusions

The relationship of defined occluding anatomic landmarks (which had been converted from photographic data to X and Y coordinates) on the occluding

ClearCorrect Exhibit 1002, Page 1098 of 3373

surfaces of the maxillary and mandibular postcanine teeth have been analyzed by a two-dimensional mathematical mode.

The total population consisted of duplicate dental casts from one twin of each set of 199 pairs of monozygotic and dizygotic twins. The dental casts were derived from the records of a semilongitudinal twin study at the Forsyth Dental Center. From the 199 twin pairs, forty-seven sets of casts exhibited a "socked-in" good occlusion. Thirteen sets of casts had a full-cusp "socked-in" Class II, Division 1 malocclusion. These selected cases represented subsamples of good occlusions and malocclusions, respectively. Only one twin of a pair was used in each group.

There were observed differences between the total population data, the good occlusion data, and the malocclusion data in terms of the magnitude and direction of deviation from the "ideal" occluding position for all of the occluding relationships. Even in the "ideal" group (good occlusion group), 2 mm. deviations from the "ideal" cusp position were commonly observed. Although statistical significance at the 5 per cent level was observed in several quadrants, there did not appear to be a general or over-all pattern of difference between Class I and Class II groups. The variation in individual cusp position within these groups was surprising. The occluding contacts were found to be normally distributed in both magnitude and direction, and there appears to be a suggestion of sidedness to the occlusion.

The model used in this study is limited in its immediate usefullness; that is, there are no clinical applications in its present form. Its value lies in the possibility of being incorporated into the framework of a more complex three-dimensional model in the future.

REFERENCES

1. Biggerstaff, R. H.: Computerized diagnostic setups and simulations, Angle Orthod. 40: 28-36, 1970.
2. Angle, E. H.: Classification of malocclusion, Dent. Cosmos 41: 240-268, 1899.
3. Case, C. S.: Techniques and principles of dental orthopedia (reprint of 1921), New York, 1963, Leo Bruder, pp. 16-18.
4. Lundström, A. F.: Malocclusion of the teeth regarded as a problem in connection with the apical base, Sven. Tandlak. Tidskr. 16: 147-296, 1923.
5. Simon, P. W.: Fundamental principles of a systematic diagnosis of dental anomalies (translated by B. E. Lischer), Boston, 1926, Stratford Co., p. 320.
6. Hellman, M.: Diagnosis in orthodontia and the method I use in practice, Angle Orthod. 13: 3-14, 1944.
7. Horowitz, S., and Hixon, E. H.: The nature of orthodontic diagnosis, St. Louis, 1966, The C. V. Mosby Company.
8. Ackerman, J. L., and Proffit, W. R.: The characteristics of malocclusion: A modern approach to classification and diagnosis, AM. J. ORTHOD. 56: 443-454, 1969.
9. Hellman, M.: Variations in occlusion, Dent. Cosmos 63: 608-619, 1921.
10. Hellman, M.: Factors influencing occlusion, Angle Orthod. 12: 3-27, 1942.
11. Friel, S.: Occlusion: Observation on its development from infancy to old age, INT. J. ORTHOD. 13: 322-340, 1927.
12. Friel, S.: The development of ideal occlusion of the gum pads and teeth, AM. J. ORTHOD. 40: 196-214, 1954.
13. Biggerstaff, R. H.: A quantitative and qualitative study of the postcanine dentition of twins, unpublished Doctoral Dissertation, University of Pennsylvania.
14. Biggerstaff, R. H.: The basal area of posterior tooth crown components: The assessment

ClearCorrect Exhibit 1002, Page 1099 of 3373

of within tooth variations of premolars and molars, Am. J. Phys. Anthropol. 31: 163-170, 1969.
15. Biggerstaff, R. H.: Electronic methods for the analysis of the human post-canine dentition, Am. J. Phys. Anthropol. 31: 235-242, 1969.
16. Biggerstaff, R. H.: On the groove configuration of mandibular molar: The unreliability of the "dryopithecine pattern" and a new method for classifying mandibular molars, Am. J. Phys. Anthropol. 29: 441-444, 1968.
17. Biggerstaff, R. H.: Morphological variations for the permanent mandibular first molars in human monozygotic and dizygotic twins, Arch. Oral Biol. 15: 721-730, 1970.
18. Proffit, W. R., Chastain, B., and Norton, L. A.: Linguopalatal pressure in children, AM. J. ORTHOD. 55: 154-166, 1965.
19. Draker, H. L.: Handicapping labiolingual deviations; a proposed study for public health purposes, AM. J. ORTHOD. 46: 295-305, 1960.
20. Summers, C. J.: A system of identifying and scoring occlusal disorders: The occlusal index, Ph.D. thesis, University of Michigan, 1966.
21. Salzmann, J. A.: Handicapping malocclusion assessment to establish treatment priority, AM. J. ORTHOD. 54: 749-765, 1968.
22. Grainger, R. M.: Orthodontic treatment priority index, United States Public Health Service Publication No. 1000, Series 2, No. 25.
23. Glauser, R. O.: Orthodontic examination and report, Public Health Service 2506-3, Section IV, Indian Health Manual TN No. 57, 1966.
24. Stallard, H.: Functions of the occlusal surfaces of the teeth, J. Am. Dent. Assoc. 13: 1392-1412, 1926.
25. Dalberg, B.: The masticatory effect, Lund, 1942.
26. Yurkstas, A., and Manly, R. S.: Measurement of occlusal contact area effective in mastication, AM. J. ORTHOD. 35: 185-195, 1949.
27. Savara, B. S.: Application of photogrammetry for quantitative study of tooth and face morphology, Am. J. Phys. Anthropol. 23: 427-434, 1965.
28. Takasaki, H.: Moire topography, Appl. Optics 9: 1457-1472, 1970.
29. Moyers, R.: Development of occlusion, Dent. Clin. N. Am. 13: 523-536, 1969.

ClearCorrect Exhibit 1002, Page 1100 of 3373

The Angle Orthodontist

January 1970

Volume 40, Number 1

Contents

1 • Treatment of Severe Malocclusions by Correlated Orthodontic-Surgical Procedures
William R. Proffit, D.D.S., Ph.D.
Raymond P. White, D.D.S., Ph.D.

11 • The His Line and Ophistion-Nasion Line in Relation to the General Pattern of Craniofacial Associations
R. Sivertsen, D.D.S.
A. Hasund, D.D.S., Dr.Odont.

20 • A Laminagraphic Study of Cuspid Retraction versus Molar Anchorage Loss
Richard C. Paulson, D.D.S.
T. Michael Speidel, D.D.S.
Robert J. Isaacson, D.D.S.

28 • Computerized Diagnostic Setups and Simulations
Robert H. Biggerstaff, D.D.S., Ph.D.

37 • Masseter Muscle Position Relative to Dentofacial Form
Alonzo D. Proctor, D.D.S., M.S.
John P. DeVincenzo, D.D.S., M.S.

45 • The Measurement of Variations in Intraoral Air Pressure
A. J. Walpole Day, F.D.S., B.D.S., D.Orth.
T. D. Foster, F.D.S., M.D.S., D.Orth.

51 • The Gradient and the Pattern of Crown-Size Reduction in Simple Hypodontia
Stanley M. Garn, A.M., Ph.D.
Arthur B. Lewis, D.D.S., M.S.

59 • Occlusal Relations in Children Born and Reared in an Optimally Fluoridated Community: I. Clinical Methods
Herschel S. Horowitz, D.D.S., M.P.H.
Bruce R. Thorburn, D.D.S.
Chester J. Summers, D.D.S., Dr.P.H.

69 • In Memoriam

s, Inc.

Computerized Diagnostic Setups and Simulations

ROBERT H. BIGGERSTAFF, D.D.S., Ph.D.

The successful integration of two-dimensional diagnostic records into a three-dimensional predictive model has been one of the outstanding goals of the dental profession. Brodie,[4,5] Wylie and Elsasser,[12] Vogel,[13] Richardson and Brodie,[9] and Lude[7] have made significant contributions to research in this area. While skeletal variations must be determined from oriented lateral and anteroposterior radiographs or pantographs, dental variations must be assayed from carefully prepared study models.

The purpose of this paper is to present a preliminary report of ongoing research related to the development of a three-dimensional predictive model that will incorporate two-dimensional diagnostic data into a synthesizing and simulating computer program. The present paper will describe the first phase of this research, a two-dimensional mathematical model for representing the major anatomical landmarks on the occlusal surfaces of the postcanine dentition, and some rather primitive computer simulations of orthodontic procedures. OSCOPO is a computer program for the oscilloscopic simulations for correcting, orthodontically, problems in occlusion.

This is a computerized approach to a consideration of the analysis and predictive corrections in orthodontic treatment procedures. It is based on a two-dimensional representation of the upper and lower dentition as photographed from an occlusal (or crown-surface) view. Involved is a computer directed realignment, in the transverse and anteroposterior planes, of the individual units of the dentition in terms of the *esthetic harmony* of the dental arch.

In substance, OSCOPO is the computer method for measuring, analyzing and evaluating the dimensional vectors involved in orthodontic correction. It is a visual method for realigning the dental elements involved in the translation from a malocclusion to a "normal" occlusion in the individual case.

MATERIALS AND METHODS

Certain pits, fissures, and cusp tips are common to the occlusal morphology of any premolar or molar.[3] Moreover, the basic hypotheses of this model assume that these occlusal landmarks of the maxilla and the mandible are highly correlated[6] and that certain selected anatomical landmarks can outline the occlusal, incisal and/or lingual surfaces of the individual components of the dentition. Moreover, these hypotheses suggest that the selected anatomical landmarks can be used to describe the type of occlusion or malocclusion. For example, the relationship of the tip of the protocone (mesiolingual cusp) of the permanent maxillary first molar to the central fossa of the permanent first mandibular molar is an accepted criterion of good occlusion.

The conversion of definable anatomical landmarks on the anterior and posterior teeth of dental casts is accomplished by recording their location as small India ink points.[2] (A Staedler Mars 700 pen with a 0.1 millimeter point is used for this purpose.) The maxillary cast is then mounted on a dental surveyor table

Supported in part by P.H.S. Grants DE-02506-01, FR-15 and DE-0087-14 and the Elementary Particles Group of the Physics department at the University of Pennsylvania.

ClearCorrect Exhibit 1002, Page 1102 of 3373

adjusted in such a way that the ...ital plane is level. A piece of one-...th inch plexiglass, on which is in...ed fiducial marks and an orienta...ion line, is placed on the incisal and ...lusal surfaces in such a way that the ...ntation line forms a line of best fit ...the median raphe of the maxilla. ...distance between the two fiducial ...ks (a known dimension) is used to ...rect for small deviations in the size ...the photographic image. The anterior ...ment of the orientation line is ad...sted to a mark on the lingual surface ...a maxillary incisor which demarcates ...most anterior limits of the mandibu...r central incisors.

The mark delimiting the most anterior limits of the mandibular dentition is determined by fitting the dentitions of the maxillary and mandibular casts together in such a way that the usual occluding relationship for the individual is manifest. The labial surface of the most anterior mandibular central incisor is then extended to and recorded on (using a thin, sharp, straight instrument) the lingual surface of the opposing maxillary central incisor or, in some instances, on the palatal mucosa. The anterior and posterior relationship of the orientation line which forms the best-fit line to the median raphe is recorded on the posterior edge of the maxillary cast and on the labial or incisal surface of the appropriate maxillary central incisor (oftentimes on the incisal aspect of the contact area of the two maxillary central incisors).

The image of the fiducial marks, the orientation line, and the anatomical landmarks (India ink marks) are then recorded on a photographic plate using a 4 × 5 Crown Graphic camera. The camera, with duplicates of the orientation line and fiducial marks recorded on the ground glass view screen, is adjusted in such a way that an approximate 1:1 relationship of the image photographed and the photographic image is achieved, but the final dimensions are adjusted to the known fiducial parameter. The dentition of the mandibular cast is again fitted to the dentition of the maxillary cast so that the subject's usual occluding relationship exists while the occlusal plane of the maxillary dentition is still level and mounted on the surveying table of the dental surveyor. Perpendiculars projecting from the anterior and posterior marks representing the extensions of the midsagittal plane are erected (using the vertical arm of the surveyor) and are recorded at a convenient place on the labial surface of a mandibular incisor and on the posterior surface of the mandibular cast. In this way the line representing the best-fit line of the median raphe of the maxillary cast is transferred to the mandibular cast. Thus, the anteroposterior and lateral relationships of the maxillary and mandibular anatomical landmarks are preserved. The mandibular cast is then adjusted and photographed in the same manner described for the maxillary cast.

The anatomical landmarks of the maxillary and mandibular dentitions are recorded as X and Y (Cartesian) coordinates. These coordinates are recorded on Hollerith cards using the Image Plane Digitizer, an auxiliary data processor control console, and an IBM 526 summary card punch. The Cartesian coordinates from the data cards are then recorded on a magnetic tape. The instructions provided by OSCOPO convert the two independent coordinate systems of the maxillary and mandibular dentition into a common coordinate system, and cause the representation of these anatomical landmarks and/or outlines of the occlusal and lingual surfaces to appear on the screen of an oscilloscope in the usual occluding relationship of the patient (Fig. 1a).

The image of a posterior tooth consists of: (1) points that describe anatomical landmarks, and (2) a series of

ClearCorrect Exhibit 1002, Page 1103 of 3373

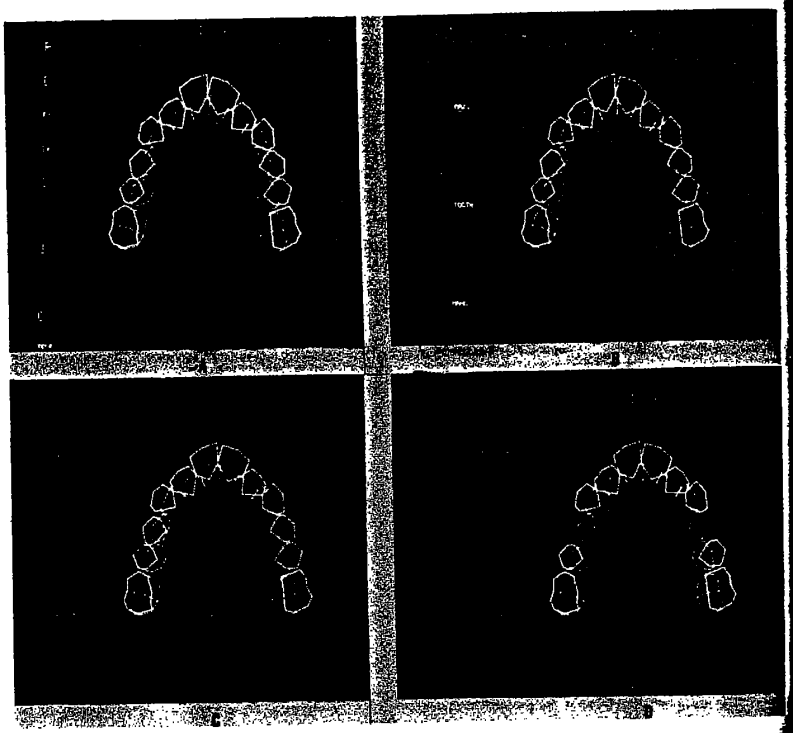


Fig. 1 (a) The "top view" or occluding view of the outlines of the maxillary and mandibular dentitions. The outlines of greater intensity are related to the maxillary dentition. The lingual and incisal surfaces of the anterior teeth are outlined by vectors connecting six points; the occlusal surfaces of the posterior teeth are outlined by a variable number of points representing the anatomical landmarks on the periphery of the occlusal surfaces. At the top is the identifying number of the cast. On the left side are code letters controlled by the penlight: R—controls rotational simulations; E—erasure or "extraction" simulations; M—translational simulations; A—causes erased images to reappear in their original position; S—causes the entire system of newly generated coordinates related to the teeth to be recorded on magnetic tape; I—reinitialized the display to conform to the original input data; and C—causes the magnitude and direction of the last simulated movement in degrees rotated or millimeters moved to be typed on the teletype. The code word "Tele" transfers control from the penlight to the teletype.

(b) When activated by the penlight, the code word "tooth" allows the operator to identify the appropriate tooth or tooth group in the proper arch. This procedure of identification is necessary before simulations of erasure or movement can be accomplished. The units of the entire maxilla or mandible may be identified by activating the code words "max." or "mand." respectively.

(c) The code word "SET" when activated by the penlight permits the computer to act in the preselected mode of simulation, i.e., rotation translation or erasure, of the tooth or tooth group previously identified. "RSET" permits corrections in identification or, if the computer is in the mode for translation, it allows an immediate transfer to the rotational mode.

(d) The extraction, "erasure", of two maxillary first premolars.

ClearCorrect Exhibit 1002, Page 1104 of 3373

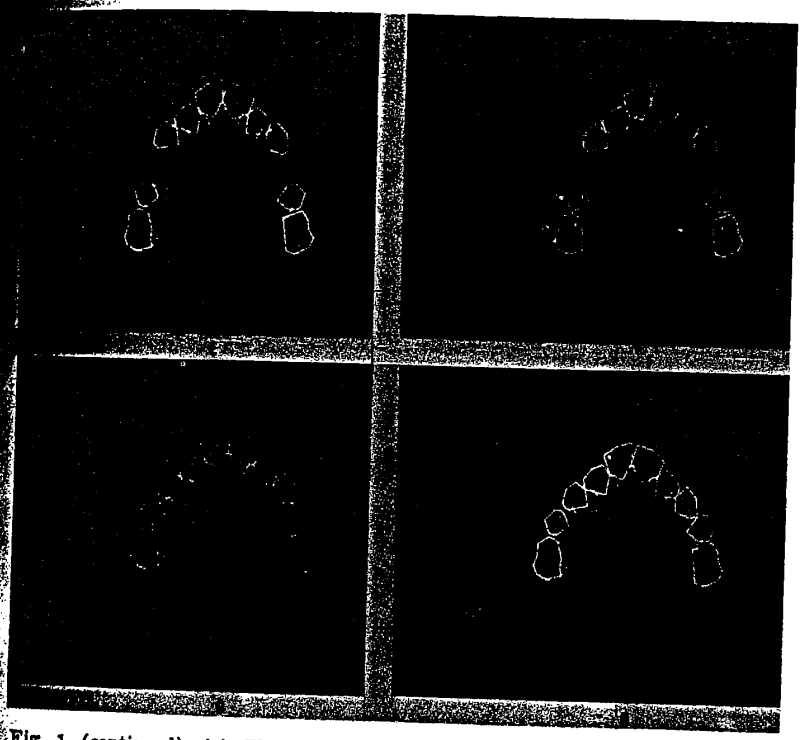


Fig. 1 (continued) (e) The extraction, "erasure", of two mandibular first premolars.

(f) The identification of all maxillary and mandibular molars and premolars prior to translating them into the space created by the extracted premolars. Note that all teeth are identified by numbers according to the Universal system of dental nomenclature. The entire maxilla is translated so that the identifying numbers are more easily visualized.

(g) When the code word "SET" is activated, the "tracking cross" appears. The "tracking cross" follows the movement of the penlight causing the identified group of teeth to translate according to the path of the cross. X and Y coordinates are typed on the teletype to effect translations with this particular device. Note that the posterior teeth have moved *en masse* to a new position.

(h) The identification of tooth number 9, the left maxillary central incisor prior to rotating.

ClearCorrect Exhibit 1002, Page 1105 of 3373

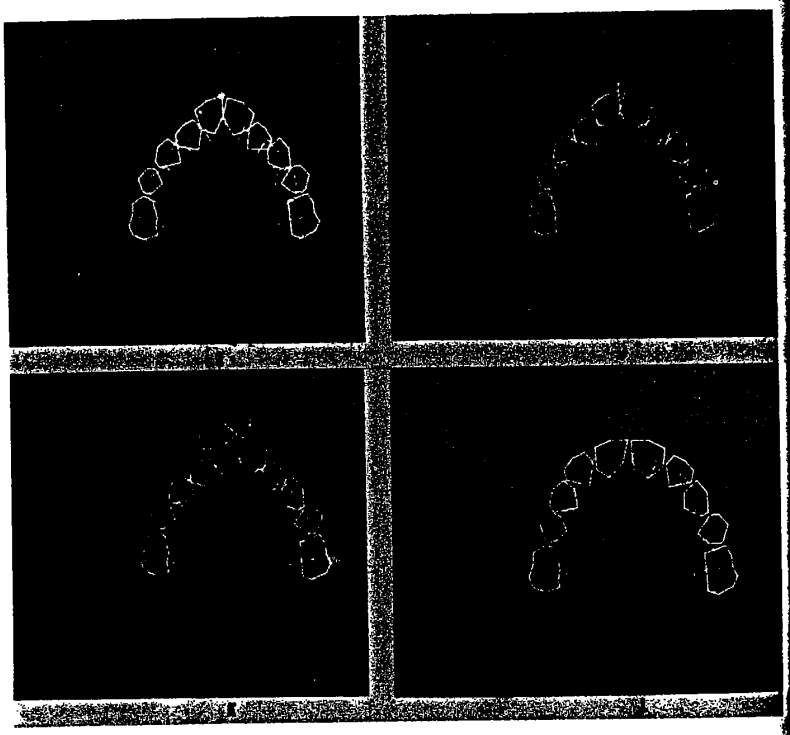


Fig. 1 (continued) (i) The fixation of the axis of rotation on the left maxillary central incisor. The asterisk appears after the activation of the code word "SET". The asterisk is positioned with the penlight at the desired point of rotation.

(j) The activation of the code word "SET" causes the "tracking cross" to appear which will follow the path of the penlight causing the target teeth to rotate in the direction and magnitude of the "tracking cross."

(k) An exaggerated rotational movement of the maxillary left central incisor about the point of rotation.

(l) The "top view" of the maxillary and mandibular dentition after simulated extractions, rotations and translations. These simulations have involved a majority of the teeth and are presumed to mimic certain orthodontic procedures. See text for limitations and compare with Figure 1a.

ClearCorrect Exhibit 1002, Page 1106 of 3373

connected vectors which outline the occlusal surface of the tooth as projected to the occlusal plane. The image of an anterior tooth consists of a series of vectors connecting points that outline the incisal surface, points that describe the maximum mesiodistal diameter, and a point that describes the most gingival extent of the lingual surface (Fig. 1a).

Standard rotational and translational formulae were incorporated into OSCOPO to cause these simulations.

Results

OSCOPO, then, gives a "top view" of the tooth images of the mandibular and maxillary dental casts as projected to the occlusal plane while recording the patient's usual occluding relationship. Other portions of the program permit translational, rotational, or erasure simulations of the image of a tooth or group of teeth changing the occlusal pattern as originally seen on the dental cast or oscilloscope. These changes can be effected by providing particular information through three operational modes: (1) the *control mode*, (2) the *identification mode*, and (3) the *incremental mode*.

The teletype and the penlight are used to transmit the necessary information controlling the operational modes. The penlight is the more versatile input device. Coded information in the form of letters and words is provided on the left side of the oscilloscope (Fig. 1a). The activation of the penlight over one of these code images causes the computer to recognize that particular set of coded instructions. In order to manipulate an image on the oscilloscope the computer must initially be in the control mode.

The control mode is used to accomplish the following: (1) to reinitialize the display ("I", Figure 1a), restoring the original display to the screen without registering any previous manipulations; (2) to save ("S", Figure 1a) the display data on a magnetic tape so that it can be utilized at another time for the purpose of redisplaying, observation, making photographs or to determine the amount of change in the location of any anatomical landmarks; (3) to obtain a type-out ("C", Figure 1a) recording the magnitude and/or direction of the last manipulation; (4) to command the computer to erase an image ("E", Figure 1a); (5) to cause erased images to reappear ("A", Figure 1a); and (6) to inform the computer that one desired to translate ("M", Figure 1a) or rotate ("R", Figure 1a) an image. "Tele," when activated, transfers control to the teletype.

To manipulate a tooth image or a group of tooth images the computer must be transferred from the *control mode* to the *identification mode*. Then it is necessary to identify the tooth or the teeth needed for the manipulation procedure. (See Figures 1b, f, and h). This is accomplished by pointing the penlight directly over a point on a tooth or by typing in the tooth number on the teletype. The tooth number immediately appears on the screen of the oscilloscope indicating that the tooth has been identified by the computer. (See Figures 1f and h). If a tooth is mistakenly identified, one may correct the situation by activating the code word "RSET" (Figures 1c, d, e, h, i, j, and k). All of the tooth images of the maxilla or mandible may be identified by activating the code words "max" or "mand" which also appear on the screen, Figure 1b. Once the identifications are completed, control may also be transferred to the increment mode by activating the code word "SET" (Figures 1c, d, e, h, i, j and k).

The *increment mode* controls the magnitude and direction for the movement of the identified tooth or tooth group. Using the penlight one may

ClearCorrect Exhibit 1002, Page 1107 of 3373

translate a tooth or group of teeth by "pushing" a "tracking cross," that appears on the screen after the activation of the code word "SET" with the penlight, Figures 1g and i. The image will therefore undergo the same magnitude and direction of movement as the tracking cross. The teletype may also be used for this manipulation simply by typing in the X-Y analytical coordinates of the translation. One may manipulate by rotation by initially identifying the object tooth or tooth group, after which the axis of rotation is fixed, Figure 1j. This is accomplished by placing the "asterisk" that appears on the screen after giving the rotational and identification commands. The penlight is useful for placing this asterisk at the desired point of rotation, then by activating the code word "SET" the "tracking cross" appears which will follow the course of the penlight causing the identified tooth or tooth group to undergo the same angular displacement about the rotation axis as does the "tracking cross," Figures 1i and 1j. OSCOPO provides the operator with the capability of alternating the use of these two types of movements, i.e., translation or rotation. For example, if one had completed a rotational manipulation and desired to translate, one need only to activate the code word "RSET" to change from a rotational type of manipulation to one of translation or vice versa. To return to the control mode one needs only to activate the control word "SET".

Discussion

OSCOPO represents a synthesis from prior research efforts[1,10,11] in an attempt to adequately evaluate the size and shape[8] of the individual dental units.[2,3] It is to be a component of a future and larger program that will incorporate skeletal and myofunctional variations as related to occlusion or malocclusion. The present model crudely and primitively moves, by translation and rotation, individual tooth units into relationships that tend to be esthetically ideal. OSCOPO expresses no consideration to the question of stability or the individual's biological limits of movement. This consideration must come with continued experimentation.

While OSCOPO, in its present form, actually simulates rotational movements, the translatory movements seen on the oscilloscope are not the same as those observed in the biological state. A tooth is a three-dimensional object, and when it is moved one must discriminate between a movement that is achieved as a total "bodily movement" and one that is the consequence of a "tipping movement." OSCOPO does not have the potential for discriminating between these two types of movements, nor can it distinguish between apicoincisal (occlusal) or tilting movements. It does, however, represent graphically the end result of movement procedures in the two defined planes of space.

One might argue that many of the same effects achieved by OSCOPO may also be reproduced through standard techniques where the teeth are removed from the cast and waxed into a new position (perhaps prior to making a new cast). The latter technique suffers from a loss of tooth structure and because accurate measurements can not be made within or between the dental arches. OSCOPO maintains the original data and the "Save" command allows the instantaneous storage of newly generated information for later use. In this respect, this model becomes a powerful tool for teaching in that different tooth positions pertaining to the same case can be observed or compared at any time by using photographs or by on-line transmissions.

A modified version of OSCOPO can

ClearCorrect Exhibit 1002, Page 1108 of 3373

use the great potential of the computer in determining, statistically, the range of variation for a particular "type" of occlusion. For example, consider the tremendous range of variation that exists in one "type" of malocclusion (Angle Class II, Division 1). The analysis of the spatial deviations observed between specific anatomical landmarks located on the occlusal surfaces of mandibular and maxillary dentitions would redefine, possibly using more acceptable criteria, normal occlusion and/or malocclusion.

OSCOPO exemplifies a way of managing a large body of diagnostic data in a variety of ways. More importantly, the relationship of each tooth to any of the other teeth in the dentition can be quantitatively assayed in terms of linear or areal dimensions. Thus, the quantitative comparison of tooth material becomes a reality as does the appraisal of the tooth-arch dimension relationships. These relationships, evaluated in this manner, will probably be of greater biological significance than many of the constructed assays.

The writer envisions that OSCOPO will become a part of a larger and more sophisticated computer program that will incorporate a variety of diagnostic data obtained from oriented radiographs, dental casts, pressure readings, and muscle function. The incorporation of such data into a mathematical model will permit, ultimately, the prediction of the expected growth processes from the initial observation (T_1) to a future point in time (T_2). Such a predictive model will be of utmost importance to the clinician because these programs will permit an almost instantaneous analysis of the pertinent morphological features, say at maturity, with and/or without orthodontic intervention. The incorporated statistical model will permit the analysis of the morphological features at any age level with a stated level of probability. More importantly, this tool will advance interceptive orthodontics and permit the initiation of treatment procedures (where indicated) at the earliest effective age. Further, this model may elucidate the treatment procedure that will yield the maximum result, in terms of esthetics, function, and stability, in the minimum time.

While the long range goals *vide supra* may seem farfetched, there are immediate clinical applications for this tool. For example, this model is sufficiently accurate and sensitive to resolve the controversy related to the use of light wire, as opposed to heavy wire, and the relative efficiency of each in effecting tooth movement. Heavy wire imparts a firm pressure upon the tooth or teeth over a short period of time. In contrast, light wire imparts delicate forces on to the tooth or teeth over a relatively long time period. This problem may be resolved quickly and in the very near future.

College of Dentistry,
Univ. of Kentucky,
Lexington, Kentucky 40506

ACKNOWLEDGMENTS

The writer gratefully acknowledges the programming assistance of Moray B. King and the generosity of the University of Pennsylvania Medical School Computer Facility for making their equipment available to our research.

REFERENCES

1. Aoyagi, F.: Morphogenetical studies on similarities in the teeth and dental occlusion of twins. I. Tooth size as shown in photographs of the occlusal plane. *Shikwa Gakuho.* 67:1-49, 1967.
2. Biggerstaff, R. H.: The basal area of posterior teeth crown components: The assessment of within tooth variations of premolars and molars. *Am. J. Phys. Anthro.*, 31:163-170, 1969.
3. ————: Electronic methods for the analysis of the human postcanine dentition. *Am. J. Phys. Anthro.*, 31: 235-243, 1969.

ClearCorrect Exhibit 1002, Page 1109 of 3373

4. Brodie, A. G.: The apical base: Zone of interaction between the intestinal and skeletal systems. *Angle Ortho.*, 36:136-151, 1966.
5. ————: Muscles, growth and apical base. *The Dental Practitioner.* 15:343-356, 1965.
6. Hellman, M.: Variations in occlusion. *Dental Cosmos.* 63:608-619, 1921.
7. Lude, J. C.: Technique for the determination of the size of the mandibular apical base; its application to growth studies. *Angle Ortho.*, 37: 272-284, 1967.
8. Moss, M. L., and Chase, P.S.: Morphology of Liberian Negro deciduous dentition. I. Odometry. *Amer. J. Phys. Anthro.*, 24:215-230, 1965.
9. Richardson, E. R. and Brodie, A. G.: Longitudinal study of growth of maxillary width. *Angle Ortho.*, 34:1-25, 1964.
10. Singh, I. J. and Savara, B. S.: A method of making tooth and dental arch measurements. *J.A.D.A.*, 69: 719-721, 1964.
11. Stanton, F. L., Fish, G. D., and Ashley-Montagu, M. F.: Description of three instruments for use in orthodontic and cephalometric investigations. *J. Dent. Res.*, 11:885-902, 1931.
12. Wylie, W. L. and Elsasser, W. A.: Undistorted vertical projections of the head and posteroanterior roentgenograms. *Amer. J. Roentgen. and Radium Therapy*, 60:414-417, 1948.
13. Vogel, C. J.: Correction of frontal dimensions from head x-rays. *Angle Ortho.*, 37:1-8, 1967.

ClearCorrect Exhibit 1002, Page 1110 of 3373

Biostar Operation & Training Manual. Great Lakes Orthodontics. Ltd. 199 Fire Tower Drive. Tonawanda. New York. 14150–5890. 20 pages total.

BIOSTAR

OPERATION & TRAINING MANUAL

Great Lakes Orthodontics, LTD.
199 Fire Tower Drive • Tonawanda, New York 14150-5890

Index

OPERATION

INTRODUCTION 2

INSTALLATION 3

MAINTENANCE 3

TECHNICAL DATA 4

OPERATION 5

TRAINING

FAMILIARIZE YOURSELF WITH PROCEDURES 6

RETAINER FABRICATION ..... 7 & 8

ADDING PATIENT'S NAME TO RETAINER 8

RETAINERS WITH BITEPLATES 9

RETAINERS WITH SPRINGS 9

RETAINERS WITH EXPANSION SCREWS 10

RETAINERS WITH TEETH 10

MODEL DUPLICATION 11

CUSTOM MOUTHGUARDS 11

SPLINTS 12

CUSTOM TRAYS 12

POSITIONERS ..... 13 & 14

SUPPLEMENT ..... 15 - 19

MATERIAL GUIDE ..... 20 & 21

TRAINING PROGRAMS ..... Back cover

ClearCorrect Exhibit 1002, Page 1112 of 3373

Introduction

You are now the owner of a Biostar–a multi-purpose molding machine universally recognized by Doctors and Technicians around the world as the complete laboratory in one machine. In your own office you can now fabricate retainers, model duplications, mouthguards, positioners, temporaries, splints, copings and custom trays.

Two factors are responsible for the Biostar's optimum forming and molding characteristics:

1. Compressed air is applied directly to the model, allowing pressure to push the heated material onto the work model.

2. The blanks and foils are heated on the surface that contacts the model.

Utilizing the principle of air pressure, the Biostar makes a wide range of hard and soft dental appliances in half the time of conventional methods with complete professional results. This manual contains all the information you need for initial set-up and maintenance.

For best results in fabrication, it is recommended that all step by step procedures are followed closely.

ClearCorrect Exhibit 1002, Page 1113 of 3373

Installation

CONTENTS:
The Biostar is shipped to you well packaged to prevent damage.

Included in the Biostar packing you will find:

- The Biostar
- One drawer for lead pellets
- One model cup
- One clamping frame
- One model platform

Auxiliary supplies contained in Set-Up Kit:

- High pressure hose with quick connect
- One hose clamp
- One container of lead pellets
- One pellet brush

1. Place clamping frame on the frame holder over the 4 pins.
2. Connect the Biostar to your air source using the high pressure hose included in the set-up kit. The end with the quick connect plugs into the back of the Biostar. The other end slips over your air jet and is secured with the enclosed hose clamp.
3. Plug in Biostar to standard 110v. outlet.

IMPORTANT- Make sure that all the packing debris is removed from the machine (under and inside the cup, inside the pellet drawer etc.).

Maintenance

MOVING PARTS

The Biostar has 3 moving parts:

1. heating element
2. pressure chamber
3. locking handle

ONLY the heating element (base) and the pressure chamber (hinge) should be lubricated; 1 or 2 drops of light oil every 6 months is sufficient.

DO NOT put oil on the locking handle!

LEAD PELLETS

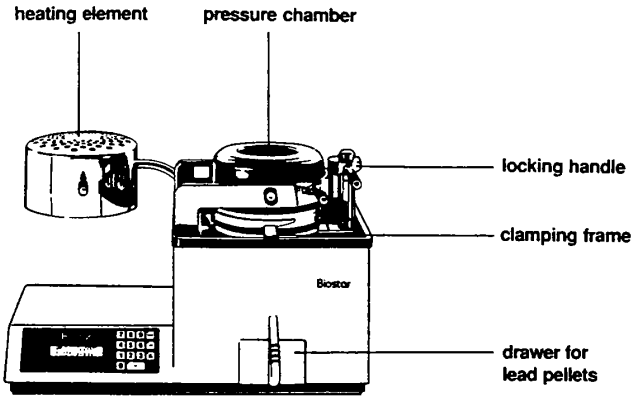
Lead pellets will become dirty with use and may be cleaned by placing them in a strainer and pouring hot water over them. Spread the pellets out on a towel until they are thoroughly dry before replacing in the Biostar.
Pellets should be replaced with new ones periodically, depending on how much they are used.

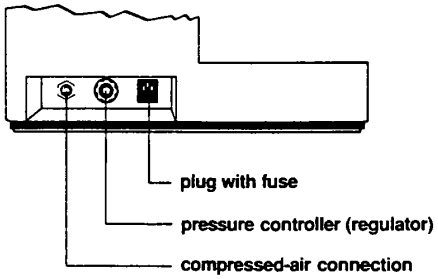
RINGS AND GASKETS

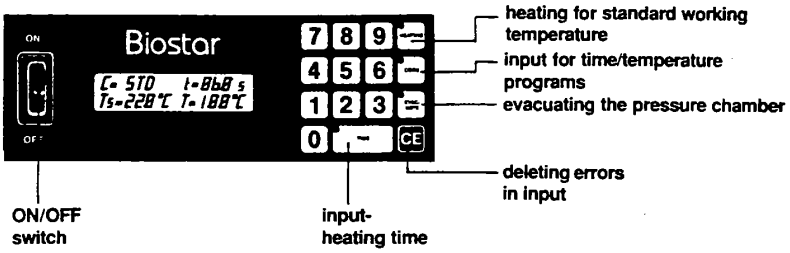
All "O" rings and rubber gaskets should be wiped with a couple of drops of liquid soap on a paper towel every 6 months. This will clean as well as lubricate them.
NOTE: Do not remove them from the machine to clean!

Water should never be used to clean any part of the Biostar, as moisture will rust the machine.

ClearCorrect Exhibit 1002, Page 1114 of 3373









(C) = code
(t) = heating time
(Ts) = desired temperature
(T) = actual temperature
(p) = pressure
(only appears every 10 seconds)

Technical data

AC	110 V/220 V
Power	500 W
Working pressure	0-100 psi/1-5 bar
l x w x h	450- x 240 x 200 mm
Weight	15 kg

ClearCorrect Exhibit 1002, Page 1115 of 3373

Operation

Operation
To turn the machine on, turn the on/off switch to the on position. The display panel indicates pressure (P) after approximately three seconds. This readout alternates with other information every ten seconds. A working pressure of 60 PSI is pre-set in the machine. If the display panel does not indicate the correct pressure, it can be regulated by the pressure regulator located on the back of the machine. To regulate the pressure, loosen the adjustment knob by pulling the outer ring of the lock and turning the knob. When switching on the machine, the infra-red heating element automatically heats to the working temperature of 427°F/ 220°C. (Display panel read out will be as follows) Ts=220°C/ 420°F. Approximately two minutes is needed for the heating element to reach this temperature. When the working temperature is reached, the display panel will read (T) of 220°C/420°F and a signal of two short beeps will sound.

Positioning Discs
Place the disc directly on the open pressure chamber between the four pins. Place the clamping frame over the material, so that the bayonet clamps slip under the bevel of the locking device of the chamber. Tighten by turning clockwise. (Do not over tighten). Only slight pressure is necessary to secure properly.

Infra-Red Heater
If the Biostar machine is not used for 15 minutes, the heating element automatically cools to an energy saving stand-by temperature of 100C°/212°F. By pressing the button marked "Heating", the heating element will increase to the working temperature of 220°C/427°F. If the pressure chamber is closed and the heater is not in its rest position, several short beeps will be heard and the display panel will show "heater in rest position". If the heater is not moved to its rest position, it will automatically shut off at this time. The display panel will read "heater switched off, C=000, Ts=000".

Heating Time
Heating time is indicated on each box of material. Press the button marked "time", and enter the desired time by pushing the buttons one through zero. For example, if the desired time is 60 seconds, push time once, then push 60. By pressing the "time" button one more time, you confirm the heating time that was entered. As the heating element is moved from its rest position to a position over the disc, the timer will automatically start and in this example, you would see the timer count down from 60 seconds to 0. When the timer reaches 0, a signal of three short beeps will sound. At this time, swing the heater back to its rest position and flip the pressure chamber over so that the material can be pressurized on the model.

Note: If the heater is moved away from the heating position while the timer is running, the timer will stop. As soon as the heater is moved back to the heating position, the timer will resume where it stopped. If you intend to use the timer for other purposes, ie. length of time for cold cure to set-up, you must press the button marked "time" twice before the timer will begin to count down. If you want to stop the timer, press the button marked "time" once.

Pressurizing
Move the heater back to the rest position and gently close the pressure chamber. It is necessary to take care that the edge of the cup is kept free of lead pellets. Turn the locking handle 180° away from the rest position to the front of the machine. An electrovalve will automatically open and the chamber will instantly fill with compressed air.

Depressurizing (Removing Model and Appliance from the Machine)
By using the button marked "evacuate" the air is released from the chamber. It takes approximately seven seconds for the chamber to empty completely. After that time, a signal of two short beeps will be heard, and the display panel will indicate "open chamber". It is necessary to wait for this signal to appear on the display panel before opening the pressure chamber.

Codes
On new packaging labels for Biostar pressure molding materials, you will find in the column "code" a three-digit figure. This code indicates the length of time recommended for heating, as well as the cooling time in the pressure chamber. The three-digit figure is entered after having pressed the button "code". Confirm this entry by pressing the button "code" again. Wait until the programmed heating temperature (Ts) is reached. Now the heater can be moved from the rest position to the heating position. The programmed heating time runs down automatically. The third figure of the code indicates the recommended duration of cooling time in the closed pressure chamber. Closing the chamber starts this cooling time. (See Display). At the end of this time the chamber can be depressurized. We recommend using these codes to minimize working steps and to guarantee optimum results.

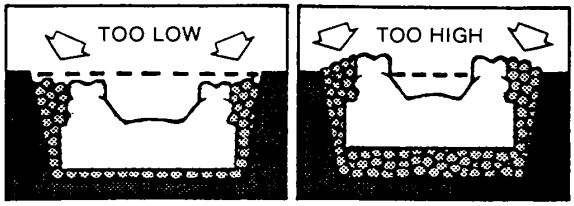
ClearCorrect Exhibit 1002, Page 1116 of 3373

Packing the Model.

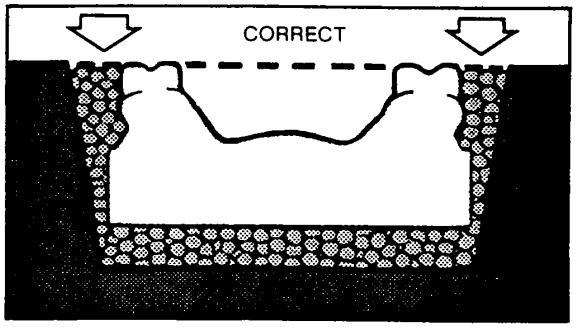
The purpose of packing the work model in cylindrical lead pellets is fourfold:

1. To support the model so that the occlusal-incisal plane is as level as possible with the platform.
2. To prevent the material from forming on the facial surfaces of the teeth, thus making it hard to remove the appliance from the work model.
3. To prevent the heated material from melting the wax supporting the wire.
4. To allow air to pass through the lead pellets as the material is forming over the model, preventing any back-pressure.

Packing the Model (cross section)



Dia. 1 (a) *Dia. 1 (b)*



***Packing the Model** (cross section)* *Dia. 1*

Procedural Steps

1. Lead pellets are placed in the bottom of the cup to compensate for the various thicknesses of models. Enough pellets should be used to allow the occlusal-incisal plane to be level with the platform edge.

2. Remove the pellet drawer and pour pellets in between the model cup margin and occlusal-incisal plane of the work model. More than the required amount of pellets should be applied in these areas.

3. The 1" brush (included with your machine) should be used to remove excess pellets and to bridge the gap between the occlusal margin of the teeth and the edge of the platform. This is done by removing the pellets from the anterior portion and sweeping the pellets toward the heel of the model both on the right and left side. (NOTE: By holding the brush on an angle with the handle forward and bristles away, the brush gently sweeps the pellets rather than gouges.)

4. By having the pellets against the occlusal-incisal margin, the pellets will touch and likely cover the waxed portion supporting the wires on the facial surface. Because lead is such an excellent thermal conductor, coolness will be transmitted from the lower lead pellets to counter the heat of the material when forming. This prevents the wax from melting and maximizes support.

BLOW-OUTS
CAUSED BY INCORRECT PACKING

It is important that there be no sudden drop on the margin of the cup (Dia. 1a) or the model (Dia. 1b). When this happens the forming surface is enlarged, the material becomes overstretched and weakened, and a hole will be blown through the material.

If a blow-out does occur it is recommended that the air pressure be released immediately and the wires removed before the liquid acrylic has set.

Mixing the Liquid Acrylic.

It is important to mix the proper consistency acrylic for the following reasons:

1. **STRENGTH**: If the mix is too thin, the wire can be pulled from the appliance.

2. **HOLDING SLUMP**: The purpose of the acrylic is to bridge the gap between the wire and the model. If the mixture is too thin, it will tend to run to the floor of the model. If too thick, the material will not flow at all. Therefore, the consistency of thick maple syrup is ideal for a strong bond.

Procedural steps

1. Place approximately 1cc of monomer (fill eyedropper 1" from the top) in the resimix cup. Turn the polymer (powder) applicator upside down approximately 1" above the resimix cup. With a circular motion, sprinkle polymer into the liquid as evenly as possible until it builds up and rests momentarily on the surface.

2. Stir the acrylic with your #7 spatula until there is a uniform consistency.

   Repeat this procedure, until you can consistently achieve a maple syrup consistency.

Now you are ready to fabricate appliances.

ClearCorrect Exhibit 1002, Page 1117 of 3373

Retainer Fabrication

Model Preparation



1. Trim model to fit the cup.
2. Eliminate all plaster bubbles and correct all defects on the model.
3. Bend wire per doctor's prescription.
4. Remove all wires from work model and apply small amount of separator to the lingual, palatal and occlusal surfaces with a brush.
5. Secure wires on the facial surface of the model with pink wax using #7 wax spatula.
   (Separator need not be dry.)

NOTE: *Sticky wax is not recommended. Distortion of wires can result when removing appliance from model.*

Appliance Fabrication

1. With the separator applied and wires secured, you are ready to place the model in the Biostar.
2. Place enough lead pellets in the bottom of the cup to support the model allowing the occlusal-incisal edges to be as level as possible with the platform edge of the cup.
3. Pour additional lead pellets on the facial surface bridging the gap between the incisal-occlusal margin and the top edge of the cup. Remove excess with brush. *(Tap Biostar cup to be sure no loose pellets fall into palate).*
4. Place a piece of material in the holding pins on the pressure chamber and secure it with the clamping frame.
5. This step combines two procedures at the same time. While the material is being heated, mix a small amount of cold cure acrylic to apply on the wires on the model.
   a) This is accomplished by starting your timer & moving the element directly over the material in the pressure chamber *(see page 5).* The correct heating time is marked on all boxes of material and will vary according to thickness.
   b) Immediately place approximately 1cc of monomer in the resimix cup and evenly sprinkle the polymer (powder) in the liquid until you achieve a mix that is the consistency of maple syrup.
6. With the #7 spatula, place a small amount of this mix on the wires, letting it flow from the gingival margin to the tip of the wire. This will assure a total bond of the wires to the material.

   Since heating and mixing are done at the same time, care must be taken that the cold cure acrylic does not set before the pressure chamber is closed.

   (The bonding of the material (disc) and the liquid acrylic can only take place when the cold cure acrylic is in its non-polymerized, or liquid state.)
7. When the correct heating time has elapsed, close the chamber by bringing it over the cup with the model in place; with the right hand bring the locking handle forward until it is facing directly toward you. *(The chamber will not be pressurized until the locking handle is in this position.)* Care should be taken when closing the chamber not to jar the machine, as it may dislodge a lead pellet from its packing into the palate area. The pressure should be maintained for a minimum of 2 min. in order for the liquid acrylic to completely polymerize and bond to the material.

ClearCorrect Exhibit 1002, Page 1118 of 3373

8. To remove the appliance from the machine, release the air pressure by pressing the "evacuate" pad. When the pressure is released, turn the locking handle directly away from you. With the left hand, turn the clamping frame handle to the left and lift the chamber back to its rest position at the left of the machine. Remove the appliance from the clamping frame. Re-load chamber with new disc for your next appliance.

9. Release all loose lead pellets from the appliance with knife or spatula (*over the Biostar to minimize pellet loss*).

10. Loosen wires with a knife, then separate the model from the appliance. If any plaster teeth have broken in the appliance blank, chip them away before the appliance is cut from the blank. (Plaster will dull the cutting bur.)

Appliance Trimming and Polishing

1. The appliance is removed from the disc with a cutting bur. Cut as close to your preferred final result as possible (Caution: Before cutting, check wire location to prevent nicking them.)

2 The peripheral edges need to be scalloped (tapered) and shaped. We recommend a carbide taper bur for maximum efficiency.

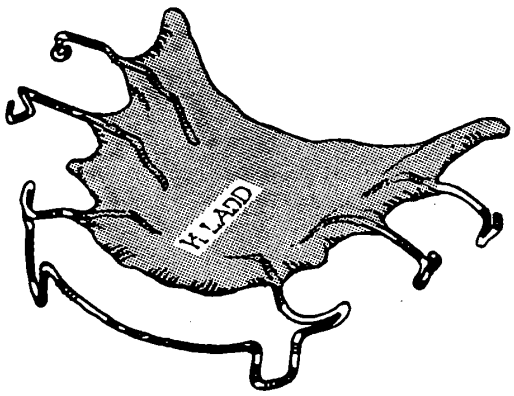
3. For professional results, bur scratches should be eliminated with medium grade pumice using a damp lead center rag wheel.

4. Tripoli removes slight pumice scratches and should be applied on a muslin buff.

5. To achieve a maximum high luster, we recommend a final polish also applied with a muslin buff.

6. To remove all polishing debris, etc., scrub your appliance in a solution of warm soapy water with a scrubbing brush. Never use hot water as it will warp the material.

Adding the patient's name to an appliance



will help the doctor match the retainer with the patient, and provide the patient with an aid to identification should the retainer be misplaced.

1. Your typewriter must have a carbon ribbon.

2. Type the patient's name on the dull side of a piece of ceph tracing paper.

3. With a pair of scissors, cut out the strip, staying as close as possible to the name.

4. While the material is heating and you are running wet cold cure down the wires, put a strip of wet cold cure in the center of the palate, and stick the name to it.

5. Close and pressurize the Biostar as usual.

ClearCorrect Exhibit 1002, Page 1119 of 3373

Biteplates

1. Bend all wires, apply a thin coat of separator on the model and wax all wires in place.

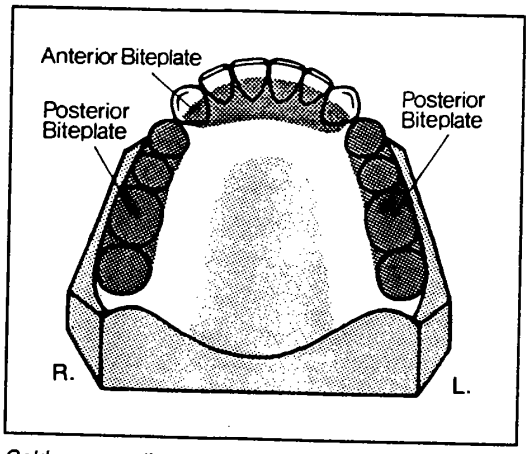
2. Pre-mix liquid acrylic to a molasses consistency and allow to become tacky. *(early setting stages approximately 30 seconds.)* Form on anterior and/or posterior biteplate and shape. *(Diagram 2.)*

3. For a smooth surface on the biteplate, use a little bit of monomer on a cement spatula or finger while shaping; this eliminates voids in the biteplate which can trap air when forming the sheet of material over the biteplate. *Note: Remember, the material is 2 mm in thickness, therefore shape the cold cure biteplate to approximately 2 mm below the required level to accommodate the material thickness. This will minimize trimming and polishing.*

4. Cure the biteplate acrylic (it is best to cure in a pressure pot).

5. Place the model in the cup and pack with lead pellets.

6. While heating the material, apply liquid acrylic not only on the wires to be imbedded in the appliance, but also to the cured biteplate. A perfect bond will result between the biteplate and the heated material.



Cold cure acrylic biteplate. *Dia. 2*

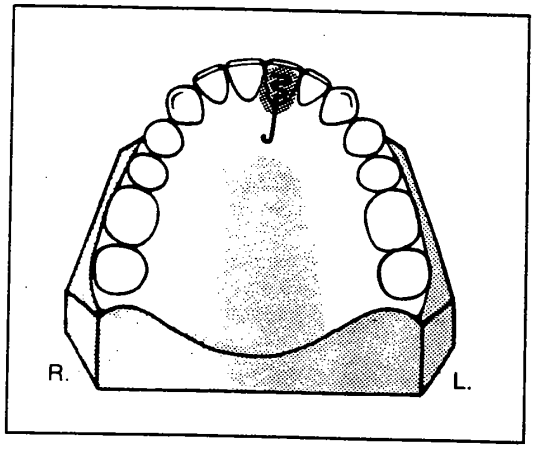
Springs

1. Bend the spring, apply a thin coat of separator on the model and wax the active portion of the spring with base plate wax. Make sure wax is as smooth as possible. *(Diagram 3.)*

2. Pre-mix a small amount of liquid acrylic and apply over the waxed portion of the spring to form a capsule and cure. Ideally, curing should be done in a pressure pot. This cured acrylic capsule prevents the wax from melting when the heated material is brought down over it and prevents the spring from moving out of place.

3. Place the model with all wires waxed in place in the cup, and pack in the lead pellets exactly the same way as for a regular Hawley retainer.

4. While heating the material, apply liquid acrylic not only on the wires to be imbedded in the appliance, but also to the cured acrylic capsule and wire. This will bond the cured acrylic capsule and the material.



Wax covered by cold cure acrylic capsule. *Dia. 3*

ClearCorrect Exhibit 1002, Page 1120 of 3373

Retainer with Expansion Screws

1. Bend wires, apply a thin coat of separator to the model and wax all wires in place.

2. Draw a line on the model where the appliance will eventually be cut. (*ie: along the mid line.*) This allows the expansion screw to be placed in perfect alignment.

3. Pre-mix a small amount of cold cure acrylic to a molasses consistency and allow to become tacky (*early setting stages, approximately 30 seconds*).

4. Apply acrylic to the model in the area of the expansion screw and press the expansion screw into the acrylic.

5. Make sure that the expansion screw is properly aligned both vertically and horizontally.

6. With the acrylic supporting the expansion screw, taper the acrylic to the upper margin, front, back and sides of the expansion screw. This prevents air from being trapped when bonding the material. Let the acrylic cure, preferably in a pressure pot.

7. Using a wire cutter, cut off the tab close to the expansion screw leaving about 2 mm of the tab.

8. Pack the model in the lead pellets as usual.

9. Follow all procedures with the addition of applying liquid acrylic not only to the wires to be imbedded in the appliance, but also to the cured acrylic and expansion screw. This will assure a perfect bond between the acrylic, expansion screw and the material.

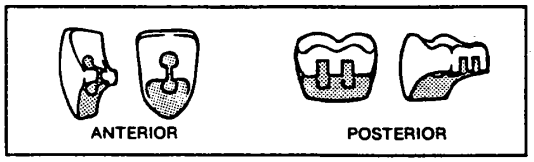
10. Split appliance with a lightning disc or small carbide bur on the palatal side of the appliance.

11. Trim and polish as usual.

Adding a Tooth to a Retainer

1. Grind down the tooth to fit the space where the tooth is missing on the work model.

2. Using a small bur, cut a groove on the lingual side of the tooth (Diagram 4).



Cut groove on lingual surface of tooth. *Dia. 4*

3. Apply separator to the model and wax all wires in place.

4. Wax the tooth securely in place on labial or buccal surface also covering either the incisal edge or occlusal surface.
DO NOT PUT WAX ON LINGUAL SURFACE (the tooth and wire will not bond properly to the material).

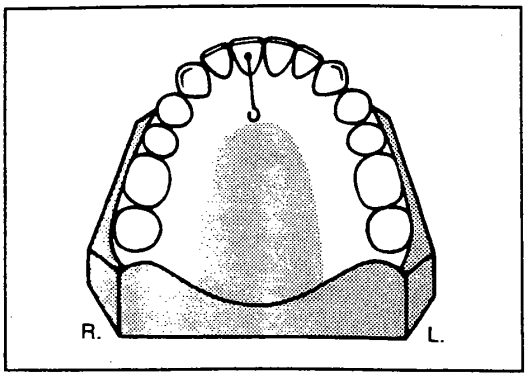
5. If you are using an anterior tooth, bend a ball clasp to fit the groove and extend it into the palate. (*Diagram 5*). This is not necessary for posterior teeth.

6. If you are using an anterior tooth, cold cure the ball end into groove and let it cure. (*Use tooth shade acrylic.*)

7. Pack the model in the lead pellets as usual and be especially careful to keep the pellets up to the incisal edge of the teeth.

8. While heating the material and running wet cold cure down the wires, also run cold cure down the lingual surface of the tooth as well as the imbedded wire. This will assure a perfect bond of the tooth to the retainer.

9. Cut out and trim as usual.



Imbed ball clasp on lingual surface of tooth with tooth shade acrylic. *Dia. 5*

ClearCorrect Exhibit 1002, Page 1121 of 3373

Model Duplication

1. Soak plaster or stone models for two minutes in water. The water will act as release agent. *Note: Soaped models are not to be soaked in water as the soap surface acts as release agent.*

2. Remove the pellets and cover the cup in the Biostar with the model platform.

3. Place the material on the open pressure chamber between the four pins and clamp securely.

4. Immediately before heating the material for the prescribed time, remove the model from the water and place on the model platform. Swing heating lamp over material.
   Special Note: Remove the pellet drawer. When the material is pressed over the model it will force the water through the model into the pellet drawer and make the pellets wet.

5. Swing the heat lamp back and close the pressure chamber.

6. Apply pressure for at least two minutes then remove from the Biostar.

7. Removal of the material from the model is accomplished by gently pulling the material away from the model and sliding the mold off. Avoid turning material inside out if possible. (Air blown in between model and material will make removal easier.) Note: Material should be cool to the touch before removing model.

8. Place the mold on a vibrator and fill with plaster. Suspend the mold in a mixing bowl filled with water to equalize the pressure of the plaster in the mold, thus assuring an exact duplication of your original model.

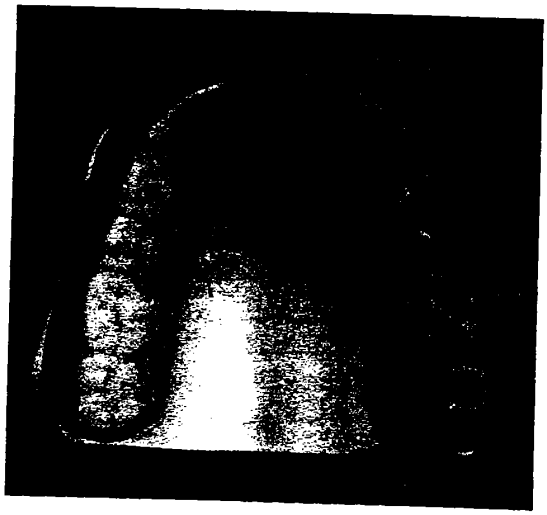
Mouthguards

1. Follow steps 1-6 for model duplication, using the desired thickness of material.

2. Before the model is removed from the duplication, draw the desired shape of the mouthguard on the mold.

3. Remove the model from the mold and cut along line with a sharp lab knife or scissors.

4. To finish and smooth down rough edges use a dampened chamois buff on a lathe at high speed.

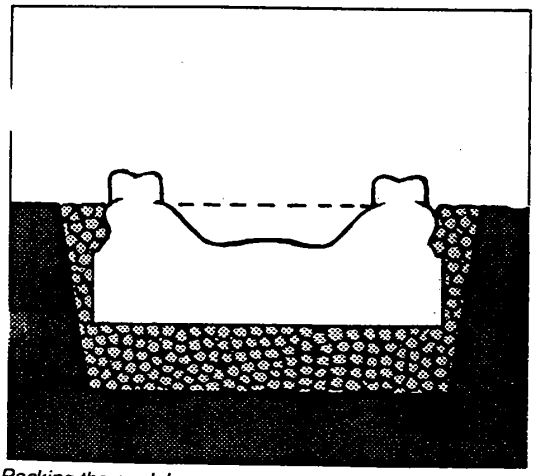


ClearCorrect Exhibit 1002, Page 1122 of 3373

Splints

Splints or "invisible retainers" may be made with any clear hard material. Thickness will be per doctor's prescription.

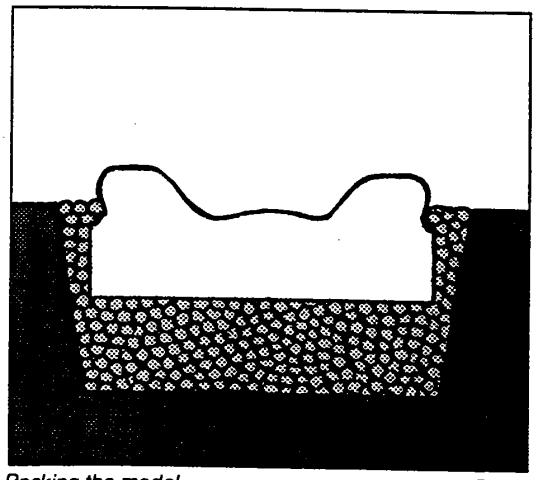
1. Apply a thin coat of separator to the model and be sure to cover all surfaces of the teeth.
2. Pack the model in the lead pellets higher than usual leaving all the teeth exposed. The lead pellets should be packed up to the buccal-gingival margin of the teeth *(Diagram 6).*
3. Heat material and close the pressure chamber.
4. Leave in Biostar for 2 min. and remove appliance from model.
5. Cut to desired shape with straight cutting bur.
6. Trim rough edges with a carbide bur.
7. Pumice and polish as usual.



Packing the model. *Dia. 6*

Custom Trays

1. Use either 2mm or 3 mm material for this procedure depending on desired thickness.
2. Pack the model in the cup leaving all areas exposed that are to be covered by tray. Make sure that pellets are level with the edge of the cup. *(Diagram 7.)*
3. Place moist foam over the model, covering it completely. Several layers *(10-30 mm)* may have to be used depending on the depth of the model's undercuts.
4. Heat material for required time and close the pressure chamber.
5. Cool in Biostar for 2 minutes.
6. Remove tray from machine; cut out and finish down to required shape.
7. Heat handle slowly over flame to reach desired curvature and attach to the tray with cold cure acrylic. *Tray handles can be ordered from Great Lakes. Order No. SDB276*



Packing the model. *Dia. 7*

ClearCorrect Exhibit 1002, Page 1123 of 3373

Positioners

The principle:
Make a wax set-up to the original arch of the teeth, soften the wax in a warming oven and manipulate the teeth into ideal alignment. The only blank (disc.) needed is 2 mm and 3 mm soft material and equipment generally found in office laboratories.

1. Take a set of impressions (upper & lower).

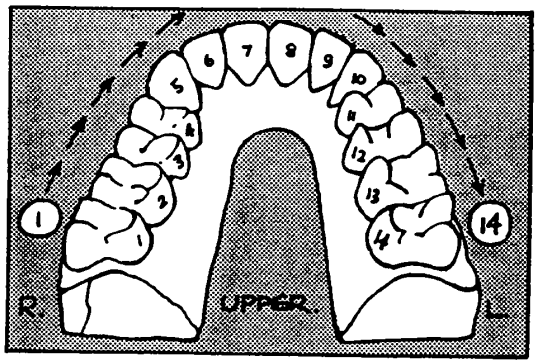
2. Pour impressions in plaster and set in base. After plaster has set, trim as a set of study models, making sure the heels are trimmed together in articulation.

3. Using the Biostar, duplicate upper and lower plaster models with 2 mm material. Remove plaster model from mold.

4. Pour plaster into mold, forming a horseshoe (teeth plus approx. 4 mm gingival tissue).

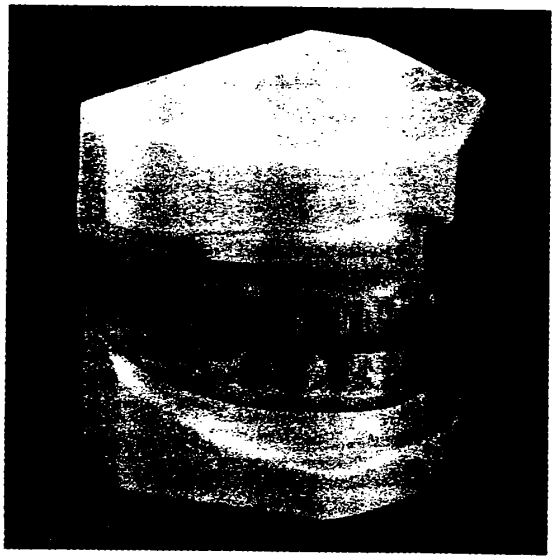
5. When plaster sets, remove horseshoe from the mold. (Note: if necessary, clean off any bubbles and fill holes with plaster.)

6. When plaster is dry, number teeth with a 2B pencil for easy identification (*Diagram 8.*) Start from the first existing tooth on upper right and number consecutively on lingual surface of existing teeth. Follow same procedure for lower. Spray with clear, fast drying lacquer to seal numbers and keep wax from soaking into plaster.

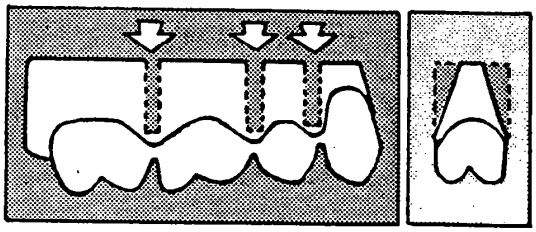


Dia. 8

7. Using a model saw, cut between each tooth in line with the interproximal margin from the base towards incisal edge or occlusal margin up to gingival margin (*Diagram 9.*) Always keep upper and lower arches separate. Then break apart at interproximal contact point to prevent loss of arch measurement. (The thickness of saw blade x 14 cuts could produce up to 7 mm difference in arch measurement.) It may be necessary to take the cut further if there is a resistance to breaking, particularly in the molar area. Do not cut from the occlusal surface.



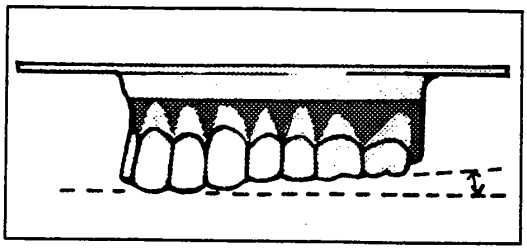
8. Trim tissue or root area so that roots do not touch each other. This allows torquing or tilting when teeth are aligned into original position. *(See Diagram 10)*



Dia. 9 *Dia. 10*

9. Place trimmed teeth back into original sockets in mold.

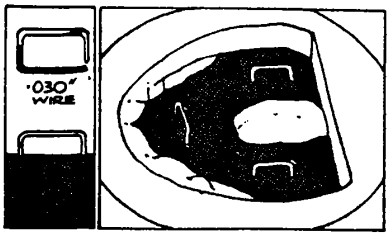
10. Heat soft pink set-up wax in a wax pot until liquefied. (rheostat set at 150°). With teeth in place, carefully add wax so that it flows to the gingival margin. Continue application till the wax is 2-3 mm over the plaster root area. Tilt the mold so that wax is evenly distributed throughout the arch. (*Diagram 11.*) For ease of application we recommend using a 4-5" eye dropper to distribute the wax.



Dia. 11

ClearCorrect Exhibit 1002, Page 1124 of 3373

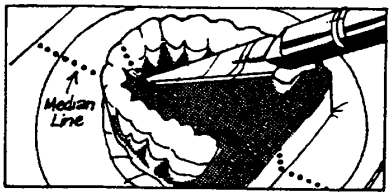
11. When wax is set, bend 3 or 4 loops of .030" wire to the size of a staple, heat and place in wax. *(Diagram 12)* These wires ensure wax will be firmly connected to the plaster.



Dia. 12

12. Make a normal mix of plaster and pour over wax. Use a vibrator and fill to top of base. Draw spatula over top to eliminate excess plaster and avoid trimming. (Note: If bases are poured correctly, there should be no need for trimming even when models are articulated.)

13. After plaster base has set and cooled, use a heated knife to cut mold in half, following median line. *(Diagram 13)* This will allow the easy removal of mold and prevent distortion or breaking of teeth.



Dia. 13

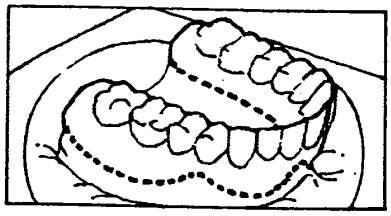
Now you are ready to ideally position and correctly align the teeth to meet the orthodontist's requirements.

14. Place upper and lower arches in an articulator. Separate upper and lower sections of articulator at hinge. Place lower section in a warming oven, (preheated to 200°) for 10 minutes to soften wax. Remove from oven, then immediately reposition teeth in softened wax to ideal alignment, maintaining arch form. A heat lamp over the work area will extend the working time, if necessary. Allow to cool.

15. When lower arch is ideally positioned and cooling, place upper section in the oven (10 minutes at 200°). Remove from oven, rejoin the upper and lower sections of articulator and ideally position the upper arch to lower arch in articulation.

16. Duplicate newly aligned wax setup, both upper and lower, in alginate, and pour the impressions in stone, allowing for a small base. This will be the work model for positioner fabrication.

17. Using the Biostar, form a 3 mm piece of soft material over maxillary stone model. With the mold still in place on model, use a heated knife & cut the buccal, labial, and lingual flanges to an ideal maxillary positioner form. (*Diagram 14*) Discard excess material.



Dia. 14

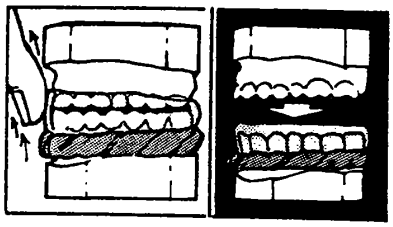
18. With the positioner form on the model, replace in Biostar and form another 3 mm layer of soft material over first layer. Trim as before.

19. Remove mold from upper model and reposition upper and lower stone models on articulator.

20. With models on the articulator, place mold on maxillary model. Take a sheet of paper towel, dampen and roll to the shape of a pencil. Position dampened paper towels around labial, buccal, and lingual flanges to prevent the peripheral edges of material from curling during heating process.

21. Place the articulator with upper model, mold form, and paper towels on Biostar platform. Swing heating unit over the occlusal surface of the material from on the maxillary arch. Heat for 1-1/2 to 2 minutes.

22. Remove from heat. Leaving paper towel in place, press lower model into softened material of upper arch while on articulator. Immediately shape or form the softened material, using moistened fingers, by draw-ing thumb or finger in a downward motion to approximately the gingiva margin on the facial and lingual surfaces of the mandibular model. (*Diagram 15.*)



Mold is hot - keep fingertips moist. Dia. 15

23. To cool after forming, run cold water over positioner while still in place on articulator.

24. Remove positioner from model and trim the buccal, labial, and lingual flanges using a lathe grinding wheel. Smooth finish using a dampened chamois buff at high speed on a lathe.

ClearCorrect Exhibit 1002, Page 1125 of 3373

Advantages of Biostar Technique:

1. Duplication is exact, therefore producing a professional looking temporary that the patient won't object to wearing. The patient looks better, feels more confident and markets his dentist because he is satisfied.
2. The Biostar method saves between 25 & 50% of the time it took to construct temporaries chairside. Auxiliaries can be utilized to do most of the work which frees the Doctor to be with other patients.
3. Because the temporary fits so well and the margins are closely adapted, it is less apt to fall out and have to be recemented.
4. The procedure is so simple and works so well that the Doctor will develop a "peace of mind" attitude regarding a procedure that previously was very difficult and time consuming; especially with full mouth rehabilitations.

Advantages of Laboratory Technique:

1. The Doctor's chair time is drastically reduced, as the assistant does the majority of the work.
2. There is less patient trauma as most of the work is done on the model, not in the mouth. The discomfort from curing acrylic (heat) is eliminated.
3. The temporary is exact and professional looking.
4. By saving models and matrix, a lost or broken temporary can be fabricated before the patient arrives and save more valuable chair time.

Disadvantages of Vacuum Machines:

1. Adaptation is not very good, therefore the temporary will not look very professional or fit as well.
2. The temporary is more apt to fall out causing the patient and Doctor additional chair time.
3. Vacuum machines wear out and have to be replaced.

ClearCorrect Exhibit 1002, Page 1126 of 3373

Temporary Procedure for The Operatory -Method A

1. Take an alginate impression of the patient and pour up a work model.

2. Reconstruct the work model to resemble as closely as possible what the finished case will look like. If teeth are missing, wax denture teeth on the model. If teeth are broken, build up with wax to the desired shape.

3. Thoroughly chill the altered work model, or take an impression of the altered work model and pour up a second work model. (Either procedure will avoid wax softening during the next step).

4. Duplicate the work model on the Biostar using 125/ .5mm copyplast for single crowns and 125/1.0mm copyplast for multiple units. It is very important to use **only** copyplast, as it will not bond to cold cure acrylic. Remove the pellets and cover the cup in the Biostar with the model platform. Place the copyplast in the holding pins and clamp with the clamping frame. (Make sure the four pins properly seat in the circular groove of the clamping frame). Place the model in the center of the model platform, heat the copyplast for the prescribed amount of time and close the pressure chamber.

5. Cool in the machine for 2 minutes and carefully remove the duplication from the model, taking care not to distort the copyplast mold.

6. Trim the excess copyplast, leaving approximately 1/2 tooth covered on either side of the operated area. (to check for complete seating later in the mouth)

7. Set aside the matrix on the model.

8. Prepare the teeth about 80%, and pack the gingival margins with retraction cord to deflect the tissue for approximately 5 minutes. Remove the cord and complete preparations; the cord avoids cutting the tissue when completing preparations at the gingival margins.

9. When the teeth are completely prepared, take a hydrocolloid, rubber base, polyvinylsiloxane or other impression for the die and articulation model to be sent to the lab for crown or bridge fabrication.

10. Insert the copyplast matrix in the patient's mouth to check for fit and/or distortion.

11. Remove matrix and mix tooth shade acrylic. (Trim, Snap, Ortho-Jet, etc.) Fill the desired teeth in the matrix. Immediately insert and have the assistant hold firmly in place checking for full seating on the teeth abutting the operated area. Do not let the acrylic extend far beyond the operated area to avoid trapping in undercuts or wedging into interproximal areas.

12. When the acrylic is almost set but still somewhat pliable, remove the matrix from the mouth. Remove the acrylic temporary from the matrix and trim most of the flash (excess) with a small manicure scissors.

13. Place the temporary back in the mouth to check the fit and allow to set completely.

14. Trim the remainder of the flash and adjust occlusion if necessary.

15. Polish and cement with temporary cement.

Temporary Procedure for The Operatory - Method B

1. Take an alginate impression of the patient and pour up a work model.

2. Reconstruct the work model to resemble as closely as possible what the finished case will look like. If teeth are missing, wax denture teeth on the model. If teeth are chipped or broken, build up with wax to desired shape.

3. Take an impression of the altered work model and pour up the second work model.

4. Duplicate the work model on the Biostar using 125/.5 mm copyplast for single crowns and 125/1.0 mm copyplast for multiple units. It is very important to use **only** copyplast, as it will not bond to cold cure acrylic. Remove the cup and pellets and cover the cup in the Biostar with the model platform. Place the copyplast in the holding pins and clamp with the clamping frame. (Make sure the four pins properly seat in the circular groove of the clamping frame.) Place the model in the center of the model platform, heat material for prescribed amount of time and close machine. Cool in

ClearCorrect Exhibit 1002, Page 1127 of 3373

machine for 2 minutes, and carefully remove duplication from model taking care not to distort the copyplast mold. Trim the excess copyplast and set aside the matrix on the model.

5. Prepare the teeth about 80%, pack the gingival margins with cord or dental tape to deflect tissue for approximately 5 minutes. Remove cord and complete preparations; the retraction of the tissue with the cord avoids cutting the tissue when completing preparations at the gingival margins.

6. When teeth are completely prepared, take a hydrocolloid impression for the work model sent to the lab.

7. Insert copyplast matrix in patient's mouth to check proper fit.

8. Remove and mix tooth shade acrylic (Trim, Snap, Ortho-Jet, etc.). Fill desired teeth in matrix with acrylic; immediately insert and have the patient bite down on a cotton roll.

9. When acrylic is set but still somewhat pliable, remove matrix from mouth. Remove acrylic temporary from matrix and trim most of the flash (excess) with a small manicure scissors.

10. Place temporary back in the mouth to check fit and allow to set almost to completion. Do not allow acrylic to set entirely as it may set in interproximal areas.

11. Trim the remainder of the flash and adjust occlusion.

12. Polish and cement with temporary cement.

Temporary Procedure For The Laboratory

1. Anesthetize the patient; while anesthesia takes effect, take an impression. Use hydrocolloid in a syringe around the gingival margins with an alginate impression of the teeth to be prepared.

2. Pour up a work model in quick set plaster.

3. Reconstruct the work model to resemble as closely as possible what the finished case will look like. If teeth are missing, attach denture teeth to the model. If teeth are chipped or broken, build them up with hydrocolloid to the desired shape.

4. Duplicate the work model on the Biostar using 125/.5mm copyplast for single crowns and 125/1.0 mm copyplast for multiple units. It is extremely important use copyplast with no substitutions, as this particular material *will not* bond to cold cure acrylic. Remove the cup and pellets and cover the cup in the Biostar with the model platform. Place the copyplast in the holding pins and clamp securely with the clamping frame making sure that the four pins properly seat in the circular groove of the clamping frame. Dampen the model in water and place it in the center of the model platform. Heat the copyplast for the prescribed amount of time marked on the package and close the pressure chamber.

5. Let cool in Biostar for 2 minutes; remove from machine but do not separate the copyplast matrix from the model.

6. Mix a small amount of quick set plaster and place over the copyplast matrix on the model to form a cover in the area of the temporary and abutting teeth only. When the plaster is set, carefully remove and set aside for future use.

7. While the lab technician is doing this, the Doctor is simultaneously preparing the teeth, which saves a lot of time.

8. When the tooth or teeth are prepared, a second impression is taken using hydrocolloid in a syringe around the margins and fast setting alginate in the impression tray. Pour the model with quick set plaster.

9. While final impressions are being taken with hydrocolloid, the technician cuts the copyplast matrix to fit over the second work model, (with prepared teeth). Leave the abutting teeth on the matrix for greater stability.

10. Brush a thin layer of separator on the prepared and abutting teeth. Mix a small amount of tooth shade acrylic and fill the desired teeth in the copyplast matrix. Place over the prepared model, cover with the plaster sleeve and wrap a rubber band snugly around everything. This will reduce expansion of the temporary due to heat as the acrylic sets.

11. When the temporary is completely cured, (preferably in a pressure pot) remove it from the matrix and trim any excess (flash) with an acrylic bur.

12. Check occlusion, adjust if necessary, polish and cement with temporary cement.

13. Pour final impressions to send to lab for permanent restorations.

ClearCorrect Exhibit 1002, Page 1128 of 3373

Linear Interpolation Revitalized

Thierry Blu, *Member, IEEE*, Philippe Thévenaz, *Member, IEEE*, and Michael Unser, *Fellow, IEEE*

Abstract—We present a simple, original method to improve piecewise-linear interpolation with uniform knots: we shift the sampling knots by a fixed amount, while enforcing the interpolation property. We determine the theoretical optimal shift that maximizes the quality of our shifted linear interpolation. Surprisingly enough, this optimal value is nonzero and close to $1/5$.

We confirm our theoretical findings by performing several experiments: a cumulative rotation experiment and a zoom experiment. Both show a significant increase of the quality of the shifted method with respect to the standard one. We also observe that, in these results, we get a quality that is similar to that of the computationally more costly "high-quality" cubic convolution.

Index Terms—Approximation methods, error analysis, interpolation, piecewise linear approximation, recursive digital filters, spline functions.

I. Introduction

STANDARD piecewise-linear interpolation, which dates back to the Babylonians [1], is by far the most popular solution for many applications such as computer vision, digital photography, computer graphics, postscript optimization for printers, image calibration and registration, textures, and re-sampling. It is reasonably fast and does not suffer from the obvious blocking artifacts of nearest-neighbor interpolation. However, when quality is an important concern, methods based on higher-degree interpolation kernels have been developed [2]: Keys' cubic convolution method [3] has become a standard in the field, even though recent studies have shown that, for the same computational cost, cubic-spline and cubic-OMOMS kernels provide a substantial gain in quality [4]–[7].

It has been previously shown that the quality of the *interpolation* method is noticeably lower than that of the *projection* method, especially for piecewise-linear approximation [8], [9]. This suggests that there remains some significant margin of gain by optimizing linear interpolation. The goal of this paper is to explore one possible approach, by shifting the standard linear interpolation kernel. Note that, what we mean here is definitely not adapting the shift to the contents of the signal to interpolate, but instead using a *uniform* shift that is genuinely *independent* of this signal. This idea seems to have been initiated by Plonka [10] in the more general case of spline interpolation, although the main problem addressed in [10] was the *stability* of the interpolation operator, and not the *quality* of the resulting interpolation. Unsurprisingly, it was concluded that the most stable configuration is reached in the absence of shifting. Apart from [10], we do not know of any other research done on shifted interpolation, although there were other shift-based attempts (nonlinear and data-dependent) to improve the quality of standard interpolation methods [11].

Counterintuitively, we show here that there exists an optimal, nontrivial shift value (close to $1/5$) for linear interpolation, for which our new shifted interpolation improves considerably the quality of the standard—nonshifted—method. A quality as high as that of the orthogonal projection may even be attained in the limit of small sampling steps—or, equivalently, of very lowpass functions.

To predict the quality of shifted linear interpolation, we rely on the theoretical tools developed in [12]. We verify our claims by experiments that show that our method provides a quality that is much better than standard piecewise-linear interpolation, for a similar computational cost.

The paper is structured as follows: First, we review basic notions about interpolation—not necessarily with shifted linear splines—which will be needed for our analysis. In particular, we describe a theoretical method to estimate the quality of an interpolator using mathematical tools such as a Fourier approximation kernel and an asymptotic interpolation constant. Next, in Section III, we present shifted linear interpolation and show that a nontrivial value of the shift results in a quality that is optimal in an objective sense. We also evaluate the computational cost of our shifted linear method and show how to minimize it even further. Finally, we provide practical results that point out the deficiencies of standard linear interpolation and that show that its optimally-shifted version may even rival the standard high-quality (but more costly) method, namely, Keys' cubic convolution.

II. Interpolation

A. Piecewise-Linear Interpolation

Given a sequence of samples $f_n = f(nT)$ that originate from the uniform sampling of a function $f(x)$ with step T, the standard method of linear interpolation builds a function $f_T(x)$ through the following process: for $x \in [(n-1)T, nT]$, $f_T(x) = a_n x + b_n$, where a_n and b_n are chosen such that $f_T((n-1)T) = f_{n-1}$ and $f_T(nT) = f_n$. This can be shown to be equivalent to

$$f_T(x) = \sum_{n \in \mathbb{Z}} f_n \Lambda\left(\frac{x}{T} - n\right) \tag{1}$$

where $\Lambda(x)$ is the "hat" function, or linear B-spline: $\Lambda(x) = 1 - |x|$ for $|x| \leq 1$ and $\Lambda(x) = 0$ for $|x| > 1$ [13]. The Fourier

Manuscript received March 25, 2002; revised November 17, 2003. The associate editor coordinating the review of this manuscript and approving it for publication was Prof. Zixiang Xiong.

The authors are with the Biomedical Imaging Group FSTI/IOA, Swiss Federal Institute of Technology Lausanne (EPFL), CH-1015 Lausanne EPFL, Switzerland (e-mail: thierry.blu@epfl.ch; philippe.thevenaz@epfl.ch; michael.unser@epfl.ch).

Digital Object Identifier 10.1109/TIP.2004.826093

1057-7149/04$20.00 © 2004 IEEE

ClearCorrect Exhibit 1002, Page 1129 of 3373

transform of this function, which will be useful in the sequel, is given by

$$\hat{\Lambda}(\omega) = \operatorname{sinc}^2\left(\frac{\omega}{2\pi}\right) = \left(\frac{\sin \omega/2}{\omega/2}\right)^2. \tag{2}$$

B. Generalized Interpolation

In a more general way, uniform interpolation is the process of building a function $f_T(x)$ through the formula

$$f_T(x) = \sum_{n\in\mathbb{Z}} c_n \varphi\left(\frac{x}{T} - n\right) \tag{3}$$

where the coefficients c_n are chosen so as to satisfy the interpolation condition $f_T(nT) = f_n$ [2], [4]. Here, $\varphi(x)$ might be any function with $\int \varphi(x)\,dx = 1$. In particular, $\varphi(x)$ does not need to be continuous, interpolating, or symmetric. As can readily be seen, the interpolation condition is equivalent to the following filtering relation:

$$f_k = \sum_{n\in\mathbb{Z}} \varphi(k-n)c_n.$$

The coefficients c_n can be obtained by convolving the samples f_n with a filter H, the z-transform of which is $H(z) = 1/(\sum_n \varphi(n)z^{-n}) = \sum_n h_n z^{-n}$.

The interpolation formula (3) can equivalently be rewritten in a more traditional form in terms of the samples f_n [4]:

$$f_T(x) = \sum_{n\in\mathbb{Z}} f_n \varphi_{\text{int}}\left(\frac{x}{T} - n\right)$$
$$\text{where } \varphi_{\text{int}}(x) = \sum_{n\in\mathbb{Z}} h_n \varphi(x-n)$$

where the equivalent interpolation function $\varphi_{\text{int}}(x)$ is obtained by applying the filter weights to the basis functions. The Fourier transform of φ_{int} takes the simple form

$$\hat{\varphi}_{\text{int}}(\omega) = H(e^{j\omega})\hat{\varphi}(\omega). \tag{4}$$

The 1D formula (3) can easily be used for image interpolation by replacing $\varphi(x)$ by the tensor product $\varphi(x)\varphi(y)$ in (3): $f_T(x,y) = \sum_{k,l} c_{k,l}\varphi(x/T-k)\varphi(y/T-l)$. This expression, as well as the prefiltering step to obtain the $c_{k,l}$, can be realized very efficiently in a separable manner (e.g., by successive processing of the lines and columns) [4].

C. Measuring the Interpolation Error

For $f_T(x)$ to be a good approximation of $f(x)$, the quality needs to improve as T gets smaller. The rate of this improvement is called the order of approximation. Usually, we assume that $f \in \mathbf{W}_2^{1/2+\varepsilon}$ (with $\varepsilon > 0$), so as to ensure that f and f_T belong to $\mathbf{L}^2(\mathbb{R})$ [12]. A natural measure for the distance between $f_T(x)$ and $f(x)$ is then $\|f - f_T\|_{\mathbf{L}^2(\mathbb{R})}$. Obviously, this approximation error is bounded from below by $\|f - \mathrm{P}_T f\|_{\mathbf{L}^2(\mathbb{R})}$, where $\mathrm{P}_T f$ is the orthogonal projection of f onto the function space made of linear combinations of $\varphi(x/T-n)$, $n \in \mathbb{Z}$.

We have shown in [4], [12] that both the interpolation error $\varepsilon_{\text{int}}(T) = \|f - f_T\|_{\mathbf{L}^2(\mathbb{R})}$ and the orthogonal projection error $\varepsilon_{\min}(T) = \|f - \mathrm{P}_T f\|_{\mathbf{L}^2(\mathbb{R})}$ can be estimated very accurately by

$$\eta(T) = \sqrt{\frac{1}{2\pi}\int |\hat{f}(\omega)|^2 E(\omega T)\,d\omega} \tag{5}$$

where the function $E(\omega)$ is what we call a Fourier kernel of approximation. This function depends only on $\varphi(x)$, in the following ways.

i) For the orthogonal projection P_T, $E(\omega) = E_{\min}(\omega)$ with

$$E_{\min}(\omega) = \frac{\sum_{k\in\mathbb{Z}\setminus\{0\}} |\hat{\varphi}(\omega+2k\pi)|^2}{\sum_{k\in\mathbb{Z}} |\hat{\varphi}(\omega+2k\pi)|^2}. \tag{6}$$

ii) For interpolation, $E(\omega) = E_{\text{int}}(\omega)$ with (7), as shown at the bottom of the page.

To be more precise, the identity between the approximation error and $\eta(T)$ holds whenever $f(x)$ is bandlimited in $[-\pi/T, \pi/T]$. In the nonbandlimited case, this identity holds *on average*—when one computes the average over all possible ξ of the error resulting from the approximation of $f(x-\xi)$ [12, Thm.2].

The above formulæ still hold for higher dimensional signals [4]—images, for instance. It is just a matter of replacing the single integral and the single summations by multiple ones, $\mathbb{Z}$ by $\mathbb{Z}^d$ and $\{0\}$ by $\{0,0,..,0\}$ in (5), (6), and (7).

D. Asymptotic Interpolation Error

When the sampling step T tends to 0, we want that $f_T(x) \to f(x)$. One can easily see from the Expression (5) that this is the case when $E(0) = E_{\text{int}}(0) = 0$ under relatively weak conditions on $\varphi(x)$ (for instance, see [14]); or equivalently, when $\hat{\varphi}(2k\pi) = 0$ for all $k \in \mathbb{Z}\setminus\{0\}$ and $\hat{\varphi}(0) = 1$, as is obvious from (7). More generally, it is known that $\|f - \mathrm{P}_T f\|_{\mathbf{L}^2(\mathbb{R})}$ tends to zero as T^L if and only if $\varphi(x)$ satisfies the Strang-Fix conditions [15]: $\hat{\varphi}^{(l)}(2n\pi) = 0$ for $n \in \mathbb{Z}\setminus\{0\}$ and $l = 0\ldots L-1$. This equivalence still holds for $\|f - f_T\|_{\mathbf{L}^2(\mathbb{R})}$. The integer L is called the approximation order of $\varphi(x)$. For instance, the approximation order of $\Lambda(x)$ is $L = 2$ because of (2).

More precisely, we have shown in [12] that

$$\|f - \mathrm{Q}_T f\|_{\mathbf{L}^2(\mathbb{R})} \approx C_\varphi \|f^{(L)}\|_{\mathbf{L}^2(\mathbb{R})} T^L$$

as $T \to 0$, where Q_T is any integer-shift-invariant linear approximation operator, such as interpolation, or the orthogonal

$$E_{\text{int}}(\omega) = \frac{\left|\sum_{k\in\mathbb{Z}\setminus\{0\}} \hat{\varphi}(\omega+2k\pi)\right|^2 + \sum_{k\in\mathbb{Z}\setminus\{0\}} |\hat{\varphi}(\omega+2k\pi)|^2}{\left|\sum_{k\in\mathbb{Z}} \hat{\varphi}(\omega+2k\pi)\right|^2}. \tag{7}$$

ClearCorrect Exhibit 1002, Page 1130 of 3373

projection. The asymptotic constant $C_\varphi = \sqrt{E^{(2L)}(0)/2L!}$ may also be expressed as follows:

i) For the orthogonal projection [16]

$$C_\varphi^{\min} = \frac{1}{L!}\sqrt{\sum_{k\neq 0} |\hat{\varphi}^{(L)}(2k\pi)|^2}. \tag{8}$$

ii) For interpolation [4], ([17], when $\varphi(x)$ is interpolating)

$$C_\varphi^{\text{int}} = \sqrt{\frac{1}{L!^2}\left|\sum_{k\neq 0}\hat{\varphi}^{(L)}(2k\pi)\right|^2 + \left(C_\varphi^{\min}\right)^2}. \tag{9}$$

Comparing (8) to (9), it clearly appears that it is the quantity $\sum_{k\neq 0}\hat{\varphi}^{(L)}(2k\pi)$ that tells apart interpolation from orthogonal projection. In particular, this quantity is substantial for piecewise-linear interpolation. In the sequel, we will show that we can use a shift to make it vanish.

The result can also be extended for higher dimensional signals. For instance, in two dimensions, we can apply a Taylor analysis and prove that the interpolation error behaves asymptotically like

$$\begin{aligned}\|f - Q_T f\|^2_{\mathrm{L}^2(\mathbb{R})} \approx \Big[&\left(C_\varphi^{\min}\right)^2\left(\left\|\partial_x^L f\right\|^2_{\mathrm{L}^2(\mathbb{R})} + \left\|\partial_y^L f\right\|^2_{\mathrm{L}^2(\mathbb{R})}\right)\\ &+ \left(\left(C_\varphi^{\text{int}}\right)^2 - \left(C_\varphi^{\min}\right)^2\right)\left(\left\|\partial_x^L f\right\|^2_{\mathrm{L}^2(\mathbb{R})}\right.\\ &\left.+\ \left\|\partial_y^L f\right\|^2_{\mathrm{L}^2(\mathbb{R})} + 2\left\langle\partial_x^L f, \partial_y^L f\right\rangle\right)\Big] T^L\end{aligned}$$

where $C_\varphi^{\min}$ and C_φ^{int} are given by (8) and (9). Similarly to the 1D case, it is $\sum_{k\neq 0}\hat{\varphi}^{(L)}(2k\pi)$ that makes the difference between the interpolation and orthogonal projection constants. This justifies that, from now on, we will only be considering the 1D case in our optimization.

III. Shifted Linear Interpolation

Instead of building $f_T(x)$ using line segments between $(n-1)T$ and nT as in Section II, we draw them between $(n-1+\tau)T$ and $(n+\tau)T$ for some $\tau \in [0, 1/2[$, as exemplified in Fig. 1. More precisely, we consider the following process: for $x \in [(n-1+\tau)T, (n+\tau)T]$, $f_T(x) = a_n x + b_n$, where a_n and b_n are chosen such that $f_T(nT) = f_n$, and where $f_T(x)$ is continuous at $x = (n-1+\tau)T$.

Theorem 1: The τ-shifted linear interpolation of the samples f_n can be expressed as

$$f_T(x) = \sum_{n\in\mathbb{Z}} c_n \Lambda\left(\frac{x}{T} - n - \tau\right) \tag{10}$$

with

$$c_n = \sum_{k\geq 0}\frac{(-1)^k}{1-\tau}\left(\frac{\tau}{1-\tau}\right)^k f_{n-k}. \tag{11}$$

The coefficients c_n satisfy the induction equation

$$c_n = -\frac{\tau}{1-\tau}c_{n-1} + \frac{1}{1-\tau}f_n. \tag{12}$$

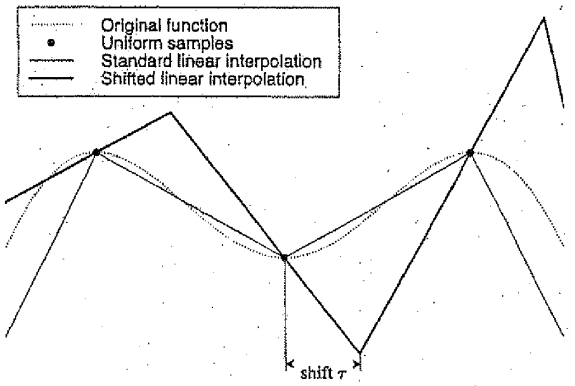


Fig. 1. "Shifted" versus "standard" linear interpolation. For clarity purpose, we have chosen $\tau = 0.4$, which is far from the optimum (15).

Proof: In order to show that $f_T(x)$ is a τ-shifted linear interpolation, we have to verify that it is piecewise-linear, continuous, and that it satisfies the interpolation condition $f_T(kT) = f_k$. Continuity and linearity are obvious since $\Lambda(x/T - \tau)$ is itself continuous and piecewise-linear. The last assertion is checked directly:

$$\begin{aligned} f_T(kT) &= \sum_{n\in\mathbb{Z}} c_n \Lambda(k - n - \tau)\\ &= c_k\Lambda(-\tau) + c_{k-1}\Lambda(1-\tau)\\ &= (1-\tau)c_k + \tau c_{k-1}\\ &= f_k \quad (\text{using}(12)).\end{aligned}$$

■

We observe that the expression (11) relates f_n to c_n through convolution by the *causal* filter H_τ with z-transform

$$H_\tau(z) = \frac{1}{1-\tau+\tau z^{-1}} = \sum_{k\geq 0}\frac{(-1)^k}{1-\tau}\left(\frac{\tau}{1-\tau}\right)^k z^{-k}.$$

Because $\tau \in [0, 1/2[$, this filter is *stable*. However, unlike standard linear interpolation ($\tau = 0$), its impulse response is *of infinite length* even if, in practice, its impulse response can be considered to be of finite support (exponential decay, see Fig. 2).

The Fourier transform of the equivalent interpolant implied by (10) is obtained by substituting the filter's response in (4):

$$\hat{\varphi}_{\text{int}}(\omega) = e^{-j\omega\tau}H_\tau(e^{j\omega})\,\mathrm{sinc}^2\left(\frac{\omega}{2\pi}\right). \tag{13}$$

Intuitively, it is expected that a small shift bring a flatter frequency amplitude because the prefilter H_τ acts like a high-pass filter that partially compensates the quadratic decreasing behavior of $\mathrm{sinc}^2(\omega/2\pi)$.

It is obvious that the computation of the coefficients c_n can be carried out very efficiently using the recursion (12): only two multiplications and one addition are necessary per data point. In order to be complete, we must initialize (12) at, say, $n = 0$. A simple choice is to assume that $f_n = f_0$ for all $n < 0$ which in turn implies the initial condition $c_0 = f_0$, by applying the nonrecursive expression (11).

ClearCorrect Exhibit 1002, Page 1131 of 3373

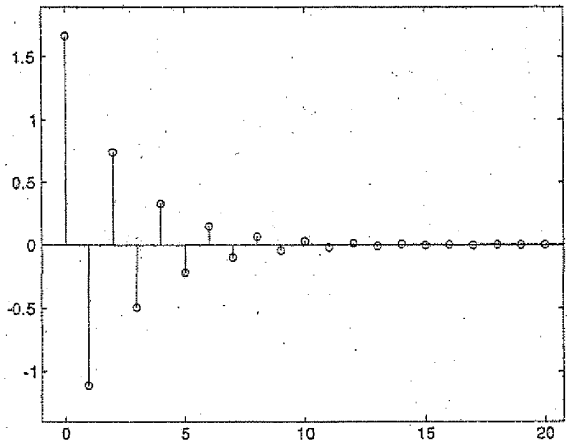


Fig. 2. Impulse response of the prefilter of the shifted linear interpolation of Fig. 1.

A. Optimal Shift

We may now apply the theory of Section II to the specific case where $\varphi(x)$ is the shifted hat function $\Lambda(x-\tau)$ which, according to Theorem 1, is the basis building block of τ-shifted linear interpolation.

Theorem 2: The asymptotic interpolation constant of the τ-shifted linear interpolation is given by

$$C_\tau^{\text{int}} = \sqrt{\frac{1}{4}\left(\tau^2 - \tau + \frac{1}{6}\right)^2 + \frac{1}{720}}. \tag{14}$$

Proof: We know from Section II that $\varphi(x) = \Lambda(x-\tau)$ is of order $L = 2$ since it satisfies the Strang-Fix conditions of order 2. According to (8) and (9), we have to compute $\sum_{k\neq 0} \hat{\varphi}''(2k\pi)$ and $C_\varphi^{\min}$. The first quantity can be evaluated as follows:

$$\begin{aligned}\sum_{k\neq 0} \hat{\varphi}''(2k\pi) &= -\hat{\varphi}''(0) + \sum_k \hat{\varphi}''(2k\pi) \\ &= -\hat{\varphi}''(0) - \sum_n n^2\varphi(n) \quad \text{(using Poisson's formula)} \\ &= \tau^2 + \frac{1}{6} - \tau \quad \text{(replacing } \varphi(x) \text{ by } \Lambda(x-\tau)).\end{aligned}$$

Then, we evaluate the asymptotic constant $C_\varphi^{\min}$. Since a shift contributes only as a phase term in the Fourier transform, we claim that $C_\varphi^{\min}$ does not depend on τ (see the expression of the orthogonal projection kernel (6)). Thus, $C_\varphi^{\min} = C_\Lambda^{\min} = \sqrt{2\zeta(4)}/((2\pi)^2 = 1/\sqrt{720}$. Putting things together in (9) gives (14). ■

Surprisingly, this expression is not minimized for the standard linear interpolation $\tau = 0$. Instead, the optimal choice is

$$\tau_{\text{opt}} = \frac{1}{2}\left(1 - \frac{\sqrt{3}}{3}\right) \approx 0.21. \tag{15}$$

This minimizes the interpolation constant and reaches the lower value of the *optimal* $\mathbf{L}^2(\mathbb{R})$ approximation (orthogonal projection). This is remarkable because interpolation is never optimal in the least-squares sense—we must keep in mind here that our result is valid only in the asymptotic regime (e.g., smooth function $f(x)$, or small sampling step T).

We have plotted in Fig. 3 the frequency response of the equivalent interpolant (13), and we have compared it with the piecewise-linear interpolant. In the Nyquist band, the amplitude response of the shifted linear interpolant is much closer to an ideal filter than in the standard piecewise-linear case. This is obtained at the price of a slight phase distortion, and larger ripples in the aliasing bands.

Using the definition of the asymptotic constant, we see that the gain of shifted over standard linear interpolation is about 8 dB asymptotically, as the sampling step tends to 0. Obviously, this performance should degrade as the frequency content of the function to interpolate gets richer, that is, when the energy at higher frequencies becomes more significant. In particular, when $f(x)$ is the step function (a limit case that does not belong to $\mathbf{L}^2(\mathbb{R})$, but for which we can still test our interpolation method), the shifted linear interpolation gives rise to a Gibbs phenomenon—unlike the standard method (see Fig. 4).

Using the Fourier kernel of approximation (7), we can be more precise about the range of frequencies over which shifted linear interpolation outperforms standard linear interpolation.

Proposition 3: The Fourier kernel of approximation of τ-shifted linear interpolation is given by

$$\begin{aligned}E_\tau(\omega) = 1 &+ \frac{1}{3}\frac{2+\cos\omega}{|1-\tau+\tau e^{-j\omega}|^2} \\ &- 2\,\text{sinc}^2\left(\frac{\omega}{2\pi}\right)\text{Re}\left(\frac{e^{-j\tau\omega}}{1-\tau+\tau e^{-j\omega}}\right).\end{aligned} \tag{16}$$

Proof: Expanding (7), we obtain

$$\begin{aligned}E_\tau(\omega) = 1 &+ \frac{\sum_{k\in\mathbb{Z}} |\hat{\varphi}(\omega+2k\pi)|^2}{\left|\sum_{k\in\mathbb{Z}} \hat{\varphi}(\omega+2k\pi)\right|^2} \\ &- 2\text{Re}\left(\frac{\hat{\varphi}(\omega)}{\sum_{k\in\mathbb{Z}} \hat{\varphi}(\omega+2k\pi)}\right).\end{aligned}$$

Then, Poisson's summation formula applied to $\varphi(x) = \Lambda(x-\tau)$ yields

$$\begin{aligned}\sum_k \hat{\varphi}(\omega+2k\pi) &= \sum_n \varphi(n)e^{-jn\omega} \\ &= \Lambda(-\tau) + \Lambda(1-\tau)e^{-j\omega} \\ &= 1 - \tau + \tau e^{-j\omega}\end{aligned}$$

and

$$\begin{aligned}\sum_k |\hat{\varphi}(\omega+2k\pi)|^2 &= \sum_k |\Lambda(\omega+2k\pi)|^2 \\ &= \sum_n \Lambda * \Lambda(n)e^{-jn\omega} \\ &= \sum_n \beta^3(n)e^{-jn\omega} \\ &= \frac{2+\cos\omega}{3}\end{aligned}$$

where $\beta^3(x)$ is the B-spline of degree 3, the Fourier transform of which is $\text{sinc}^4(\omega/2\pi)$ [13]. Putting things together we find (16). ■

ClearCorrect Exhibit 1002, Page 1132 of 3373

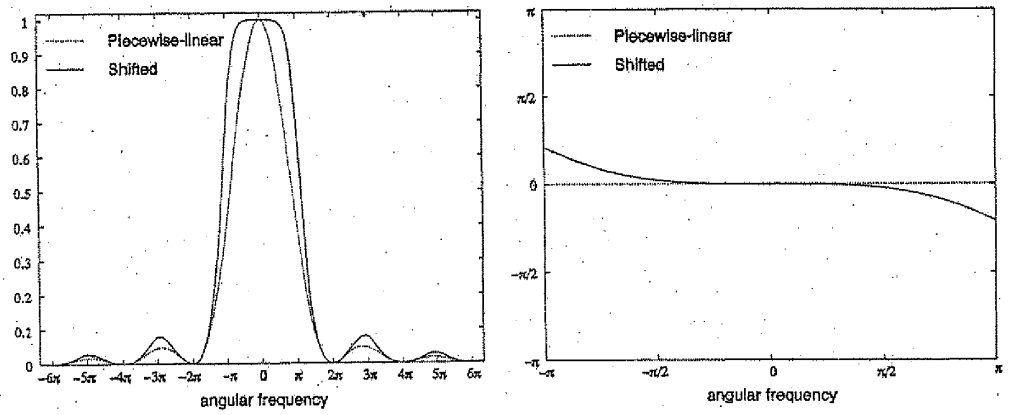


Fig. 3. Frequency plot of the amplitude (left) and of the in-band phase distortion (right) of the standard and optimally shifted linear interpolant.

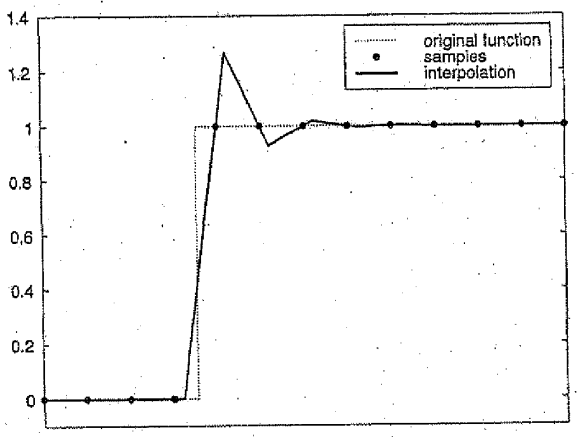


Fig. 4. Gibbs phenomenon caused by the optimally shifted linear interpolation of a unit-step function.

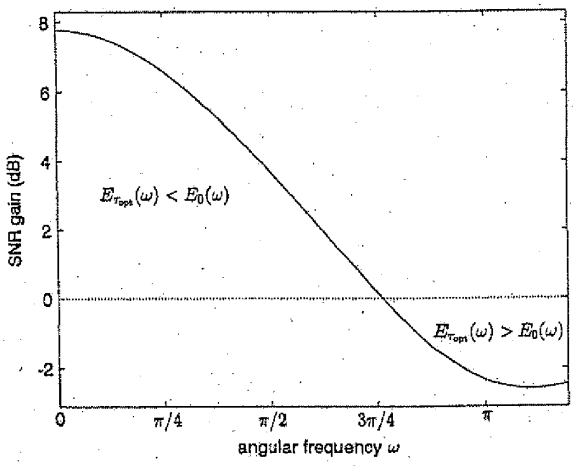


Fig. 5. Plot of the gain (17) $\gamma_{\tau_{opt}}(\omega)$ as a function of ω: for $\omega < 3\pi/4$, the optimally shifted method outperforms the nonshifted one, by up to 8 dB.

The approximation kernel evaluated at the frequency ω_0 can also be interpreted as the average power of the approximation—or here, interpolation—error of the pure unit sinusoid $e^{j\omega_0 x}$ ([12] Thm.3). Thus, the quantity $E_\tau(\omega_0)/E_0(\omega_0)$ quantifies the reduction or increase of the interpolation error caused by the τ-shifted method compared to the standard one at the angular frequency ω_0. We define this gain by

$$\gamma_\tau(\omega) = 10\log_{10}\left(\frac{E_0(\omega)}{E_\tau(\omega)}\right). \qquad (17)$$

This function is shown in Fig. 5 for the optimal shift $\tau = \tau_{\text{opt}}$. Not only does this graph confirm that this gain should reach almost 8 dB in the neighborhood of $\omega = 0$, it also shows that the shifted linear interpolation should perform better than its nonshifted counterpart for signals with frequency range up to 3/4th of the sampling bandwidth.

In principle, the same shifting trick may also be used for other kernels than $\Lambda(x)$ such as higher order splines; the optimal shift has then to be determined on a case-by-case basis.

B. Computational Cost and Implementation Options

The computational cost of an interpolation method characterized by (3) can be decomposed into two parts:

The Pre-Computation of the Coefficients c_k: This cost depends on the number N_{in} of *input* samples and the size of the prefilter H only. Typically, H is of size W where W is the length of the support of φ. If we consider image interpolation, then the full cost amounts to $2WN_{\text{in}}$ multiplications and additions (using the recursive implementation).

Note that this amount is usually a negligible overhead. In addition, for applications requiring intensive interpolation, it is also possible to do the preprocessing in advance and to work with the c_k instead of the initial data. This is especially indicated in the context of iterative algorithms, and for interactive imaging and vizualization;

The Computation of $f_T(x)$: This cost depends only on the number N_{out} of *output* samples x and on the cost of computing $\varphi(x-k)$ for all values of k such that $(x-k)$ belongs to the

ClearCorrect Exhibit 1002, Page 1133 of 3373

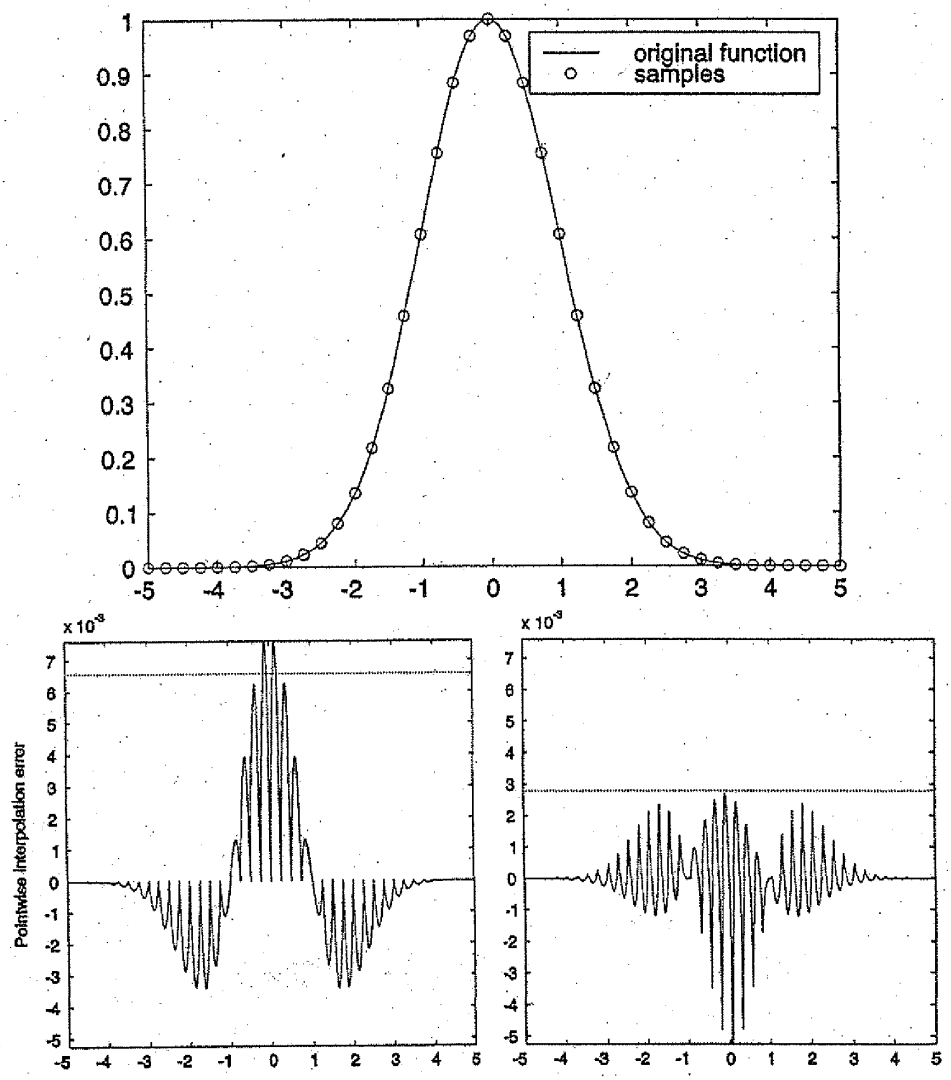


Fig. 6. Interpolation error $f(x) - f_T(x)$ for the Gaussian function $f(x) = e^{-x^2/2}$ (top) using: standard linear interpolation (bottom left) and optimally shifted linear interpolation (bottom right). The dotted lines indicate the L^2 interpolation error: in this example, the gain of the shifted method is close to 7.5 dB. See Section IV-A for more details.

support of φ. Typically, when $\varphi(x)$ is piecewise-polynomial of degree n, the evaluation of (3) requires

- $W^2 + W$ additions and multiplications (in the 2D separable implementation);
- $2W$-times the evaluation of the 1D basis kernel, which amounts to n additions and multiplications (using Horner's scheme).

The total cost is therefore of $N_{\text{out}}(W^2 + (2n+1)W)$ additions and multiplications, for given c_k.

In the case of piecewise-linear interpolation ($n = 1$ and $W = 2$), the full cost is less than what is estimated above (which is $10N_{\text{out}}$ multiplications and additions) because the computation of the kernel Λ at $(x - k)$ requires only one addition on the whole. Finally, we need $6N_{\text{out}}$ multiplications and $8N_{\text{out}}$ additions in 2D. In the case of shifted linear interpolation, the full cost amounts to a little less than $4N_{\text{in}} + 8N_{\text{out}}$ multiplications and additions.

For comparison purposes, a higher-order interpolation method like Keys' cubic interpolation ($W = 4$ and $n = 3$) would cost $44N_{\text{out}}$, which is, in general, much more than shifted linear interpolation, in particular when $N_{\text{in}} \leq N_{\text{out}}$ (e.g., zoom ins, rotations).

In fact, a great advantage of our shifted method is to allow one to take advantage of existing optimized hard- and software solutions for *standard* piecewise-linear interpolation. This can be done at the mere cost of the prefiltering step. If we consider that a linear interpolator has two inputs (the uniform samples

ClearCorrect Exhibit 1002, Page 1134 of 3373

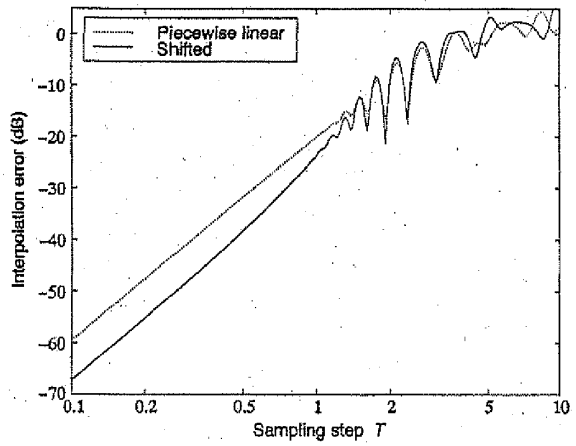


Fig. 7. Interpolation error $\|f(x) - f_T(x)\|_{L^2(R)}$ for $f(x) = e^{-x^2/2}$ using standard linear and optimally shifted linear interpolation. The asymptotic gain is close to 8 dB when the sampling step tends to 0.

f_n and the resampling points x_k) and one output (the resampled values $\sum_n f_n \Lambda(x_k/T - n)$), then shifted linear interpolation can be implemented as shown in Fig. 10.

Morever, it is possible to further reduce the computational cost of the coefficients c_n. To this end, we notice that the value of the optimal shift (15) is close to the fraction 1/5. Thus the use of $\tau = 1/5$ should result in the same pratical performance as $\tau = \tau_{\text{opt}}$. The interesting aspect brought by this value is that the induction (12) becomes

$$c_n = -2^{-2} c_{n-1} + (1 + 2^{-2}) f_n.$$

Hence, c_n can be obtained (and encoded) using finite-precision arithmetics and without a multiplication, since 2^{-2} amounts to a genuine register shift.

IV. Simulations and Practical Results

Although shifted linear interpolation is counterintuitive (in particular, because it dissymmetrizes a method that is naturally symmetric), in practice it does behave better than the nonshifted method, as we will see in this section.

A. Distribution of the Errors

One of the reasons for its better performance is, apparently, that it tends to distribute more evenly the interpolation errors. In fact, standard piecewise-linear interpolation is *systematically biased* within intervals of same convexity. This can be illustrated by performing the linear interpolation of a function $f(x)$ that would be convex in $x \in [n_0 T \leq x \leq n_1 T]$. Here, n_0, n_1 are integers, and T is assumed to be small enough so that at least two samples lie inside this segment. Hence the convexity inequality

$$\forall x \in [n_0 T, n_1 T], \quad f(x) \leq f_T(x).$$

This implies that the interpolation error is always *negative* on a *convex segment*. Similarly, the interpolation error is always *positive* on a *concave segment*. In other words, the interpolation error does not cancel on average over each of these convexity intervals; as a consequence, it adds a—significant—bias to the average square error. As the sampling step T decreases, this behavior gets even more pronounced if we assume that $f(x)$ is roughly bandlimited, because the transitions between convex and concave segments, which have length T, tend to weight less ans less.

This is exemplified in Fig. 6 where we approximate a Gaussian: the two methods have roughly the same dynamics (peak-to-peak values) within each of the convex/concave part of the graph of $f(x)$. However, the standard linear method exhibits a systematic bias within each of these intervals, whereas the shifted method does not.

We have repeated this experiment with several values of the sampling step and we have computed the L^2 interpolation error for each method, the result of which is plotted in Fig. 7. Clearly, the shifted linear method outperforms the linear one, even for large sampling steps like $T = 1$.

B. Rotation Experiments

In order to validate our theory on practical data, we designed a compounded-rotation experiment of the ubiquitous Lena image (512×512 pixels). Let $f(x, y)$ denote this original image. We have access to its samples $\{f(k, l)\}_{k,l \in \mathbb{Z}}$ only. We first interpolate them—in a separable fashion (see Section II.B)—to get $f_T(x, y)$ (here, $T = 1$); then, we rotate f_T by the angle $\theta = (2\pi/15)$, which provides $g(x, y) = f_T(x \cos\theta + y \sin\theta, -x \sin\theta + y \cos\theta)$; finally, we resample $g(x, y)$ on the original uniform grid, which gives the "rotated" image $\{g(k, l)\}_{k,l \in \mathbb{Z}}$. Iterating this procedure 15 times provides an image that has been rotated by $15 \times 24° = 360°$, and that can be readily compared to the original image.

The advantage of such an experiment is that it is likely to amplify the interpolation errors so that it is easier to rank different interpolation methods.

As is apparent from Fig. 8, the standard linear interpolation suffers from blurring, an effect that is avoided in the shifted method which provides much more details. More surprisingly, the shifted method appears to reach a quality that is comparable to that of the higher-order, more costly Keys' cubic interpolation [3], which is the reference high-quality method.

On our website [18], we have put a similar java demo which lets the reader try various rotation angles and shifts τ on several images (256×256 pixels) that differ in their high-frequency content. The results are consistent with those of Fig. 8. Note that, in this web demo, we have chosen to perturbate the rotation center by a noninteger displacement at every iteration, in order to enforce true interpolation for every angle, including for 90° rotations.

C. Zoom Experiments

We have also tested these interpolation methods in a zoom experiment, a test that is more realistic than the compounded-rotation experiment. The drawback is that it is not objective

ClearCorrect Exhibit 1002, Page 1135 of 3373

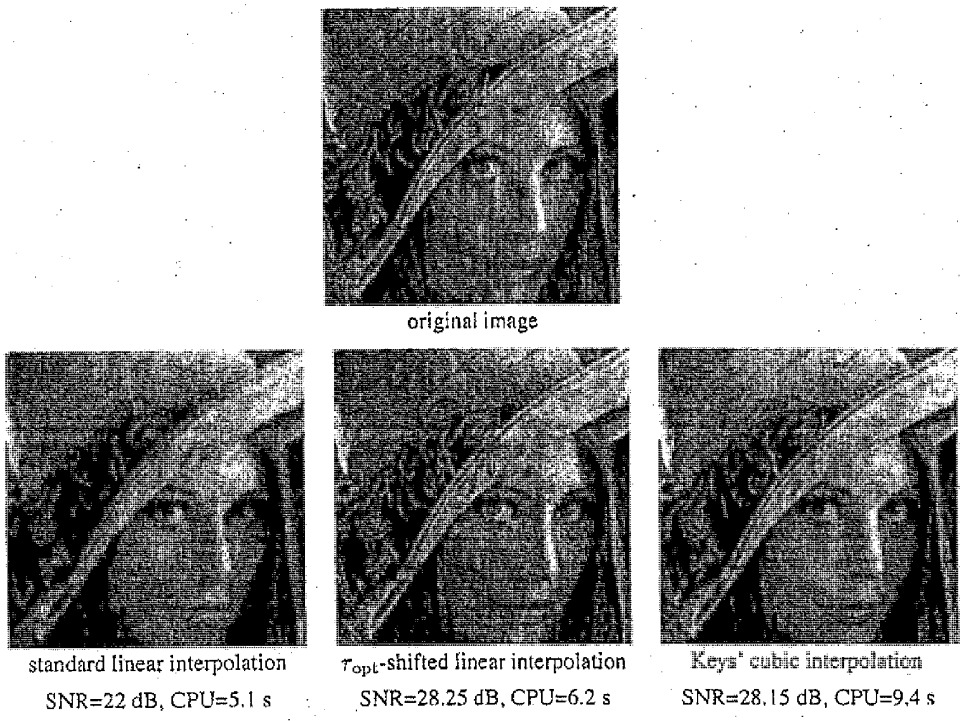


Fig. 8. Fifteen successive rotations by 24° of Lena using standard, shifted-linear, and Keys' interpolations; notice the sharpness of the result of our shifted method, as compared to the two others.

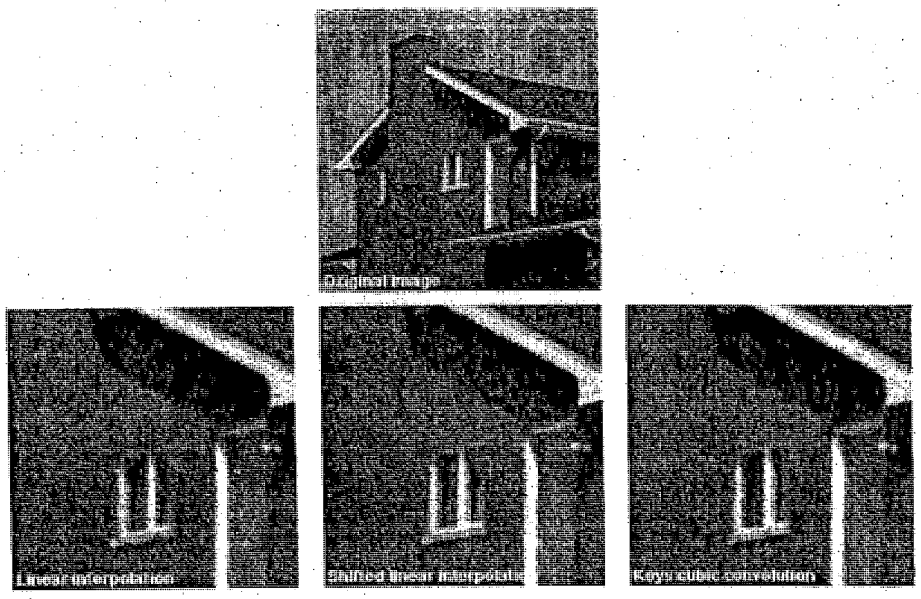


Fig. 9. Magnification by $\sqrt{5}$ of the top image using the two piecewise-linear methods and Keys' cubic convolution method. Once again, notice the sharpness of the result obtained with the optimally shifted method.

anymore, because we cannot compute Signal-to-Noise ratios. We have chosen the "House" image for its texture content (bricks). The result of a magnification by $\sqrt{5}$ is shown in Fig. 9.

ClearCorrect Exhibit 1002, Page 1136 of 3373

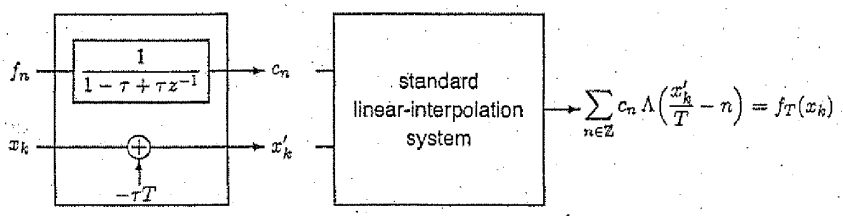


Fig. 10. Proposed implementation of τ-shifted linear interpolation using standard soft/hardware: the data are first preprocessed, which yields modified sample values c_n and shifted sampling points $x'_k = x_k - \tau T$; then, these parameters are fed into a standard linear interpolator which outputs the same result as (10).

Clearly, the standard piecewise-linear method blurs the zoomed image much more than the two other methods. A closer inspection also shows that the result of the shifted linear method is perceptually sharper than the result obtained using Keys' cubic kernel.

V. Conclusion

We have presented a simple, powerful method for improving the performance of standard linear interpolation. We proved its—asymptotic—optimality, and, more generally, we evaluated its performance using approximation-theoretical tools that we had developed in previous papers. Theory and practice are in good agreement, as illustrated by using synthetic data, by compounded-rotation experiments, and by zooming of real-life images.

For efficient implementation, we have proposed to precompute the model coefficients in a preprocessing step (simple recursive filtering), which amounts to replace the initial data by a resampled version at the shifted knot location. With such a set-up, the method can be implemented directly via standard linear interpolation, so that we can readily take advantage of existing software or of specialized hardware solutions.

References

[1] E. H. W. Meijering, "A chronology of interpolation: From ancient astronomy to modern signal and image processing," *Proc. IEEE*, vol. 90, no. 3, pp. 319–342, Mar. 2002.

[2] *Handbook of Medical Imaging, Processing and Analysis*, I. N. Bankman, Ed., Academic, New York, 2000, pp. 393–420. Image interpolation and resampling.

[3] R. G. Keys, "Cubic convolution interpolation for digital image processing," *IEEE Trans. Acoust., Speech, Signal Process.*, vol. 29, pp. 1153–1160, Dec. 1981.

[4] P. Thévenaz, T. Blu, and M. Unser, "Interpolation revisited," *IEEE Trans. Med. Imag.*, vol. 19, pp. 739–758, July 2000.

[5] E. H. W. Meijering, W. J. Niessen, and M. A. Viergever, "Quantitative evaluation of convolution-based methods for medical image interpolation," *Med. Image Anal.*, vol. 5, no. 2, pp. 111–126, June 2001.

[6] T. Lehmann, C. Gönner, and K. Spitzer, "Addendum: B-spline interpolation in medical image processing," *IEEE Trans. Med. Imag.*, vol. 20, pp. 660–665, July 2001.

[7] T. Blu, P. Thévenaz, and M. Unser, "MOMS: Maximal-order interpolation of minimal support," *IEEE Trans. Image Processing*, vol. 10, pp. 1069–1080, July 2001.

[8] M. Unser, A. Aldroubi, and M. Eden, "Enlargement or reduction of digital images with minimum loss of information," *IEEE Trans. Image Processing*, vol. 4, pp. 247–258, Mar. 1995.

[9] A. Muñoz, T. Blu, and M. Unser, "Least-squares image resizing using finite differences," *IEEE Trans. Image Processing*, vol. 10, pp. 1365–1378, Sept. 2001.

[10] G. Plonka, "Optimal shift parameters for periodic spline interpolation," *Numer. Algorithms*, vol. 6, no. 3–4, pp. 481–510, Mar. 1994.

[11] G. Ramponi, "Warped distance for space-variant linear image interpolation," *IEEE Trans. Image Processing*, vol. 8, pp. 629–639, May 1999.

[12] T. Blu and M. Unser, "Quantitative Fourier analysis of approximation techniques: Part I—Interpolators and projectors," *IEEE Trans. Signal Processing*, vol. 47, no. 10, pp. 2783–2795, Oct. 1999.

[13] M. Unser, "Splines: A perfect fit for signal and image processing," *IEEE Signal Process. Mag.*, vol. 16, pp. 22–38, Nov. 1999.

[14] T. Blu and M. Unser, "Approximation error for quasi-interpolators and (multi-) wavelet expansions," *Appl. Comput. Harmon. Anal.*, vol. 6, no. 2, pp. 219–251, Mar. 1999.

[15] G. Strang and G. Fix, "A Fourier analysis of the finite element variational method," in *Constructive Aspects of Functional Analysis*, G. Geymonat, Ed, Rome: Edizioni Cremonese, 1973, pp. 793–840.

[16] M. Unser, "Approximation power of biorthogonal wavelet expansions," *IEEE Trans. Signal Processing*, vol. 44, pp. 519–527, Mar. 1996.

[17] M. Unser and I. Daubechies, "On the approximation power of convolution-based least-squares versus interpolation," *IEEE Trans. Signal Processing*, vol. 45, no. 7, pp. 1697–1711, July 1997.

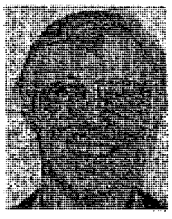
[18] http://bigwww.epfl.ch/demo/jshiftlinear/



Thierry Blu (M'96) was born in Orléans, France, in 1964. He received the "Diplôme d'ingénieur" degree from École Polytechnique, France, in 1986 and from Télécom Paris (ENST), France, in 1988. In 1996, he received the Ph.D. degree in electrical engineering from ENST for a study on iterated rational filterbanks, applied to wideband audio coding. His research interests are (multi)wavelets, multiresolution analysis, multirate filterbanks, approximation and sampling theory, psychoacoustics, optics, and wave propagation.

He is with the Biomedical Imaging Group at the Swiss Federal Institute of Technology (EPFL), Lausanne, Switzerland, on leave from France Télécom National Center for Telecommunications Studies (CNET), Issy-les-Moulineaux, France.

Dr. Blu is currently serving as an Associate Editor for the IEEE TRANSACTIONS ON IMAGE PROCESSING.



Philippe Thévenaz (M'95) was born in 1962 in Lausanne, Switzerland. He graduated from the Lausanne Swiss Federal Institute of Technology (EPFL) in January 1986, with a diploma in microengineering. He then joined the Institute of Microtechnology (IMT) of the University of Neuchâtel, Switzerland, where he worked in the domain of image processing (optical flow) and in the domain of speech processing (speech coding and speaker recognition). He received the Ph.D. degree in June 1993, with a thesis on the use of the linear prediction residue for text-independent speaker recognition.

He then worked as a Visiting Fellow with the Biomedical Engineering and Instrumentation Program, National Institutes of Health (NIH), Bethesda MD, where he developed research interests that include splines and multi-resolution signal representations, geometric image transformations, and biomedical image registration. Since 1998, he has been with the Lausanne Swiss Federal Institute of Technology as First Assistant.

ClearCorrect Exhibit 1002, Page 1137 of 3373



Michael Unser (M'89–SM'94–F'99) received the M.S. (summa cum laude) and Ph.D. degrees in electrical engineering in 1981 and 1984, respectively, from the Swiss Federal Institute of Technology in Lausanne (EPFL), Switzerland.

From 1985 to 1997, he was with the Biomedical Engineering and Instrumentation Program, National Institutes of Health, Bethesda, MD. He is now Professor and Head of the Biomedical Imaging Group at the EPFL. His main research area is biomedical image processing. He has a strong interest in sampling theories, multiresolution algorithms, wavelets, and the use of splines for image processing. He is the author of 100 published journal papers in these areas.

Dr. Unser is Associate Editor-in-Chief for the IEEE TRANSACTIONS ON MEDICAL IMAGING. He has been on the editorial boards of the IEEE TRANSACTIONS ON IMAGE PROCESSING (1992–1995) and IEEE SIGNAL PROCESSING LETTERS (1994–1998). He serves as regular chair for the SPIE conference on wavelets, held annually since 1993. He was general co-chair for the first IEEE International Symposium on Biomedical Imaging (ISBI'2002), Washington, DC, July 7–10, 2002. He received the 1995 best paper award and the 2000 Magazine Award from the IEEE Signal Processing Society.

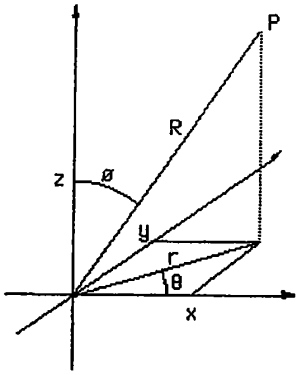
ClearCorrect Exhibit 1002, Page 1138 of 3373

Coordinate System Transformation

Written by Paul Bourke
June 1996

There are three prevalant coordinate systems for describing geometry in 3 space, cartesian, cylindrical, and spherical (polar). They all provide a way of uniquely defining any point in 3D.

The following illustrates the three systems.



Equations for converting between cartesian and cylindrical coordinates

$x = r\cos(\theta)$	$r = \sqrt{x^2 + y^2}$	$\sin(\theta) = y / \sqrt{x^2 + y^2}$
$y = r\sin(\theta)$	$\theta = \arctan(y/x)$	$\cos(\theta) = x / \sqrt{x^2 + y^2}$
$z = z$	$z = z$	

Equations for converting between cylindrical and spherical coordinates

$r = R\sin(\phi)$	$R = \sqrt{r^2 + z^2}$	$\sin(\phi) = r / \sqrt{r^2 + z^2}$
$z = R\cos(\phi)$	$\phi = \arctan(r/z)$	$\cos(\phi) = z / \sqrt{r^2 + z^2}$
$\theta = \theta$	$\theta = \theta$	

Equations for converting between cartesian and spherical coordinates

$x = R\sin(\phi)\cos(\theta)$	$R = \sqrt{x^2 + y^2 + z^2}$
$y = R\sin(\phi)\sin(\theta)$	$\theta = \arctan(y/x)$
$z = R\cos(\phi)$	$\phi = \arctan(\sqrt{x^2 + y^2}\ /z)$

ClearCorrect Exhibit 1002, Page 1139 of 3373

Reprinted from
Vol 7, No 4 December 2001

Seminars in

ORTHODONTICS

P. Lionel Sadowsky, DMD
Editor

Three-Dimensional Diagnosis and Orthodontic Treatment of Complex Malocclusions With the Invisalign Appliance

Robert L. Boyd and Vicki Vlaskalic

W. B. Saunders Company • A Harcourt Health Sciences Company

ClearCorrect Exhibit 1002, Page 1140 of 3373

Three-Dimensional Diagnosis and Orthodontic Treatment of Complex Malocclusions With the Invisalign Appliance

Robert L. Boyd and Vicki Vlaskalic

Recent developments in software technology have made it possible to create a virtual three-dimensional (3D) model of the dental arches from digitally scanned impressions of a patient's dentition. This model may then be manipulated with software to produce stages of tooth movement from the initial malocclusion to the final desired occlusion. A stereolithographic model is made for each stage of tooth movement which is the basis for construction of a series of clear, thin, overlay appliances. These appliances are worn full time by the patient to move the teeth according to the programmed stages of movement. Malocclusions involving mild to moderate crowding and space closure have been proven to be successfully treated with this appliance. The present study shows orthodontic treatment of patients with more complex orthodontic problems, requiring dental expansion, Class II and Class III correction, extraction treatment and correction of overbite. Experience with this appliance, thus far, has demonstrated excellent patient compliance with less discomfort, and improved esthetics and oral hygiene, when compared with fixed orthodontic appliances. Orthodontic treatment with this appliance is a potentially useful alternative approach to fixed appliances for treatment of a variety of malocclusions in patients with fully erupted permanent teeth. (Semin Orthod 2001;7:274-293.) ***Copyright © 2001 by W.B. Saunders Company***

Align Technology, Inc. developed the Invisalign appliance for orthodontic tooth movement in the USA in 1998. This appliance was the first orthodontic treatment method to be based solely on three-dimensional (3D) digital technology. Through the use of computer programs that can manipulate 3D images of individual malocclusions, a series of algorithmic stages is produced which move the teeth in a series of precise movements (0.15-0.25mm), or stages. Stereolithographic models are then constructed for each stage. Clear overlay appliances of 0.030-inch thickness are each worn sequentially by the patient for between 1 to approximately 2 weeks. Because this appliance is clear and removable, it provides an esthetic and hygienic appliance to correct malocclusion.

The concept of moving teeth as a series of planned, individual stages through the use of set-up models and elastic appliances was first described by Kesling in 1945[1] and later by Ponitz,[2] McNamara et al,[3] Sheridan et al,[4] Rinchuse and Rinchuse,[5] and Lindauer and Shoff.[6] The major limitation of these described methods is that only relatively small magnitudes of change are possible because of the technical difficulty of evenly dividing larger overall movement into small, precise stages manually.

The first university-based clinical study of the Invisalign appliance recently reported successful clinical results of subjects with varying degrees of mild to moderate malocclusion severity includ-

From the Department of Orthodontics, School of Dentistry, University of the Pacific, San Francisco, CA.

Supported by a grant from Align Technology, Inc., Santa Clara, CA. Dr. Boyd has a financial interest in Align Technology, Inc.

Address correspondence to Robert L. Boyd, DDS, MEd, Department of Orthodontics, School of Dentistry, University of the Pacific, 2155 Webster Street, Room 130, San Francisco, CA 94115.

Copyright © 2001 by W.B. Saunders Company

1073-8746/01/0704-0008$35.00/0

doi:10.1053/sodo.2001.25414

ClearCorrect Exhibit 1002, Page 1141 of 3373

ing cases of 3 to 6 mm crowding and 3 to 6 mm of space closure.[7] This report contains treatment results for subjects in that study with more complex malocclusions, including extractions. Two additional university clinical studies investigating treatment of complex malocclusions with this appliance are currently underway at the Universities of Florida and Washington.

Treatment Procedures

Case Acceptance

Based on our results thus far, treatment outcome is highly dependent on clinician experience, as well as specific case selection. Because certain tooth movements are more predictable than others with this technique, case selection is at present ultimately determined by the manufacturer, Align Technology, Inc. (Santa Clara, CA).

Computerization of Treatment

Once a diagnosis has been made by the clinician, polyvinylsiloxane (PVS) impressions are made of the arches. It is imperative that this impression is accurate and stable, as it is the basis for the 3D dental arch image that is scanned into the computer. The impression, a wax bite, radiographs, photographs and treatment plan are then sent to the manufacturer. After the clinician's treatment-plan has been computerized, the program may be accessed via the Internet for either acceptance or alteration by the clinician, to this virtual treatment (referred to as ClinCheck). Any modifications to the plan are reviewed by an Align staff orthodontist and are available on-line at the manufacturer's web-site for final approval. A specific file is maintained on the website for all patients each individual clinician has treatment-planned.

Manufacture of Appliances

Once treatment is approved by the clinician, it is sequenced into a series of evenly divided, 0.15 to 0.25 mm movements. This threshold of movement is an important aspect in the development of this appliance because it reflects the maximum amount of activation possible, given the virtual tooth position, modulus of elasticity of the appliance material and thickness. Sterolithographic, resin models are then constructed for each arch, and for each stage of treatment. The clear, 0.030-inch thickness, overlay appliances or "aligners" are subsequently made for each resin model.

One advantage of this appliance system is that the virtual treatment sequence presents an opportunity to the clinician and the patient for evaluation of the proposed post-treatment occlusion on-screen, before treatment commences. Proposed treatments can be evaluated by thorough examination of the entire sequence of tooth movement, from many visual perspectives. Final agreement of this virtual treatment is the most important step for the clinician because once approved, the only way to modify the treatment-plan is to generate a new computer plan.

The virtual treatment plan also provides a powerful communication tool between the clinician and patient. Patients can see their own treatment on the computer at the exact stage they are at as well as visualize the final result and all the steps in between. Patients may also have a copy made of their virtual treatment file, to review their own treatment sequence as their treatment progresses.

Treatment Progress

The initial treatment visit involves inserting the first appliance of the series and carefully checking to be sure the appliances are fully seated (Fig 1). Some patients require attachments to their teeth to facilitate certain movements such as extrusion, extraction space closure or rotation of lower premolars. These attachments are applied using a clear, 0.015- to 0.020-inch thick template and posterior composite restorative material, cured with light activation in a method similar to indirect bonding (Fig 2). Appliances are commonly worn for 7 to 14 days, with progress being patient and movement specific. Patient visits are similar to orthodontic visits with other types of appliances and include evaluation of the occlusion and treatment progress. The actual clinical movement of the teeth should be compared periodically with the specific computer stage to ensure that they match.

After the final appliances are worn, the clinician may determine whether additional stages of treatment are required. If the last appliance fits well, the addition of stages requires no rescan-

ClearCorrect Exhibit 1002, Page 1142 of 3373

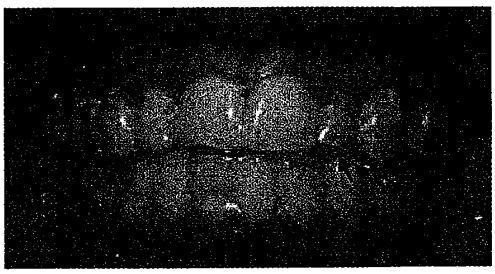


Figure 1. Frontal intraoral view of a patient showing a fully seated appliance. Note that there is a slight space between the upper left lateral incisor, the upper right canine, and the appliance. These spaces are present because the incisal edges had been reduced with a bur after PVS impressions were taken. This could lead to less effective tooth movement for these teeth due to a less than complete fit of the appliance. Significant changes in crown form from stripping, restoration or contouring should always be done whenever possible before the PVS impressions.

ning. However, if the patient's teeth do not fit the appliance, or if the teeth do not simulate the final computer stage, a new PVS impression will be necessary for rescanning.



Figure 3. An appliance showing a lack of seating as evidenced by space between the appliance and the upper central incisors. Extrusion was planned into the virtual computer plan for these teeth, but the teeth did not extrude because attachments were not placed on these teeth to allow the appliance to engage the undercut area of the attachment.

Compliance

Compliance has been excellent in most cases. This may be due to our case selection of motivated, adult patients, or due to the formation of a slight posterior open bite in the first few weeks of wear. The open bite is caused by slight poste-

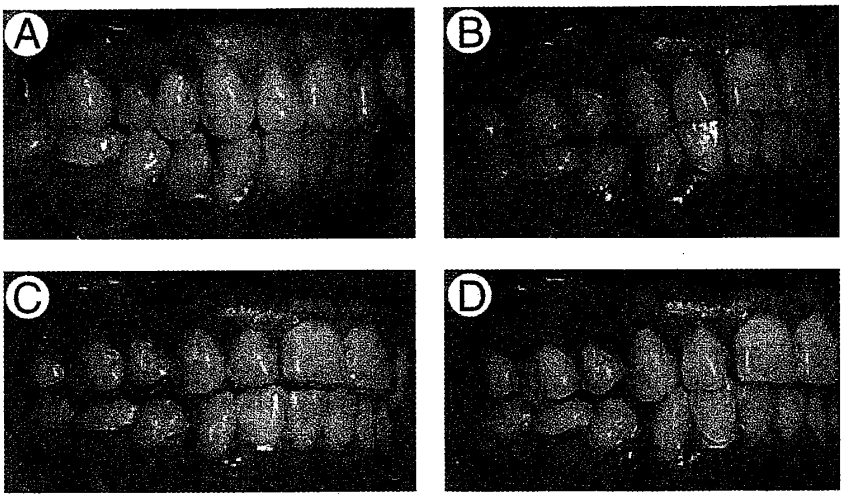


Figure 2. Intraoral views of patient who will have four premolars extracted because of crowding and protrusion (A). The patient at pretreatment (B), at 10 months of active treatment (C), and after 15 months treatment (D). Attachments to the upper canine and second premolar have been bonded with composite restorative material. Panel C illustrates patient with the appliance in place showing that the appliance encircles or engages the attachment. These attachments provide a method for controlling tooth movement by keeping the appliance in place so that the tooth movement does not unseat the appliance and to hold the tooth upright for extraction space closure. Note that on the day of delivery of the appliance, in this case, that it is not fully seated on the second premolar attachment. It is important to tell the patient not to progress to the next appliance until the appliance completely covers the tooth.

ClearCorrect Exhibit 1002, Page 1143 of 3373

rior tooth intrusion due to the thickness of the appliance increasing vertical dimension (approximately 0.06 inch). Patients generally prefer the occlusal pattern of the more even contacts between their teeth when the appliances are in place, rather than the heavier anterior contact when the appliances are removed.

An early finding was that patients who progressed too quickly (usually less than 1 week per appliance), may present with appliances that did not fit the teeth for the indicated stage of treatment (Fig 3). Thus it is important that clinicians monitor patients carefully, especially during the first four to five stages, and not dispense more than two appliances at each of the first two visits. Patients should be warned of the risks of progressing too quickly, which may cause the appliances to not fit properly and lead to increased laboratory costs and time delays.

Discomfort and Speech Effects

Subjective evaluation of patient discomfort during treatment has demonstrated generally less discomfort than seen with traditional fixed appliances. This is most likely because the magnitude of the tooth movements are only 0.2 mm, on average. In addition, speech problems have rarely been a problem, particularly after the first week of treatment.

Problems During Treatment

Any discrepancy between the actual clinical appearance of the occlusion and the virtual treatment sequence program indicates that treatment should be fully reviewed. Possible reasons for this discrepancy are that the patient has lost, or is not wearing their appliances for a sufficient time (at least 20 hours per day), or that the appliances have not been fully seated. This can usually be corrected by remaining in a specific appliance for more than 20 hours per day for 2 weeks or more to allow the appliance to recapture tooth position.

For maximum treatment efficiency, it should be stressed to patients at the outset that if they lose an appliance, they should progress to the next stage if that stage seats fully, or return to the previous stage. For this reason, appliances should not be discarded until the patients are at least two stages ahead. If the patient's occlusion cannot be recaptured by an appliance, it may be useful to use the computer program to identify which stage visually matches the clinical appearance most closely, and return to that particular stage. If this fails, the patient should be placed in clear, overlay retainers and another PVS impression taken for rescanning, with a new treatment plan devised.

If bonded attachments are lost during treatment, this may hinder treatment progress. Patients should be informed to report this as soon as possible to have them replaced. If successive appliances are worn before the attachment is replaced, the position of the attachment on the tooth surface is altered and mechanical advantage is lost.

If the appliances are fully seated and the final result is not ideal, it may be attributed to two possibilities. The first is that a tooth position discrepancy between the desired occlusal result and the plan that was approved by the clinician exists. Scrutiny of the initial virtual treatment plan reduces this problem. The second is that the magnitude of small tooth movements may lie below the activation range of the appliance material, so that final tooth position is not expressed. For these reasons, overcorrections of certain movements such as rotations, torque and bite opening should be incorporated into the occlusal goals before final approval of the virtual plan of treatment. Patients who have complex malocclusions should understand that it may be necessary to place fixed appliances for several months either before or after use of this appliance, to fulfill treatment goals.

To date, 3 patients of the 40 enrolled in this feasibility study have required fixed appliances to complete treatment. Further clinical study will help to reveal the true limits of this appliance, with regard to particular tooth movement ability. This information should assist decisions regarding the particular categories of malocclusion that may be treated more efficiently with combined use of this appliance with fixed appliances.

Tooth Movement

The biomechanics involved with this appliance have not been reported in the literature. They differ from those described for traditional fixed appliances because of the greater surface area of force application to the tooth. Bodily tooth

ClearCorrect Exhibit 1002, Page 1144 of 3373

movement is possible, particularly if the entire crown is tightly held with no space between the appliance and the tooth. The activation in the appliance can then move the tooth bodily because the tooth is a rigid body, and at least two points of contact are in play. However, for the appliance to fit tightly, it may be necessary to add attachments. The forces involved for the 0.02 mm activations are most likely of a light, continuous nature due to the elastic properties of the appliance and the small magnitude of individual activation at each stage. The effects of tooth movement can only be described clinically at this point because of the lack of scientific data on biomechanical principles involved with tooth movement created by this appliance. Examples of various types of treatment are presented.

Treatment of Crowding

Buccal expansion, in the range of 2 to 4 mm, can be achieved with this appliance to provide space for crowded anterior teeth or to change arch form (Figs 4, 5). It is likely that this expansion is largely of a tipping nature, however, if bodily expansion is required, this may be specified (usually as an overcorrection) as the goal for treatment into the computer plan initially.

This appliance, as is true of most removable appliances, is relatively efficient at tipping movements. Patients who usually progress most rapidly are those that have required primarily tipping of their crowns. Anterior tooth alignment achieved by proclining of anterior teeth (Fig 4) is predictably accomplished, provided appropriate overcorrection is done for accompanying rotations or overbite corrections.

Treatment of crowding with premolar extraction is shown in Figure 6, where the upper left canine was initially positioned labially which responded well to first premolar extraction and primarily a tipping movement of the canine crown back into the arch. Usually attachments are required for extraction treatment in order to bodily move teeth into the extraction space.

Deep Overbite Correction

Correction of deep overbite is one of the most predictable movements possible with this appliance, provided attachments are placed for retention. Figure 7A shows a 33-year-old man who had orthodontic treatment for a Class II Division 2, deep overbite with crowding of incisors. He had previous orthodontic treatment as an adolescent with extraction of four first premolars. Orthodontic treatment was performed due to his chief complaint of continued tooth movement since he had stopped wearing his retainers. Because of severe lingual inclination of the maxillary incisor crowns, labial movement was necessary. Treatment with this appliance corrected the incisor crowding and also decreased the overbite by more than 4 mm. The cephalometric superimpositions show this correction was achieved primarily through labial tipping and intrusion of anterior teeth. Comparison of pretreatment and posttreatment panoramic radiographs showed no signs of root resorption or root malalignment.

Another example of intrusion is demonstrated by the posterior teeth which usually intrude in the first 3 months of treatment because of the double layer of material (total thickness 0.06 inch) between the posterior teeth. This example of intrusion is easily corrected at the end of treatment by cutting away the appliance material distal to the premolars (Fig 8) and allowing re-eruption to occur, typically within 2 to 4 weeks.

Molar Distalization

One of the most interesting possibilities for treatment with this appliance is the ability to distalize molars, followed by premolars and canines, with the anchorage segment involving remaining teeth. Figure 8 shows a patient with Class II Division 2, deep overbite with moderate upper and mild lower arch crowding. She was initially presented a treatment plan of upper premolar extraction treatment with fixed appliances. However, because she did not want extraction treatment, a treatment plan with this appliance was selected which involved distalization of maxillary molars, followed by premolars and canines, which provided space to align the incisors. (Fig 8) shows the progressive movements of first molars distally, as evidenced by spaces opening mesial to the teeth and that the distance increased from the palatal rugae by more than 3 mm. Cephalometric superimposition corroborates that bilateral distal movement of the maxillary posterior teeth was accom-

ClearCorrect Exhibit 1002, Page 1145 of 3373

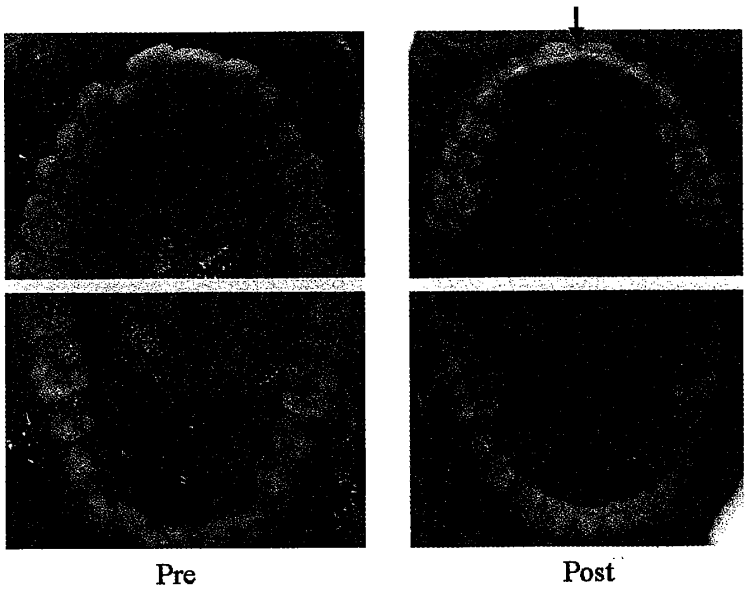


Figure 4. Shows a crowded maxillary arch that was treated with labial tipping of upper and lower anterior teeth and incisor rotation. Note that the rotations were not fully corrected (see arrows). Overcorrection of the virtual treatment for this type of treatment is necessary to completely correct rotated incisors.

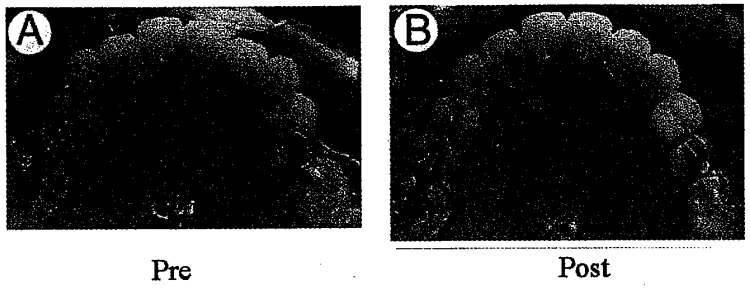


Figure 5. Shows a crowded maxillary arch (A) that was treated by premolar expansion and incisor rotations (B). Treatment time was 8 months.

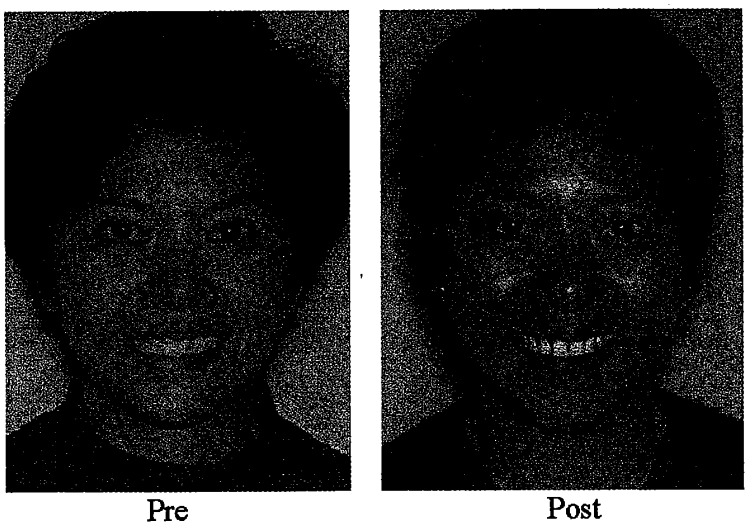


Figure 6. Shows the pre- (A) and posttreatment (B) facial and intraoral views of a 31-year-old woman with an ectopic maxillary left canine that is tipped labially. Treatment involved extraction of the maxillary left first premolar and primarily a distal tipping movement of the canine. No attachments were required as the movement did not require bodily tooth movement.

ClearCorrect Exhibit 1002, Page 1146 of 3373

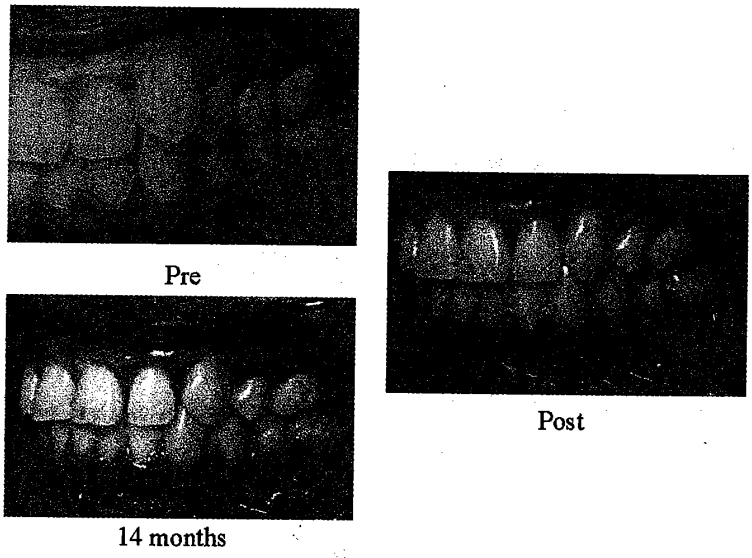


Figure 6. (cont'd) No attachments were required as the movement did not require bodily tooth movement.

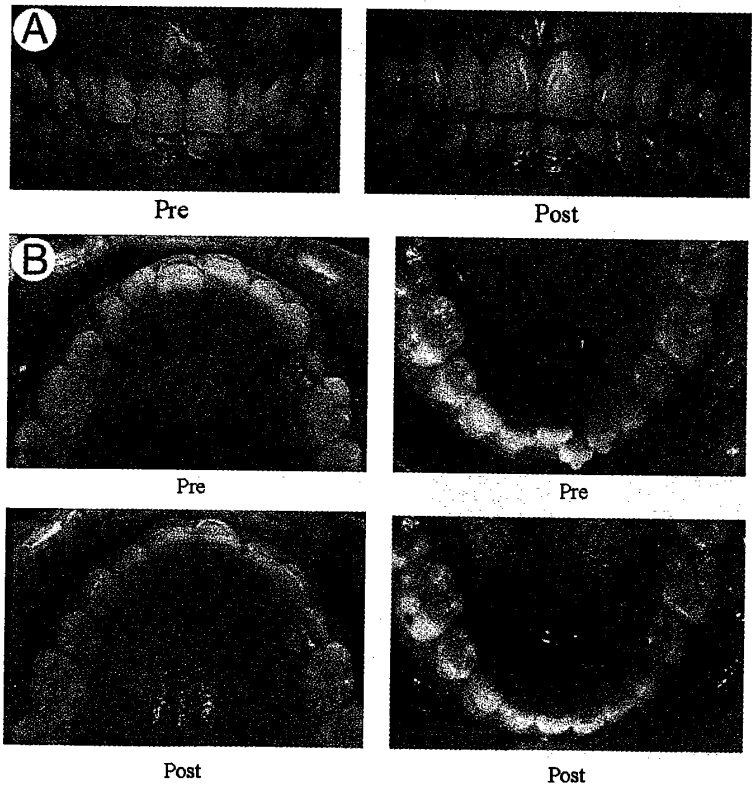
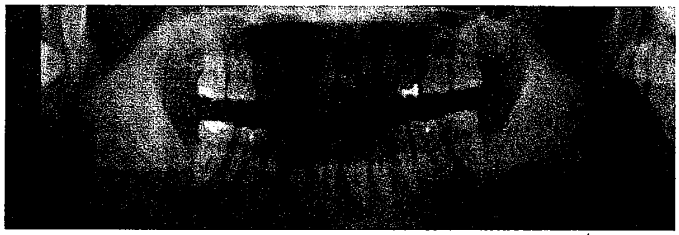


Figure 7. Pre- and post-treatment intraoral views of a 33-year-old male patient with a Class II, Division 2 deep overbite, lingually inclined incisors and anterior crowding. This patient's chief complaint was that his previous orthodontic treatment as an adolescent had been gradually "shifting" since he had stopped wearing retainers (A). Post-treatment intraoral views and cephalometric superimpositions showed correction of the deep overbite and correction of the lingually inclined incisors (B-D). Ideally, additional over correction of the upper incisor long axis should have been achieved.



Pre



Post

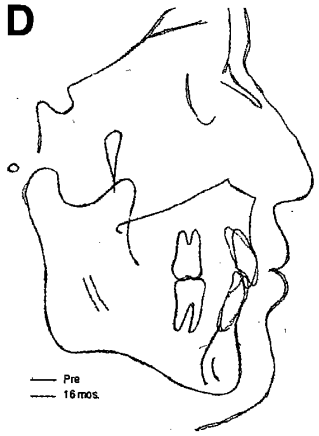
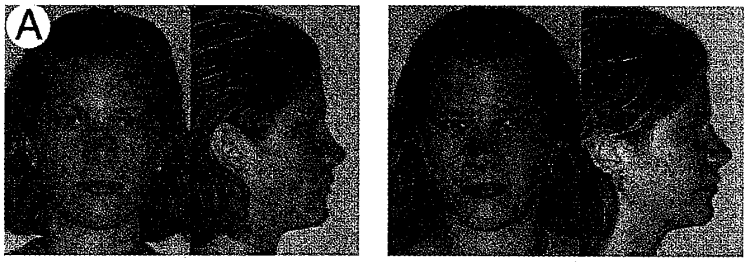


Figure 7. (cont'd)



Pre Post



Pre Post

Figure 8. Show pre-, and post-treatment facial views of a 24-year old woman with a Class II, Division 2, deep overbite and upper moderate and lower mild crowding (A-B). Show pre-, 8 months, post-, and one year post-treatment. The midlines were corrected at the end of active treatment of 13 months by placing light elastics from the bottom on the upper right canine areas to the molar area of the lower left side (C-E). Shows when treatment was complete, the appliances were cut distal to the premolars to allow the molars to erupt into full occlusion (F). Cephalometric superimposition showed movement of molars distally, intrusion of upper and lower incisors, and 4 mm of overbite correction. Cephalometric superimpositions at one year post-treatment showed good stability of this result with no opening of the mandibular plane angle (I). Shows the distance from the rugae that the posterior teeth were distalized (G). Shows the lower occlusal views (H).

ClearCorrect Exhibit 1002, Page 1148 of 3373

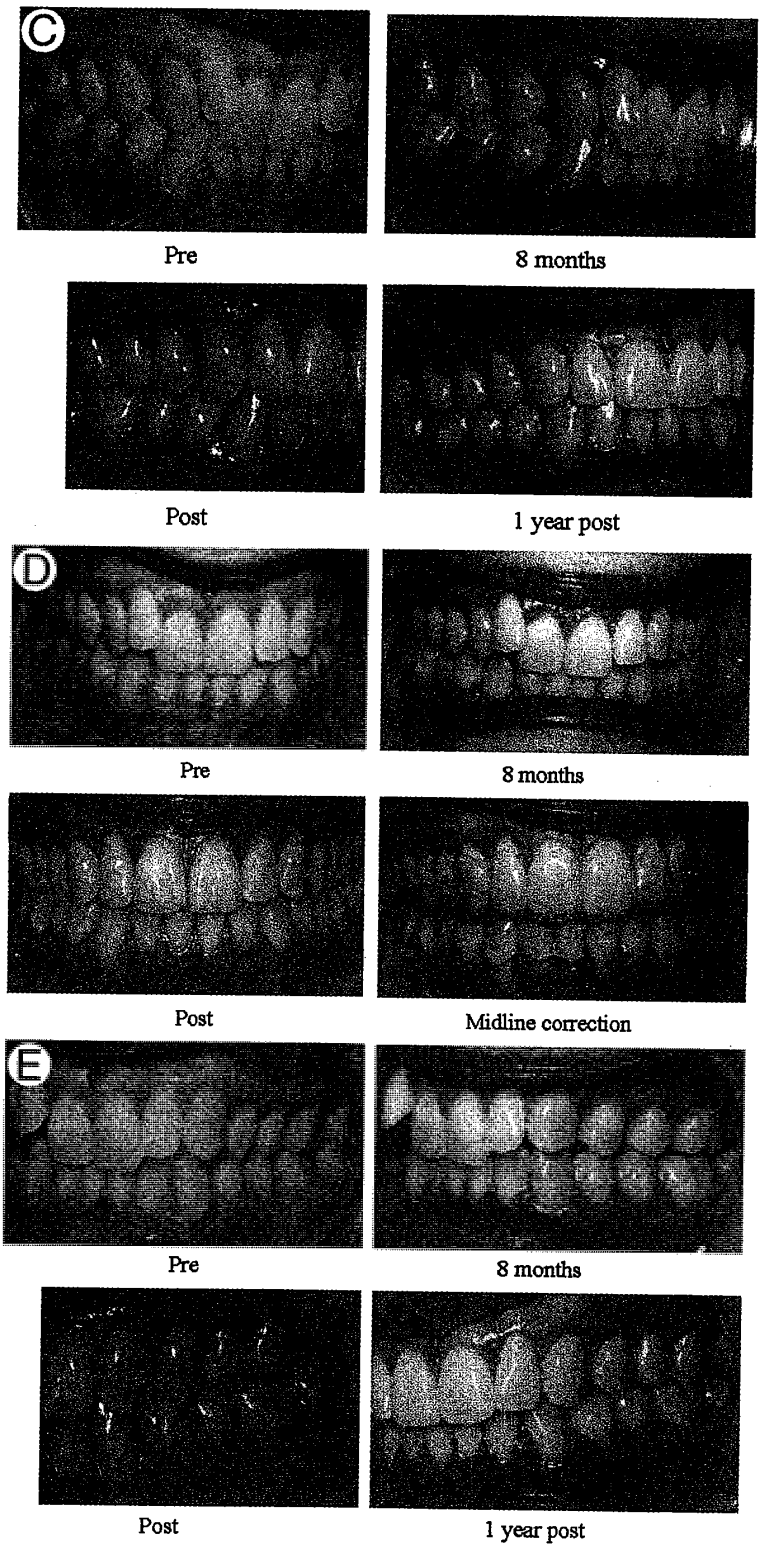


Figure 8. (cont'd)

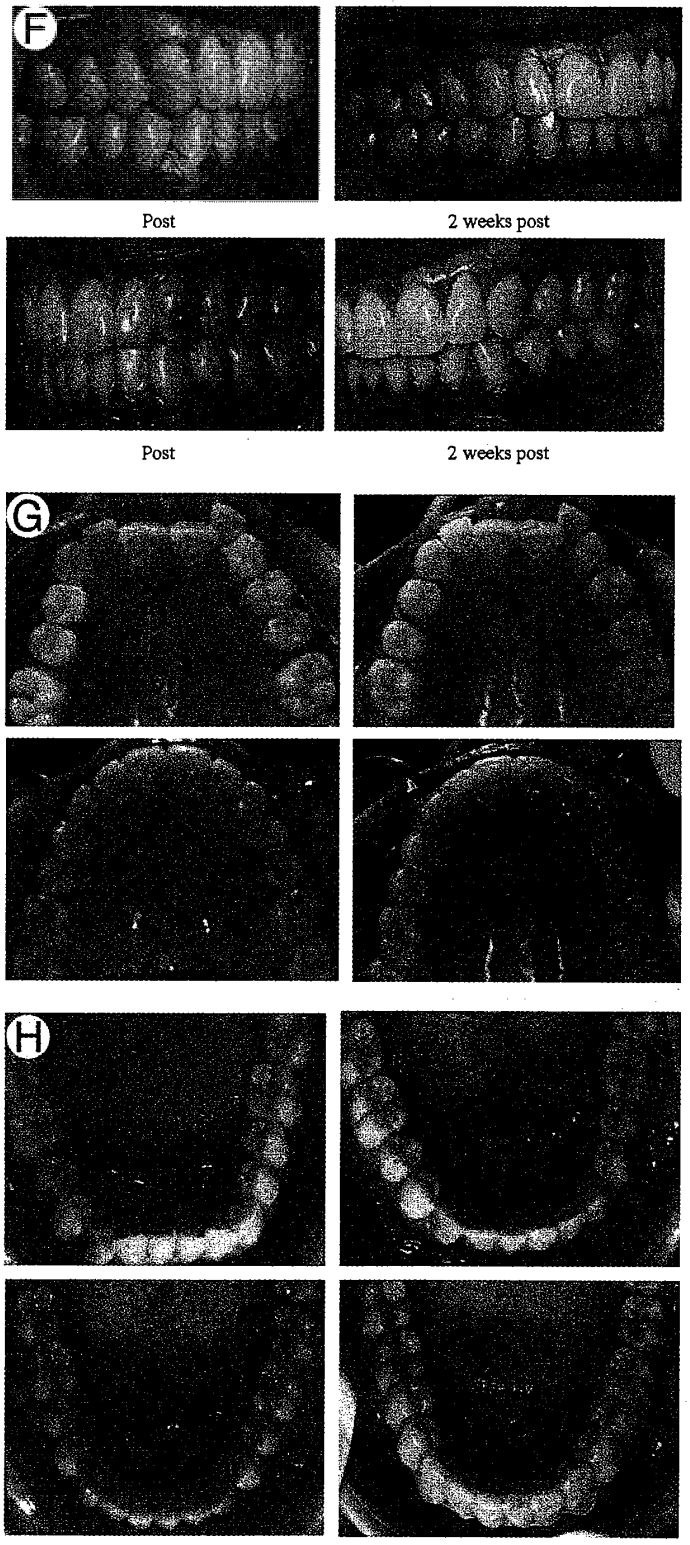


Figure 8. (cont'd)

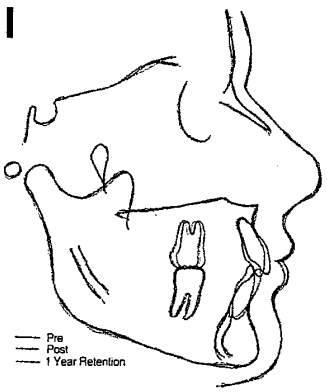
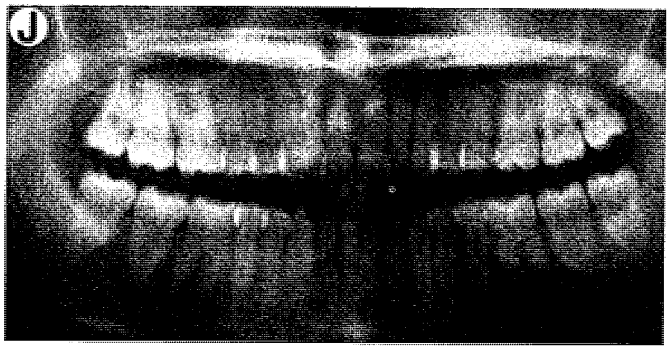
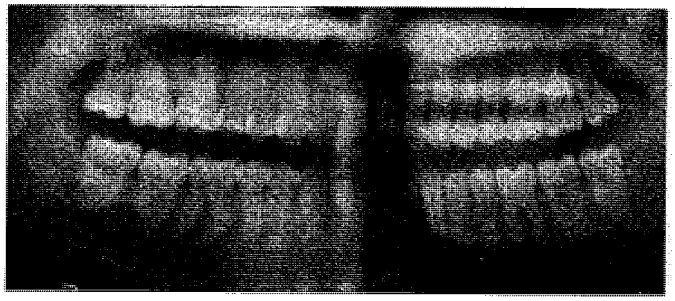


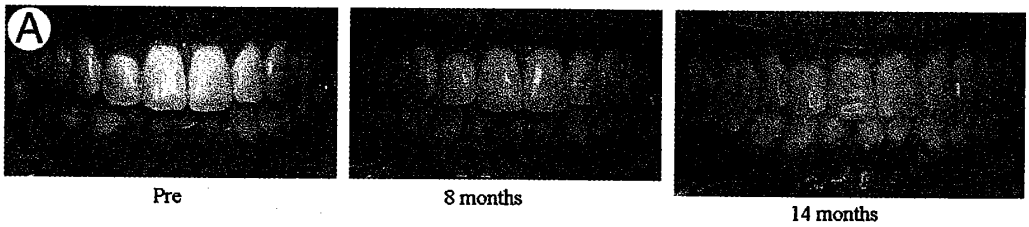
Figure 8. (cont'd)



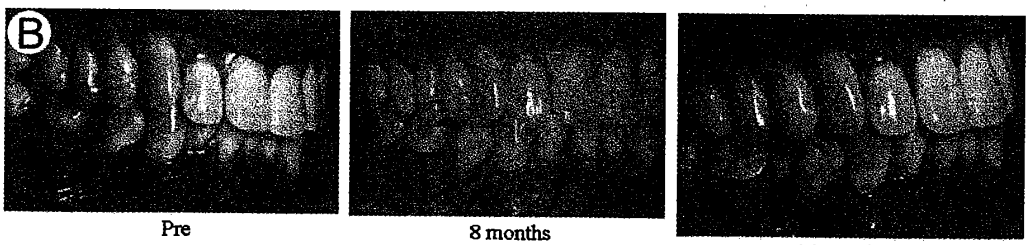
Pre



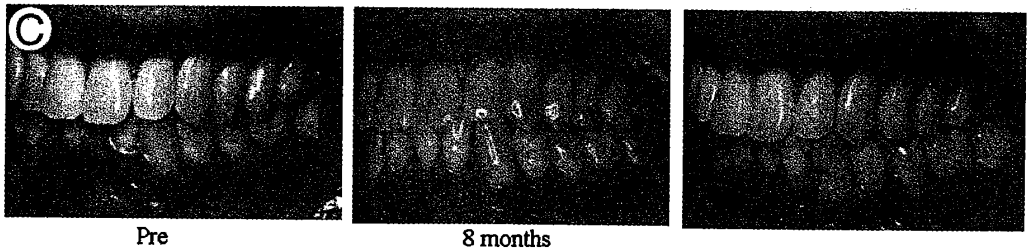
Post



Pre 8 months 14 months



Pre 8 months 14 months



Pre 8 months 14 months

plished. Slight intrusion of the maxillary incisors, bite opening and proclination of incisors was also noted in the superimposition. No opening of the mandibular plane was evident at posttreatment or 1 year later. Comparison of the pretreatment and posttreatment panoramic radiograph did not reveal any increased tipping of molars after this distal movement or root resorption (Fig 8).

Premolar Extraction

Early results with this appliance caused teeth to tip into extraction spaces, especially if there were short clinical crowns and more than 2 mm of mesial movement of posterior teeth required. However, the use of 5-mm long, rectangular, vertical attachments corrected this limitation (Fig 2). Due to the success of molar distalization in a limited number of patients, end on anterior-posterior relationships of the buccal segments would be treated with this approach in less treatment time than for an extraction approach. Further study is needed to determine if these movements can predictably achieve bodily distalization while maintaining anterior tooth position.

Mandibular Incisor Extraction

Mandibular incisor extraction cases have shown acceptable results and have been part of the manufacturer's acceptance protocol for more than 2 years. Attachments are usually used to control any tipping movements (Fig 9).

Ectopically Positioned Teeth

Another difficult type of tooth movement to achieve with this appliance initially was in the movement of severely, ectopically positioned teeth. The use of more flexible materials and extension of material further gingivally was necessary to complete this type of treatment (Fig 9). Ectopically positioned teeth beyond the degree of this lower right second premolar should be corrected first, at lease partially, with fixed appliances.

Rotation

Rotation of teeth with rounded anatomy, such as lower premolars, has been challenging to accomplish with this appliance. The addition of attachments on the labial or lingual surfaces (or both) is required for these teeth to be rotated (Fig 10). Rotated molars may also be treated in this manner. If the rotation is more than 45° (Fig 11), fixed appliances may be employed initially to reduce the magnitude of the rotation or used after other movements are completed with this appliance. Incisors usually rotate more easily with this appliance with no need for attachments. Canines, however, are more difficult to rotate and may require attachments.

Extrusion

Extrusion has proven to be one of the most difficult movements to achieve with this appliance. Bonded attachments are necessary to assist movement by securing an undercut area. Figure 12 shows a case where incisor extrusion has been achieved with the use of attachments.

Open Bite Treatment

One of the most successful types of treatment, with this appliance has been in the correction of mild to moderate open bite malocclusion. For the patient in (Fig 13), cephalometric superimpositions showed that the bite closed even though there were no computer programmed extrusive movements on the anterior teeth. The superimpostions showed intrusion of the molars with counter clockwise rotation of the mandible. Although further study is required to determine

Figure 9. Pre-, 8 months, 14 months, and posttreatment facial and intraoral views of a 24-year-old male with Class III, bimaxillary protrusion, moderate lower arch crowding, deep overbite, and an ectopically positioned lower right second premolar (A-F). Because the lower right molars had drifted mesially (most likely from the early loss of a primary second molar), and mandibular excess tooth mass was present, a decision was made to remove the lower right labially positioned central incisor and distalize the right mandibular molars slightly. Fourteen months of active treatment showed significant bite opening and space for the ectopically positioned lower right second premolar. To bring in the ectoptically positioned second premolar, it was necessary to extend the appliance material further gingivally and use more resilient material to completely cover this tooth (F).

ClearCorrect Exhibit 1002, Page 1152 of 3373

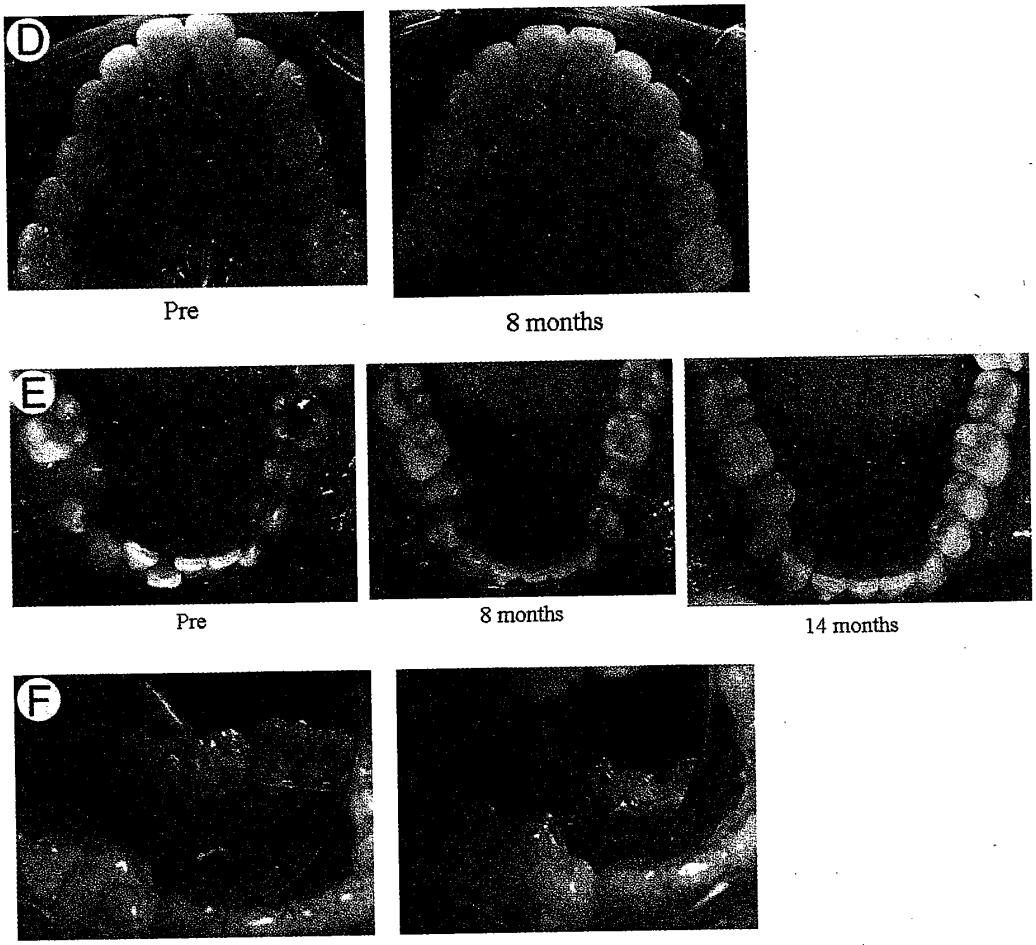


Figure 9. (cont'd)

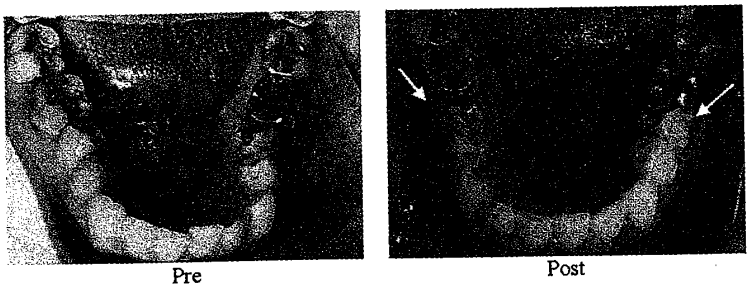


Figure 10. Shows the use of small, bonded attachments to allow the appliance to engage rotated lower premolars (see arrows). These attachments were necessary because these teeth are rounded in contour which makes the application of force difficult.

ClearCorrect Exhibit 1002, Page 1153 of 3373

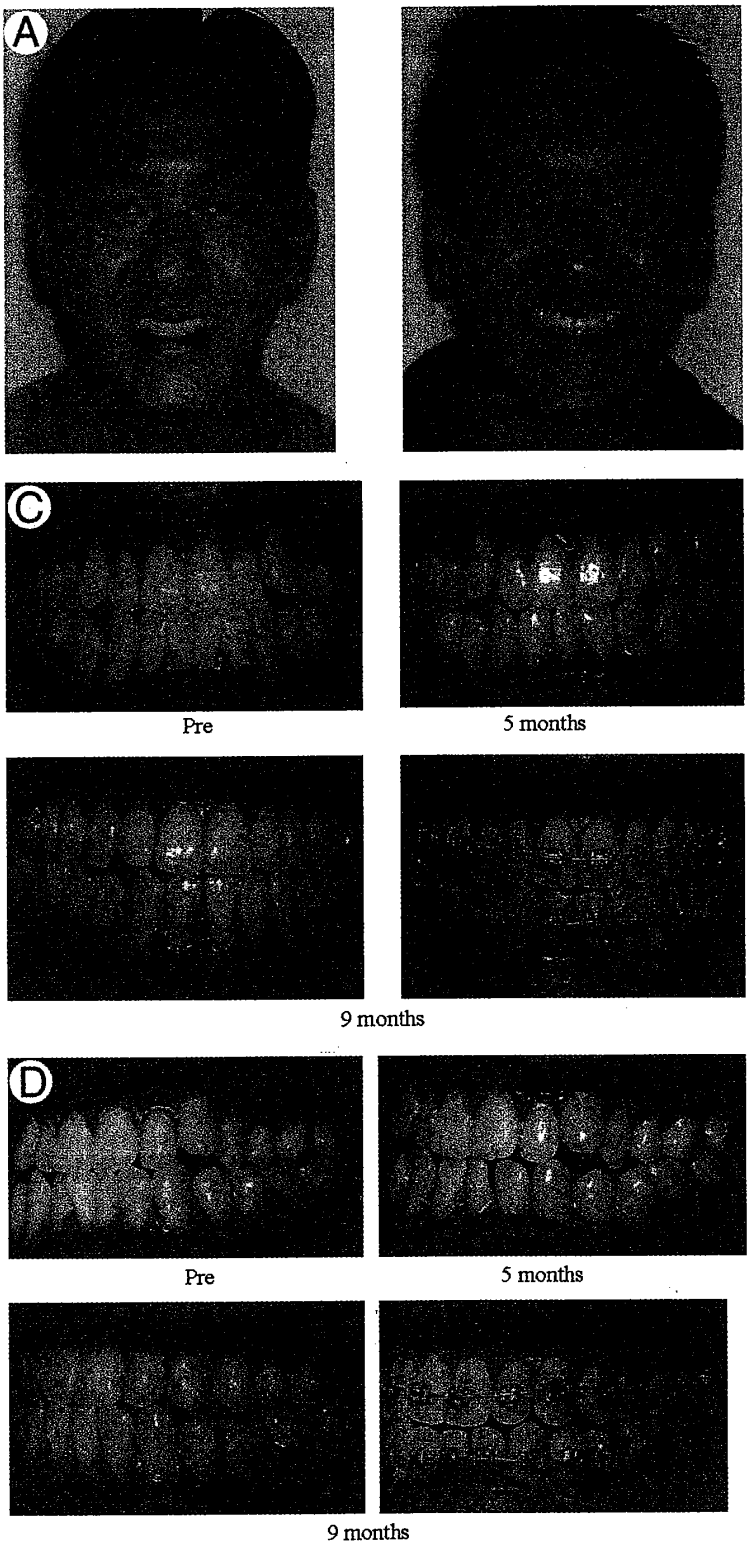


Figure 11. A 24-year-old male with a Class III malocclusion with moderate lower arch crowding and good facial balance (A-F). A decision was made to extract the lower right central incisor and introduce dental compensations to mask the mild skeletal problem. Unfortunately, the severely rotated lower left second premolar could not be successfully rotated with this appliance. Fixed appliances were placed at 9 months on the patient to complete treatment (C-D) (Please see page 288 for 11B).

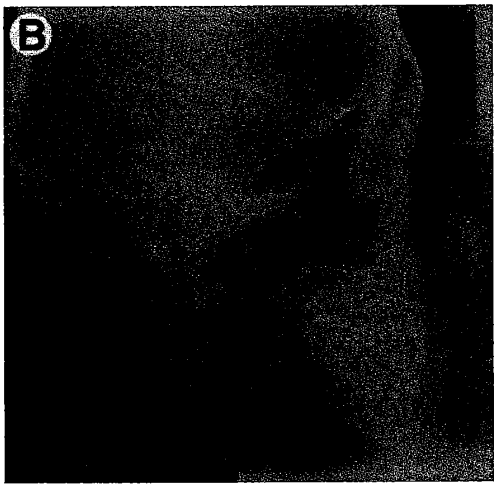


Figure 11. (cont'd)

the exact nature of this effect, the results thus far are promising for cases with an increased vertical jaw relationship and open bite.

Periodontal Implications

Subjects within this study who had good oral hygiene standards appeared to continue to maintain that level during treatment. Investigation is necessary to determine exactly how well patients' periodontal health is maintained during treatment when compared with fixed appliances. A strong motivating factor for many patients to have excellent oral hygiene during treatment is to prevent build up of plaque on the inside of their appliances, thus avoiding unpleasant odor and slight discoloration of the appliance. As plaque accumulates inside the appliance, it becomes more opaque, and therefore less esthetic.

To determine if the lower plaque level associated with this appliance would be advantageous for patients who were susceptible to periodontal disease, several young adult patients who had previous treatment for periodontal disease with significant bone loss were treated with this appliance. Usually younger patients who have significant bone loss are considered at greater risk for future periodontal breakdown with fixed appliances.[8] Figure 14 shows a 23-year-old woman who had severe, generalized bone loss, and who was treated with this appliance. Evaluation at 3-month and 6-month periodontal maintenance visits revealed no additional increase in pocket depth or signs of inflammation. The anterior crowns were initially reduced in height to decrease the crown to root ratio and to reduce mobility. The anterior crowns were also initially reduced in width to decrease the presence of dark triangles between the teeth after incisor alignment. The upper right molars were distalized to provide a Class I buccal occlusion and space to relieve upper anterior crowding.

Examination of intraoral radiographs during and after treatment of study patients showed no signs of root resorption in any of the patients. A controlled clinical study that uses standardized periapical radiographs[9-11] will be needed to determine the extent of root resorption with this appliance.



Figure 14. This 23-year-old patient had generalized severe bone loss. Six months of orthodontic treatment with smaller magnitudes of tooth movements showed excellent progress. At the 3- and 6-month periodontal maintenance visits there were no increases in pocket depth or bleeding on probing noted (A-C).

ClearCorrect Exhibit 1002, Page 1155 of 3373

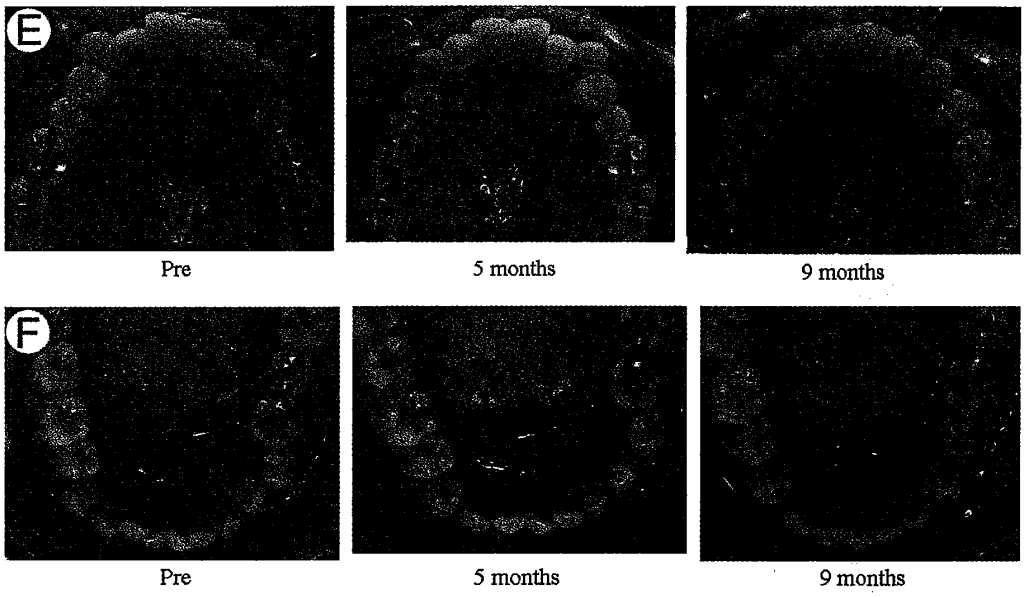


Figure 11. (cont'd)

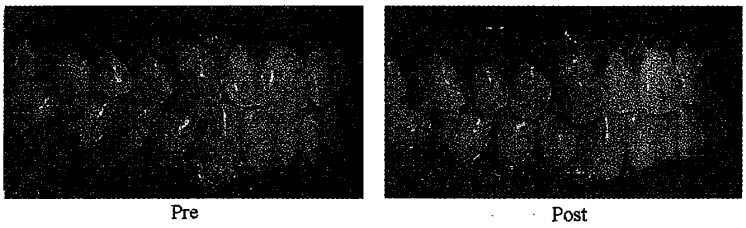


Figure 12. Show pre and postextrusion of anterior teeth with attachments placed at the gingival third for a purchase point.

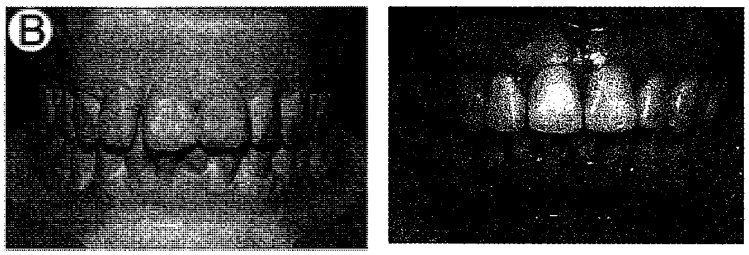


Figure 14. (cont'd)

All patients had routine dental care completed before starting orthodontic treatment and were requested to visit their general dentist at regular 6-month intervals during treatment. This was important because if a large restoration was needed during treatment, the appliances would potentially not fit and a new set of PVS impressions would be needed. No patients developed any areas of decalcification during the treatment.

ClearCorrect Exhibit 1002, Page 1156 of 3373

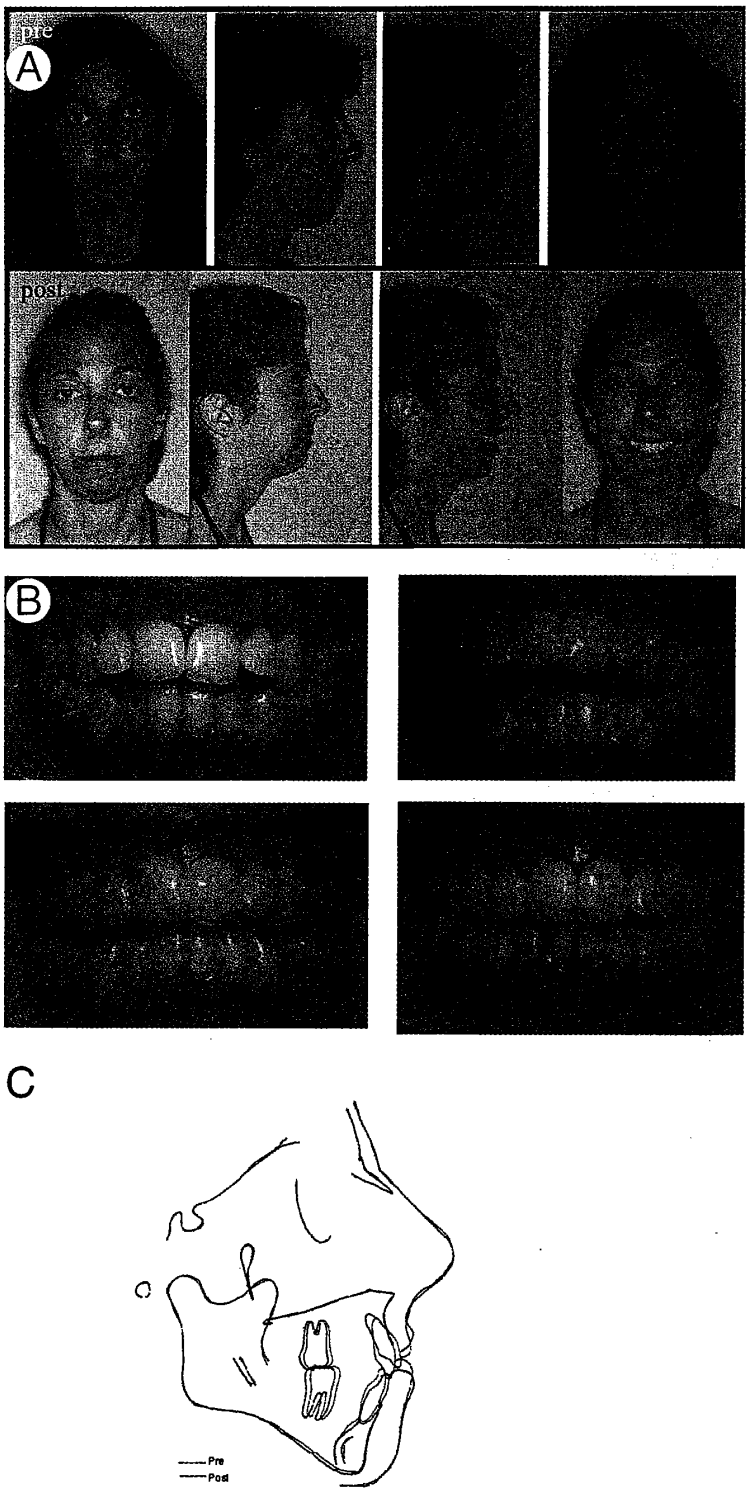


Figure 13. This 32-year-old female had a Class II Division 1 malocclusion with and increased vertical jaw relationship (long-face syndrome) (A). Panel B shows that this appliance intruded the molars which allowed the mandible to rotate counter clockwise. Cephalometric superimpositions showed that incisors were retracted into extraction spaces with some extrusion from these tipping movements (C).

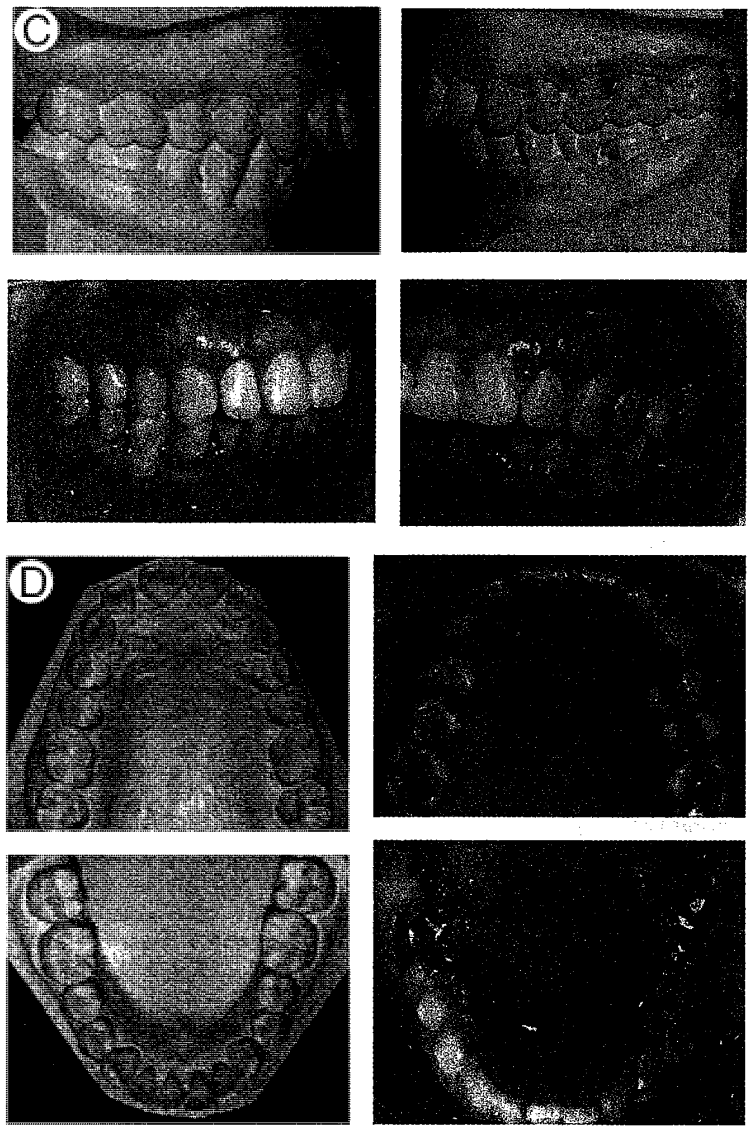


Figure 14. (cont'd)

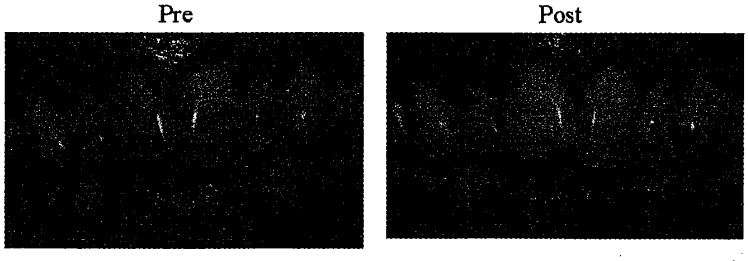


Figure 15. Pre and postbleaching views of a 54-year-old male who used his first appliance to bleach his teeth over five daily, 1-hour sessions with a zero clearance 18% type of carbonide peroxide, viscous gel bleaching agent.

Retention and Stability

At present, retention protocol with this appliance is similar to that used with other types of appliances. Usually, the final appliance or a thicker version (0.04 inch) of it is worn full-time for 6 months, followed by nighttime wear indefinitely. As with any orthodontic appliance, additional research is required to determine whether alternate protocols are superior in terms of post-treatment stability. Stability has not been studied, as this appliance has only recently been introduced.

Advantages

The greatest advantage of this appliance compared to fixed orthodontic appliances is the improved esthetics and ability to remove the appliance. For these reasons, patients to whom appearance and public speaking are a priority are good candidates for its use.

Once tooth movement has begun, treatment time with this appliance is usually equivalent to traditional fixed appliances. However, this aspect of treatment requires further investigation.

Another advantage is that teeth can be bleached with the appliance at the beginning of, and during treatment (Fig 15).

The current popularity of "esthetic restorative dentistry" in which otherwise healthy but rotated teeth may be prepared for porcelain veneers may be reduced by dentists informing their patients that there is an esthetic alternative to fixed appliances which may be less costly and damaging to the teeth.

Limitations

All permanent teeth should be fully erupted for treatment using this appliance, as it is difficult to achieve retention of the appliance on short clinical crowns. The treatment procedures do not allow for continued eruption of teeth, or significant dental arch changes during growth that may occur during the mixed dentition phase. There is currently no capability to incorporate basal orthopedic change with this appliance system, thus restricting it to malocclusions requiring purely dental movement.

A benefit of the removable nature of the appliance is that routine dental care in terms of routine examinations and prophylasix may continue unimpaired. However, due to the fact that the surface anatomy of the teeth cannot undergo change during treatment, major restorative work should be performed before the commencement of treatment.

Unlike fixed or other types of removable appliances, the treatment plan cannot be changed once the appliance series has begun. If change in treatment goals is desired, the current series may be completed and a new plan and appliances made, or the current series may be stopped. Either scenario, however, will lead to increased cost for treatment and increased treatment time.

Currently, only crown position is displayed on the computer program. Because the clinical appearance of crown inclination is not always predictive of root inclination, the potential exists for a virtual treatment to be approved, in which crown position appears optimal but root position is not ideal. However, upcoming advances in the design of patient imaging and software programs make it possible to include virtual roots onto the software application.

Recently the ability to record an eccentric jaw position (centric occlusion not coincident with centric relation) has been made possible by having the clinician provide a wax bite that records this discrepancy. The technician then sets the models in the computer to this bite relationship. Sending mounted models to the lab is an even more effective way to provide this information for the technician. The computer software also has the ability to have the rotational path of closure programmed into the virtual plan which is determined from the mounted models and lateral cephalometric radiograph.

Another limitation of the current appliance is the inability to integrate hard and soft tissues of the head into the computer treatment. Thus, the clinician has no direct indication of where teeth are in relation to basal bone or in relation to the lips or other soft tissues of the head. In a previous article in this journal by Baumrind, Boyd and Curry, a prototype for a 3D system that positions the scanned in 3D surface map of the teeth used for this appliance in real space with frontal and lateral stereo cephalometric radiographs is described. This system also places a 3D surface map of the face in its exact relationship to the skeletal structures by overlaying the face on radiopaque markers seen in both the 3D-face map and the stereo x-rays. With a volumetrically

ClearCorrect Exhibit 1002, Page 1159 of 3373

correct 3D digital model of the hard tissues of the head which is now available (the Newtom),[12] it will be possible to include all of the skeletal structures of the head into this system. With this "virtual patient" 3D diagnostic system the clinician will be able to overcome the shortcomings of the present software which has only the crowns of the teeth available to the clinician.

Generally, the cost to patients is greater for this appliance than fixed appliances. This is due to the cost of the technology used to scan in models and to develop a virtual treatment, in addition to manufacturing, packaging, and shipping costs for as many as 40 to 80 appliances. However, doctor and chair time, instrument and sterilization costs are significantly lower when compared with other esthetic orthodontic options, such as clear or lingual appliances.

Summary

A new system for orthodontic tooth movement using established methods for minor correction to achieve greater magnitudes of correction has been introduced. The system has been tested in university clinical trials and is now available to the public. The major advantage of the system is the esthetic, hygienic, low discomfort and removable nature of the appliance.

There are currently limitations to this appliance in terms of case selection, increased cost, experience required for computer treatment planning, difficulty obtaining certain tooth movements, and the lack of potential in cases involving mixed dentition or impacted teeth. However, as the number of clinicians using this appliance increases, more information will be available for clinicians and researchers to further evaluate the risks and benefits of this system for their patients.

Because clinical judgement of the relative crown inclination in relation to adjacent teeth is required to use this appliance, having only the crowns of the teeth currently available for viewing limits the accuracy of this appliance. Other soft and hard tissue landmarks should also be considered throughout the planning and treatment process. Thus the clinician must have an in-depth understanding of the biomechanics, biology, periodontal concerns, and optimal therapeutic occlusion achieved during orthodontic treatment to successfully plan and use this appliance.

A great help in the future will be to use one of the emerging intraoral scanning devices to replace the PVS impressions and to record treatment changes or modifications immediately in a digital format.[13] Adding the other 3D compartments (skeletal, facial, jaw movement and animation to the current surface map of the teeth) will greatly enhance the diagnostic and treatment capabilities of this new appliance.

References

1. Kesling HD. The philosophy of the tooth positioning appliance. Am J Orthod 1945;31:297-304.
2. Ponitz RJ. Invisible retainers. Am J Orthod 1971;59:266-272.
3. McNamara JA, Kramer KL, Juenker JP. Invisible retainers. J Clin Orthod 1985;19:570-578.
4. Sheridan JJ, Ledoux W, McMinn R. Essix retainers: Fabrication and supervision for permanent retention. J Clin Orthod 1993;27:37-45.
5. Rinchuse DJ, Rinchuse DJ. Active tooth movement with essix based appliances. J Clin Orthod 1997;31:109-112.
6. Lindauer SJ, Shoff RC. Comparison of Essix and Hawley retainers. J Clin Orthod 1998;32:95-97.
7. Boyd RL, Miller RJ, Vlaskalic V. The Invisalign system in adult orthodontics: mild crowding and space closure. J Clin Orthod 2000;34:203-213.
8. Boyd RL, Leggott P, Quinn R, et al. Periodontal implications of orthodontic treatment in adults with reduced or normal periodontal tissues versus adolescents. Am J Orthod 1989;96:191-98.
9. Baumrind S, Boyd RL, Korn EL. Investigating the correlates of apical root resportion, vol 31, in McNamara JA (ed): Orthodontic Treatment: Management of Unfavorable Sequelae. Ann Arbor, MI, The University of Michigan, Center for Human Growth and Development, Craniofacial Growth Series, 1996.
10. Baumrind S, Korn EL, Boyd RL. Apical root resportion in orthodontically treated adults. Am J Orthod Dentofac Orthop 1996;110:311-320.
11. Vlaskalic V, Boyd, RL, Baumrind S. Etiology and sequelae of root resorption. Sem Orthod 1998;4:124-131.
12. Mozzo P, Procacci C, Tacconi A, et al. A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results. Eur Radiol 1998;8:1558-1564.
13. Sachdeva R. A total orthodontic care solution enabled by breakthrough technology. J Clin Orthod 2000;34:223-323.

ClearCorrect Exhibit 1002, Page 1160 of 3373

Internet Sites

The following list of sites may be of general interest to the reader. Other links pertaining to specific subjects are supplied among the References of several papers.

Institutions:
American Association of Orthodontics (AAO): www.aaortho.org
Case Western Reserve University School of Dentistry: www.cwru.edu/dental/casewebsite
Craniofacial Research Instrumentation Laboratory/UOP: www.cril.org
National Institutes of Health (NIH Image): rsb.info.nih.gov/nih-image
Temple University School of Dentistry: www.temple.edu/dentistry
University of the Pacific School of Dentistry: www.uop.edu/dental
University of Southern California School of Dentistry: www.usc.edu/hsc/dental

Commercial Sites:
3DMetrics: www.3dmetrics.com
Acuscape: www.acuscape.com
Align Technology: www.aligntech.com
Cadent, Inc. (OrthoCad): www.orthocad.com
Gendex Corporation: www.gendexxray.com
GeoDigm Corporation (*E*model Digital Orthodontics Model): www.dentalmodels.com
NewTom: www.zerobase-usa.com
Minolta Corp. (Vivid 700): www.minolta3d.com
OraMetrix: www.orametrix.com

ClearCorrect Exhibit 1002, Page 1161 of 3373

W.B. SAUNDERS
Elsevier Science

To order reprints, call: 1-212-633-3813; fax 1-212-633-3820
email: reprints@elsevier.com

Journal of Dental Research

CONTENTS

Volume 64/Special Issue/Abstracts

Acknowledgments 400

Abstracts of Hatton Awards Competitors 162

Abstracts of Symposium Speakers 166
AADR/AADS (Symposium I, Abstracts S1-S4)
AADR/AADS (Symposium II, Abstracts S5-S8)
AADR/AADS (Symposium III, Abstracts S9-S13)
AADR Science Information Committee (Symposium IX, Abstracts S44-S49)
Behavioral Science Group (Symposium VI, Abstracts S25-S29)
Cariology Group (Symposium IX, Abstracts S44-S49)
Craniofacial Biology Group (Symposium V, Abstracts S19-S24)
Dental Materials Group (Symposium III, Abstracts S9-S13)
Experimental Pathology Group (Symposium V, Abstracts S19-S24)
Microbiology/Immunology Group (Symposium VIII, Abstracts S37-S43)
Mineralized Tissue Group (Symposium V, Abstracts S19-S24)
Oral & Maxillofacial Surgery Group (Symposium X, Abstracts S50-S55)
Periodontal Research Group (Symposium IV, Abstracts S14-S18)
Pharmacology/Therapeutics/Toxicology Group (Symposium IX, Abstracts S44-S49)
Prosthodontics Research Group (Symposium X, Abstracts S50-S55)
Salivary Research Group (Symposium VII, Abstracts S30-S36)

Abstracts of Papers 174
Behavioral Science: S26-S29, 93-115, 273-283, 440-449, 654-665, 868-877, 1054-1064, 1309-1317, 1534-1544, 1696-1706
Cariology: S44-S49, 116-138, 284-293, 450-459, 666-687, 878-888, 1065-1075, 1320-1337, 1545-1555, 1707-1716
Craniofacial Biology: S19-S24, 256-264, 294-304, 460-470, 846-867, 889-899, 1076-1086, 1505-1526, 1556-1576, 1717-1737
Dental Materials: S9-S13, 27-92, 305-314, 471-490, 605-653, 900-930, 1087-1106, 1250-1303, 1577-1606, 1738-1767
Diagnostic Systems: 265-272, 315-324, 491-499, 931-939, 1527-1533
Experimental Pathology: S19-S24, 241-255, 325-334, 821-834, 940-950, 1107-1116, 1495-1504
Implantology: 1117-1124, 1304-1308, 1607-1614
Microbiology/Immunology: S37-S43, 155-195, 335-344, 500-508, 726-756, 951-970, 1125-1134, 1385-1430, 1615-1634, 1768-1777
Mineralized Tissue: S19-S24, 139-154, 345-354, 688-705, 971-980, 1135-1144, 1338-1359, 1635-1644, 1778-1796
Neuroscience: LR1, 355-363, 509-518, 811-820, 981-990, 1145-1155, 1481-1494, 1645-1654
Oral & Maxillofacial Surgery: S50-S55, 364-374, 835-845, 991-1001, 1156-1166
Periodontal Research: S14-S18, 196-237, 375-396, 519-538, 757-798, 1002-1022, 1167-1187, 1431-1467, 1655-1684, 1797-1817
Pharmacology/Therapeutics/Toxicology: S44-S49, 238-240, 397-407, 539-549, 799-810, 1023-1032, 1188-1198, 1468-1480
Prosthodontics Research: S50-S55, 12-26, 408-418, 550-560, 589-604, 1033-1042, 1199-1209, 1240-1249, 1685-1695, 1818-1828
Pulp Biology: 1-11, 419-429, 561-570, 579-588, 1043-1053, 1210-1219, 1230-1239
Salivary Research: LR2, S30-S36, 430-439, 571-578, 706-725, 1220-1229, 1360-1384, 1829-1838

Index to Authors 380

Founded by William J. Gies in 1919.

Official publication of the International Association for Dental Research and all of its divisions. The Journal is owned and managed by the American Association for Dental Research, 1111 Fourteenth St., NW, Suite 1000, Washington, D.C. 20005.

The *Journal of Dental Research* is dedicated to the dissemination of knowledge pertaining to the oral cavity, its contents and contiguous parts, and its relation to and effect on the total human organism. The *Journal* publishes original investigations in these and related fields.

Editor
All manuscripts and manuscript correspondence should be addressed to: The Editor, **Dr. C. Dawes**, JOURNAL OF DENTAL RESEARCH, Dept. of Oral Biology, Faculty of Dentistry, University of Manitoba, 780 Bannatyne Ave., Winnipeg, MB, Canada R3E 0W3. Telephone: (204) 786-3614. Articles are accepted only if they are contributed solely to this Journal. For current "Instructions to Authors", refer to the July, 1984, issue of the Journal.

Associate Editor for Special Issues
Dr. A.R. Hand

Publication Committee
J. W. Bawden, R. J. Genco, P. R. Garant, L. M. Silverstone, C. Dawes, H. J. Sandham, A. R. Ten Cate, P. Innes, H. Schroeder, L. Garcia-A., F. Miura, B. J. Baum, *Chairman*.

Publications Department
Linda T. Hemphill, Director of Publications; Judith Gauchel, Newsletters; and Joseph Gauchel, Subscriptions Manager.

Advertising
Bashian Publishing, Inc.
1501 Euclid Ave.
Cleveland, Ohio 44115
(216) 621-2858 and (301) 924-4473

Subscriptions
For IADR members: Joseph Gauchel, Membership Coordinator, International Association for Dental Research, 1111 Fourteenth St., NW, Suite 1000, Washington, D.C. 20005. (202) 898-1050

For non-IADR-member subscriptions: Subscription Department, International Association for Dental Research, 1111 Fourteenth St., NW, Suite 1000, Washington, D.C. 20005. (202) 898-1050

Changes of Address
Please notify the IADR/AADR Subscription Department and your local postmaster of changes of address, giving both the old and the new addresses. Please allow six weeks for the change. Claims for missing numbers should be made within the month following the regular month of publication. The publisher expects to supply missing numbers free only when the losses have been sustained in transit and when the reserve stock will permit. *IADR does not keep a reprint file.*

Back Issues ($18.50 each)
Joseph Gauchel, IADR, 1111 Fourteenth St., NW, Suite 1000, Washington, D.C. 20005. (202) 898-1050

The Journal of Dental Research is published monthly plus semi-monthly in January and May for the American Association for Dental Research. Printed in USA. Second-class postage paid at Washington and additional mailing office. Copyright ©1985 by the American Association for Dental Research. Material protected by this copyright may be photocopied for the non-commercial purpose of scholarship or research. JOURNAL OF DENTAL RESEARCH. ISSN 0022-0345. Postmaster: Send address changes to JDR, 1111 Fourteenth St., NW, Suite 1000, Washington, DC 20005. (202) 898-1050

Subscription Rates	N. America	Overseas
Active, Affiliate, Sustaining Members	$27.00	$29.00
Life Members	27.00	29.00
Student Members	12.00	12.00
Nonmembers, Institutions	165.00	175.00

SOCIETY OF NATIONAL ASSOCIATION PUBLICATIONS

ClearCorrect Exhibit 1002, Page 1163 of 3373

ed the accumulation of cyclic AMP (cAMP), ornithine decarboxylase(ODC) activity which is the rate limiting enzyme in polyamine biosynthesis and glycosaminoglycan(GAG) synthesis, a characteristic of the cartilage phenotype, without any effect on DNA synthesis. HC stimulated both GAG and DNA syntheses. EGF stimulated DNA synthesis but not GAG synthesis. The degree of the increases of cAMP level, ODC activity and GAG synthesis in response to PTH was the highest in MCC-chondorcytes, moderate in SOS-chondorcytes and the lowest in NSC-chondrocytes. In contrast, the stimulation of DNA synthesis by HC or EGF was the highest in NSC-chondrocytes, moderate in SOS-chondrocytes and the lowest in MCC-chondrocytes.

These findings suggest that MCC-chondorcytes are highly differentiated and low proliferative, whereas NSC-chondrocytes are highly proliferative but less differentiated. In contrast, SOS-chondorcytes are moderately differentiated and proliferative. These different characteristics of chondrocytes from various craniofacial cartilage may play a regulatory role in the normal growth and development of the craniofacial complex.

Supported by Grant-in-Aid for Scientific Research from the Ministry of Education in Japan(No.57480377 and No.58570849)

7.5mm apart on the gingiva nea six 1 year old female cats. Th the faradaic effects at the el irritation by the elimination products at the electrodes(Die Soc. 125:1246, 1978). In Grou duration current of 100uA was group B(3 cats) were treated sections, 5 um thick, of each was stained for either adenos or prostaglandin E(PGE) by an method. Measurements of stain cells opposite each electrode sites were performed by a Zei interfaced with a Zonax compu the osteoblastic staining for increased near both electrode 22.8±7.4, control:42.1±7.6; a ±13.5 percent light transmitt found for PGE. These results current, transmitted via tant capable of stimulating alveol blasts in cats.

Supported by OSU College of D

305

Computer Machined Ceramic Inlays: In Vitro Marginal Adaptation. M. BRANDESTINI*, W. MOERMANN, F. LUTZ & I. KREJCI. University of Zurich, Dental Institute, CAR/PER/PDM, Switzerland.

Under thermal stress, the marginal adaptation of adhesive composite inlays is readily degraded due to the high coefficient of thermal expansion pertinent to the currently used resin materials (J Dent Res 63:175, IADR Abst 37, 1984). The purpose of this study was to evaluate esthetic inlays made of dental ceramic using a new fabrication technique.

Six MOD inlay cavities were prepared in extracted human molars. Ceramic inlays were made using an optical topographic scanning procedure and an electronically controlled machine which mills prefabricated blanks of dental ceramic according to the data obtained from the scanning process. The cavity margins were etched and a simultaneously light- and chemically curing luting composite was used to insert the ceramic inlays. Six MOD gold inlays and six amalgam fillings of similar size served as controls. The proximal margins of all restorations were examined: the micromorphology of the restoration / tooth interface was analyzed before and after 2500 thermal cyclings (10° - 60° - 10°C) using a replica technique and the SEM; the marginal seal was evaluated by dye penetration tests run after thermal cycling only.

Complete absence of dye penetration was found in 2 gold-, 4 amalgam-, and 10 ceramic-restored proximals out of 12 per group. In the SEM analysis (400 x), the percentages of 'Excellent Margin' before and after thermal cycling were 11 and 3 for gold, 64 and 9 for amalgam, and 99 and 88 for ceramic restorations. In regard to both marginal seal and micromorphology of the tooth / restoration interface, in vitro adhesive ceramic inlays were significantly superior ($p<0.001$) to comparable amalgam and gold restorations showing an unprecedented high quality of marginal adaptation.

306

Two-Dimensional Ph
Castable Ceramic B
CRAIG*, and G. T.
University of Mich
Dentsply Internati

Two-dimensional photoelastic the optimum design of a conne ceramic bridge. The connecto attachment with the male port which is cemented to one of t tion is located in the pontic Several design variables were modulus cement, (2) short vs. thicknesses of cements for ce nector, (4) occlusal vs. cerv of male attachment-molar vs. (6) four loading sites.

Eighteen photoelastic bridges actual size were prepared wit above design variables and we four sites: (A) distal ridge attachment, (C) pontic adjace ridge of molar. Stresses wer strategically located points.

The following conclusions wer cement imparts more rigidity 30% lower stress concentrati sulted in 20% higher stresses sites A and B. Length of ma one-half the mesial-distal le mediate thickness of cement distribution. (4) Occlusal than cervical eccentricity. tralize location of male con (5) Male connector was best in this case the 2nd molar, in stress. (6) Most undesir directly above the connector

This study was supported by PA.

ClearCorrect Exhibit 1002, Page 1164 of 3373

IADR/AADR ABSTRACTS 1985

298 Root Resorption During Experimental Orthodontic Tooth Movement. I. Modulation by Antiarthritic Therapy with Gold.

E. FREEMAN*, G. ALTUNA and J. BOETTO, University of Toronto, Canada.

Root resorption is an undesirable effect of orthodontic tooth movement. Systemic administration of gold salts for treatment of arthritis is thought to limit tissue destruction through alteration of inflammatory cell function. The present study was to determine if gold salts could modify the root resorption associated with experimental orthodontic tooth movement. Therapeutic levels of serum gold salts were established in four 250 gram Wistar-strain albino rats (experimental) by IM injection of gold sodium-thiomalate at 5 mg/kg body weight at three day intervals for a period of 12 days. Orthodontic tooth movement was then initiated. In order to create extensive and uniform root resorption, it was decided to move the upper right and left molars palatally into the cortical plate. This movement was achieved by using Closed Energy Chain elastics (J-120, Rocky Mountain Orthodontic Company). Orthodontic tooth movement was initiated at the corresponding teeth in four animals (control) which had not received gold salts. Serum levels of gold salts were maintained in experimental animals, and all animals were killed 2 weeks after the initiation of tooth movement. Root resorption was evaluated on the mesial root of the maxillary first molar of each tooth on step-serial sections. Control specimens showed compression of the periodontal ligament with frontal and undermining bone resorption along with extensive lateral root resorption associated with these compression zones. In the specimens from gold-receiving animals, compression of the periodontal ligament seemed less apparent and resorption of root and bone appeared to be reduced. Although measurements were not made, the findings of this study seem to suggest that administration of systemic gold salts appear to modify the root resorption found during experimental orthodontic tooth movement.

299 The Effect of Parathyroid Hormone on Alveolar Bone Cyclic Nucleotides.

C. STEPHENS JR.*, F. CORDRAY, J. SHANFELD, B. ZWILLING, R. FERTEL, R. LARESE AND Z. DAVIDOVITCH. O.S.U. College of Dentistry, Columbus, Ohio 43210

Parathyroid hormone (PTH) is known to activate bone cells through adenosine 3',5'-monophosphate (cAMP) as a second messenger. Guanosine 3',5'-monophosphate (cGMP) appears to play a mediatory role in synthetic and secretory activities in a variety of tissues (Y Koide et al., J Biol Chem 253:4439, 1989). However, little is known on its role in mediating the effects of hormones on bone cells. The objective of this study was to determine whether fluctuations in either cyclic nucleotide (cN) occur in alveolar bone cells following PTH administration.
Four groups of 4 one-year old female rats received three injections of PTH, 12hrs apart, at doses of 0,30,100 and 300 U/kg, respectively. The animals were sacrificed 10min after the last injection, the mandibles sectioned horizontally at 5 µm and stained for cAMP and cGMP using monoclonal antibodies. The intensity of staing for cN's of alveolar bone osteoblasts, cementocytes and osteoclasts was determined in 15 cells of each type per cat by a microphotometer at 600 nm wavelength, where peak light transmittance for 3',3'-diaminobenzidine occurs. For cAMP, the per cent light transmittance of control osteoblasts (50.4± 10.2) intensified significantly following PTH administration, i.e. 20.1±7.6, 6.9±2.2 and 13.3±7.6%, respectively. Osteoclasts and osteocytes responded similarly. Staining for cGMP was also significantly increased, e.g. for osteoblasts: 50.2±5.0(control), 28.2±5.2, 24.4±4.1 and 15.1± 3.5%, respectively. These results demonstrate that PTH increases the contents of both cAMP and cGMP in bone cells in vivo, suggesting that both cN's may be involved in mediating the effects of PTH on various types of bone cells in a dose response fashion. Moreover, microphotometry appears to be a useful tool in determining the biochemical response of bone cells to external stimuli in vivo.

This study was supported by NIDR grant No. DE 06923 and O.S.U. College of Dentistry Research Intern Program.

300 Biochemical Aspects of Tooth Eruption: cAMP and PGE in Periodontal Cells. D. VAYDA*, P. EGAN, J. SHANFELD, B. ZWILLING, R. FERTEL, R. LARESE AND Z. DAVIDOVITCH. O.S.U. College of Dentistry, Columbus, Ohio 43210

Periodontal fibroblasts (PF's) and alveolar bone cells have been implicated in the process of tooth eruption (Wess AR, in: Mechanism of Tooth Support, p. 84, Wright, Bristol, 1967). Adenosine 3',5'-monophosphate (cAMP) was localized in tissues surrounding erupting teeth (Gustafson GT, et al. J. Dent Res 36:407, 1977). In vitro experiments have demonstrated that prostaglandins (PG's) modulate the effects of external stimuli in fibroblasts (Hassid A, Am J Physiol 243:C205, 1982) The objective of this study was to determine the relative concentrations of cAMP and PGE in periodontal cells of erupting teeth.

Three groups of 5 cats each were sacrificed at 3.5, 4.5 and 5.5 mos, respectively. Serial sagittal mandibular sections, 5 µm thick, were stained for cAMP or PGE using monoclonal antibodies. The staining intensity of osteoblasts, cementoblasts and PF's was determined at 600 nm wavelength by a Zeiss microphotometer. Per cent light transmittance of 15 cells in each zone was measured and results analyzed by ANOVA. At all times osteoblasts and cementoblasts stained intensely for cAMP (35.6±3.4 and 41.7±5.5%). Apical cells were most intensely stained for each cell type. For PGE, PF's near bone (42.9±2.1%) and near cementum (43.2±2.1%) stained darker than PF's in between (52.8±2.0%), p<0.001. There was no difference in PGE staining intensity along the length of the periodontium and age-related difference was found. These results demonstrate that mineralized tissue cells contain relatively high levels of cAMP during tooth eruption and that PGE content of PF's during tooth eruption is elevated suggesting enhanced responsiveness to local and systemic regulatory signals in cells associated with the eruptive process.

This study was supported by NIDR grant No. DE 06923 and O.S.U. College of Dentistry Research Intern Program.

301 Effect of Indomethacin on PGE Content in Dental Cells During Tooth Eruption.

J.SHANFELD*, B.ZWILLING, R.FERTEL, R.LANESE, Z.DAVIDOVITCH. The Ohio State University College of Dentistry, Columbus, Ohio 43210

Prostaglandins (PG's), particularly PGE, have been shown to mediate bone resorption and bone apposition (L.G.Raisz and T.J.Martin, Bone and Mineral Research Annual 2; W.A.Peck, ed, pp 286-310, 1984; Elsevier, Amsterdam). The objective of this experiment was to study the effect of indomethacin (IM), a cyclooxygenase inhibitor, on PGE levels in a variety of cells at sites of active bone resorption and apposition during the process of permanent tooth eruption in kittens.

Twenty-four kittens, 8 in each of 3 groups, were sacrificed at 3.5, 4.5 and 5.5 months of age, respectively. IM, 1.5 mg/kg, was administered subcutaneously to 4 of the animals in each group every 12 hrs for 10 days. The other animals received buffer only and served as controls. Frozen, unfixed, undecalcified mandibles were sectioned sagittally at 5um and stained for PGE with monoclonal antibodies in an immunoglobulin-peroxidase method. Staining intensity in 15 cells at each site of interest was measured by the use of a Zeiss microphotometer (optimal wavelength 600nm) interfaced with a Zonax computer. Alveolar bone osteoblasts at crestal sites in IM treated kittens showed a significant decrease (p<0.05) in PGE content as compared to control (52.0±5.9 and 34.4±6.5 percent light transmitted, respectively). A similar decrease in PGE staining intensity due to IM was observed in alveolar bone osteoblasts, odontoclasts and fibroblasts from gingiva, PDL and pulp. These results demonstrate that cells at sites of tissue remodeling respond to IM with decreases in PGE content. This effect of IM can thus be demonstrated in vivo with the use of quantitative immunohistochemistry.

Supported by NIDR grant No. 06923.

302 Studies on Chondrocytes from Rabbit Craniofacial Complex in Culture.

T.TAKANO*[1], K.NAKAGAWA[1], H.INOUE[1], M.SAKUDA[1], M.TAKIGAWA[2], F.SUZUKI[2]. Depts. of Orthod.[1] and Biochem.[2], Fac. of Dent., Osaka Univ.,Osaka,Japan

In order to understand the role of cartilage in the craniofacial growth, we previously developed a method to isolate chondrocytes from rabbit craniofacial cartilage; spheno-occipital synchondrosis(SOS), nasal septal cartilage(NSC) and mandibular condylar cartilage(MCC) (J.Dent.Res., 63:19, 1984).
In the present study, we compared the effects of parathyroid hormone(PTH), hydrocortisone(HC) and epidermal growth factor(EGF) on the differentiated cartilage phenotype and the proliferation of MCC-, NSC- and SOS-chondrocytes in culture. In these three chondrocytes, PTH increased the accumulation of cyclic AMP (cAMP), ornithine decarboxylase(ODC) activity which is the rate limiting enzyme in polyamine biosynthesis and glycosaminoglycan(GAG) synthesis, a characteristic of the cartilage phenotype, without any effect on DNA synthesis. HC stimulated both GAG and DNA syntheses. EGF stimulated DNA synthesis but not GAG synthesis. The degree of the increase of cAMP level, ODC activity and GAG synthesis in response to PTH was the highest in MCC-chondrocytes, moderate in SOS-chondrocytes and the lowest in NSC-chondrocytes. In contrast, the stimulation of DNA synthesis by HC or EGF was the highest in NSC-chondrocytes, moderate in SOS-chondrocytes and the lowest in MCC-chondrocytes.
These findings suggest that MCC-chondrocytes are highly differentiated and low proliferative, whereas NSC-chondrocytes are highly proliferative but less differentiated. In contrast, SOS-chondrocytes are moderately differentiated and proliferative. These different characteristics of chondrocytes from various craniofacial cartilage may play a regulatory role in the normal growth and development of the craniofacial complex.

Supported by Grant-in-Aid for Scientific Research from the Ministry of Education in Japan(No.57480377 and No.58570849)

303 Stimulation of Periosteal Osteoblasts by Capacitively Coupled Pulsed Electric Currents.

C.Wheeler*, C.Hassler, J.Shanfeld, B.Zwilling, R.Fertel, R.Lanese, Z.Davidovitch. The Ohio State University College of Dentistry and Battelle Memorial Institute, Columbus, Ohio

Bone remodeling may be stimulated by the use of direct electric currents. Previously we used stainless steel (cathode) and gold(anode) and observed periosteal osteoblastic stimulation as early as 15 min after the onset of current application(Davidovitch et al. Calcif. Tissue. Int. 36:S86-S97). In experiments of longer duration, gingival irritation was found near the anode. The objective of this experiment was to test other electrode metals for biological effectiveness. Anodized tantalum capacitor electrodes(.127mmx1.5mmx10.0mm) were placed 7.5mm apart on the gingiva near one maxillary canine in six 1 year old female cats. These electrodes eliminate the faradaic effects at the electrodes and minimize irritation by the elimination of oxidation reduction products at the electrodes(Diegle & Hessler J. Electrochem. Soc. 125:1246, 1978). In Group A(3 cats) a 5 msec pulsed duration current of 100uA was applied for 15 min, while group B(3 cats) were treated for 60 min. Serial horizontal sections, 5 um thick, of each frozen undecalcified maxilla was stained for either adenosine 3'5'monophosphate (cAMP) or prostaglandin E(PGE) by an immunoglobulin-enzyme bridge method. Measurements of staining intensity of periosteal cells opposite each electrode and corresponding control sites were performed by a Zeiss microphotometer(600nm) interfaced with a Zonax computer. At both time periods the osteoblastic staining for cAMP was significantly increased near both electrodes (i.e. at 60 min:cathode: 22.8±7.4, control:42.1±7.6; anode :16.4±6.0, control:43.4 ±13.5 percent light transmitted). A similar effect was found for PGE. These results indicate that pulsed direct current, transmitted via tantalum capacitor electrodes, is capable of stimulating alveolar bone periosteal osteoblasts in cats.
Supported by OSU College of Dentistry Fund No. 272131

304 Simulated Weightlessness and Osteogenic Cells in Periodontal Ligament (PDL) and Tibia.

P.J. Fielder*, E.R. Morey, and W.E. Roberts, NASA-Ames and Bone Research Lab., UOP Dental School, 2155 Webster St., S.F., CA 94115

Weightlessness of spaceflight inhibits bone formation (Science 201: 1130, 1978) via a specific-block in pre-osteoblast differentiation (Physiologist 24(6): 5-75, 1981). The forward fluid shift and hind limb unloading of spaceflight was simulated with 30° head-down, tail suspension. Five 83 day old S-D rats were suspended by the tail with an orthopedic harness for 21d. Maxillary first molar PDL and primary spongiosa of proximal tibial metaphysis (PS) were demineralized and sectioned at 3µm. According to nuclear volume (NV) measured at 1000X, 100 fibroblast-like cells/animal in PDL and PS were classified as: A/A' (< 80), B(80-119), C(120-169), D(≥ 170), and C/D combined (≥ 120 µm³). The differentiation of a fibroblast-like precursor cell to a preosteoblast involves a shift in NV from A'→C/D. Comparing experimental to control, tibia PS cell distributions increased in A/A' cells (45.8±3.7 vs 36.0±1.6 p<0.05), but decreased in D (10.8±1.8 vs 16.8±1.0 p< 0. 02), and C/D cells (26.4±2.3 vs 34.0±1.9 p<0.05). There was no difference in total osteogenic cells (76.5 ±5.5 vs 75.9±11.4/mm). Cell distributions in PDL increased in A/A' cells (46.0±3.4 vs 27.8±4.4, p< 0.01), but decreased in D(5.6±1.2 vs 16.2± 2.3 p< 0.01) and C/D cells (20.4±3.1 vs 38.0±3.6, p< 0.01). No difference in PDL cell density (3.7±0.7 vs 4.1±1.5/ 1000µm²), with an increase in PDL width of unloaded rats, indicates increased precursor cell accumulation. Results suggest a similar block in preosteoblast differentiation as spaceflight in PS and PDL, but effects on PDL width and total cell counts are opposite. It is concluded that head down suspension only partially simulates the effects of weightlessness on osteogenic cells. Supported by NASA Grant No. NAGW-356, NASA-Ames Cooperative Agreement NCC2-224, Biomed. Res. Support Grant No. SO7 RR05301, and The Pacific Dental Research Foundation.

305 Computer Machined Ceramic Inlays: In Vitro Marginal Adaptation.

M. BRANDESTINI*, W. MOERMANN, F. LUTZ & I. KREJCI. University of Zurich, Dental Institute, CAR/PER/PDM, Switzerland.

Under thermal stress, the marginal adaptation of adhesive composite inlays is readily degraded due to the high coefficient of thermal expansion pertinent to the currently used resin materials (J Dent Res 63:175, IADR Abst 37, 1984). The purpose of this study was to evaluate esthetic inlays made of dental ceramic using a new fabrication technique.
Six MOD inlay cavities were prepared in extracted human molars. Ceramic inlays were made using an optical topographic scanning procedure and an electronically controlled machine which mills prefabricated blanks of dental ceramic according to the data obtained from the scanning process. The cavity margins were etched and a simultaneously light- and chemically curing luting composite was used to insert the ceramic inlays. Six MOD gold inlays and six amalgam fillings of similar size served as controls. The proximal margins of all restorations were examined: the micromorphology of the restoration / tooth interface was analyzed before and after 2500 thermal cyclings (10° - 60° - 10°C) using a replica technique and the SEM; the marginal seal was evaluated by dye penetration tests run after thermal cycling only.
Complete absence of dye penetration was found in 2 gold-, 4 amalgam-, and 10 ceramic-restored proximals out of 12 per group. In the SEM analysis (400 x), the percentages of 'Excellent Margin' before and after thermal cycling were 11 and 3 for gold, 64 and 9 for amalgam, and 99 and 88 for ceramic restorations. In regard to both marginal seal and micromorphology of the tooth / restoration interface, in vitro adhesive ceramic inlays were significantly superior (p<0.001) to comparable amalgam and gold restorations, showing an unprecedented high quality of marginal adaptation.

306 Two-Dimensional Photoelastic Simulation of a Castable Ceramic Bridge.

J. W. FARAH, R. G. CRAIG*, and G. T. EDEN. School of Dentistry, University of Michigan, Ann Arbor, MI and Dentsply International, York, PA.

Two-dimensional photoelastic models were used to determine the optimum design of a connector for a three-unit castable ceramic bridge. The connector is a male/female type of attachment with the male portion extending from the crown which is cemented to one of the abutments. The female portion is located in the pontic of the three-unit bridge. Several design variables were examined: (1) low and high modulus cement, (2) short vs. long connector, (3) three thicknesses of cements for cementing the male/female connector, (4) occlusal vs. cervical eccentricity, (5) site of male attachment-molar vs. pre-molar abutment, and (6) four loading sites.
Eighteen photoelastic bridges, seven and one-half times the actual size were prepared with various combinations of the above design variables and were loaded with 100 lbs. at four sites; (A) distal ridge premolar, (B) pontic over attachment, (C) pontic adjacent to molar, and (D) mesial ridge of molar. Stresses were evaluated at twenty-four strategically located points.
The following conclusions were drawn. (1) Higher modulus cement imparts more rigidity to the bridge and results in 30% lower stress concentration. (2) Shorter connector resulted in 20% higher stresses, especially for loading sites A and B. Length of male connector should not exceed one-half the mesial-distal length of pontic. (3) Intermediate thickness of cement resulted in the best stress distribution. (4) Occlusal eccentricity was less desirable than cervical eccentricity. It is best, however, to centralize location of male connector within the pontic. (5) Male connector was best attached to bulkier abutment, in this case the 2nd molar, and resulted in ~25% reduction in stress. (6) Most undesirable loading site was at B directly above the connector.
This study was supported by Dentsply International, York, PA.

ClearCorrect Exhibit 1002, Page 1165 of 3373

An Image Analysis System for the Determination of Tooth Dimensions from Study Casts: Comparison with Manual Measurements of Mesio-distal Diameter

A.H. BROOK[1,3], N.B. PITTS[2,4], F. YAU[1], and P.K. SANDAR[1]

[1]*Department of Children's Dentistry and Orthodontics and* [2]*Department of Conservative Dentistry, Faculty of Dentistry, University of Hong Kong, Hong Kong*

A first comparison of an image analysis method with classical hand measurement was made using the mesio-distal diameter data derived by the simplest image analysis method, the jawview mode. Fifty casts of male Hong Kong Chinese dental students, mean age 20.4 years, were examined by both methods. The two techniques gave comparable overall results, the correlation coefficients generally being greater than 0.9. A combination of the buccal and occlusal image analysis views gave the best correlation with hand measurement with a comparable variability for different tooth types. For certain teeth, particularly posteriors, reproducibility was better using hand measurement. Optimal weighting of the data from these two different image analysis views can give an "estimated hand measurement" value. Further development of the method to deal with differing orientations of teeth is possible.

J Dent Res 65(3):428–431, March, 1986

Introduction.

The measurement of tooth dimensions from casts is of value in orthodontics, anthropology, and studies of genetic and environmental variables in tooth development. Use of the classical manual methods (Moorrees *et al.*, 1957) permits only linear measurements to be derived. To permit measurement in three dimensions, techniques using the Optocom (Van der Linden *et al.*, 1972) and the Reflex Metrograph (Butcher and Stephens, 1982; Takada *et al.*, 1983) have been reported, while an alternative image analysis method has been developed (Brook *et al.*, 1983). This system can derive for each tooth a series of measurements from curved surfaces, such as perimeter and area (from both occlusal and buccal views), in addition to the linear dimensions previously attainable.

The aim of this study was to quantify the reliability of image-analysis-assisted measurement by comparing the system (in its simplest and most rapid arrangement, the "jawview mode") with standard hand measurements of the mesio-distal diameters of the same set of casts.

Materials and methods.

The configuration of the image analysis system (Toltec Dentiscan, Toltec Computer Ltd., Cambridge, England) has been described previously (Brook *et al.*, 1983). To summarize, a cast is placed on the variable calibrated stage, and an image is gained *via* the TV camera and stored in the image memory (GEMS, CADCENTRE, Cambridge, England). It is digitized, stored in an array of 512 × 512 pixels, calibrated, and displayed on a monitor. The periphery of each tooth is, in turn, automatically outlined at 32 points; these peripheral points can be modified manually where necessary. Next, the orientation of the tooth is put into the system by aligning "cross-hairs" superimposed over the image of the tooth seen on the monitor (Fig. 1).

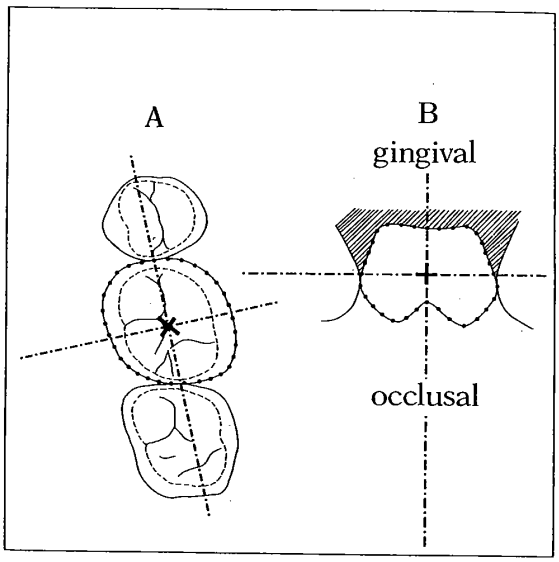


Fig. 1 — Tooth outlined by 32 peripheral points and aligned with "cross-hairs" from the occlusal (A) and buccal (B) views.

The teeth are viewed from both occlusal (OV) and buccal (BV) aspects, and the co-ordinates of each point from each view are stored. Automatic calculations are made to determine the mesio-distal diameters. Data are stored on floppy discs and can be recovered as a printed page of values, a scaled plot of tooth outlines in their anatomical relationships (Fig. 2), and 1:1 plots of individual teeth. Following a pilot study (Pitts and Brook, 1983), all measurements were made by one trained technician. In the "jawview" mode used here, the whole "jawset" of upper and lower casts is divided into eight different jawviews (Fig. 2); hence, results for each set of casts are derived from eight separate images.

The same casts were also measured manually by means of a dial caliper (Mitutoyo Manufacturing Co. Ltd., Japan) with beaks sharpened to improve the access approximally. The criteria used for the mesio-distal diameter were those of Moorrees *et al.* (1957). The greatest distance between the contact points was measured with the calipers held parallel to both the buccal and occlusal surfaces. Following calibration, all hand measurements (HM) were made by one operator (P.K.S.).

Casts were obtained from alginate ("Jeltrate", L.D. Caulk

Received for publication December 18, 1984
Accepted for publication December 17, 1985
This investigation was supported by a research grant from the University of Hong Kong.

[3]Present address: Department of Child Dental Health, London Hospital Medical College, Dental School, Turner Street, London E1 2AD, England

[4]To whom correspondence and reprint requests should be addressed. Present address: Dental Health Services Research Unit, Department of Periodontology and Community Dentistry, Dental School, Park Place, Dundee DD1 4HR, Scotland

ClearCorrect Exhibit 1002, Page 1166 of 3373

Co., Milford, DE) impressions of 50 young adult male Chinese dental students, whose ages ranged from 19 to 24 years with a mean of 20.4 years. A comparison was made between estimates of the mesio-distal diameter of each permanent tooth (excluding third molars) as obtained by the image analysis system and by hand measurement. The reproducibility of both techniques was considered by triple determinations for 20% of the study casts. Intra-class correlations, where the between-casts and within-casts variances were estimated from the analysis of variance (ANOVA) model for each tooth type, were employed as a measure of reproducibility.

Model: $Yijk = Aij + eijk$ ($i = 1,\ldots,10$; $j = 1,2$; $k = 1, 2, 3$)

(Note: $j = 1,2$ represents the left & right sides of a model cast.)

ANOVA:

Source of Variation	d.f.	Expected Mean Square
Total	59	
Between casts-pairs	19	$\hat{\sigma}_e^2 + 3\hat{\sigma}_A^2$
Within casts-pairs	40	$\hat{\sigma}_e^2$

$$\hat{\rho}\ \text{(reproducibility)}\ \% = \frac{\hat{\sigma}_A^2}{\hat{\sigma}_A^2 + \hat{\sigma}_A^2} \times 100\%$$

Because it may be desirable to convert image analysis data into "estimated" hand measurement values to facilitate future comparison with existing data, regression techniques were used to explore the optimal weights of occlusal view and buccal view results. A simple regression equation was used on equal weighting of OV and BV values, whereas a multiple regression equation was used to obtain the optimal weightings when OV and BV values were fitted into the equation separately.

$$\text{Prediction Equations}: HM = b_0 + b_1\left(\frac{OV + BV}{2}\right)$$

(Equal weight)

$$: HM = b_0 + b_1 OV + b_2 BV$$

(Optimal weight)

The F test was used to decide whether there were significant increases in the coefficients of determination.

Results.

The image analysis system derives the mesio-distal diameter from both occlusal and buccal views. Since these estimates may well be taken from slightly different points on the tooth and may vary systematically, both are given in Tables 1 and 2. Moreover, since both occlusal and buccal aspects of the tooth are considered when positioning the caliper beaks for hand measurement (Moorrees *et al.*, 1957), the means of the image analysis occlusal and buccal views are included for comparison.

The image analysis system generally produced slightly larger mean estimates than did hand measurements (Table 1). The exception was in the buccal view, where the image analysis mean values for maxillary and mandibular lateral incisors and the maxillary first molars were considerably smaller than the corresponding means for hand measurement.

All correlation coefficients were significant at the $p = 0.05$ level, with the exception of OV *vs.* BV for maxillary lateral incisors ($r = 0.21$). In general, the correlation of the image analysis OV with hand measurement was higher than that of the image analysis BV. However, the mean of both views, ½(OV + BV), produced results that gave the highest correlations with the hand measurements. Since the different methods yielded different means and standard deviations, the coefficient of variation (CV) was used to compare the variability of each individual view and method of measurement (Table 2). In general, hand measurement produced less variability than did the image analysis methods. The mean of both image analysis views [½(OV + BV)], however, exhibited a degree of variability comparable with that of hand measurement.

Table 2 also gives the results of the simple and multiple regression analyses and the percent reproducibility for all measurements. The mean reproducibility (for both maxillary and mandibular teeth) was 96% for the hand measurement technique, as compared with 81% and 66% for the image analysis OV and BV, respectively. When the data from the OV and the BV were averaged for each determination, the reproducibility was 79%, close to that obtained from the OV alone.

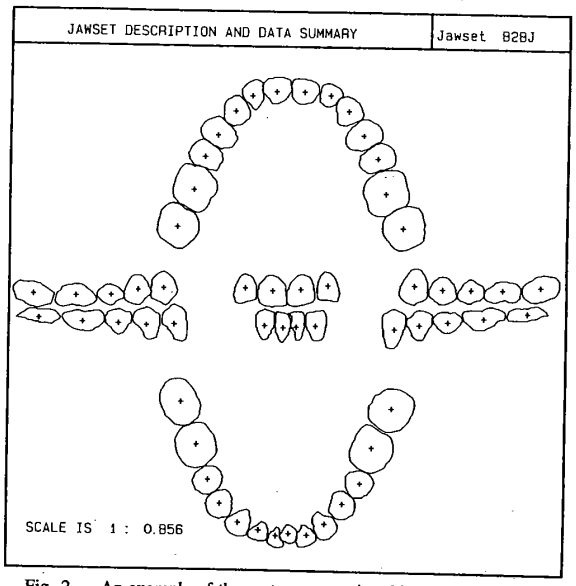


Fig. 2 — An example of the system output in which the peripheries of the stored tooth outlines are plotted to scale for all eight jawviews. Note the imbrication of the lower central incisors.

Discussion.

For the majority of teeth, image analysis measurements produced slightly larger values of mesio-distal diameter than did hand measurements; the discrepancy between methods was greater the more posterior the tooth. This finding may be partially due to the limitations of access experienced with the caliper beaks used in hand measurement. These are more difficult to position approximally than the "peripheral points" (equivalent width = 0.1 mm) displayed on the monitor. Another factor may be the difference between the definition of Moorrees *et al.* (1957) for the mesio-distal diameter and that used for the machine-made measurement [the smallest width perpendicular to the long arm of the orientation cross-hair (Fig. 1), which just touches the tooth periphery].

ClearCorrect Exhibit 1002, Page 1167 of 3373

TABLE 1

MEANS AND STANDARD DEVIATIONS OF MESIO-DISTAL DIAMETERS OF DIFFERENT TEETH MEASURED BY IMAGE ANALYSIS AND MANUAL METHODS WITH INTER-METHOD CORRELATIONS (N = 50)

	Mean ± SD of Different Measurements (mm)				Correlation Coefficients			
Tooth Type	OV*	BV†	½(OV + BV)	HM‡	OV *vs.* BV	OV *vs.* HM	BV *vs.* HM	½(OV + BV) *vs.* HM
Maxilla:								
I_1	8.73 ± 0.54	8.77 ± 0.52	8.73 ± 0.48	8.66 ± 0.53	0.66	0.85	0.80	0.91
I_2	7.41 ± 0.59	6.39 ± 0.71	6.88 ± 0.51	7.10 ± 0.52	0.21	0.86	0.46	0.83
C	8.27 ± 0.49	8.19 ± 0.59	8.20 ± 0.50	8.08 ± 0.47	0.66	0.71	0.78	0.83
PM_1	7.79 ± 0.53	7.81 ± 0.45	7.77 ± 0.46	7.58 ± 0.40	0.69	0.70	0.72	0.76
PM_2	7.51 ± 0.50	7.25 ± 0.65	7.35 ± 0.49	7.11 ± 0.48	0.44	0.77	0.62	0.80
M_1	11.38 ± 0.65	10.47 ± 0.64	10.89 ± 0.57	10.59 ± 0.54	0.53	0.61	0.58	0.66
M_2	11.16 ± 0.85	10.29 ± 0.72	10.72 ± 0.71	9.97 ± 0.63	0.55	0.62	0.53	0.67
All upper	8.75 ± 1.61	8.34 ± 1.49	8.52 ± 1.51	8.35 ± 1.35	0.89	0.95	0.92	0.96
Mandible:								
I_1	5.81 ± 0.45	5.74 ± 0.35	5.75 ± 0.34	5.59 ± 0.31	0.48	0.65	0.60	0.73
I_2	6.33 ± 0.41	5.78 ± 0.51	6.02 ± 0.38	6.07 ± 0.37	0.42	0.73	0.49	0.68
C	7.33 ± 0.53	6.98 ± 0.57	7.14 ± 0.45	7.00 ± 0.41	0.36	0.57	0.49	0.63
PM_1	7.61 ± 0.44	7.60 ± 0.50	7.57 ± 0.42	7.38 ± 0.42	0.55	0.80	0.56	0.74
PM_2	7.86 ± 0.67	7.47 ± 0.62	7.64 ± 0.56	7.38 ± 0.44	0.54	0.71	0.54	0.72
M_1	12.01 ± 0.59	11.56 ± 0.74	11.76 ± 0.58	11.57 ± 0.48	0.49	0.85	0.54	0.78
M_2	11.96 ± 0.68	10.70 ± 0.82	11.31 ± 0.62	10.78 ± 0.60	0.36	0.76	0.41	0.69
All lower	8.05 ± 2.24	7.67 ± 2.09	7.83 ± 2.14	7.66 ± 2.05	0.96	0.98	0.97	0.99
All teeth	8.41 ± 1.98	8.02 ± 1.84	8.19 ± 1.88	8.01 ± 1.76	0.93	0.97	0.95	0.98

Note: Values output from the system are truncated to one decimal place, ½ (OV + BV); results were therefore also truncated prior to calculation of mean and SD, which are given to two decimal places. Apparent discrepancies are due to truncation errors.

*Image analysis occlusal view.

†Image analysis buccal view.

‡Hand measurement.

TABLE 2

COMPARISON OF THE COEFFICIENTS OF VARIATION FOR DIFFERENT ESTIMATES OF MESIODISTAL DIAMETER, A LEAST-SQUARES ANALYSIS OF IMAGE ANALYSIS *VS.* HAND MEASUREMENT DATA AND THE REPRODUCIBILITY FOR 20% OF THE CASTS MEASURED THREE TIMES BY BOTH METHODS

	Coefficient of Variation (%)				Simple Regression			Multiple Regression				Reproducibility (%)			
Tooth Type	OV*	BV†	½(OV + BV)	HM‡	b_0	b_1	R^2	b_0	b_1	b_2	R^2	OV	BV	½(OV + BV)	HM
Maxilla:															
I_1	6.19	5.93	5.50	6.12	0.03	0.99	0.82	−0.01	0.56	0.43	0.83	95.4	93.5	96.4	99.3
I_2	7.96	11.11	7.41	7.32	1.30	0.84	0.68	0.48	0.71	0.21	0.82§	94.4	62.8	86.7	98.8
C	5.93	7.20	6.10	5.82	1.59	0.79	0.68	1.67	0.34	0.44	0.68	87.4	61.1	78.2	97.6
PM_1	6.80	5.76	5.92	5.28	2.32	0.68	0.58	2.07	0.30	0.40	0.60§	79.2	55.2	76.1	97.2
PM_2	6.66	8.97	6.67	6.75	1.37	0.78	0.64	0.89	0.58	0.26	0.69§	88.6	44.7	79.0	96.1
M_1	5.71	6.11	5.23	5.10	3.83	0.62	0.44	3.55	0.34	0.30	0.46	74.9	62.7	74.6	98.1
M_2	7.62	7.00	6.62	6.32	3.67	0.59	0.44	3.74	0.34	0.24	0.43	70.6	85.7	86.5	98.0
All upper (Mean)	6.70	7.44	6.21	6.10	—	—	—	—	—	—	—	84.4	66.6	82.5	97.9
Mandible															
I_1	7.75	6.10	5.91	5.55	1.82	0.66	0.53	1.81	0.32	0.33	0.53	94.1	55.8	73.2	97.0
I_2	6.48	8.82	6.31	6.10	2.09	0.66	0.46	1.56	0.56	0.16	0.57	89.6	44.4	63.8	98.1
C	7.23	8.17	6.30	5.86	2.94	0.57	0.40	2.81	0.35	0.23	0.42	82.5	79.9	85.7	96.0
PM_1	5.78	6.58	5.55	5.69	1.80	0.74	0.54	1.17	0.67	0.15	0.66§	56.9	73.9	81.3	85.3
PM_2	8.52	8.30	7.33	5.96	3.09	0.56	0.52	3.13	0.39	0.16	0.54§	61.4	71.3	71.5	97.2
M_1	4.91	6.40	4.93	4.15	3.99	0.64	0.61	2.88	0.62	0.11	0.74§	82.6	53.0	70.0	95.1
M_2	5.69	7.66	5.48	5.57	3.25	0.67	0.48	2.19	0.62	0.11	0.60§	86.0	86.2	88.7	92.5
All lower (Mean)	6.62	7.43	5.97	5.55	—	—	—	—	—	—	—	79.0	66.4	76.3	94.4

*Image analysis occlusal view.

†Image analysis buccal view.

‡Hand measurement.

§Significant increase in coefficent of determination, R^2 ($P<0.05$).

That the image analysis BV produced smaller mean values than did corresponding hand measurements of maxillary lateral incisors, maxillary first molars, and mandibular lateral incisors probably reflects the limitations of this view of the jawview mode in coping with imbricated teeth and the curvature of the arch in anterior segments. Some of the considerable inter-method discrepancies for maxillary and mandibular second molars may be attributed to the ability of the image analyzer to measure from a point at the distal gingival margin, unlike the calipers, and to the increasing curvature of the occlusal plane in this region.

High correlations between the results for all teeth measured

ClearCorrect Exhibit 1002, Page 1168 of 3373

with image analysis OV and hand measurements, and between the mean of image analysis OV and BV and hand measurements were seen (Table 1). However, when data for individual tooth types are examined, considerable variation is evident. In general, agreement between the two methods is poorer for maxillary molars, for many mandibular teeth, and for the image analysis BV.

The regression analysis explored the relationship between the two methods. In comparing a single variable by averaging the OV and BV values *vs.* two independent variables with different weights on OV and BV, the increases in R^2 provided a guide as to whether the different weights applied on OV and BV gave a better fit of the data than just the average of the two. Generally, the R^2 was larger in the models with different weights than in the single variable models, with the exceptions of the maxillary canine and second molar, where the two models are almost identical. The increase in R^2 was great whenever the correlation between the OV and BV measurements was low, such as in the maxillary lateral incisors, mandibular lateral incisors, first pre-molars, and second molars. In this paper, we have emphasized the classical linear regression approach in the calibration of the image analysis system. However, other methods of calibration are possible and may yield optimal results under different conditions (Krutchkoff, 1967).

The reproducibility of the technique was less than that achieved during the pilot study. The results indicated that the image analysis system in its current form is prone to errors; the coefficients of variation for measurements from the separate image analysis views were higher than those for hand measurement. It is noticeable that while the overall percentage reproducibility for image analysis OV and ½(OV + BV) was of the order of 80%, excellent reproducibility of better than 95% was achieved for maxillary central incisors. This result, comparable with hand measurement figures, suggests that the error is due not to inconsistencies in calibrating the system or in its accuracy but rather to a problem which affects more posterior teeth. The major source of variability may be in the subjective rotation by the operator of the orientation cross-hairs superimposed over the tooth (Fig. 1), since this procedure defines the specific peripheral points used to generate the mesio-distal diameter measurement. Thus, it is this part of the method which may require modification in future, there being little difficulty in outlining reproducibly the 32 peripheral points, or in obtaining excellent repeatability of area and perimeter values for posterior teeth.

The system operating in the jawview mode can provide useful data even when restricted to a single linear measurement of mesio-distal diameter. It is hoped that the simultaneous automatic derivation of additional values (for perimeter, area, and crown height, for example) will offer some advantages over conventional hand measurement. This study has demonstrated some limitations of the jawview mode, principally in the area of reproducibility of mesio-distal dimensions. Evaluation of the "axial mode" method of measurement, in which each tooth can be individually oriented under the TV camera, is indicated. This should obviate some of the difficulties experienced using only eight views to image 28 teeth from both occlusal and buccal directions. Software modifications to enable the printing of results to a greater number of decimal places are also in hand.

Acknowledgments.

We are indebted to Professor C.E. Renson for assistance in preparing the manuscript, to Mr. A. Lai for technical assistance, and to the Dental Illustrations Unit for the Figs.

REFERENCES

BROOK, A.H.; PITTS, N.B.; and RENSON, C.E. (1983): Determination of Tooth Dimensions from Study Casts Using an Image Analysis System, *J Int Assoc Dent Child* 14:55–60.

BUTCHER, G.W. and STEPHENS, C.D. (1982): Rapid Three Dimensional Measurements in Clinical Dentistry — A New Approach, *Proc SPIE* 361:36–40.

KRUTCHKOFF, R.G. (1967): Classical and Inverse Regression Methods of Calibration, *Technometrics* 9:425–439.

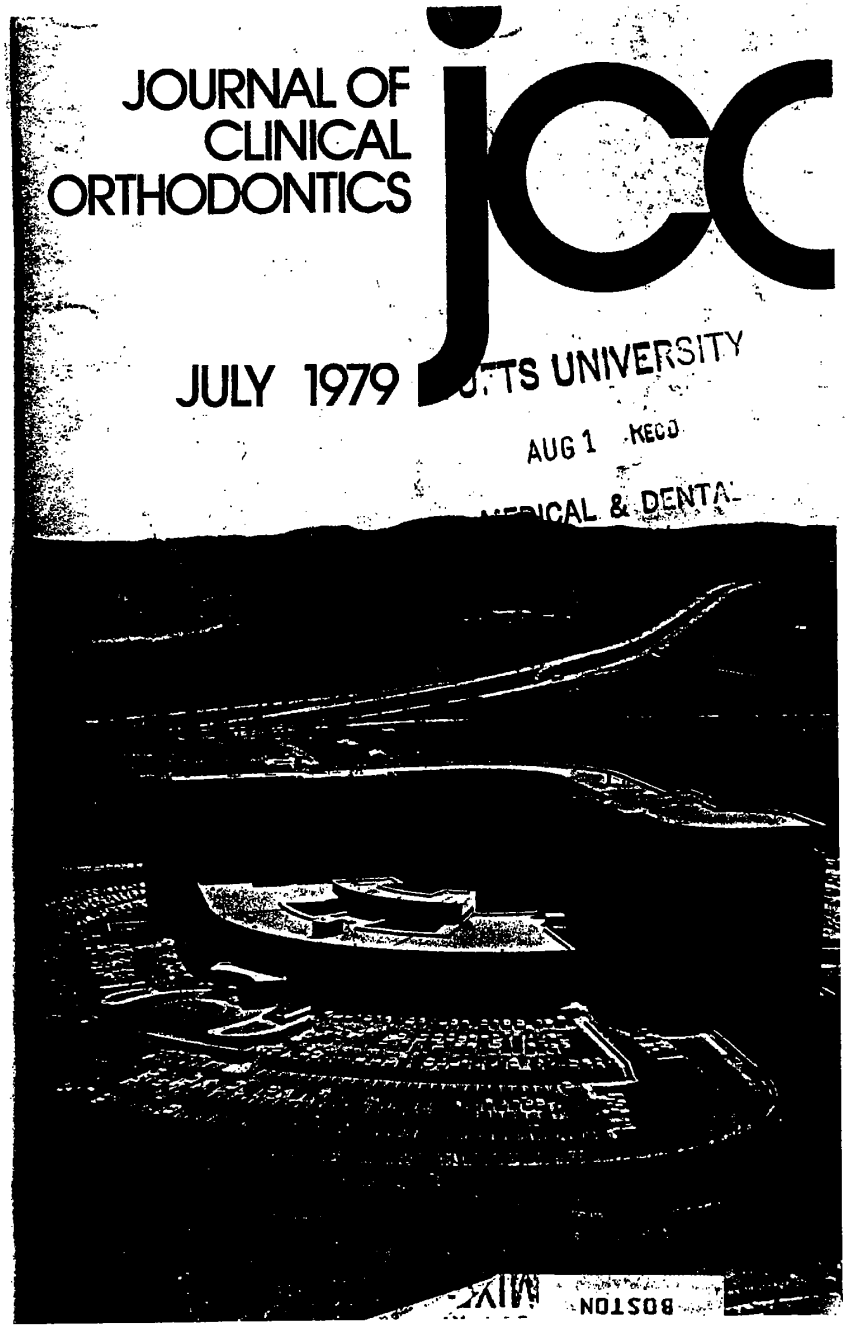
MOORREES, C.F.A.; THOMSEN, S.O.; JENSEN, E.; and YEN, P.K.-J. (1957): Mesiodistal Crown Diameters of the Deciduous and Permanent Teeth in Individuals, *J Dent Res* 36:39–47.

PITTS, N.B. and BROOK, A.H. (1983): Further Software Development for Tooth Dimensions Derived by Image Analysis, *J Dent Res* 62 (Sp. Iss.): 660, Abst. No. 93.

TAKADA, K.; LOWE, A.A.; and DECOU, R. (1983): Operational Performance of the Reflex Metrograph and its Applicability to the Three Dimensional Analysis of Dental Casts, *Am J Orthodont* 83:195–199.

van der LINDEN, F.P.G.M.; BOERSMA, H.; ZELDERS, T.; PETERS, K.A.; and RAABEN, J.H. (1972): Three-dimensional Analysis of Dental Casts by Means of the Optocom, *J Dent Res* 51:1100.

ClearCorrect Exhibit 1002, Page 1169 of 3373



ClearCorrect Exhibit 1002, Page 1170 of 3373

jco/interviews

DR. CHARLES J. BURSTONE on The Uses of the Computer in Orthodontic Practice (Part 1)



Dr. Burstone

JCO What is the future of computers in orthodontics?

DR. BURSTONE Within five to ten years, I expect that you are going to see computers in most orthodontic offices (Fig. 1).

JCO How much are orthodontists going to have to learn about computers?

DR. BURSTONE The average orthodontist may not have to know very much about computers, just as he might drive a car and not know anything about how it works.

JCO Do you think that the individual orthodontic office will have a computer terminal with a case analysis program in it?

© 1979 JCO, Inc.

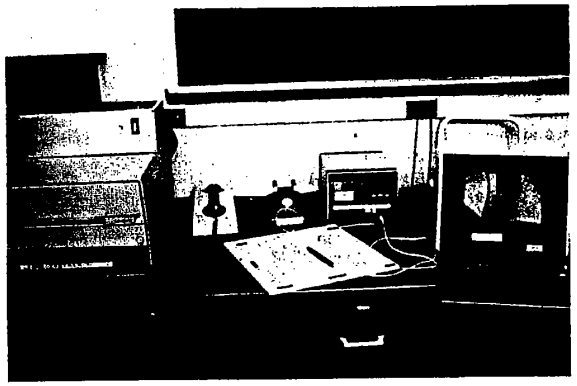


Fig. 1. Minicomputer consisting of a central processing unit, discs for storage, and peripherals such as a CRT terminal and a digitizer.

DR. BURSTONE Yes. Our interest here has been primarily the development of programs which will help the orthodontist from the point of view of case analysis, treatment planning, and treatment. Of course, the use of computers relates to the business aspects of practice as well. So, I think that orthodontists will need a small computer in their offices for business, scientific and clinical purposes. Combining these usages provides a most valuable office tool, and that is most certainly the direction in which we are going.

JCO You use the computer for these purposes here at the Health Center clinic?

DR. BURSTONE Our patient scheduling is all done by computer. We record clinical exams, recall our patients, find patients who are suitable for treatment by students. We get monthly printouts on the status of all our patients, including what stage of treatment they are in and how long they have been under treatment. I think that our treatment time here may be a little shorter than average and one reason for it is that we monitor it so closely. It cannot be monitored as easily by hand.

The computer stores and retrieves information about patients under treatment in this facility. Every patient has a treatment card. After the doctor has seen the patient, the procedure is entered by code number, and the amount of time spent. We want to know how long each procedure takes and how long it takes to treat a case. Information can also be typed directly into the computer at the terminal.

ClearCorrect Exhibit 1002, Page 1171 of 3373

If we want to look up something about a patient, we have a "Look Up" routine. By putting in the correct identification number — and the terminal will tell us if we are putting in an incorrect number — we can retrieve a patient's identification frame. The information normally on a patient history card is flashed on the screen — name, address, phone number, parent's name, and other information. We can retrieve his financial frame, admission date, treatment history. The treatment information frame tells us the date of the last visit, what was done, who the student was, who his preceptor is.

If we want to know what patients are going to be in the clinic next Thursday, we retrieve the scheduling data for that date. If there are more than fit on one frame, it is advanced until you see all the patients scheduled for that day.

JCO What can the computer do in the individual orthodontist's office?

DR. BURSTONE In the past, many orthodontists felt it wasn't practical to do a complete cephalometric examination. They felt limited by the demands of their office to only a few measurements. I think now it is possible to make many measurements and do a thorough analysis for your patient. It is important in the average orthodontic case, but particularly important where you are planning an orthopedic change or any type of orthognathic surgery. There is a special surgical-orthodontic cephalometric analysis, which we published in the Journal of Oral Surgery. This is one type of data base. Minis can also be used to recall information from your clinical exams and records. In addition to the usual information about patient control, an orthodontist might be interested in information such as the number of cases he started versus the number he finished. The things that you have written about as indices to look for in a practice are the kind of things that computers do easily. They can be done by hand, but computers make the information automatically and easily available to the busy clinician. The computer can draw graphs, such as you have published in JCO, of how the practice is doing in various regards.

JCO Are orthodontists perhaps too individualistic to accept a prepared program?

DR. BURSTONE I think there will be a number of very good programs and the orthodontist will select the program he likes. It is inconceivable that every orthodontist will want to program his own material, unless it was his hobby. If there were resistance to good, suitable programs, perhaps the orthodontist would have to be educated to what a good program is. A good program must be flexible, taking into consideration individual variation in both the business and professional components of the office.

JCO Which diagnostic records do you use for treatment planning?

DR. BURSTONE Since the early '50s, I've worked with two records — a lateral treatment plan tracing (Fig. 2) on which we fix facial profile and where the teeth are to be moved, and an occlusogram. I developed the occlusogram for treatment planning, because I consider it to be a valuable record, since a good part of our decision making is in the occlusal plane. I think it is necessary to bring in the third dimension for computer treatment planning. The occlusogram is a tracing of the occlusal of the study cast from a

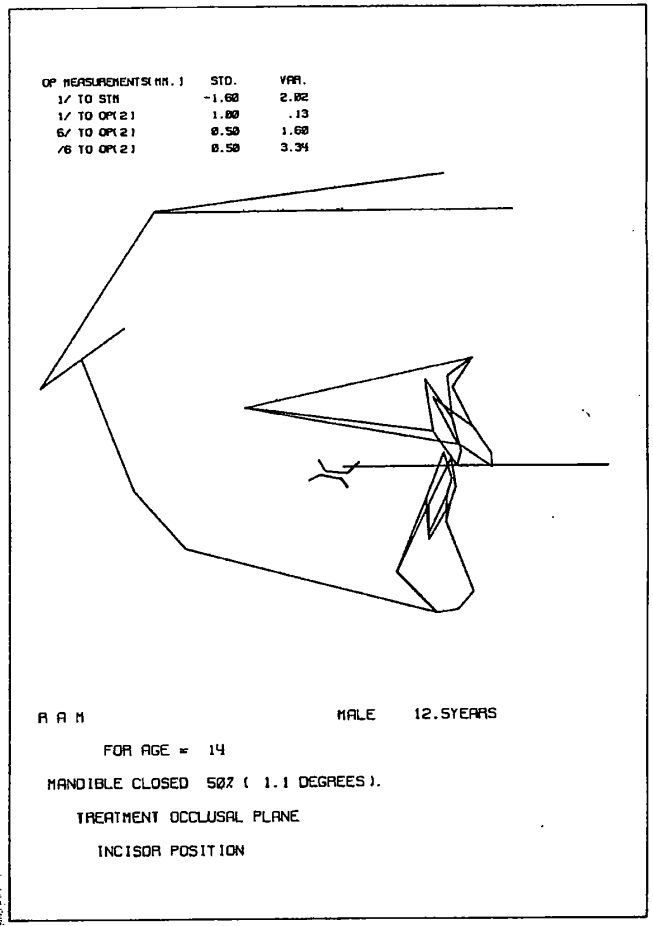


Fig. 2. Lateral treatment plan tracing, showing computer plot of tooth position before and after treatment.

ClearCorrect Exhibit 1002, Page 1172 of 3373

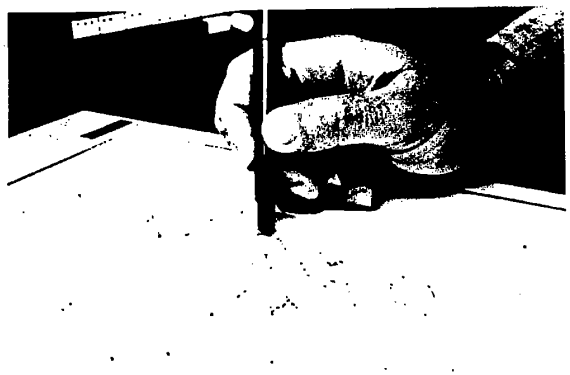


Fig. 3. Digitizing a headfilm tracing. By pointing to the landmark, the point is automatically recorded and stored in the computer.

1:1 photograph.

All the important treatment decisions can be made from these two views. To do many lateral tracings and occlusograms manually is very time consuming. The computer does them accurately and rapidly. It doesn't do any more than you could do by hand, but it makes very detailed workups feasible for the first time. This means better treatment plans and, hence, better mechanics, since we know where we are going in treatment.

JCO How do you use the equipment for cephalometric analysis?

DR. BURSTONE We have a digitizer that interfaces with the computer. We digitize headfilm tracings (Fig. 3). We could digitize the headfilm itself, but we feel it is more accurate to make a tracing and to number the various landmarks. An assistant may not see the landmarks on the film so well. Also, the tracing gives the orthodontist a chance to check it if he wants to. Since the points have to be digitized in sequence, it may help to actually number the points on the tracing in the beginning. As each point is digitized, a beep lets you know that it recorded. We have 52 landmarks which include all the points in our cephalometric analyses. The computer draws the tracing on the screen as a check for digitizing errors. If the diagram on the screen doesn't look like the tracing, you can redo the digitizing.

The unit attached to the computer prints out a hard copy of the cephalometric analysis as a permanent record. The printout gives a mean by age or sex and the individual's variation from it in millimeters or degrees

of deviation.

JCO Let's talk about the data base in your computer program. Where did your normals come from?

DR. BURSTONE We traced and measured headfilms from the Denver Child Growth Center, where an excellent longitudinal sample had been collected. We look askanse at samples that are not longitudinal, which use cross-sectional material or, even worse, patients from orthodontic offices. You end up with a mixture that probably won't describe the population you are interested in. This is particularly important if growth data is to be individualized for the patient. We have standards for age and sex from 5 years to 21 years. In addition, growth increments have been established using facial age, which is a developmental age rather than a chronological age.

JCO What about race?

DR. BURSTONE This sample is from Colorado and is not applicable, for example, to a Puerto Rican population. But the way I look at cephalometrics is that it describes what you have and is not a treatment plan. For descriptive purposes, this sample is useful, until we get more specialized data for race.

JCO How does your analysis compare to others?

DR. BURSTONE The means were pretty close to Downs and other similar analyses.

JCO Many clinical orthodontists question the validity of the concept of normals and treating your patient to a set of cephalometric standards. The orthodontist says, "I am treating this individual. I am not treating him by the numbers."

DR. BURSTONE I would agree that the reason you do cephalometrics is to get a better understanding of the orthodontic case you are going to treat, and not to develop a treatment plan. I look at the head film very much as a general looks at his maps before he plans a battle. He wants to know the terrain he is dealing with. I think that the reason we do cephalometrics is to find out the variation inherent in the individual, by comparison to a standard. The treatment planning is separate. It is a misuse of cephalometrics to use any of those numbers as a goal for treatment planning. For some years, it was common for orthodontists to treat by the numbers. I hope that most orthodontists have gotten away from that idea and that they use cephalometrics for its legitimate function, to let you know the morphology you are dealing with and to describe how the patient differs from the standards.

There are certain measurements that may give us some clues to growth patterns and measurements that let us know how much change we produce with treatment, but in no way are any of these standards to be used as guidelines to treatment. A specific example of this is, as Bjork is suggesting, that there are certain criteria that should be looked at in the shape of the mandible and other parts of the face that would indicate what type of rotation in the mandible you might expect with growth. This is proper use of cephalometrics, looking at variation in the shape of the jaw. Improper use of cephalometrics would be to take some specific number and we could use, as an example, lower incisor to APo as a guide to lower incisor position.

JCO That's one relationship that a great many orthodontists use for a treatment goal.

DR. BURSTONE Lower incisor on

ClearCorrect Exhibit 1002, Page 1173 of 3373

the average is 2mm forward of APo. The interesting point is that the standard deviation is ±2mm from the mean. 99% of the population of good occlusions falls within 3SD. Three times 2mm is 6mm on either side of the mean. So, there is about a 12mm range of variation normally for the position of lower incisor to APo in untreated people. Well, most orthodontists are probably not going to vary their incisors more than 12mm, and 12mm is too large a range to give a definitive plan.

But, the big fallacy would be to think that the lower incisor always should be 2mm forward of APo. If the mean is +2 and you have a patient who is 8, you can say that the lower incisor is protrusive. But, 8 might be very desirable for that patient. There are a number of patients with adequate lip length and a very large soft tissue chin who are stable and esthetically attractive with protrusive lower incisors. We don't want to fall into the trap of using any of these standards as absolutes.

We could make the same comments about lower incisor to Frankfort, which is a Tweed measurement. It has a standard deviation, depending on age, of about 5 degrees. Three standard deviations is 15 degrees. So, there is a 30-degree variation in the position of lower incisor to Frankfort. Most orthodontists would not go beyond that range anyway.

JCO Even two standard deviations would be quite a range.
DR. BURSTONE Right.

JCO Do you not have any bias with regard to protrusion? Does it offend you if somebody is protrusive in appearance, or do you say, "People can be protrusive and it's not up to me to judge whether they should or shouldn't be"?
DR. BURSTONE Beginning with my graduate thesis back in 1955, I have always said if you want good facial esthetics you have to look at soft tissue. Measurement of teeth and hard tissue will not be predictive of esthetics. Before you start to determine what tooth movement you need for the kind of face you want, you have to have a concept of what type of face you are interested in.

JCO What is your concept of good facial harmony and beauty?
DR. BURSTONE In Indianapolis, we collected a sample of adolescent individuals who had good faces. I have often found that orthodontists are the poorest judges of good faces. After a while you see your treated results and you think that type of face looks good. So, we had an independent group of artists and housewives look at photographs of children to identify the faces they thought were the best. It was very interesting, because all of the judges agreed on what the good faces were. They categorized faces on a scale of 1 to 5, and we selected 1 and 2 for our cephalometric studies to see if there were any soft tissue measurements that would give us good facial form. We took headfilms, and we measured hard tissue as well as soft. We found a great deal of variation in the amount of lip protrusion and facial convexity in faces that were considered good looking. There was also a great deal of variation in any of the typical cephalometric measurements — lower incisor to APo, lower incisor to Frankfort — in untreated people that have good faces. So, if you want good faces, you don't treat to any dentoskeletal mean.

JCO What do you do?
DR. BURSTONE Though I don't believe in averages for cephalometrics, I think there is some merit to using averages in evaluating facial harmony. If you have lips that are protrusive, most people will not consider that to be good looking. If there is only a little bit of variation, you can still have a good face. If you are too many standard deviations away from normal, as you walk down the street everybody knows that you are different. So, means have some value in our society where people want to conform to certain ideas of appearance. If you look at the faces that are used in advertising, they are very close to my soft tissue means.

JCO So, a standard for facial esthetics is a soft tissue standard, with little or nothing to do with the hard tissues?
DR. BURSTONE The reason you can't go by hard tissues is that there is a great deal of variation in soft tissue thicknesses, almost more variation than there is in the dental-skeletal pattern. So you cannot just look at teeth and bones. A good part of treatment planning is a consideration of facial form and it should relate to a soft tissue analysis.

JCO What factors do you use in your soft tissue analysis?
DR. BURSTONE The components of the soft tissue analysis that we have in our computer include the facial profile, lip protrusion, lip thickness and the function of the lips — how they close and their functional relationship. As far as lip protrusion is concerned, we have a reference line that goes from subnasale to pogonion. We purposely avoid structures like the nose, which is highly variable.

JCO Nevertheless, the orthodontist has to make a treatment decision about the location of the anterior teeth and when he does, at least for most orthodontists, facial esthetics is one of the criteria he is thinking about.
DR. BURSTONE Right. It is one. The other criteria are stability and ease of lip closure. Let's see how this might fit together to give us the determination we want. We might have two patients, both with protrusive lips. In one instance, there might be adequate lip length and no difficulty in covering the vertical dimension anteriorly and no problem with arch length inadequacy. We would probably leave that patient in protrusion. Certainly if someone can close over protruded teeth without a great deal of strain, this can be esthetically desirable. On the other hand, we may have another patient with the same protrusion who may have a large interlabial gap and can't close the lips. That's a different story; reduction of the dental protrusion is needed.

JCO Supposedly, there is a balance among health, function, stability, and esthetics — dental and facial esthetics. Do you have any evidence with regard to stability which would influence you as far as the position of the upper and lower incisors is concerned?
DR. BURSTONE Stability is in the no man's land of orthodontics. There has been research in which the forces of the tongue and lips were measured with strain gauges. But, in the average patient, it appears that if you move lower incisors lingually the tongue will adapt. So, there are minimal limitations on lingual movement of incisors. There are always special cases of tongue thrust where this can't be done, perhaps an abnormal swallowing pattern, or a larger tongue, or a forward positioned tongue. But, typically, it appears that the tongue will adapt to lingual movement of the lower incisor.

ClearCorrect Exhibit 1002, Page 1174 of 3373

:O What about the lips?
R.BURSTONE If you attempt to ›ve the incisors labially, then we ve to determine if we are going to be ›ving the incisors against the pres- re of the lips when the lips are ›sed. My soft tissue analysis in- ıdes guides for looking at lip drape of per and lower lips with respect to the isors. For example, if one had ade- ate lip length in the relaxed lip posi- n and the lower lip is hanging out terior to the incisors, maybe you uld move the lower anteriors for- ırd. On the other hand, if you have an ıividual with a tight lower lip, you nnot move the lower incisors safely rward, even though this might seem ost desirable esthetically. This is mmonly seen in patients with large ıin buttons. It isn't the chin button that large. It is the lower incisors and veolar process that are back. Unless e can eliminate some of the tension the lower lip, we probably wouldn't ıve a stable result moving the lower cisors forward. But all of these things e only guides.

Strain gauges can measure mus- e forces, but no one has been able to ıd what determines tooth stability. It more than a summation of forces. At ıy given time, the summation of the ngue and lip forces will not be neces- ırily zero.

:O Of course, the force is not con- ant.
R. BURSTONE Yes. There is a ne factor. The periodontal ligament sponds to the sum of all forces aced on it over a period of time. eadgears, for example, do not have be worn continuously to produce oth movement.

:O How about function? There are any schools of thought, but if, for example, an orthodontist believed in anterior guidance, he could apply some principles of function to where he would place the anterior teeth.
DR. BURSTONE There seems to be some agreement in dentistry on certain objectives — the correspondence of centric occlusion and centric relation, vertical dimension and interocclusal space, functional movements related to cuspid rise or mutually protected occlusion. Certainly, one's concept of functional occlusion affects the position of the anterior teeth, since occlusal forces as well as tongue-lip forces determine tooth position. Theoretically, greater overbite or incisal guidance should increase the lingual component of force during incision. This could be a factor in treatment planning lower incisor position.

JCO Are we not then saying that if one doesn't really know what esthetics, stability and function are or ought to be and doesn't know how all this relates to health and longevity of the teeth too well, that it is not surprising that some orthodontists say there is nothing to any of it and treat in a free-wheeling manner, while others say, "I need specific number guides and normals are as good as any, because people cluster around normal"?
DR. BURSTONE Just because treatment planning is complicated is no reason not to consider the real factors that go into it. If I thought that computers should be used to treat by the numbers, then I would have designed the programs that way. The programs are designed to be interactive, to vary with how an orthodontist would look at a case and to vary from patient to patient. There are a number of different goals that we should establish and then determine how we are going to reach them in treatment. That is what I mean by treatment planning.

JCO How do you determine where the incisors are to be positioned?
DR. BURSTONE Rather than determine the position of the teeth first, I'd rather start with a consideration of what kind of a face we want, recognizing that that might be partly a personal judgment. If we establish the type of face for the individual patient, then we can figure the position of the teeth. For example, typically the lower lip protrudes 2mm to the subnasale-pogonion line; upper lip, 3mm. If I want to treat to that, then for that patient I would figure out where the lower incisor would go to get that lip position. That's far different than just treating to a dental-skeletal standard.

If we measure lip thickness, particularly if we use the lower lip as a guide, we can then estimate the position of the lower incisor. We can individualize lip position for the patient. If you think the patient would look better with more protrusive lips — instead of 3/2, maybe 4/3 or 5/3 — the lower incisor could be moved further forward. We put that together with ease of lip enclosure and what will be stable. If someone has very short lips, that tells us we probably want to get those lower incisors as far back as we can without unduly flattening the face. It has nothing to do with standards. I think that standards have held back the development of orthodontics. They are good for descriptive purposes. They make you aware of things, but they stop the orthodontist from thinking.

JCO Let's say he has positioned the lower incisor, based on his treatment objective for that. What about the effects of treatment? Suppose he were to consider using mechanics which might have an adverse effect, such as the effect that Class II mechanics might have on the rotation of the mandible or the cant of the occlusal plane. Does he plug that expectation into the various treatment options to see its effect on the tooth relationships and on the face?
DR. BURSTONE I'd like to differentiate between the goal and the plan and what the orthodontist is capable of achieving at the end of treatment. We can't have a goal that is impossible to achieve, and the clinician must be aware of limitations, such as an inaccurate growth estimate or unpredictable cooperation.

I object to building into a treatment plan the effects of treatment, many of which may be undesirable. Let's take the example of deep overbite correction. In big ANB discrepancies, you don't want to correct the overbite by hinging the mandible open. If you have built that into your treatment plan, there would be no motivation to improve the quality of your treatment. Your treatment plan should actually reduce the vertical dimension. It might also demonstrate that you need a great deal of intrusion of upper incisors. Therefore, your mechanics should seek to produce that type of tooth movement. If you merely built in the computer what might normally happen in treatment, many of these results are undesirable.

Some have thought it would be nice to take a lot of treated cases and get a computer bank of what happens, but this has very little relevance to the treatment of the individual case. We hope that the quality of orthodontics will improve and what has been done in the past need not be the guide to treating cases in the future. Let's not confuse the goal with what might happen in treatment. Once you see your goal, then your mechanics should be mod-

ClearCorrect Exhibit 1002, Page 1175 of 3373

ified for each patient. For example, deep overbite is not going to be corrected in the same way on a rapidly growing patient as on one who is a minimal grower; not in the same way on a patient with a big AB discrepancy in comparison with a more normal skeletal pattern.

JCO So, you don't believe in building the expectations of the tooth movement that your particular treatment will accomplish in trying to evaluate what the finished result is going to look like.
DR. BURSTONE It may be a bad analogy, but if Jascha Heifitz is going to play a concert tonight, he can anticipate that he will have a few false notes in there. But he does not build that into his practicing and planning for the concert. We do have to have clear-cut objectives. On the other hand, if we start building in the usual mistakes and particularly the national average, I think we are whittling away the quality of orthodontics.

JCO There are times, for example, in a brachyfacial pattern where you could open the mandibular plane and not have an adverse effect.
DR. BURSTONE Then that should be part of the treatment plan. You purposely want to do this and you would design your mechanics to erupt teeth, possibly by the removal of the curve of Spee. Many patients with small vertical dimensions have strong musculatures and though it might be desirable for facial form to increase the vertical, it might not be stable. So, our goal should be our best estimate of what is possible and stable, based on our understanding of the patient's musculature. That doesn't mean we will achieve it. We must monitor it.

Another way to get at your question is that I could devise a computer program which could be poor treatment, and I could show that I was reaching that objective every time. That isn't what we want. We want the highest possible objectives that are reasonable for the patient. We want to minimize adverse treatment responses and not build them into treatment.

JCO Of course, mandibular plane can be affected by an interplay of growth and treatment.
DR. BURSTONE The decision on rotating the mandible is based upon what might be stable. Many times you can hinge the mandible open and it might be stable. There might be excessive interocclusal space, or there may be a great deal of growth yet to come during the period of treatment. So, you may temporarily hinge the mandible open and in time it may recover.

JCO In fact, most of the time the mandible grows in a counterclockwise direction.
DR. BURSTONE Yes. That is the work of Bjork, that most mandibles tend to rotate in a counterclockwise direction. In a short period of time — a couple of years of treatment — this can be relatively small. But, it is so easy to erupt teeth in treatment, that most clinicians will show a great deal of rotation of the mandible in a clockwise direction on patients that have deep overbites or Class II occlusions. Indiscriminate leveling of arches and the use of Class II elastics are associated with this.

JCO Do you use a frontal film?
DR. BURSTONE We use a frontal film primarily for determination of symmetry and to evaluate facial width.

JCO Don't you find asymmetry is more the rule than symmetry?
DR. BURSTONE Yes, and diagnosis of asymmetry really counts in planning a case. Many of the midline discrepancies are caused by a skeletal asymmetry. Many times this is missed in treatment planning and, if it is missed, these asymmetries can come back to haunt you at the end of treatment.

JCO Do you do a separate analysis of the two sides if you have an asymmetry?
DR. BURSTONE That's an interesting point you bring up. All of our analysis is done by quadrants. To be meaningful, it has to be done by quadrants. For example, a 7mm arch length inadequacy may be used by a primary molar that has been lost unilaterally and, hence, represents a quadrant problem only. If you do your analysis by quadrants, the decision about where you think the midline should be is a very significant one. It will affect the arch length inadequacy by quadrant, and the type of asymmetrical mechanics required.

JCO Don't you frequently find that the occlusal plane is tipped, from the anterior view?
DR. BURSTONE To me, one of the important considerations in treatment is the cant of the occlusal plane. From the lateral view, it is necessary to maintain the proper plane by controlling intrusion and extrusion. Now, with regard to the question of the anterior cant, individual teeth may be off the occlusal plane at the beginning of treatment, but it may be satisfactory overall. On the other hand, after treatment has commenced, it is very common to see unusual cants to the occlusal plane from the anterior view. These are produced by side effects from the mechanics used. My graduate students know if they really want to get me excited, all they have to mention is such mechanics as putting Class II elastics on one side and Class III elastics on the other; and anterior crisscross elastics. This treatment produces undesirable cants to the occlusal plane, which are easily recognized as unesthetic, even by the patient.

JCO That is an important point you are making here about tipping the occlusal plane with those mechanics.
DR. BURSTONE When you have a skeletal asymmetry, the midlines of the maxilla and mandible don't line up. I call it an apical base midline discrepancy. You have to plan your mechanics accordingly. You could use asymmetric extractions. You could translate on one side and tip on the other, so you vary anchorage loss from side to side. There are many possibilities. You don't want to use unilateral elastics very much. Occlusogram planning lets you solve the problem optimally at the beginning of treatment, so that desirable mechanics can be planned.

(TO BE CONTINUED IN NEXT ISSUE)

ClearCorrect Exhibit 1002, Page 1176 of 3373



ClearCorrect Exhibit 1002, Page 1177 of 3373

proper treatment plan can be defined and our goals of improving facial esthetics, achieving a healthy anatomical and functional occlusion and establishing stable results can be realized.

ACKNOWLEDGEMENT

The authors acknowledge with sincere appreciation the editorial assistance provided by Mrs. Beatrice Saltzman in the preparation of this manuscript.

REFERENCES

1. Epker, B.N. and Fish, L.C.: Surgical-orthodontic correction of open-bite deformity. *Am. J. Orthodont.* 71:278-299, 1977.

2. Epker, B.N. and Wolford, L.M.: Midface osteotomies: their use in the correction of the developmental and acquired dentofacial and craniofacial deformities. *J. Oral Surg.* 33:491-514, 1975.

3. Burstone, C.J.: Lip posture and its significance in treatment planning. *Am. J. Orthodont.* 53:262-284, 1967.

4. Profitt, W.R. and Ackerman, J.L.: Rating the characteristics of malocclusion: a systematic approach for planning treatment. *Am. J. Orthodont.* 64:258, Sept. 1973.

5. Bolton, Wayne A.: Disharmony in tooth size and its relation to the analysis and treatment. *Angle Orthodont.* 28:113-130, 1958.

6. Goldsmith, D., Berkman, M.D., Shprintzen, R.J., Rothschild, D. and Trieger, N.: Functional adaptation of the speech and swallowing mechanism following correction of dentofacial deformities. *Abstract 145,* 3rd International Cleft Palate Congress, Toronto, Canada. June, 1977.

7. Worms, F.W., Isaacson, R.J. and Speidel, T.M.: Surgical Orthodontic Treatment Planning: Profile Analysis and Mandibular Surgery. *Angle Orthodont.* 46:1-25, 1976.

8. Shprintzen, R.J., McCall, G.N. Skolnick, M.L., and Lencione, R.M.: A three-dimensional cinefluoroscopic analysis of velopharyngeal closure during speech and nonspeech activities in normals. *Cleft Pal. J.* 11:28-35, 1974.

9. Rothschild, D. and Shprintzen, R.J.: Velopharyngeal incompetence following maxillary advancement in cleft deformity. *Abstract. 58th Annual Meeting of the American Society of Oral Surgeons.* New York, September 1976, p. 46.

jco/interviews

DR. CHARLES J. BURSTONE on The Uses of the Computer in Orthodontic Practice (Part 2)

JCO Now, will you demonstrate how you make and use the occlusogram?

DR. BURSTONE Digitizing the points of the 1:1 occlusal photograph of the model gives us both measurements and a diagram of the tooth positions (Fig. 4). While we are talking, out came a printout of tooth size discrepancy. The computer does a setup.

JCO Do you relate this to overbite?

DR. BURSTONE Oh, yes. This is a real tooth size discrepancy analysis since a setup is done by the computer. A Bolton analysis, by contrast, is only a screening mechanism.

JCO Are your tooth size means from the same Denver sample?

DR. BURSTONE This is from Moorrees' work.

JCO What points do you digitize?

DR. BURSTONE Points are digitized at the mesial and distal contacts and the tips of the buccal cusps of the lower, and the functional cusps on the upper will be the tips of the lingual cusps. The computer draws the teeth. These are schematic representations of the upper and lower teeth.

The computer calculates the variations from the mean in tooth size. The reason for seeing this on the screen at this time is to find out if there are major tooth size differences. This is used if we want to make a decision on extraction, or to point out a mistake in digitizing. Later, we will actually set up the teeth on the computer to see how they are going to fit.

Now, the first question the computer asks is if the right molar should be moved so that we can determine the geometric midline. There are other determinants of the midline, including what looks good for the face and also if there is any skeletal discrepancy anteriorly. The geometric midline is a point right in the center of the arch if we like the relative positions of the posterior teeth on the right and left sides.

 © 1979 JCO, Inc.

ClearCorrect Exhibit 1002, Page 1178 of 3373



Fig. 4 A. Digitizing points on a 1:1 occlusal photograph. B. Occlusogram. Computer-drawn original and final arch forms. Arch length inadequacies and movement required of each tooth are calculated and shown.

The first judgment I want to make in treatment planning is if I think that the two posterior segments are symmetrical to each other.

So, the computer asks if you would like to move one buccal segment back in respect to the other, just to equalize their axial inclination or their position. It will then calculate where the center of the arch is — the geometric midline.

JCO You use a soft tissue point, the median palatal raphe?
DR. BURSTONE That's just an arbitrary point, only used for reference. We definitely do not use it for a treatment midline.

Next, to determine where the midline should be on the patient, we use all our knowledge as an orthodontist. We consider the facial midline based on esthetic considerations, anterior apical base discrepancies, and the geometric midline which we just established.

Now the computer will first of all draw the original malocclusion on which you see certain control points which the orthodontist decides. He decides what the width should be. He digitizes where he wants the lower incisor to be. This is all individualized. All the computer does is make it easy to handle. Now, we have the new arch form constructed. Both the original and final arches are shown on the screen.

JCO Do you have an arch form formula that you have worked out?
DR. BURSTONE Yes. The anterior part of the arch is a segment of a parabola, so it fits a parabola between the points that you select. There are enough control points, so that each arch form is individualized for the patient. When we have decided where to position the midline, the computer stores that decision and it then calculates the arch length inadequacy. Also, the computer graphically shows us where each tooth will be in our individualized arch.

JCO What are the control points that the orthodontist decides in determining arch form?
DR. BURSTONE One is a midline point — how far backward or forward you want the incisor. He also selects the width points where he thinks the tips of the cuspids should be, and the mesiobuccal cusp of the first and second molars.

JCO These are selected by the orthodontist and digitized.
DR. BURSTONE Yes. The clinician must make those decisions. No computer can make them. However, our

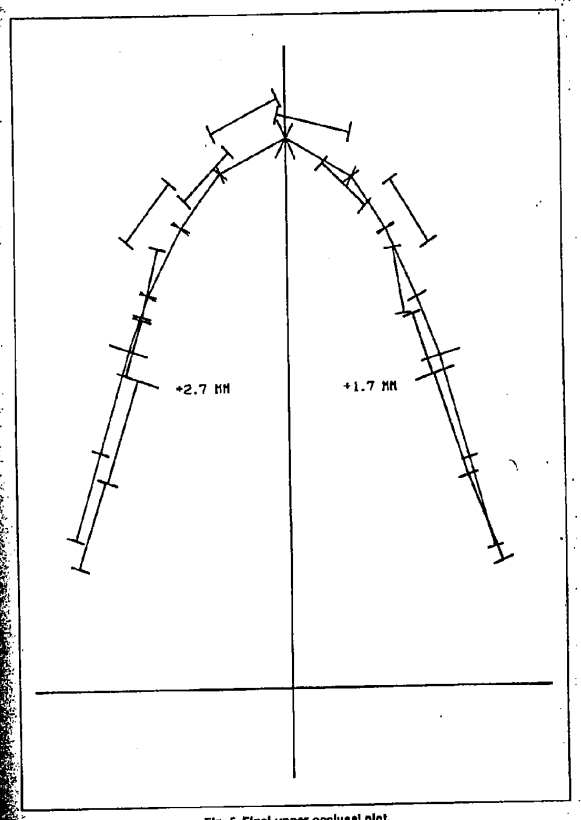


Fig. 5 Final upper occlusal plot.

lateral treatment planning program helps with the decision of where the lower incisor goes.

Now, the computer asks if we want to see a hard copy. Normally hard copies are made as a permanent record at the end. The printout is three times life size, so we can see what the relationships are in detail. The longer lines represent the mesials of the first molars (Fig. 5).

The occlusogram plots may look

ClearCorrect Exhibit 1002, Page 1179 of 3373

strange if you are not used to looking at them, but you can quickly get used to this representation of the teeth. The original malocclusion is in blue. The final position of the teeth is in red. The arch length inadequacy is the difference between the long red and blue lines at the first molars.

We found out from the computer that we are short on arch length. Now the computer asks what we would like to do about it. Do we want to remove teeth? We can choose to extract and see the "treated case" on the screen. If we don't like the results, we can go back and go through another treatment plot. We can try one with different extractions or nonextraction. A number of different treatment plans can be tried to arrive at the best possible one.

We decided to take out upper first bicuspids. A double check of tooth dimensions on the hard copy shows that the upper bicuspids were over 7mm in width. Therefore, this becomes a reasonable solution. We treated the lower arch on the computer and established the lower arch form. The computer now fits upper arch to lower. We have already instructed the computer to give us a set amount of overjet. We used 1mm for the incisor and for the cuspid. We could have used 2mm for the incisor and 2½mm for the cuspid if we wanted more cuspid rise. In fitting the upper arch to the lower, the computer calculates the arch length inadequacy based on the two arches. Once again, the final decision about what the clinician wants in overjet and overbite is left to him.

The computer tells us that, in the upper arch, on the left side the buccal segments can come forward 2.7mm and on the right side they can go back 1.7mm, based on the repositioning of the incisors. This becomes a severe anchorage problem. The computer once again asks you if you have any other solutions to try. We don't. The final upper arch fits the final lower.

Finally, let us do a computerized wax setup, so to speak (Fig. 6). The red is the lower — central groove, tip of mesiobuccal cusps, tip of distobuccal cusps. The green goes the other way — central groove, mesiolingual cusps, distolingual cusps. Typically, when we set this up with normal overjet, the tip of the mesiobuccal cusp of the first molar will be at the embrasure. So, our patient is a little Class III-ish in the molar region.

We are looking again at where the cusps will fit. The tip of the cuspid would normally go right in the embrasure and this one is pretty close. We can also see how the upper buccal cusps fit with the lower lingual and how the buccolingual widths relate.

JCO Would you please summarize the computer procedures for the occlusogram?

DR. BURSTONE The orthodontist makes the major decisions in our program. He starts with a photograph of his models and determines how far backward or forward he wants the lower incisor to be. He determines what his cuspid and first and second molar widths should be. The dental assistant will then digitize all of the teeth by landmarks on the teeth. The computer will then determine the arch length inadequacy per quadrant. The orthodontist will then decide how he is going to solve the problem — either by extraction or posterior movement of teeth. The computer will then replot the position of the teeth and determine where the posterior segments should be at the end of treatment.

In an extraction case, it will tell us how many millimeters forward the buccal segments can come in each quadrant. The computer also makes calculations along the way that are useful to the orthodontist in arriving at his decision. It measures the mesiodistal diameters of the teeth, compares them to standards, sees if there is a tooth size discrepancy, compares right and left sides for discrepancy. It also gives consideration to the posterior segments and determines where the correct midline

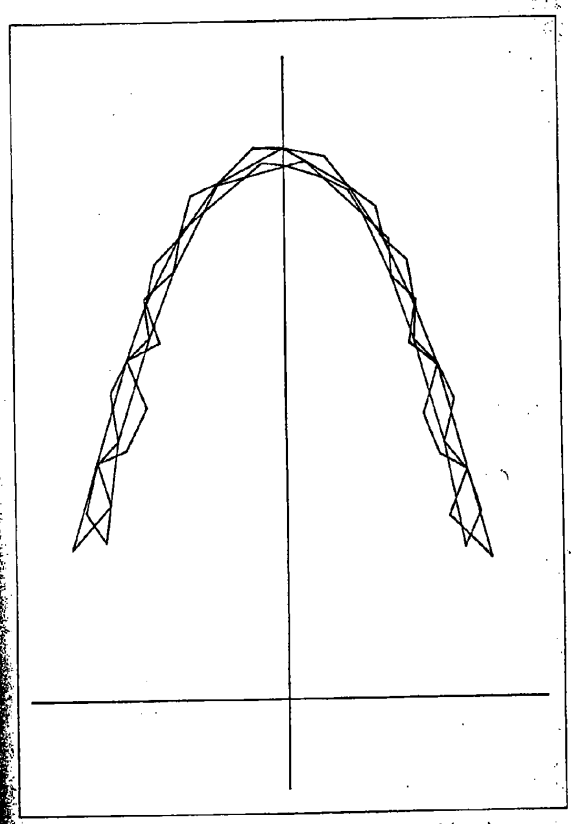


Fig. 6 Computerized setup. Lower teeth (red) and upper teeth (green).

ClearCorrect Exhibit 1002, Page 1180 of 3373

should be. Finally, the computer will set the teeth with detailed intercuspation, similar to a wax setup, to see if there are any tooth size discrepancies. At any stage, the orthodontist can cycle back and try another solution.

JCO What is the value in comparing to average tooth sizes?
DR. BURSTONE We really want to know how the teeth fit together. Average tooth size is not the most important factor, because you can have teeth that are uniformly much larger than average and no problem. The comparison between the standard and the individual gives us a way of checking our digitization for big discrepancies. The other way that it is used is that it lets you know the sizes of teeth in case you plan to extract teeth or do some atypical extraction.

JCO Is the margin for error in digitizing less than for other methods of tooth size measurement?
DR. BURSTONE In digitizing, we figure operator error is between ¼mm and ½mm. Most of our devices are accurate to a quarter of a millimeter. I find it far superior to dividers, which have a certain amount of give to them. With a Vernier guage, it is hard to get exact mesiodistal diameters of teeth. Provided axial inclinations are fairly normal, the use of a photograph is more accurate than other methods of measurement; atypical axial inclinations are compensated for in our system.

JCO How about using a plastic table over the occlusal surface of the model?
DR. BURSTONE I have been teaching occlusograms since 1958 and many of our graduates have elected not to get an occlusogram camera and have used a piece of plastic over the occlusal surface of the model and made tracings manually. I still think it is preferable to use a photographic record, since it eliminates the step of tracing and gives a permanent record.

JCO What is the special camera used to take the occlusal photograph?
DR. BURSTONE The occlusograph uses a view camera with a Polaroid back. By changing the bellows distance, you can make a 1:1 photo. A stage has been made for positioning of the model. All of our models are ground with a V-shaped groove, and they are mounted in centric relation, which is useful for diagnostic purposes. Once the groove is oriented on the stage, we know that the models are in a centric relation relationship. I think the occlusal view is the key to planning. I think you almost learn more about what is going on from this view than from the lateral view. You can see your width problems and your asymmetries.

JCO Do you think that centric relation is an absolute?
DR. BURSTONE Many of our goals might be hard to defend on scientific grounds, but we can't declare a moratorium in orthodontics until we know all the answers. Many goals like centric relation are reasonable goals until proven otherwise. For treatment planning, we need a reproducible reference position. If our patient slides 3mm forward and 5mm to the left, that is no position on which to do our treatment planning. So, we use centric relation as a reference position. That is particularly true of our lateral head films. How are we going to interpret growth changes if we have no stable reference? Can you imagine attempting growth prediction and including the variation in jaw position?

JCO Do you use the machine to make growth predictions?
DR. BURSTONE Yes. Let's try one. The computer is asking the number of years you would like to predict.

JCO Five.
DR. BURSTONE All right. Let's do a five-year growth prediction. You have two options. You can use mean growth data or you can modify these because of certain hunches that you may have about the way treatment will be.

JCO Let's use a normal growth program.
DR. BURSTONE We just ask the computer for that and here is the original on the screen and now the growth prediction. We are interested in knowing how much the lower facial height will increase. The computer calculates that for you. Vertical height of lower face (ANS to Menton) originally was 75 and afterward was 83. It has increased 7.8mm.

We are also interested in horizontal change. AB to occlusal plane was originally −2.7 and after it is 5.9. So there is a change of 8.6.

Now the computer asks if you want to do that again. You might want to go out a different number of years. You might want to go to maturity. You might want to vary the type of growth. We have the option of using a percentage of the mean for mandibular growth. We don't have to use the averages. We may feel because of skeletal pattern, morphology, or any hunch we have, that instead of average growth, we may have 125% of the average. We may also feel that we are going to have rotation of the mandible and we can build that in.

With our growth prediction procedure, you see the interactive nature of the computer. It is the orthodontist working with the computer. The orthodontist may think, "Well, I have three types of growth that I might expect. Let's see what each will look like before I make my decision." One of the reasons that minicomputers will be useful in an office is that they increase the options you look at. It is also a design tool for treatment planning and appliance design.

JCO It ought to be particular fun when you come to adding treatment.
DR. BURSTONE I believe that the orthodontist wants to individualize his treatment. We are developing programs that go beyond treatment planning, which help the orthodontist in designing his appliance and using it optimally.

JCO What do you think of the idea of successive films — let's say annual films — to determine a pattern of growth?
DR. BURSTONE When I was back in Indiana, one of our graduate students, using the same Denver growth material, made measurements of growth patterns from year to year on the whole sample from age 5 to 21, and there were no correlations between the amount of growth and the direction of growth from one increment of time to the next. No one has demonstrated any way of interpreting two or three serial x-rays to show direction of growth over a short interval of time. Bjork's suggestion of looking at facial morphology is more helpful.

JCO What value do you ascribe to growth prediction?
DR. BURSTONE I think growth predictions are very useful. The first person to point out the value of growth prediction was Ricketts. Any growth

ClearCorrect Exhibit 1002, Page 1181 of 3373

prediction is still better than no growth prediction at all, if it is based on good data. Most growth predictions are based pretty much on averages, but you should be aware of what the variation is. Your patient isn't necessarily going to grow down the center. If you assume that there will be no variation from your prediction, you are not understanding what you are doing with growth prediction. Determining a developmental age, like my facial age concept, is a big help.

JCO Would you say that for most people pattern extension growth prediction is somewhat useful, because most people could be expected to grow that way?

DR. BURSTONE There is a lot of confusion about the word "pattern", I think. At usual treatment ages, a high percentage of facial development is completed. If you have a 12-year-old, maybe there is only 5-10% of growth yet to come. In that sense, the pattern is set. What can happen in that 10%? But, clinically, we are interested in the difference, because even that 10% can give us a change in jaw relationship of 5,7,10mm which might correct a Class II case. So, we want to predict incremental change and that is not patterned. Bjork, for instance, has shown that the magnitude of jaw growth and the magnitude of jaw rotation can change from one period of time to the next.

JCO But, is not the whole essence of growth prediction to take the pattern that you have and enlarge it by the average expected amount of growth of the various parts in the direction in which they are going?

DR. BURSTONE I think it may depend on how you use your prediction. If you think you use the prediction to see what the face will look like five years after you start treatment, then we could say that an average growth prediction may be pretty good, because the face isn't going to change very much in five years.

JCO Why even do it, if there is not going to be that much change?

DR. BURSTONE The way I use growth prediction is different. I am more interested in the incremental change during that time than what the face will look like later, because the total face isn't going to be changing that much. I want to know if the mandible is going to pull out ahead of the maxilla, and by how much. If I have a 7mm Class II case and the mandible is to pull out 5mm with respect to the maxilla, that's what I am interested in. If I have a deep overbite and the distance from ANS to Menton is going to increase 5mm, that's what I want to know.

JCO Perhaps you could bias that to some extent, if you had some intuition about the way this person was going to grow.

DR. BURSTONE I think that the biases probably are intuition at this point. The work of Bjork on the pattern of rotation of the mandible would be part of your bias. There can be knowledge about other members of the family, which might tell you something about increments. Since none of that can really be put on a scientific basis, I think you should call it intuition or art, but it is important that any good computer program have the potential for that intuition. Even with good standards and intuition, part of being a good clinician is to understand that we are not completely predictive, that we must monitor cases carefully, that we must decide on a treatment plan that doesn't put us in a box where we have no other options later in treatment.

JCO Do you first run through a prediction based on the standards and, perhaps, a five-year prediction just laying out an extension, and then modify it if you wanted to, throwing the intuition into a second view of the problem?

DR. BURSTONE One of the advantages of the computer is that it is not time consuming to do both. I could do an average one and then probably do some in which we alter the increments and also try to build some rotation in. A printout or plot will give you some of the variations that could possibly happen in growth and, because all of your options would be reasonable options, it also lets you know why the average by itself might not be the only type of growth pattern the patient could have.

JCO Do you then consider what your treatment options are and whether they are achievable under each of these growth circumstances?

DR. BURSTONE Yes. I like to keep the treatment decision separate from the decision on how the jaws will grow, though they do interrelate. First, I want to know what the bony base relationships will be with growth. Even if it's wrong, it should be your best estimate. Then, when you know where the jawbones are going to be, you can make your decisions about tooth movement and if the treatment options are achievable.

JCO How do you establish the occlusal plane?

DR. BURSTONE I look at the axial inclinations of the posterior teeth and establish what I call a natural plane of occlusion. I also look at the relationship of the lip to the upper incisor to make sure that not too much incisor is showing; and I look at the amount of alveolar process in the upper arch. In the lower arch, I notice the amount of attached gingiva for periodontal considerations. Then I look at the effect of occlusal plane on the AB relationship. The steeper you make the plane, the less AB discrepancy in a Class II case. It may or may not help you, depending on how you look at it. It certainly minimizes the discrepancy. Based on all of those factors, we establish the treatment plane of occlusion. The computer supplies a data base while we make this decision. The next major decision, and the only remaining decision, is how far back we want the anterior teeth on our lateral view.

Following this, the computer draws the positions of the teeth and establishes the occlusal plane. The red line is the skeletal pattern after growth and after rotation of the mandible. Final tooth position is in blue.

JCO You also use the computer to determine forces and select archwires and loop configurations.

DR. BURSTONE Yes. Our use of computers started out as a research tool. We were measuring forces from orthodontic appliances. That developed a great deal of data and it was necessary to use a minicomputer to make it easier to interpret the data. The stereometric development started with our search for a better understanding of forces of orthodontic appliances. If you want to predict the force, you have to know the shape of the appliance. Our wires were bent in all sorts of unusual shapes in three dimensions. We had to record the shape, and that is how we developed our stereometric program.

JCO Are the forces you get in the laboratory transferrable to the mouth

ClearCorrect Exhibit 1002, Page 1182 of 3373

1:1? Is there anything about the mouth environment that changes the rules?

DR. BURSTONE There can be variations between calibrations of springs in the laboratory and the forces you get in the mouth due to changes in configuration such as adjustment for patient comfort. But, the most predictable thing about orthodontics is and should be the force system.

Less predictable is the biological response to the force systems. But, a lot of things that are attributed to biological response by the clinician probably are more due to variations in the force system. For example, we talk about teeth that don't move as possible ankylosis. It may be ankylosis of the appliance.

JCO You also use the computer for appliance design?

DR. BURSTONE Once the orthodontist has a treatment plan and knows where he is going in terms of tooth movement in three dimensions, then he can design his mechanics. Let's look at a program for space closure and see how computers can help us in appliance design. The key to any of these programs is flexibility so that the clinician can make his own decisions about what he wants to do.

Let us suppose that we want to use a vertical loop of the simplest design, even though that might not be the preferred choice for space closure. The principle is that loop height should be as long as possible to lower the load-deflection rate and to afford better root movement. We are limited by the mucobuccal fold. The computer asks how high you want the loop to be. The usual range in height of the loop is from 4–10mm. Let's input say 8mm. Now the computer asks what is the distance between the bicuspid and cuspid brackets. It can be from 5–21mm. We input 14mm. Loop diameter is not a critical variable. We input 1mm.

Most orthodontists would probably put the loop mesial next to the cuspid bracket. If you do, you get a side effect, an eruptive force on the cuspid. Let's put is 2mm off center. The computer asks how much force we want to use to translate the cuspid back. We input 175 grams. We have just input the yield strength of the wire and how much of a safety factor we want for permanent deformation.

JCO The computer will select the size of the wire?

DR. BURSTONE The computer is going to select the size of the wire. That's almost been the fallacy of the orthodontics of the past. Decision on the size of the wire should be on the basis of all of these factors. The computer is going to figure out what cross section to use. We want the wire that gives us the most constant force without permanently deforming.

Note on the screen the computer says that the best round wire section is .016 if that is how much force you want, but it also tells us that if the horizontal force is 175 grams, the vertical force is roughly 25 grams. So, you are going to have force erupting the cuspid of 25 grams, which may not be what you want. It tells us that the moment at the cuspid is 635 gram millimeters and on the posterior is –286, which means that the buccal segments are going to dump in. If we were going to use this wire, we would need a tipback posteriorly.

The force deflection rate is 118 gm mm. That means that you have to activate the loop 1.5mm to get 175 grams. The computer also tells us that one of the weaknesses of this loop system is that the force is going to be dissipated pretty rapidly. Typically, if you wanted to translate the tooth bodily, you would need a moment to force ratio anteriorly at least 10 to 1. This is 3.6. Therefore, the cuspids are going to tip and the posterior segment is going to tip in badly. Knowing that, you can interact with the computer to improve your design.

If you decided to use a square cross section, the computer tells you that .014 × .014 would be the wire of choice. Again, the computer tells you the whole force system. It is a design tool.

If you wanted to use rectangular wire, the best flat section is .012 × .028. That would give you the best properties for this type of tooth movement. The clinician is still making the final decision. If that is what he thinks he wants to do and that is what comes out of the computer, he can use the wire and the activations recommended by the computer. Hopefully, he should know better than to use a simple loop like this for this purpose.

JCO He could change the loop system and see the effect of that.

DR. BURSTONE That is correct.

JCO In your laboratory, you are testing the forces produced by retraction springs and putting the forces and torques on the computer.

DR. BURSTONE Yes. We are calibrating prefabricated springs. You have forces and torques on either end of a retraction spring. Our data for these goes directly into the computer. Starting with 1mm activation, we can measure and record the forces and torques on either end of the springs at various activations. This is where the data comes from for the design of prefabricated springs. We design these springs so they have the proper torques to control the axial inclinations of both the posterior and the anterior teeth.

JCO One of the things that is said about the "by the numbers" diagnostic routine is that, given those numbers and the parameters that the orthodontist may include for various characteristics — how far forward he would consider moving a lower anterior, how far distally he thinks he can move a molar, how much expansion suits him in the cuspid, bicuspid and molar areas — given that, the orthodontist would always make the same diagnostic decision. This is compared to the more common experience in which the orthodontist could diagnose the same case differently on different days, and different orthodontists might diagnose the case differently.

DR. BURSTONE To me, stereotyped treatment is wrong, and this would be a misuse of the computer. If you have a science in which all the parameters are known, then you can input the information and always get the same answer coming out. But, in orthodontics, we have partly an art and partly a science. There are very many parameters that are not part of any computer program, including ours. So, we need some judgment decisions by the orthodontist. If I had to put some number on it, I would say 20% science and 80% judgmental. If it is 80% judgmental, then maybe an orthodontist will get a different treatment plan from day to day. There is more to treatment planning than a few parameters. The fewer parameters you build into your program, the easier it is to come up with the same answer. But, if I start considering such factors as stability, tongue posture, swallowing patterns, the thought process is not always going to be the same. That's why the

ClearCorrect Exhibit 1002, Page 1183 of 3373

final decision always has to be made by the orthodontist. I think he wants to use his knowledge and he only wants the computer to help him a little. He doesn't want the computer to do the whole job for him.

JCO A corollary to that other point of view about computers is that the computer can be used to set standards of quality.

DR. BURSTONE Part of this can also be a misuse of the computer. Somehow, if a computer comes up with a plot or information, many orthodontists are more apt to believe that than if someone drew it by hand. But the thinking process is the same as without a computer. If we use computers, we should always be aware of the assumptions behind how the computer arrived at the conclusion. That's another reason why I like to put the orthodontist in the driver's seat and make him make his own decisions. I don't want to tell him that his cuspid width should always be 52.3mm. Just because the computer said it, he might believe it. If he is deciding this himself, he is not going to come up with conclusions which may not be valid.

In line with what you suggested about setting standards of quality with a computer, the danger is that people are quick to accept what the computer says somehow, because it is not human. It dominates people to an extent, especially the older generation who never worked with it. On the other hand, computers can set the standard for quality workups and treatment planning by making them universally more comprehensive.

JCO The way you are suggesting using the computer is not as a straight jacket, but as a working tool.

DR. BURSTONE It can help raise standards in orthodontics, because it can give you knowledge that will help treat more completely and more rapidly. But, one should not believe that the computer knows more than the people who programmed it. The key phrase about our program is that it is an interactive approach to computer use. The orthodontist interacts with it. Computers can do things for the orthodontist that he would hesitate to do himself by hand. It can draw pictures, and make rapid calculations. I can also give him a data base when he needs it. But the decision making can never be done by the computer. If we honestly think that computers can do the treatment planning, then we think that general practitioners can do orthodontics, because the mechanical parts of orthodontics are more easily taught. What makes an orthodontist is his knowledge and his ability to do treatment planning. I think in the future, the best orthodontists will be those who can do the most careful treatment planning and are most creative. Knowing what you are dealing with can help you in your treatment plan, but there are no numbers in cephalometrics, be they means or standard deviations, to do that.

JCO Do you also make use of the computer for progress reporting and post-treatment evaluation?

DR. BURSTONE One of the valuable applications of the computer is for reanalysis, monitoring progress of the case during treatment and in the retention and post-retention period. We envision computers being able to demonstrate a three-dimensional representation of what happens with growth and development and with treatment.

JCO Three-dimensional cephalometry and cast analysis would be a great advance.

DR. BURSTONE We have developed some new stereometric techniques which allow random photographs of study casts or intraoral photographs to be analysed in such a way as to enable the computer to calculate the position of teeth from them, and the position of bones from x-rays, in three-dimensional space.

JCO Is that a usable clinical tool?

DR. BURSTONE We are currently using this primarily as a research tool. Eventually we should develop it as a clinical tool.

JCO Do you have a way to monitor response?

DR. BURSTONE There are many different types of estimates we can make in orthodontics. We talked about growth estimates and tooth and jaw position estimates. Every clinician makes an estimate of what he expects to happen with his appliance from one visit to the next. In a sense, we are all bioengineers. All of us will look at the patient when he returns, and we would like what we see to be predictable. A good part of orthodontics may not be that predictable. One of the reasons is that force systems and the biologic response are not well understood. Cooperation and growth are not completely predictable. What makes a fine clinician is his ability to be more able to look in the mouth and monitor undesirable side effects and correct for them. The ultimate goal is to minimize the discrepancy between what you anticipate will happen and what really happens. I think most of that discrepancy is at the appliance level now. Maybe, when we have better appliances, more of it will be at the biological level. By integrating the clinical evaluation of progress with progress headfilms and models, computers should go a long way in monitoring where the orthodontist is at any stage of treatment, so that his plan can be updated.

JCO It looks as if orthodontists are going to be able to do a lot more thinking about their cases, and that should not only be good, but welcome.

DR. BURSTONE This is where I think that computers are going to be helpful to orthodontists. Computers will free them from the details and allow them to do what they were trained to do and that is to think.

JCO This could permit orthodontists to operate on a plane a lot higher than bending wires. We already have assistants who can bend wires very well.

DR. BURSTONE Not too long ago, the best orthodontists were the ones who were technically superior with appliance fabrication. The best hands. Orthodontics has changed with bonding and prefabrication, and the computer will change it further. The orthodontist will not be spending his time on mechanical things. In computer terms, orthodontics will be more of a software than a hardware profession.

JCO The work should certainly be even more interesting and exciting for orthodontists.

DR. BURSTONE That's right. I think the exciting things in orthdontics are in treatment planning and appliance design. Optimizing treatment is what differentiates the orthodontist from the technically proficient auxiliary. When the time necessary to do these things becomes less of a factor, then I think that the quality of orthodontics will increase. Most of the troubles we get into are usually problems of poor planning. □

ClearCorrect Exhibit 1002, Page 1184 of 3373

American Journal of ORTHODONTICS

Volume 79, Number 2 February, 1981

ORIGINAL ARTICLES



Dr. Burstone

Precision adjustment of the transpalatal lingual arch: Computer arch form predetermination

Charles J. Burstone* and Herbert A. Koenig**
Farmington, Conn.

Correction of widths and axial inclinations with a transpalatal lingual arch has the advantage of distributing forces across the arch, thus minimizing undesirable side effects. The proper shape of an arch to deliver the required force systems for both unilateral and bilateral width change was determined by using an analytical approach which enabled the deactivated shape of the arch to be established and drawn by computer. The transpalatal lingual arch is extremely sensitive to shape in producing a force system. The critical nature of this shape requires the clinician to understand the over-all pattern of properly forming the arch for various applications and the clinical procedures for evaluation before final insertion. The deactivated shape and the force systems for representative applications are presented; these differ significantly from the concept of the ideally shaped wire.

Key words: Transpalatal lingual arch, iterative method, computer, force systems, constriction, expansion, unilateral mechanics

From the University of Connecticut School of Dental Medicine.
This study was supported by Research Grant DE-03953 from the National Institute of Dental Research, National Institutes of Health, Bethesda, Md.
*Professor and Head, Department of Orthodontics.
**Professor, Departments of Orthodontics and Mechanical Engineering.

0002-9416/81/020115+19$01.90/0 © 1981 The C. V. Mosby Co.

ClearCorrect Exhibit 1002, Page 1185 of 3373

Many wire configurations, such as lingual arches, are used for orthodontic therapy. In order to produce a desired force system, it is important that the clinician create a shape that, when activated, will produce the force system that is anticipated. It is our intent in this publication to describe methods that are capable of determining the required shape of lingul arches or similar appliances. The methods are analytical and are based upon beam theory, which allows for large deflections. It takes advantage of computers, so that in a sense orthodontic appliances can be designed by the computer with the interaction of the orthodontist.

It is important to define a number of different shapes that any given lingual arch can assume. First, a lingual arch can be contoured so that it is passive to the molar attachments and ideally shaped for comfort and lack of soft-tissue impingement. This is the *passive* shape. In order to produce tooth movement, the clinician must now modify this arch to produce a new shape, the *deactivated* shape. If the deactivated shape is proper, once the wire is placed in the attachments, the correct force system will be produced for the desired tooth movement. The shape produced when the wire is fully engaged in the attachments is the *activated* shape. Ideally, the activated shape and the passive shape should be identical so that comfort and soft-tissue contouring are optimal. Our analytical methods were designed with these two criteria in mind, so that the deactivated arch not only produces the proper force system but also returns to the desired passive shape when activated. In order to solve this problem, two approaches were used: the deactivation force approach and the iterative (repetitive) approach.

The analytical formulation which was first presented by Koenig and Burstone[1] and later modified by Defranco and colleagues[2] was recast to allow for the prediction of force systems delivered by the large activations of arbitrarily shaped orthodontic appliances. This method has the advantage over previous methods because of its greater generality which makes it capable of handling three-dimensional configurations and large displacements.[3, 4] The code was adjusted to accept geometric parameters as interaction variables. This technique allows the user to search for the correct force system as the appliance is deformed. The new algorithm results in a complex computer code which has the capability of treating large clinical activations, as well as designing the deactivation shapes of wires which are required to deliver prescribed force systems.

The process is started by allowing the analysis to calculate the small deflection solution to the pertinent problem. New geometric characteristics are obtained from this solution and used as the new estimates of curvature and twist for the next attempt at the solution of the large activation problem. New geometric characteristics are obtained from this solution and used as the new estimates of curvature and twist for the next attempt at the solution of the large activation problem. This procedure is continued until a convergence is obtained between the estimated solution and the calculated solution.

The deactivation force approach

The deactivation force approach to the design of orthodontic appliances was studied by means of an analytical analysis. This procedure consists of determining the deactivation shape of a wire by applying a deactivation force system to any appliance which fits into attachments (that is, passive shape), Fig. 1 will aid in the description of this approach.

Let us assume that the wire shape A has geometric characteristics which will allow it to fit passively into attachments C and D, which are at a distance (d) apart and at some

ClearCorrect Exhibit 1002, Page 1186 of 3373

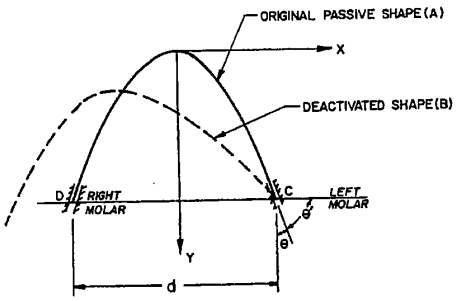


Fig. 1. Deactivation force approach. Passive shape is represented by solid line. Deactivated shape *(dotted line)* is produced by applying a force in the direction needed for tooth movement.

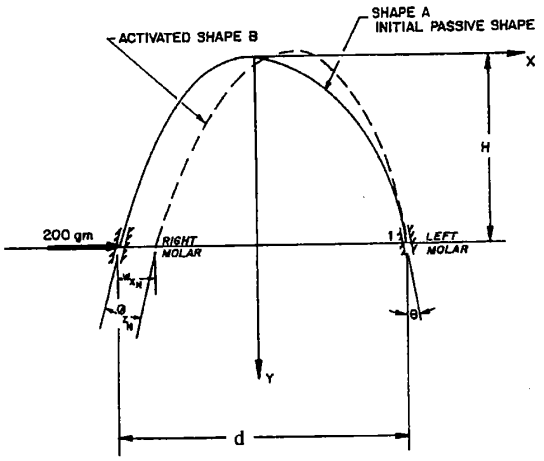


Fig. 2. Deactivation force approach used to determine shape of a transpalatal lingual arch used for constriction. The shape is formed by applying a 200 Gm. lingual force on the arch. This approach gives an erroneous solution for configurations of this type.

known orientation with respect to the occlusal plane (angle θ'). Further, let us assume that this wire is required to deliver a buccal force ($-F_x$) and an occlusal force (F_y) to the teeth as shown. The deactivation approach proceeds as follows. The force $-F_x$ and F_y is applied to the arch wire, deforming its shape to a new equilibrium shape shown as shape B. Shape B is now considered the required deactivated shape which, when activated by F_x and $-F_y$, will return the wire to the activated shape so that it may be inserted into the attachments and deliver forces $-F_x$ and F_y to the teeth. This procedure can be erroneous, as will be shown by the following example.

Fig. 2 shows a transpalatal lingual arch wire which is required to deliver a lingual

ClearCorrect Exhibit 1002, Page 1187 of 3373

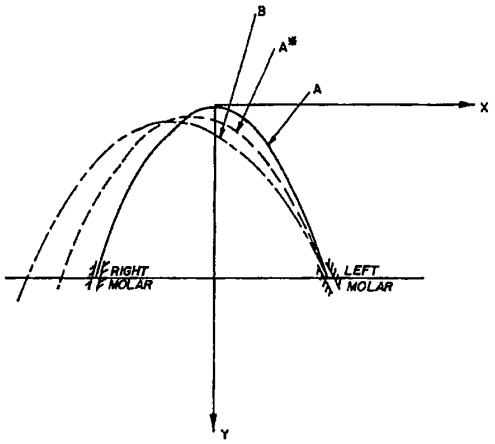


Fig. 3. Iterative force approach. Wire *A* is deformed into wire *B* as in the deactivation force approach. Wire *A** is obtained after the activation force is applied. Wire *B* is modified by a computer iteration until *A* and *A** coincide at all points along the arch.

force F_x = 200 Gm. and must fit into molar tubes which are 35 mm. apart at an angle θ = 20 degrees. The distance H is set at 14 mm. Employing the deactivation force approach to this wire, the appliance is deformed by F_x. For a 0.036 inch (0.91 mm.) steel wire with a modulus E = 16 (10^6) Gm./mm.^{2}, the entire deformed shape is obtained. The end point N has the following deflection:

$$W_{xn} = +2.03 \text{ mm.}$$

$$\phi_{yn} = -0.086 \text{ rad.} = -4.945 \text{ degrees.}$$

If one constructs a wire of this new shape (shape B) and then activates the appliance so that it fits into the molar tubes, the following force system is produced. for $W_{xn} = -2.03$ mm. and $\phi_{yn} = +0.086$ rad. = +4.945 degrees.

$$F_x = -275 \text{ Gm.}$$

$$M_{yl} = +600 \text{ Gm.-mm.}$$

$$M_{yn} = -600 \text{ Gm.-mm.}$$

It is obvious that the force system actually delivered by a wire shape which was obtained from the deactivation force approach does not exactly match the desired clinical force system. The force is 37 percent higher than desired, and significant rotational moments are produced.

This example demonstrates the error which is inherent in the deactivation force approach. Many other examples may be cited but are eliminated for the sake of brevity.

A new approach must therefore be developed which is capable of determining the proper shape of an orthodontic appliance for deliverance of any desired force system.

Table I. Deactivated shape of a transpalatal lingual arch delivering 200 Gm. lingual forces

Coordinates from deactivation force system method			*Coordinates from iterative force method*			*Nodal points*
X	*Y*	*Z*	X_0	Y_0	Z_0	
−0.175E + 02	0.140E + 02	0.0	−0.175E + 02	0.140E + 02	0.0	1
−0.170E + 02	0.121E + 02	0.0	−0.169E + 02	0.121E + 02	0.0	2
−0.164E + 02	0.105E + 02	0.0	−0.164E + 02	0.104E + 02	0.0	3
−0.158E + 02	0.895E + 01	0.0	−0.158E + 02	0.892E + 01	0.0	4
−0.152E + 02	0.761E + 01	0.0	−0.152E + 02	0.757E + 01	0.0	5
−0.146E + 02	0.641E + 01	0.0	−0.146E + 02	0.637E + 01	0.0	6
−0.140E + 02	0.536E + 01	0.0	−0.139E + 02	0.532E + 01	0.0	7
−0.134E + 02	0.443E + 01	0.0	−0.133E + 02	0.438E + 01	0.0	8
−0.127E + 02	0.362E + 01	0.0	−0.126E + 02	0.357E + 01	0.0	9
−0.120E + 02	0.290E + 01	0.0	−0.120E + 02	0.286E + 01	0.0	10

Iterative force approach

In order to overcome the deficiences which were evident when the deactivation force approach was used, a new technique has been developed. This new method, called the iteration force approach, will be delineated with reference to Fig. 3.

The approach begins in the same manner as with the deactivation force approach. Wire A is deformed into wire B by application of the force system which is delivered to the teeth. Wire B is then activated by the force system opposite that previously used. This results in wire A*. This approach differs from the previous deactivation approach in that the desired activation force system is used and *no* attempt to reach the attachments is made. At this point, wire A is compared to wire A* and the deviation is noted for the entire length of the appliance.

The geometry of wire B is now modified by a percentage of the deviation between wires A and A*. This produces a new shape B* (not shown). Appliance B* is now activated with a reversed force system and a new shape A* is attained. This iteration process is continued until A and A* coincide. At this point, the desired deactivated shape is B*. The mathematical analysis performs this iteration automatically, and the number of iterations is small for arch wire problems.

Thus, an accurate mathematical iterative technique has been developed to determine the deactivated shape B* of a wire which will produce a desired force system when inserted into brackets at a given tooth geometry. The results of this iterative technique as applied to lingual arches is presented in this article.

A comparison of the coordinates for ten nodal points of a transpalatal arch (Fig. 3) is given in Table I. The deactivated arch shapes produced by the deactivated force approach and by the iterative approach are very similar. The force inaccuracies of the deactivated force approach are magnified in orthodontic appliances when force systems are very sensitive to small changes of geometry. In *less* sensitive appliances, the deactivated force approach could give a good approximation of the proper shape.

The transpalatal lingual arch

The lingual arch is an important adjunct to treatment in that it allows forces to be distributed across the arch for first-, second-, and third-order movements. In this study we

ClearCorrect Exhibit 1002, Page 1189 of 3373

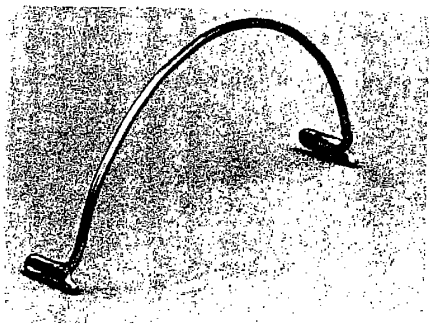


Fig. 4A. Transpalatal lingual arch. The folded terminal ends are soldered to allow better fit in the lingual sheaths and definitive tying in place. Wire size, 0.036 inch.

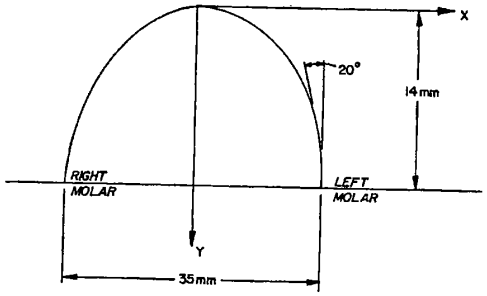


Fig. 4B. Overall dimensions of typical lingual arch described in the study. Frontal view.

shall attempt to answer the following questions: First, what is the proper shape of a lingual arch if it is to deliver the desired force system? Second, how sensitive is this shape or, in other words, how exactingly must it be bent in order for the clinician to approach an approximate force system? Third, what are some of the common pitfalls in using a lingual arch and what is the solution to these problems?

The method to be used is the iterative approach described in the first section of this article. A representative transpalatal lingual arch will be described. The lingual arch is constructed from 0.036 inch round wire. At its terminal ends, the wire is folded for insertion into a horizontal tube on the first molars (Fig. 4*A*). A rigid attachment at the lingual tubes of the molar is assumed. This approaches the clinical situation where the folded ends are soldered and no play is present between the tube and wire. The over-all dimensions of the lingual arch are shown in Fig. 4*B*. Only activations in the x-y plane (that is, activations as seen from a frontal view) will be considered. The clinician would like the lingual arch to return to the passive shape shown in Fig. 4*B* when activated. This assures comfort and lack of impingement on the soft tissues of the palate. The shape given in Fig. 4*B* will be referred to as the *activated* shape. It is our intent to describe the

ClearCorrect Exhibit 1002, Page 1190 of 3373

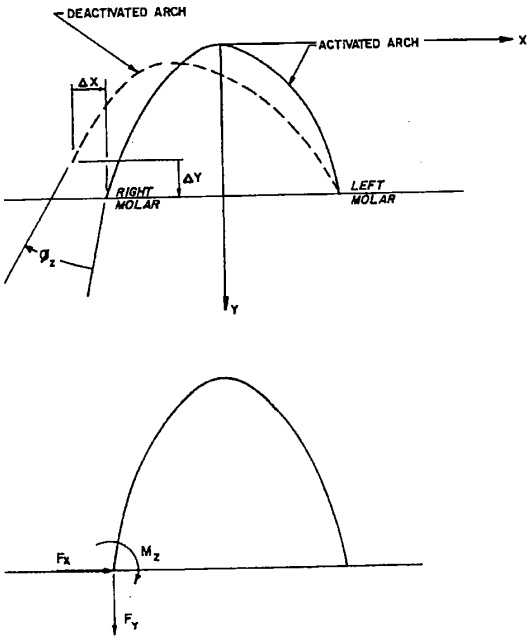


Fig. 5. Sign conventions. *Above:* Displacements. *Below:* Forces and couple. Arrows denote positive sign.

deactivated shape that is required to produce the desired or specified force systems: (1) expansion or constriction with a simple lingual or buccal force. (2) expansion and constriction with a pure moment or a couple alone, (3) constriction or expansion by translation, and (4) unilateral expansion.

Sign conventions are shown in Fig. 5. Typically, we will place the lingual arch in the sheath of the left molar and then measure the linear and angular displacement required to place the free end into the tube on the right molar. Δ_x refers to horizontal displacement and Δ_y to vertical displacement; the angle ϕ_z measures the angular displacement of the terminal point of the free end. The direction of the arrows denotes a positive sign. Unless stated to the contrary, all displacements and forces given refer to the displacements and forces required to obtain engagement into the molar tube; hence, all forces are activation forces acting on the lingual arch. It should be remembered that the forces and moments acting on the teeth (deactivation forces) are *equal* in magnitude and *opposite* in sign.

Expansion and constriction with a single force

Commonly, the clinician is called upon to produce symmetrical tipping of the molars or an entire posterior segment and may choose a lingual arch as the appliance of choice. If an initial 200 Gm. force was desired from the lingual arch, the shape of the lingual arch

ClearCorrect Exhibit 1002, Page 1191 of 3373

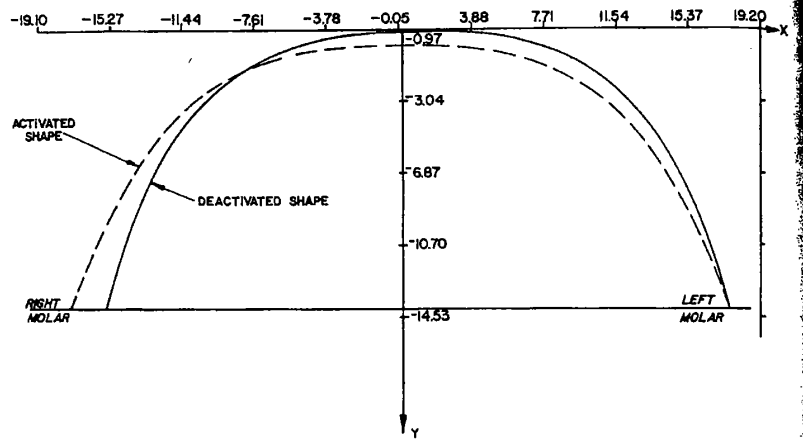


Fig. 6. Computer plot of a transpalatal lingual arch of proper shape to produce a constrictive force of 200 Gm. The free end of the deactivated arch is constricted and angulated. It lies on a line connecting the two molar sheaths.

from the iterative method can be determined. Table II summarizes pertinent data from a lingual arch used in this manner and should be referred to in the following description of both the force system and the shape of the lingual arch.

The shape of the lingual arch in both its activated and deactivated forms is shown in a computer-drawn plot in Fig. 6. During activation, 200 Gm. of force and no moments are produced. From Table II it can be seen that the force system and the difference between the activated and deactivated free end positions are identical in constriction and expansion, differing only in sign.

In order to produce a force of 200 Gm., 1.9 mm. of horizontal constriction or expansion is required in the lingual arch, as measured from the right free end after insertion in the left tube. This produces a relatively high load-deflection rate of 105 Gm./mm., which implies a reasonably rapid decay of the force as the teeth move lingually or buccally. An important application of the lingual arch is in preserving arch widths. In that function, a high load-deflection rate is desirable, since the appliance has greater rigidity to withstand forces that may be introduced during treatment. On the other hand, if one were to use it in its transpalatal form for arch width change, it would be desirable to lower the load-deflection rate. This could be accomplished by using a wire with a smaller cross section; a 0.030 inch stainless steel wire would reduce the load-deflection rate approximately *one half* to 50.6 Gm./mm. This would allow approximately 4 mm. of activation to reach a 200 Gm. load. Another approach is to fabricate the lingual arch from a different material, such as beta-titanium. A beta-titanium lingual arch would have 0.4 the load deflection rate of 42 Gm./mm., which allows 4.7 mm. of activation for 200 Gm. Other approaches, such as using a horseshoe lingual arch or placing a loop at the palatal portion of a transpalatal lingual arch, are possible in reducing the load-deflection rate.

No vertical displacement (Δ_y) is required in a lingual arch that delivers only horizontal

Table. II. Bilateral constriction and expansion

	Constriction	*Expansion*
Force (left)	200.0 Gm.	−200.0 Gm.
Force (right)	−200.0 Gm.	200.0 Gm.
Moment (left)	0.0 Gm.-mm.	0.0 Gm.-mm.
Moment (right)	0.0 Gm.-mm.	0.0 Gm.-mm.
Δ_x (right)	−1.9 mm.	1.9 mm.
Δ_y (right)	0.0 mm.	0.0 mm.
ϕ (right)	4.8°	4.8°
F/Δ_x (right)	107.0 Gm.-mm.	107.0 Gm.-mm.
ϕ/Δ_x (right)	−2.6°/mm.	−2.6°/mm.

Table III. Bilateral constriction

Force (left)	537.0 Gm.
Force (right)	−537.0 Gm.
Moment (left)	0.0 Gm.-mm.
Moment (right)	0.0 Gm.-mm.
Δ_x (right)	−5.0 mm.
Δ_y (right)	0.0 mm.
ϕ (right)	12.6°
F/Δ_x (right)	107.2 Gm.-mm.
ϕ/Δ_x (right)	−2.5°/mm.

forces. This is unlike other activations, to be described, which require both horizontal and vertical activation.

If one compares the angle formed by a tangent at the free end, between the deactivated and activated shapes, it is noticed that a definite twist of 4.8 degrees must be placed in the lingual arch. If one were to make a ratio between the angle of twist and the amount of horizontal activation (ϕ/Δ_x), the ensuing ratio would denote the relative twist required in the wire for the horizontal deflection. In this case the ratio of ϕ/Δ_x is −2.5 mm. Thus, to allow tipping with a single force, a definite ϕ angle is required.

One of the problems confronting the clinician is his ability to place the proper ϕ/Δ_x ratio in his lingual arch, since small errors could radically alter the force system. Although this ratio could be estimated, there may be other solutions to the problem of producing single forces across the arch. One obvious solution is not to fold the terminal end of the lingual arch as it enters the tube but to use only a single wire so that the tooth is free to turn on the wire in the tube. In this way, only a single force will be produced. If a lingual arch is constructed in this manner of the same dimensions outlined above, the activations are slightly different to produce a force of 200 Gm. For expansion, 2.0 mm. (Δ_x) is required and, for constriction, −1.7 mm. at the right molar. The load-deflection rate is somewhat lower in expansion (98.5 Gm.-mm.) in comparison to constriction (119 Gm.-mm.). Unlike activations found when a folded wire was placed in the tube, activations are not equal and opposite for expansion and constriction. This is based on the fact that in opening a transpalatal arch more force is required to open a U shape than to close it, which is true of many similar configurations used in orthodontics.

In considering a restrained lingual arch by a folded wire in the molar tubes, the

ClearCorrect Exhibit 1002, Page 1193 of 3373

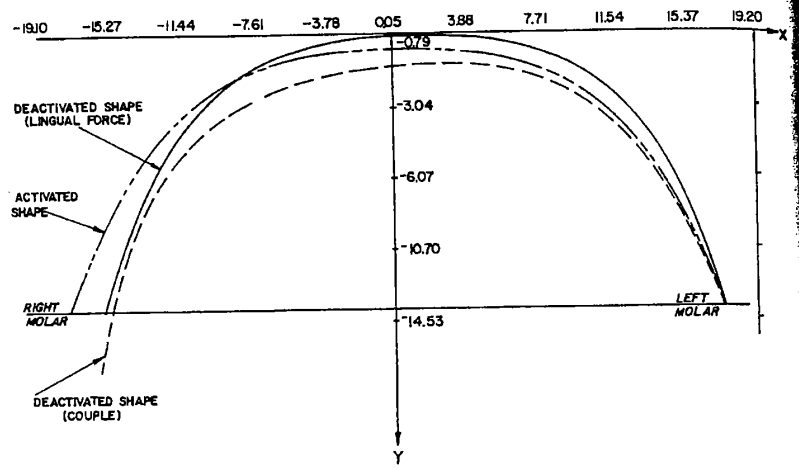


Fig. 7 Computer plots of transpalatal lingual arches which produce constriction by couples (---) or lingual forces (——). More constriction of the wire is needed for the couple. Note that after insertion in the left tube the free end lies occlusally, unlike the single force which has no vertical displacement.

configuration for only 200 Gm. has been described. The question arises whether a shape parameter such as ϕ/Δ_x changes as the force is varied. With this in mind, the shape of a lingual arch capable of delivering 537 Gm. of force was determined. Table III gives the force system and the change of shape between the deactivated and the activated lingual arches. It should be noted that the load-deflection rate and the angle of twist to horizontal deflection (ϕ/Δ_x) are approximately the same as found with the 200 Gm. activation. Because of changes in geometry associated with large deflections, one might anticipate some difference between lingual arches designed to produce large or small forces; however, even with our methods which consider large deflection, only small differences were noted.

Expansion and constriction with equal and opposite couples

A single force is capable of constricting or expanding a molar or buccal segment, producing tipping around a point somewhat apical to the center of resistance. On the other hand, if one desires to have expansion and constriction using a center of rotation close to the center of resistance, equal and opposite couples could be employed. If pure moments are to be placed in a transpalatal lingual arch, its shape is different from the shape associated with single forces, as seen in Fig. 7. If one places the lingual arch into the left molar attachment, it is necessary to displace the free end both horizontally and vertically. For a 2,000 Gm.-mm. couple on each molar, the horizontal displacement (Δ_x) is 1.7 mm. and the vertical displacement (Δ_y) is 3.1 mm. With single horizontal forces on the molar, it should be remembered that no vertical displacement was required. If one compares the ϕ/Δ_x ratio between couples and single forces for change in arch width, the ratio for couples is 6.1 in comparison for 2.6 for the forces alone. Thus, if the clinician desires to

ClearCorrect Exhibit 1002, Page 1194 of 3373

Table IV. Bilateral constriction and expansion with equal and opposite couples

	Constriction	*Expansion*
Force (left)	0.0 Gm.	0.0 Gm.
Force (right)	0.0 Gm.	0.0 Gm.
Moment (left)	−2,000.0 Gm.-mm.	2,000.0 Gm.-mm.
Moment (right)	2,000.0 Gm.-mm.	−2,000.0 Gm.-mm.
Δ_x (right)	−1.7 mm.	1.7 mm.
Δ_y (right)	−3.1 mm.	3.1 mm.
ϕ (right)	10.3°	−10.3°
M/ϕ (right)	194.9 Gm.-mm./degree	194.9 Gm.-mm./degree
ϕ/Δ_x (right)	−6.1°/mm.	−6.1°/mm.
ϕ/Δ_y (right)	−3.3°/mm.	−3.3°/mm.

place couples in a lingual arch, he must both twist the wire and constrict or expand the arch. Δ_x,Δ_y, and ϕ are identical for expansion and constriction, with the exception of a sign difference for the same moment magnitudes (Table IV).

The moment-to-twist ratio (M/ϕ) for the application of 2,000 Gm.-mm. at either end of the lingual arch is 194.9 Gm.-mm. degrees. This may be somewhat reasonable, since it allows a 5 degree twist in the wire at either end, totaling the 10.26 degrees of angular deflection at the free end. However, if smaller load-deflection rates are required, a different alloy such as beta-titanium, or wire with a smaller cross section, such as 0.030 inch stainless steel, could be used. The lower-modulus alloy may be preferable since some play may exist between a 0.030 inch lingual arch and the molar tubes.

The orthodontist can produce constriction or expansion by tooth tipping of an arch by the application of single forces or equal and opposite couples with the transpalatal arch. In arriving at the desired activated shape, the clinician should keep the following in mind: For a single force, the lingual arch should be bent by contouring proportionately more at the superior portion of the arch. With the production of equal and opposite couples, contouring should be done equally throughout the entire lingual arch. For single forces only, the lingual arch should be checked by first inserting the arch on one side and checking the relationship at the free end. The free end will be found to lie either buccal or lingual to the tube. There should be no vertical displacement. If the procedure is reversed and the other end is placed into the opposite tube, the same relationship should be found. The clinician should also attempt a trial activation by pushing the free unattached end with a single force so that it approaches the tube. If no twist is needed from this position, it is anticipated that the force system will approach a single force. In a similar manner, when a lingual arch is activated to produce couples, one end is placed into the tube and the other end is observed. Unlike the single force, a noticeable vertical displacement is found, as well as a larger angle of twist (ϕ) than in the application of single forces. By reversing placement of the lingual arch into the opposite tube, a similar geometry should be observed, so that the vertical distance from the free end to the tube is identical on both right and left sides. This will ensure equal and opposite couples. For checking the over-all configuration, a trial activation wherein the clinician holds the unattached free end with pliers and twists, simulating a couple, is indicated. The wire should line up with the tube. Any horizontal, vertical, or angular deviation from the tube suggests that couples are not produced.

ClearCorrect Exhibit 1002, Page 1195 of 3373

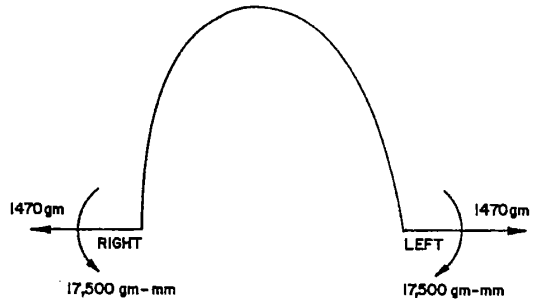


Fig. 8. A transpalatal lingual arch was formed so that the free ends were twisted 10 degrees on a side (so-called lingual crown torque), crossing the centers of the molar tubes. The force system produced on the molars is shown above. Lingual tipping of the crowns will not occur because of the 1,470 Gm. buccal force. Slow buccal translation or root movement of the molars may occur instead.

Since the centers of rotation are very close between couples and single forces applied to the crown of a tooth, the orthodontist has a choice in his force system for tipping movements of the posterior teeth. It is probably easier to use a single force with a nonrigid attachment allowing freedom of rotation in the molar tubes, since one does not have to be concerned with the over-all geometry of the appliance and, in particular, the angle of twist (ϕ).

Some orthodontists believe that if a transpalatal lingual arch were made with the free arms equally crossing the tubes, equal and opposite couples would be produced. The actual force system produced on the teeth can be seen in Fig. 8. The forces on the lingual arch are equal and opposite. By placement of a bend 1.7 mm. apical to the tube, a lingual arch was contoured so that the free ends equally crossed the brackets 10 degrees on either side. At the point of attachment to the tube on either side, the lingual arch was positioned 0.3 mm. lingual to the tubes so that, for all practical purposes, the arch crossed the tubes equally. Note that this activation of the lingual arch does not produce equal and opposite couples alone but a very large buccal force of 1,470 Gm. The moment of 17,500 Gm.-mm. produced at each molar is in a direction to constrict the arch and move the molars lingually. Combined with the buccal force, however, a moment-to-force ratio of 11.9 is produced. Depending upon the length of the molar roots, a ratio of this type could have varying effects, but most likely it would produce root movement with a center of rotation somewhere around the crown of the tooth. If this activation were placed to constrict the arch, one would be disappointed, since root movement would take place instead. Since root movement is very slow, the clinician would also find small rates of tooth movement.

Although this activation shape would be undesirable for constricting a dental arch, it could be useful for molar root movement. The 20-degree activation suggested would exceed the yield strength of most stainless steel wires. A 10-degree activation, 5 degrees on either side, would be more realistic and might be suitable for root movement of an entire posterior segment. Moment-to-force ratios are very critical and variable, depending upon the teeth involved, and thus one must carefully monitor the action of a lingual arch in this application. As will be seen in the next section, similar moment-to-force ratios could be used for translatory movement of a posterior segment. Thus, placing a twist in the

ClearCorrect Exhibit 1002, Page 1196 of 3373

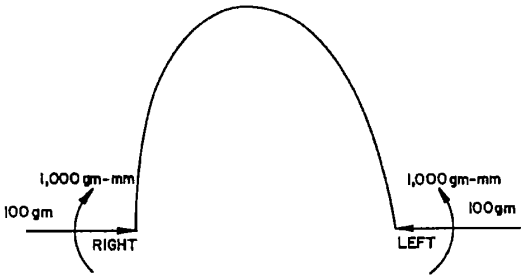


Fig. 9. Force required on the molars for bilateral constriction if translation is required. A 10:1 moment-to-force ratio is assumed. Both a lingual force and lingual root torque are needed. Higher forces can be used; however, the ratio of force to moment must be maintained.

Table V. Constriction by translation with a −10:1 moment-to-force ratio

Force (left)	100.0 Gm.
Force (right)	−100.0 Gm.
Moment (left)	1,000.0 Gm.-mm.
Moment (right)	−1,000.0 Gm.-mm.
Δ_x (right)	−0.11 mm.
Δ_y (right)	−0.12 mm.
ϕ (right)	−0.4°
F/Δ_x (right)	925.9 Gm.-mm.
ϕ/Δ_x (right)	−3.6°/mm.

lingual arch by itself does not enhance its constriction potential. One should also narrow the lingual arch to produce constriction. A constriction and lingual crown twist, working together, are needed for lingual crown tipping. We have seen that a lingual crown twist placed in the arch alone could actually produce a buccal force. This can be readily visualized by fabricating a lingual arch and twisting the free ends so that a lingual crown torque is present. Two pliers are used to simulate twisting the wire to engage it into the tubes. As equal and opposite couples are placed on the wire, the wire will be observed to expand, producing the buccal force that we have described. This reaffirms the importance of having a proper $\phi/\Delta x$ ratio and of the need for a trial activation before final insertion of a lingual arch.

Translatory mechanics and root movement

Up to this point, only tipping movements have been considered. Translatory buccal expansion is commonly accomplished with jackscrew devices. It is possible to produce translation in both a buccal and a lingual direction by means of a lingual arch. The distance between the tube on the molar and the center of resistance of the molar, or a buccal segment, can vary. For purposes of our analysis, let us assume a distance of 10 mm. This implies that a 10:1 moment-to-force ratio is required for translatory constriction; a positive force and a positive moment are required on the right teeth (Fig. 9). For a −100 Gm. and −1,000 Gm. mm. (right side), very small horizontal (Δx) and vertical (Δy) deflections are required (Table V). If the lingual arch is placed in the left tube and its

ClearCorrect Exhibit 1002, Page 1197 of 3373

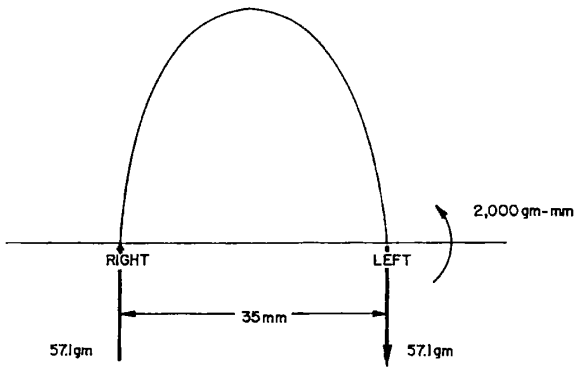


Fig. 10. Unilateral cross-bite correction with a transpalatal lingual arch. Buccal crown torque is placed only on the cross-bite side to produce buccal movement. The side effect is vertical forces. Forces and moments on molars are shown above.

free end is observed on the opposite side, the free end will be found to lie 0.1 mm. lingually and 0.1 mm. gingivally; ϕ is -0.4 degree. The ratio ϕ/Δ_x is $-3.6°$/mm. Note that ϕ is in the opposite direction from that required for tipping movements.

The most obvious weakness in the use of a transpalatal arch for translation is that the load-deflection rates are very high (925.9 Gm./mm.). Assuming a linear relationship if the lingual arch were deflected a total of 1 mm., approximately 925 Gm. of force would be produced, provided that a -3.6 degree twist (ϕ) was placed at the right free end. It can be seen that, since the load-deflection rates are high, the appliance is not very forgiving of inaccuracies in activation if translation is attempted. This explains one of the reasons for the popularity of jackscrew appliances for translatory movement.

If the orthodontist desires to use a transpalatal lingual arch for translation, he should remember that very small activations are needed, a maximum of 1 mm. or so horizontally and vertically with a very small ϕ. The load-deflection rate can be improved and reduced by selection of beta-titanium wire which, for the same force system, increases the activation two and one half times. The placement of a loop at the apex of the lingual arch could also reduce the load-deflection rate. The purpose of this article is not to consider the effect of loop placement on the activations of a lingual arch but only to point out that the potential is present in a transpalatal lingual arch of proper design for movements of the translatory type.

The direction of the force and moment for root movement is identical to that for translation. The difference lies in a higher moment-to-force ratio for root movement. It is apparent that the transpalatal lingual arch without loops in stainless steel can be used for translatory and root mechanics but is relatively unforgiving in its activation and, hence, a redesign using lower-modulus alloys and proper loop placement is desirable.

Unilateral cross-bite correction

Asymmetrical width correction is commonly encountered where one side of the arch requires either buccal or lingual movement. One approach to correction might be the use

ClearCorrect Exhibit 1002, Page 1198 of 3373

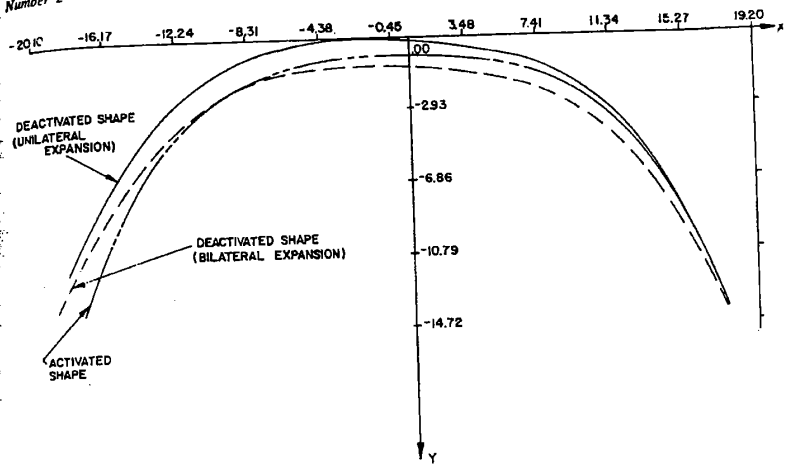


Fig. 11. Comparison of transpalatal lingual arch shapes for bilateral expansion 200 Gm. force (---) and unilateral expansion with a single couple (2,040 Gm.-mm.) and a vertical force (——). The major difference is in the gingival position of the free end when placed in the tube on the side requiring expansion.

of criss-cross elastics. Associated with criss-cross elastics would be deleterious changes in the opposing arch and vertical forces. Another modality is the use of a lingual arch with an asymmetric activation. Fig. 10 shows the force system on the teeth that could be used to tip the upper left segment laterally. For a moment of 2,040 Gm.-mm. on the left molar, by equilibrium, it can be seen that 57 Gm. of extrusive force would be present on the left molar and −57 Gm. on the right molar.

Almost all asymmetric mechanisms will have undesirable side effects, and in this instance the major side effect is the vertical extrusive force. If one could accept the extrusive force, or if the forces of occlusion negated it, the lingual arch can be useful for unilateral cross-bite correction.

The shape of the lingual arch which will produce 2,040 Gm.-mm. can be compared to the shape of the previously discussed lingual arch that produces 2,000 Gm. for bilateral expansion. If the lingual arch is placed into the left tube, the free end on the right side is slightly expanded in the situation where bilateral couples as well as unilateral couples are produced. The unilateral couple configuration requires only 0.8 mm. of expansion, in comparison to 1.7 mm. for the bilateral couples. The free end is displaced vertically much more than horizontally. Δ_y is 2.2 mm. for the unilateral couple and 3.1 mm. for the bilateral couple. Angle ϕ for the unilateral couple is −5.1 degrees in comparison to −10.3 degrees for the bilateral couple. Fig. 11 compares the shape of the lingual arch for bilateral expansion with 200 Gm. and unilateral expansion of the left side using 2,040 Gm.-mm.

In forming a lingual arch to produce unilateral couples, the lingual arch is bent proportionately more as one approaches the tooth that requires the cross-bite correction. On the other hand, with equal and opposite couples, equal curvature is placed throughout

ClearCorrect Exhibit 1002, Page 1199 of 3373

Table VI. Unilateral expansion of the left molar

Force (left)	−57.1 Gm.
Force (right)	57.1 Gm.
Moment (left)	2,040.0 Gm.-mm.
Moment (right)	0.0 Gm.-mm.
Δ_x (right)	0.8 mm.
Δ_y (right)	2.2 mm.
ϕ (right)	−5.1°
M/Δ_y (right)	910.7 Gm.-mm./mm.

the entire lingual arch. It is apparent in comparing the shape of a lingual arch for bila and unilateral action that the shapes be very similar. The clinician would have a grea of difficulty accurately determining the precise shape of a unilateral activation and c hope only to approach the desired shape. There is a practical solution to this prob Instead of a folded wire into the tube opposite the side requiring cross-bite correctio single wire which is free to rotate in the molar tube is employed. With this design, forces and not moments are applied, and hence the shape does not become so crit With unilateral expansion, the lingual arch is formed so that the folded end lies in deactivated state gingivally and is activated by placing a force in an occlusal direction insert it into the tube. One should not forget to place some expansion in the arch.

The forces that have been described are only the instantaneous forces that act when lingual arch is inserted. In unilateral cross-bite correction, as the left tooth moves la ally, forces will be produced in the lingual arch which will displace the right tooth to t left. This can be compensated for by some expansion placed in the lingual arch.

Discussion

The lingual arch is a very useful modality for orthodontic treatment, since forces a distributed across the dental arch rather than to adjacent teeth, which is characteristic of continuous arch. The lingual arch can be used for altering arch widths, unilateral expan sion or constriction, correction of axial inclination and maintenance of arch widths. There are a number of possible force systems that could be delivered from the lingual arch which, in many instances, offers the greatest potential for minimal side effects in produc ing the desired tooth movement. When symmetrical bilateral movements are required, the orthodontist can take advantage of the reciprocal anchorage. Even in asymmetrical activations, side effects may be considerably less than would be found working between adjacent teeth with arch wires placed on the buccal surface of the tooth. Theoretically, any activation that would place the lingual arch in equilibrium is possible. Five major possibilities and their force systems are shown in Fig. 12, in which activations have been placed in the x-y plane. The force system is shown on the teeth. In Fig. 12 *A* and *B* show the force system for expansion and constriction with single forces and couples. The force system for translation of root movement is shown in *C*. *D* and *E* demonstrate unilateral asymmetrical tipping with an associated side effect force which is in a vertical direction. Given the possibility of varying the force system to meet the needs of the clinical problem, this article addresses the question of what should be the shape of a transpalatal lingual arch to produce the desired force system. Ideally, an optimal force system should have the proper force magnitude, a low load-deflection rate, and the proper moment-to-force ratio.

ClearCorrect Exhibit 1002, Page 1200 of 3373

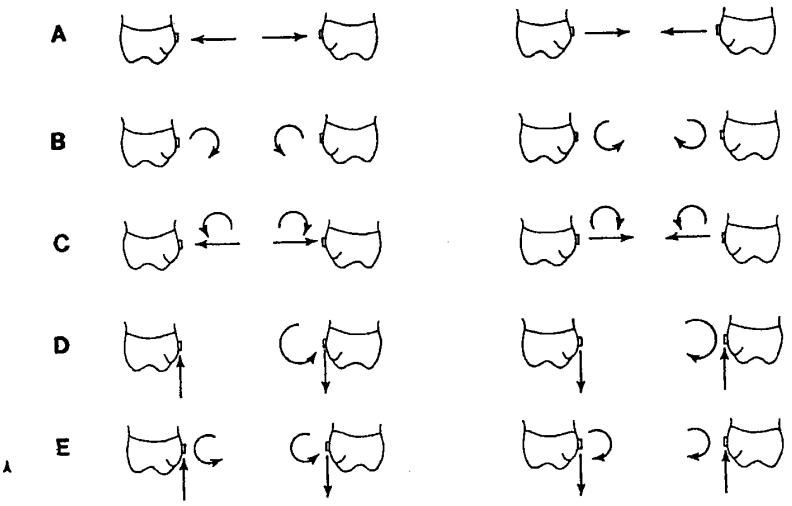


Fig. 12. Possible force combinations with a transpalatal lingual arch. Forces are shown on the molars. The equal and opposite activation forces and moments must be in equilibrium. **A,** Expansion and constriction with forces. **B,** Expansion and constriction with couples. **C,** Translation and root movement. **D,** Unilateral expansion and constriction. **E,** Bilateral movement to the patient's left and right.

The most important of these characteristics is the moment-to-force ratio. A minimum requirement is that the moments and forces be in a proper direction; if this objective is not reached, the teeth will obviously not move to the desired position. It is apparent that, with few exceptions, one cannot produce the force system simply by using the ideal arch concept, that is, shaping the lingual arch so that the free end is displaced to the position where the molar should be positioned. As seen in the previous clinical situations, the shapes are usually not "ideal" for the instantaneously produced force systems.[5]

If one cannot use the ideal arch as a guide for forming a lingual arch, how should the clinician approach the problem of developing active appliances that approach the forces that he needs? In a general way, he could approximate some of the shapes described for typical applications in this article. This could be of major assistance, for it could avoid some of the obvious errors in shape that might be attempted. Since the transpalatal lingual arch is very sensitive to small differences in shape, variation in over-all shape and dimension could significantly alter the activations required from those described.

The following steps are suggested as a means of improving the precision of adjustment in a lingual arch and hence making tooth movement more predictable:

Step 1. The lingual arch should be formed so that it lies passive in the molar tubes and is contoured to the palatal tissues to allow optimal comfort without impingement. This is the shape that we would like the lingual arch to return to following activation and, therefore, is the same as its future activated shape.

Step 2. One should simulate the deactivation force system (the force system in the

ClearCorrect Exhibit 1002, Page 1201 of 3373

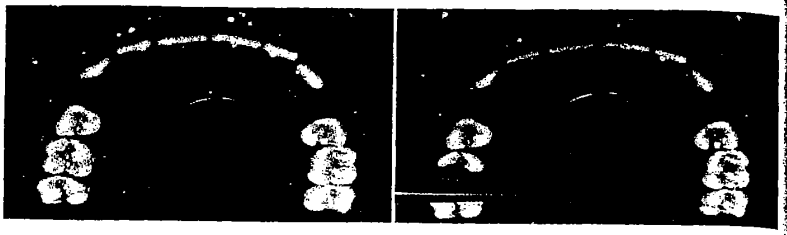


Fig. 13. Clinical method of checking proper lingual arch shape. Shown is shape that will produce constriction by a couple on the upper left buccal segment. **A,** Lingual arch is placed in the left molar tube; Δx, Δy, and ϕ are checked as described for any given application. **B,** Free end is deflected with a single gingival force so that free end is aligned with tube. If no other buccal or lingual displacements or twists are required to insert the right side, the shape is correct. Step shown in **B** is called a trial activation.

direction of the tooth movement) and permanently deform the lingual arch. This first approximation can be carried out with pliers or fingers. When using a deactivation force system, the clinician can see where the lingual arch is bending and he will try to duplicate these bends so that they are permanently placed in the arch.

Step 3. The lingual arch is then tried alternately into the molar tube on the right and left sides, each time with observation of the geometry of the free end with its appropriate tube. The horizontal (Δ_x), the vertical (Δ_y), and the angular (ϕ) differences are checked to see if the geometries approach the general guides described for each of the situations described in this article. Then using fingers, pliers, or any suitable instrument, the clinician attempts a trial activation, (Fig. 13). If only a force is desired, the clinician can place a single force on the free end of the lingual arch and see if the free end requires no further angular deflection when it is brought to the level of the tube. If only couples are desired, one should simulate a couple with the pliers and make sure that there is no horizontal or vertical linear displacement, once the angle of the free end is parallel to the tube. If both a force and a couple are desired, this is more difficult to simulate. A couple is placed on the free end, and the horizontal or vertical deflection of that free end when it is parallel to the tube is observed. Maintaining the free end parallel to the tube and displacing it so that it superposes on the tube, the clinician now feels the direction of the moment produced. This in no way guarantees an accurate moment-to-force ratio but should assure that at least the force and the moments will be in the correct direction. Another useful guide is checking asymmetry of right and left free ends when the arch is alternately placed in each molar tube. In many force systems, such as equal and opposite forces, opposite couples, and other symmetrical activations Δ_x, Δ_y, and ϕ, magnitudes should be the same when the lingual arch is placed in the right tube as well as in the left tube.

Step 4. The shape of the lingual arch is modified on the basis of the above observations and the trial activations in Step 3. The new shape of the lingual arch is a second approximation; if need be, after future trial activations, additional, more exacting approximations can be achieved. Like our mathematical program, this can be thought of as an iterative technique.

In addition to greater precision and activation, the clinician should take advantage of

ClearCorrect Exhibit 1002, Page 1202 of 3373

freedom of rotation around the Z (buccolingual) axis. In those situations in which a moment is not required, this minimizes the need for greater precision in shape. Typical situations in which a lingual arch with a single wire rather than with the folded double wire could be used are expansion and constriction with forces alone; in asymmetrical expansion or constriction one of the arms could be single and the other double.

Since the forces of the transpalatal lingual arch, as most lingual arches, are highly sensitive to its shape, it is necessary to monitor the patient carefully. In addition, considerable variation among patients in root length and periodontal support can be found, and hence different moment-to-force ratios might be needed. Careful determination of shape does not limit the need for clinical monitoring but assures the minimizing of tooth movement that is unpredicted and undesirable.

It is apparent that the transpalatal lingual arch could be improved in design in many respects. For some activations, the load-deflection rates are very high. This can be most easily solved by reducing the cross section of the wire or by using alloys with a lower modulus of elasticity than steel. Like many orthodontic appliances, its greatest limitation in predicting the desired force system is its high sensitivity to shape. Although it has not been presented in this article, the proper placement of loops in a transpalatal lingual arch has the potential to reduce the sensitivity. It is hoped that new designs will allow greater leeway for the clinician in his fabrication of a lingual arch.

In this article the transpalatal lingual arch has been studied in only one plane. However, the concepts can be related to other planes as well. The force systems described have been the initial forces after activation. These are the forces of greatest magnitude that are most responsible for the tooth movement. As a lingual arch works out, both force magnitudes and moment-to-force ratios change. An ideal lingual arch would be one in which the moment-to-force ratio could be maintained constantly throughout the entire range of tooth movement so that a constant center of rotation is produced.

An iterative approach using computers has been developed and allows the determination of the exact and accurate shape of a lingual arch which delivers the desired force system. Unfortunately, it is not practical for the clinician in his office to take advantage of such programs; instead, his adjustments must be based upon a thorough knowledge of the mechanisms of force-system production by lingual arches outlined in this article. It is hoped that in the future new designs which are less sensitive to small changes in geometry may be developed; if so, the proper activation shapes for lingual arches can be radically simplified. Until that time, precision adjustment requires placement of shapes that can be at variance with the so-called "ideal arch" shape which is commonly used.

REFERENCES

1. Koenig, H. A., and Burstone, C. J.: Analysis of generalized curved beams for orthodontic application. J. Biomechanics 7: 429-435, 1974.
2. Defranco, J., Koenig, H. A., and Burstone, C. J.: Three-dimensional large displacement analysis of orthodontic appliances. J. Biomechanics 9: 793-801, 1976.
3. Yang, T. Y., and Baldwin, J. J.: Analysis of space closing springs in orthodontics, J. Biomechanics 7: 21-28, 1974.
4. Drenker, E. W.: Forces and torques associated with second-order bends. AM. J. ORTHOD. 42: 766-773, 1956.
5. Burstone, C. J., and Koenig, H. A.: Force systems from an ideal arch, AM. J. ORTHOD. 65: 270-289, 1974.

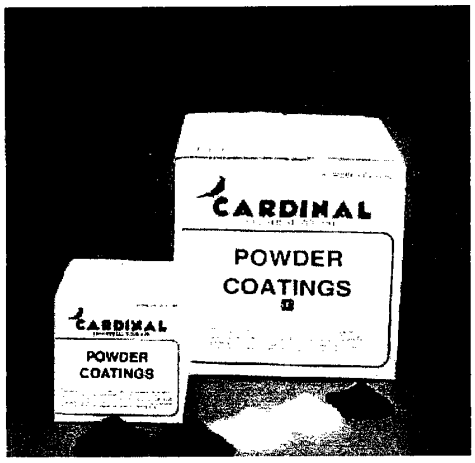
ClearCorrect Exhibit 1002, Page 1203 of 3373

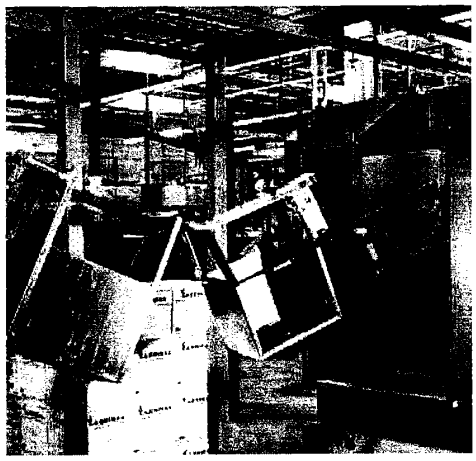
Powder Coatings

Up | Contents | Locations | Latest News

Cardinal Industrial Finishes

For Liquid and Powder Coatings





Powder Coatings

Cardinal has become an industry leader in specialized powder coatings that are fine tuned for your specific application. We utilize four major resin types for thermosetting powders in our formulas to fit each product need. Our full line of stock powders can be found on our Color & Product Guide brochure that is available from all of our Cardinal locations or by sending e-mail to clinte@cardinalpaint.com. We also offer panels of the actual powder for final verification of color and texture,

POWDER COATING

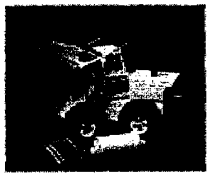
The Benefits of Powder Coating
PCI Members
For Industry
For Consumers
For Media
What is PCI?
PCI Publications and Materials
PCI Events
PCI Membership Roster
How to Become A PCI Member

What Is Powder Coating?
What Are Its Advantages?
Where Is Powder Coating Used?

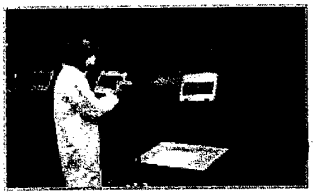
THE BENEFITS OF POWDER COATIN







What Is Powder Coating?



Powder coating is an advanced method of ap
decorative and protective finish to a wide ran
materials and products that are used by both
and consumers. The powder used for the pro
mixture of finely ground particles of pigment
which is sprayed onto a surface to be coated
charged powder particles adhere to the elect
grounded surfaces until heated and fused int
coating in a curing oven. The result is a unifo
durable, high-quality, and attractive finish. Po
coating is the fastest-growing finishing techn
North America, representing over 10% of all
finishing applications.

POWDER COATED TOUGH™

ClearCorrect Exhibit 1002, Page 1205 of 3373

Where Is Powder Coating Used?

Thousands of products and parts are currently powder coated:

Appliances



The appliance industry benefits from powder coating on front and side panels of ranges and refrigerators, washer tops and lids, dryer drums, air-conditioner cabinets, water heaters, dishwasher racks, and cavities of microwave ovens. Powder coating has also replaced porcelain enamel on many washer and dryer parts.

Automotive



The automotive industry uses powder coating on wheels, bumpers, hubcaps, door handles, decorative trim and accent parts, truck beds, radiators, filters, and numerous engine parts. A clean powder topcoat has been developed to protect auto bodies. BMW and Volvo are using it on their new model cars, and GM, Ford, and Chrysler have formed a consortium to test this technique on their production lines.

Architecture/Building



The architectural and building market powder coats aluminum extrusions used on frames for windows and doors and modular furniture. Many highway and building projects use powder coating on light poles, guard rails, signs, posts, and fencing.

Everyday Products



There are also innumerable everyday uses for powder coated products such as lighting fixtures, antennas, and electrical components. Farmers have powder coated tractors and farm equipment. Fitness buffs use golf clubs and golf carts, ski poles and bindings, snowmobiles, bicycles, and exercise equipment that are powder coated. Shop owners have powder coated display racks, shelves, store fixtures, and vending machines. Office workers use metal furniture, computer cabinets, mechanical pencils and pens, thumbtacks, and other desk accessories that are powder coated. Parents have powder coated baby strollers, cribs, metal toys, and wagons. And home owners have lawn mowers, snowblowers, barbecue grills, patio furniture,

ClearCorrect Exhibit 1002, Page 1206 of 3373

garden tools, electronic components, bathroom scales, tool boxes, and fire extinguishers which benefit from a powder coated finish.

Non-Metal Products



While powder coating started as an alternative to finishing metal products only, the development of powder that can be cured at lower temperatures has allowed powder coating to expand to non-metal surfaces such as ceramics and some wood and plastic applications. Powder coating on wood is growing by leaps and bounds. Manufacturers of home-office furniture, kitchen cabinets, children's furniture, and outdoor grill tables are discovering that powder coating makes these "hard use" products retain their new look much longer.

ClearCorrect Exhibit 1002, Page 1207 of 3373

What Are Its Advantages?

More Durable

Powder coating gives consumers, businesses, and industry one of the most economical, longest-lasting, and most color-durable quality finishes available.



Powder coated surfaces are more resistant to chipping, scratching, fading, and wearing than other finishes. Color selection is virtually unlimited with high and low gloss, metallic, and clear finishes available. And colors stay bright and vibrant longer. Texture selections range from smooth surfaces to a wrinkled or matte finish, and rough textures designed for hiding surface imperfections.

Protects the Environment



Powder coating is also highly protective of our environment. While liquid finishes contain solvents which have pollutants known as volatile organic compounds (VOCs), powder coating contains no solvents and releases negligible amounts, if any, of VOCs into the atmosphere. Thus, there is no longer a need for finishers to buy costly pollution control equipment. In addition, most powder coating overspray that does not adhere to the part can be retrieved and reused, virtually eliminating the waste commonly found in liquid finishing processes.

Saves Money

Elimination of VOCs and reduction of wastes saves money and helps companies comply more easily and economically with the regulations of the U.S. Environmental Protection Agency.



In fact, one of the major elements in expanding the market for powder coating has been the implementation over the past 30 years of stringent air pollution control legislation.

ClearCorrect Exhibit 1002, Page 1208 of 3373

just let us know which color. ** For exterior use, always look for a product code that begins with a T, C, or P (T009-BG01). This will ensure that the resin is exterior durable. Also of interest is that some of the metallic powders do require a clear topcoat, even though they are a TGIC powder, to keep the metals near the surface from oxidizing. You will see an asterisk next to the name on those products that are effected. Any T code number followed by a 3 (T375-BK26) does require a clear topcoat for exterior use.

Cardinal also offers an excellent color matching system in either an acrylic or nitrocellulose lacquer touch-up aerosol can. We offer 6 packs of our stock powder colors from the Color Guide (other than the veins, hammertones, and multi-colors). We can also custom match other liquid or powder coatings from any manufacturer once we get an actual color sample to use. These have a 20 can minimum.

The Powder Coating Institute has a great web site with information about powder application and a list of powder applicators across the country that are members. You may want to visit that site to find a applicator in your area or to find an equipment supplier.

- **TGIC Polyesters**
- **TGIC-Free Polyesters**
- **Polyurethane**
- **Epoxy-Polyester Hybrid**
- **Epoxy**
- **Custom Formulations**

For data sheets and/or panels of any of our stock powders, please feel free to e-mail, fax, or phone us with the code numbers of the products needed. We can usually get them out the same day.

Home Page News Page Contents Aerosol Touch-Up Liquid Coatings Locations

ClearCorrect Exhibit 1002, Page 1209 of 3373

IEEE Xplore RELEASE 2.1

AbstractPlus - Print Format

< Bi

An alternative to holograms for the portrayal of human teeth

Carnaghan, R.M. Reed, E.W. Spamer, T.C.
Leeds Metropolitan Univ.;

This paper appears in: **Holographic Systems, Components and Applications, 1993., Fourth International Conference on**
Publication Date: 13-15 Sep 1993
On page(s): 228-231
Meeting Date: 09/13/1993 - 09/15/1993
Location: Neuchatel, Switzerland
ISBN: 0-85296-578-8
References Cited: 10
INSPEC Accession Number: 4577683
Posted online: 2002-08-06 18:55:05.0

Abstract
Currently holograms are being developed to portray casts of human teeth, known as study models, for dental purposes such as orthodontic requiremen for the assessment of atheistic unacceptabilities. The paper describes a technique using light striping and artificial vision to create 3-D representations which can be portrayed and manipulated on a computer screen

Index Terms
Inspec
Controlled Indexing
medical image processing

Non-controlled Indexing
artificial vision atheistic unacceptabilities computer screen dentistry human teeth light striping orthodontic requirements three dimensional representations
Author Keywords
Not Available

References

No references available on IEEE Xplore.

Citing Documents

No citing documents available on IEEE Xplore.

Indexed by Inspec

© Copyright 2005 IEEE – All Rights Rese

ClearCorrect Exhibit 1002, Page 1210 of 3373

AN ALTERNATIVE TO HOLOGRAMS FOR THE PORTRAYAL OF HUMAN TEETH

R. M. Carnaghan, E. W. Reed & T. C. Spamer
UK

Abstract Currently holograms are being developed to portray casts of human teeth, known as study models, for dental purposes such as orthodontic requirements for the assessment of atheistic unacceptabilities.

Vast numbers of study models are used worldwide and in addition in UK dental practitioners have to submit study models both before and after treatment. Whilst study models themselves are cheap and easy to produce their transportation and storage, necessary for eleven years in UK involves considerable cost. The use of holograms promises to create considerable savings. Standard photographs have been tried and are unacceptable. This paper describes a technique using light striping and artificial vision to create 3-D representations which can be portrayed and manipulated on a computer screen.

Basically an object has a series of strips of light shone on it and pictures are taken using a digital camera: these lines are then reconstituted to produce a representation of a 3-D picture. Generally this technique is used by manufacturers to capture shapes, say of car bodies, for subsequent reproduction by computer controlled machining. Teeth being small and intricate and complex in shape require special considerations and involve particular problems. This paper describes the techniques and the specific problems and how they are being overcome. It is likely that this technique will prove complementary to holograms rather than merely a straight alternative.

INTRODUCTION

Use and Storage of Study Models

Plaster casts of teeth properly called study models are widely used in dentistry. They are easy to make but they chip and are easily broken and are bulky and heavy. In the UK, audit and medico-legal matters require them to be stored for eleven years or even longer for minors. Keating et al (1) in their paper discussing the use of holograms report that a busy practice or clinic can require 200 sets per day. McGuinnes and Stephens (2) further emphasise the problem producing tables and statistics. The American scene is no different and Machen (3) stresses the importance of records in litigation proceedings. In UK the need to send models to the Dental Estimates Board further aggravates the situation. Storage, filing, recovering and transmission are patently major problems involving space, time and costs.

Attempts at Alternatives

Several attempts to solve this problem have been tried. Savage(4) tried conventional photography as far back as 1972 without success. Ryden et al (5) in 1982 used holography to measure changes in tooth position in dental casts. Nassiri et al (6) tried grinding away study models, a cross section at a time, and reconstituting the data as computer graphics diagrams and the method was very accurate though the process was slow and he was frustrated by the inadequacy of the equipment available at the time. More recently Martensson & Ryden (7) have got good results using holograms; using different colours they superimpose sets of teeth before and after treatment and the movement of teeth can be seen clearly.

LIGHT STRIPING

The general technique, usually with a laser and called laser striping, is easily understood. An object is subjected to a series of stripes of

ClearCorrect Exhibit 1002, Page 1211 of 3373



Figure 1: Study model with light stripe

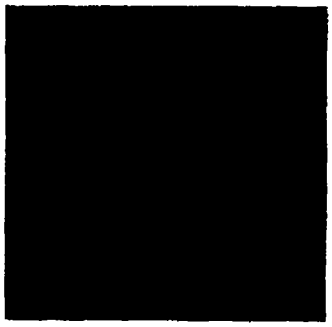


Figure 2: Light stripe captured by vision system

light which are recorded by digital camera placed to view obliquely and then reconstituted under computer control to make the well known wire type diagrams on computer screen. Such a system, reported by Risk & Anderson (8) has been developed by a consortium of industry, several universities and UK Department of Trade and Industry seemingly at considerable expense and effort and at a scale both in size and cost which is totally out of order for a dental practice.

Here is presented a method which offers to meet the requirements of the dental profession. The experiences of the authors have been that the most difficult part of any advanced engineering project is the obtaining of accurate data and this project is no exception. By deciding at the start exactly what a project is to achieve and to remain within those bounds then good results at a modest cost are achievable and this has been done here. In particular teeth are infinite in shape but in general they form roughly the shape of a hollow crown as worn by ancient kings, of a quite small but consistent size; there are particular and difficult problems and hence the system developed is limited to teeth.

METHOD

A strip of light is shone onto a model, fig 1. A tungsten lamp shining on a slot and focused onto the model is found to be adequate. This strip is then recorded by a digital camera based, artificial vision system, fig 2. A low-cost, desk-top, publishing vision system is used although, thanks to the advent of the camcorder, there are now several high quality and cheap systems available. The model is rotated by stepper motor through a series of positions. There were several lesser problems to overcome such as the fuzziness of the lines which were dealt with by programming the computer - a mixture of turbo pascal and machine code was used - but the most difficult problems were as follows:

Picture Distortion. Apart from the simplest of cases, cameras almost invariably record distorted images and especially so if space dictates that they are close to their target; this can be for a number of reasons. Lens distortion is prevalent though often used to good effect by photographic journalists: fierce dogs have extra large teeth, buildings appear extra tall, straight lines appear curved.

ClearCorrect Exhibit 1002, Page 1212 of 3373

Attempts to correct this by calculation using an empirical formula are only partially successful, Pennington et al (9).

Hidden Parts and Position of Camera. In order to make the calculation of the aspect of a line easy the teeth are to be viewed straight on from the front: the back is completely hidden. The use of a mirror to "see" the backs was not successful, Spamer et al (10). If the camera is placed to view some of the tops and backs of the teeth as well as the front then the calculation of the aspect becomes very difficult and without exact 3-D position data, meaningless.

Perspective. Viewing at an angle produces obvious error: analogous to a door or window viewed from an angle and appearing to the beholder as a trapezium.

Datum Location. A general problem in 3-D space situations, robots and so on, is locating sets of points relative to others. Previous workers (6) and (9) merely collected a series of lines on the surface of the teeth and re-assembled them to a datum by trial and error leaving the problem of absolute point location unsolved.

Calibration Grid



Figure 3: Calibration grid

Fortunately all the above problems can be solved using a calibration grid, fig 3. which with hindsight can be seen as a fairly obvious approach. Basically a grid is placed in the plane of the cross section of the teeth with the point of rotation clearly defined. Points on the grid can be identified by the vision system and under program control transferred to an absolute grid, fig 4. Intermediate points are identified by interpolation. Various grids were tried including a lattice but a board with a series of holes, through which a light shone, was found the most effective. Interpolation was done by considering relative positions within triangles: this was a very involved piece of computer program writing.

Figure 4: Grid and stripe as seen by vision system, top, transferred, below, to absolute positions.

ClearCorrect Exhibit 1002, Page 1213 of 3373

DISCUSSION



Figure 5: Graphics produced study model

Figure 5 shows the points reconstituted into what is currently a crude diagram. Clearly this data needs refining to close up gaps between points and to remove hidden lines and perhaps reduce the number of lines. This process is now in-hand. Full wire diagrams using splines in order to create a mesh are possible.

A complete investigation is necessary to determine the accuracy of the system. Martensson et al (7) report accuracies of around 0.1 mm in the z, or height of teeth, direction and about 0.05 mm in the other directions.

The work to date looks promising and indeed demonstrates the feasibility of the system. The work, yet to be done, is no more than an exercise in computing and computer graphics which is now well understood. A major breakthrough would be to be able to display both upper and lower sets of teeth working together. Showing cross sections and giving measurements are simple to do by computer and are extremely useful pieces of information for dentists. If data can be stored electronically then it can be transmitted electronically. This is likely to be the main attraction of the system. Holograms may perhaps have the edge for accuracy.

1. Keating, P.J., Parker, R.A., Keane, D., Wright L., 1984, British Journal of Orthodontics, 11, 119-125
2. McGuinness, N.J., Stephens, C.D., 1992 British Journal of Orthodontics. 227-232
3. Machen, D.E., 1989, Am. J. Orthod. Dentofac. Orthop., 95, 267-268, 357-359,445-447 524-525
4. Savage, M., 1972 The Orthodontist, Spring
5. Ryden, H., Bjelkhagen, H., Martensson, B., 1982 Am. J. Orthod. Dentofac Orthop.81 310-313
6. Nassiri, R., 1988 MPhil Thesis, Leeds Polytechnic.
7. Martensson, B., Ryden, H., 1992 Am. J. Orthod. Dentofac. Orthop., 102, 2, 113 -119
8. Risk, I.C., Anderson, J., 1993, SHRC Bulletin, 4, 22-23.
9. Pennington, L.A., Spamer, T.C., Reed, E.W., 1991, ECSE91 Conf, Coventry Polytechnic
10. Spamer, T.C., Carnaghan, R.M., Reed, E.W., 1992, IMC-9 Conf. Proc. 729-734

ClearCorrect Exhibit 1002, Page 1214 of 3373

The DigiGraph Work Station

Part 1 Basic Concepts

SPIRO J. CHACONAS, DDS, MS,
GARY A. ENGEL, AB, MS,
ANTHONY A. GIANELLY, DMD, PHD, MD,
JOHN C. GORMAN, DMD, MS,
DUANE C. GRUMMONS, DDS, MSD,
MARC S. LEMCHEN, DMD,
RAM S. NANDA, DDS, MS, PHD

The DigiGraph Work Station (Fig. 1) is a powerful clinical tool that offers advantages in a wide range of orthodontic activities:

1. Non-Radiographic Cephalometrics

Lateral and frontal cephalometric tracings and virtually any set of measurements can be produced in moments without radiation. Progress records can therefore be taken as often as desired. Tracings from different treatment stages can be superimposed and manipulated on the screen.

2. Video Imaging

Live patient images can be displayed on the computer screen (Fig. 2). A non-radiographic tracing can be superimposed over the corresponding facial image, giving the practitioner and patient the opportunity to see the tracing and facial soft tissues together (Fig. 3). Live intraoral and dental cast video images (Fig. 4) can also be displayed and recorded for future reference. Paper or photographic copies can be generated in second, and images can also be stored on 3½" computer disks to be recalled at any time.

3. Treatment Planning

The orthodontist can alter any screen image, using computer "cut and paste" procedures, to derive a Visual Treatment Objective. As the clinician modifies the facial image, the superimposed cephalometric tracing and measurements change correspondingly.

4. Patient and Parent Consultations

During a patient's initial appointment, the staff can obtain all records within a few minutes. The orthodontist can then evaluate the data and be fully prepared for an immediate consultation.

System Design

ClearCorrect Exhibit 1002, Page 1215 of 3373

The DigiGraph Work Station is about 5 feet long, 3 feet wide and 7 feet high. A working area of 25 square feet is suggested. The main cabinet contains the electronic circuitry, and the patient sits next to the cabinet in an adjustable chair similar to those used with cephalometers.

The head holder is suspended from a boom, supported by a vertical column attached to the cabinet (Fig. 5). It is designed to be sturdier and more comfortable than cephalometer head holders, allowing the patient to remain in the holder for several minutes. Ear rods and forehead and posterior head pieces are used to minimize patient movement. The ear rods can be removed so that facial and intraoral images can also be recorded while the patient is sitting in the adjustable chair.

Two video cameras, permanently aimed and focused, are mounted on the vertical column. Lighting emanates from sources inside the boom, thus insuring that all images are properly illuminated.

A model board can be inserted into the head holder, and images of various views can be recorded (Fig. 6) . A light box can also be attached to the head holder for imaging headfilms, wristfilms, laminagraphic films, and panoramic x-rays (Fig. 7).

The video monitor (Fig. 8) is attached to a swivel arm that can be rotated around the boom as the operator moves. Images are at least as sharp as those on a standard color television. The images, text, and numerical data can be displayed, stored, and modified using either a light pen or a standard computer keyboard. The light pen is a wand that can be pressed against a specific portion of the screen to initiate an activity, or to modify images on the screen.

Any image appearing on the screen can be reproduced instantaneously with one of three "hard copy" output devices:

- Sony video imager— makes 5 " x 7 " color prints in 60 seconds (Fig. 9).
- Polaroid freeze-frame camera— produces Polaroid prints in 10 seconds; a 35mm slide back can be added to make slides, which can be sent out for processing.
- Hewlett Packard Paintjet printer— makes 8 " x 10 " paper color copies in 4 to 8 minutes.

The digitizing handpiece (Fig. 10) is used to record cephalometric data while the patient is in the head holder. The removable, sterilizable tip of the handpiece is placed directly on the patient to record a series of facial and intraoral landmarks. As each landmark is located, the handpiece button is depressed and the location is recorded in three-dimensional coordinates (x,y,z). Each time the handpiece button is depressed, an audible sound is picked up by an array of four microphones on the boom. The time it takes the sound to reach each of the microphones determines the landmark location.

Some practices may need additional work stations where records are not taken, but can be viewed, modified, or analyzed. The Consultation Station (Fig. 11) is more mobile and compact than the basic Work Station— its cabinet is 31 " high by 26 " deep (the dimensions of a standard desk) by 15 " wide, so it can be placed in the orthodontist's private office. It is built on casters and can easily be moved from chair to chair in the operatory.

Record-Taking Procedure

1. Beginning the Session

Any assistant who has done cephalometric tracings can be trained in minutes to take DigiGraph records. Other staff members will be proficient after a few hours of cephalometric training.

After turning on the machine, the assistant loads two blank 3½" disks into the DigiGraph. The monitor will then display the format for entry of basic patient data, including name and identification number, birthdate, sex, race, missing and primary teeth, etc. (Fig. 12). After the assistant enters this information, the system's main menu appears on the monitor (Fig. 13). The assistant then uses the light pen or keyboard to select the Video Imaging option.

2. Video Imaging

Images can include left or right lateral, frontal full face, standard intraoral, or dental casts. These can be viewed on the monitor singly (Fig. 4) or in traditional groupings (Fig. 14).

The operator locks the head holder in the appropriate lateral or frontal position. The patient is seated in the chair and placed in the head holder (Fig. 15). The operator looks at the live image on the monitor and makes any necessary adjustments to the patient's position. Then the user strikes a key on the keyboard or touches the light pen to the proper screen icon, and the image is captured. The patient should remain in the head holder if direct landmark digitizing is to occur next.

3. Digitizing Landmarks

Before digitizing, the user selects the cephalometric analyses to be performed on the patient. The DigiGraph then automatically prepares a landmark list, which appears on the screen. The user need only digitize those points needed for the selected analysis.

Skeletal landmarks are digitized one by one directly from the patient's head, using the sonic handpiece (Fig. 16). As each point is digitized, its location is shown on the screen, superimposed on the patient's previously captured video image (Fig. 17). A pictorial view of the next point to digitize is shown on the graphic in the upper left screen area, and the name

ClearCorrect Exhibit 1002, Page 1217 of 3373

of this point is highlighted on the landmark list.

Digitizing is done in this order: 1) facial landmarks, 2) mouth-closed intraoral landmarks, and 3) intraoral landmarks requiring a disposable bite opener to be inserted.

There is a fourth category that is not digitized directly: the extrapolated landmarks. Such frequently used points as sella, incisor root apices, and anterior nasal spine cannot be measured directly from the patient using the digitizer. Locations of these points are calculated by the DigiGraph program based on the locations of other related landmarks, using specific mathematical algorithms. Several studies have been performed to evaluate these techniques, and they will be described later in this series of articles.

If both lateral and frontal data are being recorded, the lateral imaging and digitizing are performed first. Then the patient is removed from the head holder while it is rotated to the frontal position. An experienced operator can perform a lateral or frontal imaging and tracing in approximately two minutes.

At this point, the patient is no longer required to be present. The information is ready to be analyzed by the orthodontist.

4. Cephalometric Analysis Display

The program produces any of 14 cephalometric analyses:

- Ricketts lateral
- Ricketts frontal
- Vari-Simplex
- Holdaway
- Alabama
- Jarabak
- Steiner
- Downs
- Burstone
- McNamara
- Tweed
- Grummons frontal
- Standard lateral
- Standard frontal

The standard lateral and frontal analyses consist of a combination of measurements from other widely used analyses, including skeletal anteroposterior relationships, dentoskeletal

ClearCorrect Exhibit 1002, Page 1218 of 3373

relationships, vertical dimension, craniofacial width, and intra- and interarch dental relationships. These two analyses were developed because they rely on a minimum of extrapolated measurements and a maximum of direct measurements. Additional custom analyses may be set up, using any combination of more than 150 cephalometric measurements programmed into the Work Station.

Measurements for any analysis that was selected before digitizing can be displayed on the monitor (Fig. 18). The observed value is shown along with the patient norm— adjusted for age, sex, race, and head size— and standard deviations from the norm.

5. Tracing Display

Tracings based on the digitized landmarks can be displayed immediately. These include planes relevant to the selected cephalometric analysis; for instance, a Steiner tracing includes sella-nasion, and a Ricketts tracing includes Frankfort horizontal.

An advantage of the DigiGraph over cephalometers is that the nonlinear distortion associated with radiographs is eliminated. It is mathematically impossible for a tracing of a radiograph to be superimposed exactly over a video image. The overall size may be correct, but the location of the individual landmarks within the tracing will be incorrect, because the radiograph contains two-dimensional rather than three-dimensional data. With the DigiGraph, all points are recorded in a direct, one-to-one manner, allowing precise superimposition of patient tracings over video images (Fig. 19).

6. Visual Treatment Objective

In performing a traditional surgical VTO, the doctor uses scissors and tape to cut-up the tracing and reassemble it in the proposed optimal configuration. This procedure can be dope more easily with the DigiGraph, while reflecting soft tissue changes realistically.

The clinician first calls up the image to be modified on the monitor. To move part of the picture, the clinician simply touches the light pen to two points on the screen, at opposite extremes of the area to be moved. The computer draws a box with the two points at opposite corners (Fig. 20A). Then, by touching the light pen to another spot on the screen, the boxed image is moved to that spot (Fig. 20B). Boxes can be moved vertically, horizontally, or diagonally, or they can be rotated about any point.

The DigiGraph software automatically blends skin tones and smoothes profile lines so they are consistent with the surrounding tissue. Consecutive changes can be made to the image until the desired visual objective is reached. If the "cut and paste" procedure is performed on an image with the cephalometric tracing superimposed, the tracing lines and numerical cephalometric values will change as the boxes are moved.

ClearCorrect Exhibit 1002, Page 1219 of 3373

One useful application is to modify an initial patient image and then display it with the current facial image in a "before and after" format (Fig. 21). The patient can immediately understand potential treatment benefits.

The light pen can also be used for freehand drawing over any video image. The clinician can use this function to make notes that are then saved with the appropriate image, or to draw over an image as a visual aid in a patient consultation (Fig. 22).

7. Finishing a DigiGraph Session

At this point, the operator saves the data onto the two 3 ½ " patient disks . The information on the two disks is identical, but one is a backup. These disks should be stored in separate locations— perhaps one in the patient folder and the other in a container next to the DigiGraph. All the information for one patient's treatment usually fits on a 3½" disk.

Consultation

The information described above can be generated and analyzed within 15 minutes. The doctor can conduct a consultation at the initial appointment, complete with cephalometric tracings and analyses, facial and intraoral photos, VTOs, and images of how the patient might look at the end of treatment. If appropriate, treatment might even be started immediately. Orthodontists have long wanted to be able to produce a picture of the patient's dental and hard tissues as they relate to the facial soft tissue. Only facial photographs and study casts were available at first, but cephalometric radiographs; introduced in the 1930s, gave the orthodontist the ability to view much of this information and to trace key anatomical features. The inability to view the patient's soft tissue, other than in profile, was more than compensated for by the condensation of key data into one radiographic image.

As computer technology has become more sophisticated, it has become possible to combine the benefits of the cephalogram, patient photos, and study models into one diagnostic package. Initial DigiGraph users say these superimposed images can be effective visual aids in improving doctor-patient-parent communication, especially at the pretreatment conference.

Patients may not respond positively to radiographic images because they don't recognize the images as themselves. They can't easily see or understand the implications of their skeletal irregularities. They might even find their radiographs unsettling. Dental casts help somewhat, but even these are not useful to many patients.

When the superimposed tracing and video image are shown to the patient, he or she readily identifies with the image. This identification makes it easier to explain the benefits of

the proposed treatment. When cut, paste, and draw capabilities are added to the consultation, communication and patient interest improve even more dramatically.

SPIRO J. CHACONAS



Dr. Chaconas is Professor and Founding Chairman of Orthodontics, University of California, Los Angeles.

GARY A. ENGEL



Mr. Engel is Vice President, Software, of Dolphin Imaging Systems, 24841 Avenue Tibbetts, Valencia, CA 91355. The other authors are consultants to Dolphin Imaging Systems.

ANTHONY A. GIANELLY



Dr. Gianelly is Chairman, Department of Orthodontics, Boston University.

ClearCorrect Exhibit 1002, Page 1221 of 3373

JOHN C. GORMAN



Dr. Gorman is in the private practice of orthodontics in Marion, IN.

DUANE C. GRUMMONS



Dr. Grummons is in the private practice of orthodontics in Marina del Rey, CA.

MARC S. LEMCHEN



Dr. Lemchen is in the private practice of orthodontics in New York City.

RAM S. NANDA





Dr. Nanda is Chairman, Department of Orthodontics, University of Oklahoma.

Station

Dolphin Imaging Systems, 24841 Avenue Tibbetts, Valencia, CA 91355. Dolphin and DigiGraph are trademarks.

FIGURES

Fig. 1

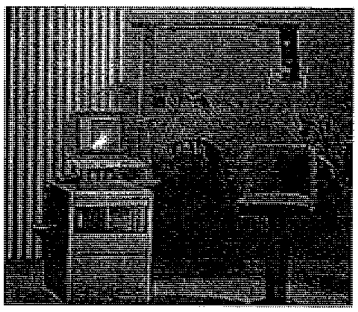


Fig. 1 DigiGraph Work Station.

ClearCorrect Exhibit 1002, Page 1223 of 3373

Fig. 2



Fig. 2 Patient video image.

Fig. 3



Fig. 3 Frontal video image with the superimposed cephalometric tracing.

ClearCorrect Exhibit 1002, Page 1224 of 3373

Fig. 4

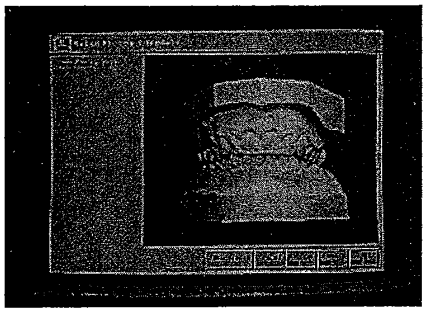


Fig. 4 Dental cast image

Fig. 5

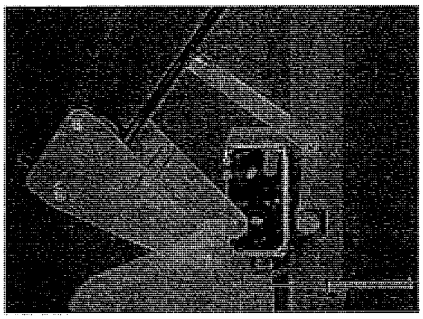


Fig. 5 DigiGraph head holder.

ClearCorrect Exhibit 1002, Page 1225 of 3373

Fig. 6

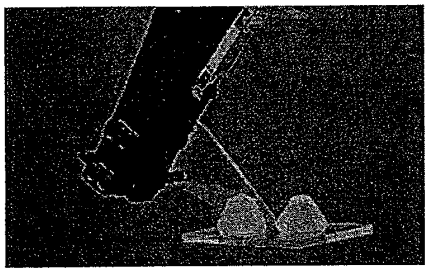


Fig. 6 Model board inserted in head holder.

Fig. 7

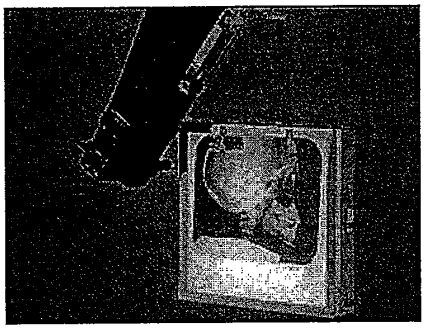


Fig. 7 Light box attached to head holder.

ClearCorrect Exhibit 1002, Page 1226 of 3373

Fig. 8



Fig. 8 DigiGraph monitor and keyboard.

Fig. 9

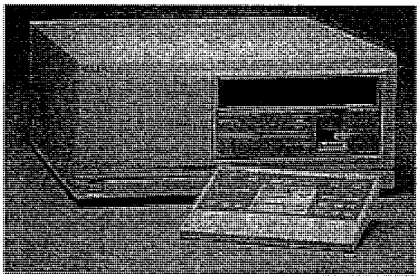


Fig. 9 Sony video printer

ClearCorrect Exhibit 1002, Page 1227 of 3373

Fig. 10

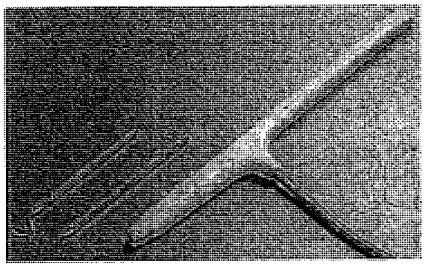


Fig. 10 Digitizing handpiece with removable tips.

Fig. 11



Fig. 11 DigiGraph Consultation Station.

ClearCorrect Exhibit 1002, Page 1228 of 3373

Fig. 12

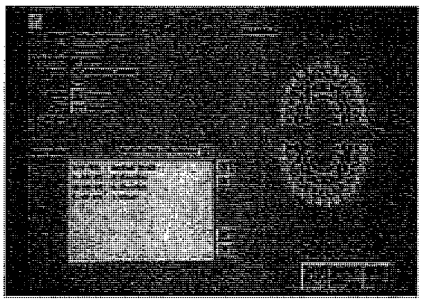


Fig. 12 Patient history screen.

Fig. 13

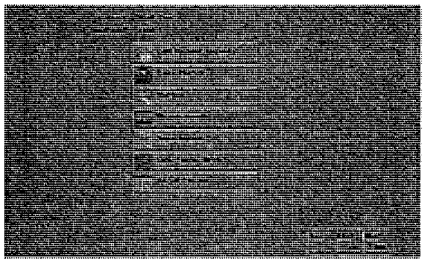


Fig. 13 DigiGraph main menu

ClearCorrect Exhibit 1002, Page 1229 of 3373

Fig. 14

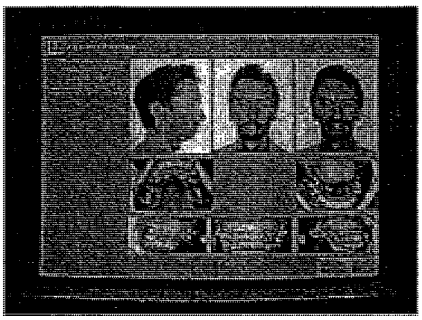


Fig. 14 Patient images in traditional grouping.

Fig. 15



Fig. 15 Adjusting patient's position in head holder.

ClearCorrect Exhibit 1002, Page 1230 of 3373

Fig. 16



Fig. 16 Landmarks digitized directly from patient.

Fig. 17

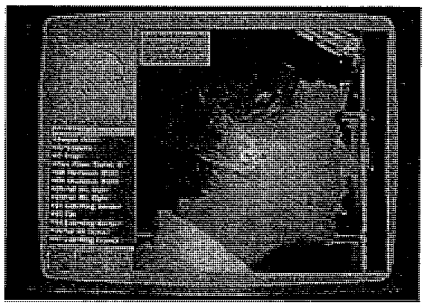


Fig. 17 As each landmark is digitized, it is superimposed over video image.

ClearCorrect Exhibit 1002, Page 1231 of 3373

Fig. 18

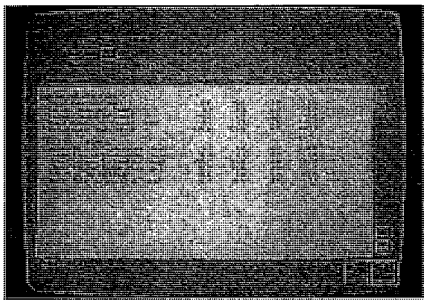


Fig. 18 Screen display of cephalometric analysis.

Fig. 19

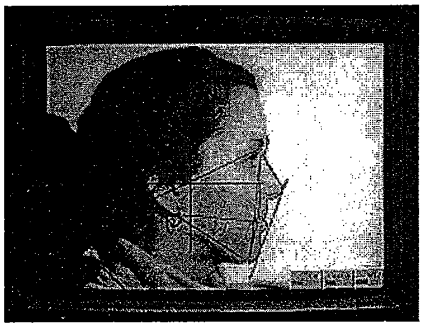


Fig. 19 Ricketts lateral tracing superimposed on video facial image.

ClearCorrect Exhibit 1002, Page 1232 of 3373

Fig. 20



Fig. 20 Video image (A) modified by dragging light pen across screen to produce new image (B).

Fig. 21

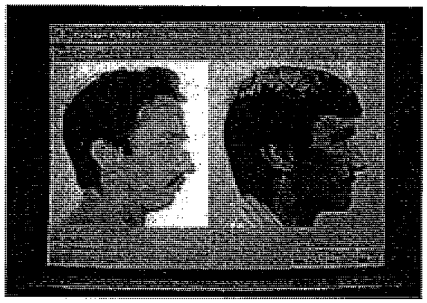


Fig. 21 "Before and after" images produced with "cut and paste" function.

ClearCorrect Exhibit 1002, Page 1233 of 3373

Fig. 22



Fig. 22 Light pen used to draw over video image.

ClearCorrect Exhibit 1002, Page 1234 of 3373

Subsidence of the Femoral Prosthesis

A Stereophotogrammetric Evaluation

NEIL CHAFETZ, M.D.,* SHELDON BAUMRIND, D.D.S., M.S.,**
WILLIAM R. MURRAY, M.D.,† HARRY K. GENANT, M.D.,‡
AND EDWARD L. KORN, PH.D.§

A quantitative three-dimensional measurement method, radiographic stereophotogrammetry (SPG), was employed to assess the relation between early subsidence of the femoral prosthesis after total hip arthroplasty (THA) and subsequent clinical course. The SPG technique and the authors' error control mechanisms are described in 15 patients in the early postoperative period, and the findings are correlated with those of follow-up clinical examinations. Among the 12 patients who remained clinically asymptomatic with respect to pain, only one had an SPG estimate of subsidence in excess of 1 mm at any point in time. Each of the three patients who later became symptomatic had SPG estimates of subsidence in excess of 1.75 mm within six months of the operation. Thus far, the patient with the largest estimate of subsidence is the only one who required surgical revision.

The evaluation of patient status following total hip arthroplasty (THA) continues to be a complex and difficult endeavor. Current hip scores[4,6,9] frequently fail to identify patients who are asymptomatic but who also have roentgenographically evident changes that may be predictive of future failure. Many hip surgeons place emphasis on roentgenographic findings following THA, but the interpretation of roentgen films made with currently conventional techniques is relatively subjective and somewhat less reliable than would be desired.

This paper reports early clinical experience with an alternative relatively objective technique called radiographic stereophotogrammetry (SPG). In the present series, this technique has been used to monitor the pattern of subsidence of the femoral prosthetic component during the early postoperative period following THA. Subsidence may be defined as the gradual "sinking" of the femoral prosthesis distally into the femoral shaft. The clinical data and the characteristics and limitations of the SPG method are presented.

MATERIALS AND METHODS

MEASUREMENT METHOD

SPG is a method for locating the positions of objects in space by use of pairs of photographs taken from different perspectives. It is widely used in engineering for making terrain maps from airplanes and earth satellites. Its operation depends on the principle that any object that is imaged on a pair of photographs taken from different camera positions can be located in three dimensions by use of the method of similar triangles provided the relation between the two camera positions is known with accuracy and precision. This same

* Assistant Professor, Department of Radiology, University of California, San Francisco.
** Professor, Departments of Growth and Development, Radiology, and Orthopaedic Surgery, University of California, San Francisco.
† Professor and Chief, Department of Orthopaedic Surgery, University of California, San Francisco.
‡ Professor and Chief, Skeletal Section, Department of Radiology, University of California, San Francisco.
§ Assistant Professor of Biomathematics, School of Medicine, University of California, Los Angeles.
Supported by NIH-NIDR Grants DE#03598 and DE#03703 with supplementary funding from the Academic Senate Committee on Research, University of California, San Francisco.
Reprint requests to Neil Chafetz, M.D., Dept. of Radiology C309, School of Medicine, University of California, San Francisco, CA 94143.
Received: January 31, 1984.

ClearCorrect Exhibit 1002, Page 1235 of 3373

head. The estimated blood loss was 1700 ml. The patient was kept in bed for three weeks and was gradually taught to walk with crutches. At the last follow-up examination, 59 months after the operation, she was free of pain and walked with a cane. The radiograph shows solid incorporation of the graft without evidence of loosening (Fig. 2B).

DISCUSSION

Total hip arthroplasty for traumatic arthritis caused by fracture–dislocation of the hip was reported by Boardman and Charnley.[2] Acetabular deficiency was overcome by the use of an extra volume of cement. The overall results were excellent.

Coventry[3] reported five cases of chronic fracture–dislocations of the hip treated by total hip arthroplasty. He recommended a two-stage regime. At the first stage, the femoral head was removed and the acetabulum was reconstructed. Five to eight weeks later, a total hip arthroplasty was performed. The use of the femoral head as a bone graft in combination with total hip arthroplasty for a deficient acetabulum, due to congenital dysplasia but also due to trauma, was reported by Harris *et al.*[4]

An alternative method of treatment would have been arthrodesis of the hip. Arthrodesis of the hip is probably the procedure that should be advocated for young, active patients who would otherwise need a total hip arthroplasty. Sponseller *et al.*[5] recently reviewed a large series of fused hips with a long-term follow-up period. Their results were satisfactory in 78% of the cases, yet none of their cases presented a similar situation of persistent traumatic dislocation of the hip.

Abbott and Fischer[1] suggested that in chronically dislocated hips, the dislocation should be reduced and the hip fused in abduction, and at a second stage an osteotomy should be performed. Yet it is well known that this operation is technically difficult to perform and fusion is not always achieved.

The authors' two patients were severely injured in road accidents. Even after successful reconstructive surgery they were not expected to lead very active and physically demanding lives. The risk of future mechanical loosening did not seem to be very great. The authors' purpose was to render them pain-free and mobile as quickly as possible, which could be achieved only by a one-staged total hip arthroplasty.

Acetabular reconstruction was achieved by bone grafting; the femoral head served as an excellent autograft. The use of autologous bone was preferred to the use of extra volumes of cement, thus decreasing thermal bone damage at the cement–bone interphase and providing a solid bone socket for the acetabular component of the prosthesis.

At a follow-up period of 55 months in one case and 59 months in the other, there are no signs of mechanical loosening so far.

The authors conclude, therefore, that total hip arthroplasty in combination with acetabular bone grafting in one operation provides satisfactory results in cases of chronic posterior fracture–dislocation of the hip, bringing those patients literally back on their feet.

REFERENCES

1. Abbott, L. C., and Fischer, F. J.: Arthrodesis of the hip, with special reference to the method of securing ankylosis in massive destruction of joint. Surg. Gynecol. Obstet. 52:863, 1931.
2. Boardman, K. B., and Charnley, J.: Low friction arthroplasty after fracture dislocation of the hip. J. Bone Joint Surg. 60B:495, 1978.
3. Coventry, M.: The treatment of fracture dislocation of the hip by total hip arthroplasty. J. Bone Joint Surg. 56A:1128, 1974.
4. Harris, W. H., Crothers, O., and Oh, I.: Total hip replacement and femoral head bone grafting for severe acetabular deficiency in adults. J. Bone Joint Surg. 59A:752, 1977.
5. Sponseller, P. D., McBeath, A. A., and Perpich, M.: Hip arthrodesis in young patients. J. Bone Joint Surg. 66A:853, 1984.

ClearCorrect Exhibit 1002, Page 1236 of 3373

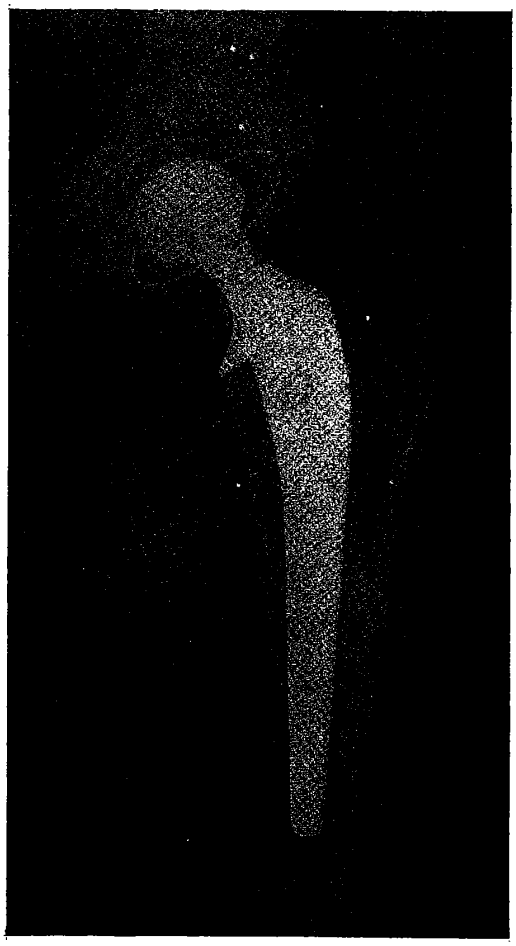
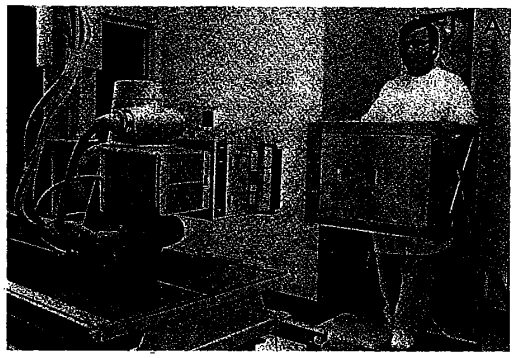
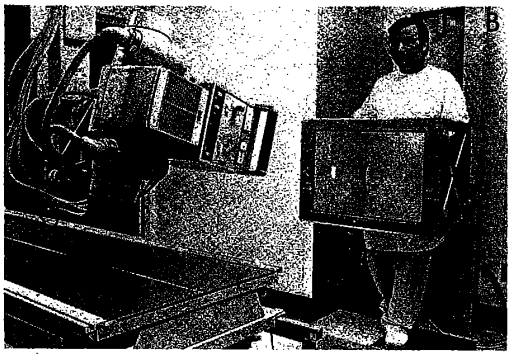


FIG. 1. A representative radiograph of a total hip arthroplasty showing metal reference spheres in the proximal portion of the femur.

principle can be used for any stereopair of radiographs for which the focus-film distances and the tube shift are known precisely. In the authors' application,[1,7] three to five Vitallium spheres (0.8 mm in diameter) are implanted at surgery in the shaft of the femur surrounding the femoral prosthetic component (Fig. 1). The spheres are spaced as widely apart as is feasible without altering the usual surgical procedure. A specially designed calibration cage with a number of radiopaque markers is attached to the cassette holder and surrounds the patient while the radiographs are taken (Fig. 2). Two stereopairs of anteroposterior radiographs are taken at each time point, one in a weight-bearing mode and the other in a non–weight-bearing mode. The weight-bearing stereopair is taken with the patient standing with both feet on wooden blocks and with his weight shifted over the affected joint. In this position, the affected joint is loaded with the weight of the body superior to it. The non–weight-bearing stereopair is taken with the affected limb dangling after the removal of one of the supporting blocks. The weight of the dependent limb acts as a distracting force while the weight of the body is borne by the contralateral limb.

The images of the metal spheres implants in the femur, the reference points in the calibration cage, and selected points on the femoral prosthetic component are all identified on the surface of each film by a technician, and their locations are encoded in digital form with a computer-controlled electronic XY digitizer. Once the technician has located and digitized the points on the films in appropriate order, all subsequent calculations are performed automatically by computer. The digitized values of the opaque cage markers are used to determine the tube shift and the focus-film distances by means of trigonometric calculations. Once these parameters are known, the spatial locations of the center of the head of the femoral





FIGS. 2A AND 2B. (A) Apparatus positioned for the first film of an SPG stereopair. Note the calibration cage surrounding the patient. (B) Apparatus positioned for the second film of the same stereopair. The roentgen tube has been moved vertically by hand.

ClearCorrect Exhibit 1002, Page 1237 of 3373

component, the distal tip of the femoral component, and the several metal spheres in the femur are computed. The computer then prepares a three-dimensional coordinate map from each pair of stereoradiographs oriented in a frame of reference whose origin is the center of the head of the femoral component. The X axis of this coordinate system passes through the distal tip of the femoral component, and the XY plane passes through one of the metal implants in the femur.

The relation between the osseous femur and the forward prosthetic component for each map is then computed as shown in Figure 3. If the distance (E) from the midpoint of the prosthesis (C) to the projection upon the X axis of the implant midpoint (D) varies beyond the reasonable limits of measurement error for different maps from the same patient, it is concluded that a true displacement of the prosthesis with respect to the femur has occurred.

For minimization of the incidence of false-positives in the reporting of such displacements, an estimate of total measurement error is computed separately for each patient. This calculation is based on the assumption that since the femoral prosthesis and the femoral shaft are both rigid bodies, neither the shape of the prosthesis nor the true relation among the metal implants in the femur should change between successive maps for the patient regardless of whether or not the prosthesis moves with respect to the bone. To the extent that the rigid body assumption is valid, between-map differences in the measured length of the femoral component and in the relation among the metallic implants within the femur should constitute good estimates of the total within-patient error in the map-making system. Figure 4 represents schematically the manner in which this principle is applied. The top row illustrates a situation in which there are only minimal measurement errors in two maps (A and B) made from different stereopairs for the same patient. The bottom row illustrates an alternative situation in which the second map (B) contains consequential distortions. In a computer operation, the rigid components of maps A and B are disassembled and are mathematically reassembled superimposed as shown in C. In the top row, the separate components from the two maps match rather closely, although certain small technical errors in fit between superimposed points may be seen. In the bottom row, where consequential distortions have been introduced in map B, a poorer fit among the superimposed points is seen in C. Deviations from perfect fit, such as those shown among the points in Figure 4, may be expressed quantitatively for each patient in the form of a pooled standard error. This standard error is then used to establish a confidence interval around the

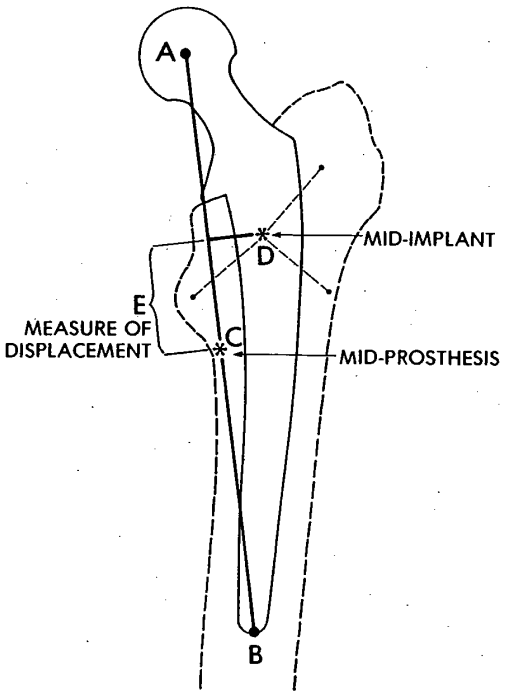


FIG. 3. Schematic representation of the measurement method. Point "C" represents the midpoint of the line segment AB, while point "D" is the calculated midpoint among the femoral implants. Within each individual patient, changes in the length of the line segment "E" on successive SPG studies constitute measurements of displacement of the femoral prosthesis with respect to the femur.

best estimate of prosthesis settling or extrusion, which has been computed with the method described in Figure 3. The best estimates and confidence intervals thus calculated for each patient in the present sample are reported in Figure 5.

A more detailed statement of the statistical rationale for these procedures has been presented elsewhere.[8]

MATERIALS

The presently reported data are from SPG studies at multiple time points for 15 patients, all of whom had total hip arthroplasties performed by a single surgeon (W.R.M.). The criterion for including a subject in the sample is solely the availability of technically satisfactory radiographs. No attempt has been made to group subjects on the basis of precise clinical diagnosis or of individual treatment plan.

Only data from the weight-bearing stereopairs are reported in the present study because the

ClearCorrect Exhibit 1002, Page 1238 of 3373

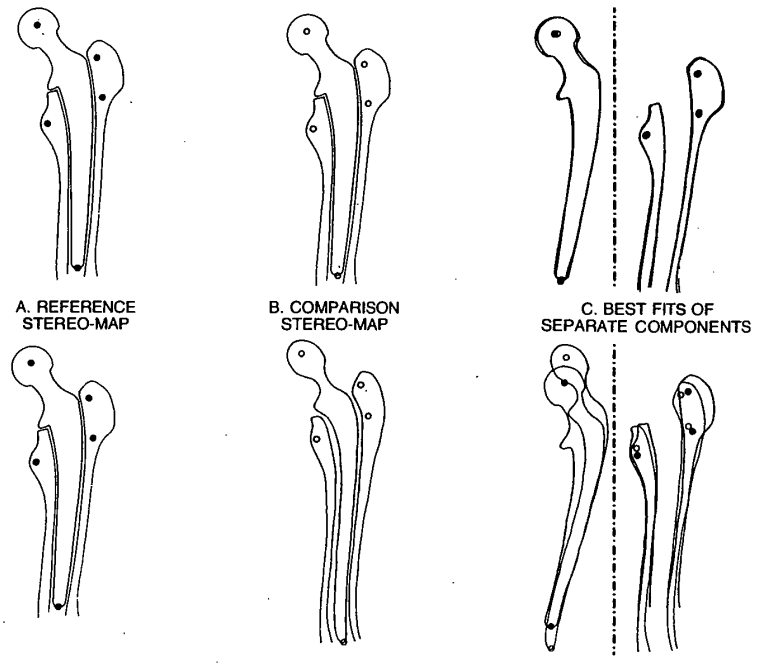
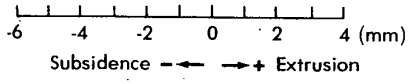


FIG. 4. Schematic representation of the method used to estimate intraindividual measurement error from all sources.

A	B	C	D	E	F	
					Days After Surgery	
Case No.	Best Estimate of Displacement	Standard Error	D.F.*	95% Confidence Interval for Displacement	First Study	Last Study
1	−0.01	0.77	6	−1.89 to +1.87	11	320
2	−0.05	1.29	9	−2.97 to +2.87	26	353
3	0.26	0.21	15	−0.19 to +0.71	15	711
4	−0.02	0.33	15	−0.72 to +0.68	12	404
5	−0.04	0.30	3	−0.99 to +0.91	15	456
6	−1.31	0.94	8	−3.48 to +0.86	14	735
7	−3.01**	0.97	15	−5.08 to −0.94	22	368
8	0.04	0.36	4	−0.96 to +1.04	13	825
9	0.83	0.37	6	−0.08 to +1.74	12	346
10	−0.75	0.54	4	−2.25 to +0.75	20	284
11	−0.13	0.57	12	−1.37 to +1.11	17	753
12	+0.10	0.41	12	−0.79 to +0.99	18	346
13	−1.05	1.24	12	−3.74 to +1.66	13	724
14	−2.23	1.51	6	−5.93 to +1.46	21	670
15	0.36	0.28	9	−0.27 to +0.99	17	612



*D.F.=degrees of freedom associated with the standard error.

** P<.05 significantly different from timepoint 1, t-test adjusted for three comparisons(Dunnett).

FIG. 5. Best estimates of prosthesis displacement and intraindividual confidence interval for each subject.

ClearCorrect Exhibit 1002, Page 1239 of 3373

authors are considering here subsidence through time rather than motion at any single time point. For each of the 15 subjects, SPG studies are available both shortly after surgery ($\bar{X}$ = 16.4 days; range, 11–26 days) and at a time point at least ten months after surgery ($\bar{X}$ = 521 days; range, 284–825 days). Varying numbers of additional studies are available at intermediate time points. In all, 60 studies have been performed and processed for these 15 patients.

Findings

Table 1 lists displacements between the femur and the femoral prosthetic component for each subject at each time point. These values have been calculated with the method illustrated in Figure 3. They represent best estimates of displacement as compared to the first time point without consideration of measurement errors. Negative values imply possible subsidence, while positive values imply possible extrusion. Subsidence values in excess of 1 mm are shown in boldface.

Figure 5 summarizes the displacement data for all patients between the initial time point and the last available time point. Here, the intrapatient estimates of measurement error have been taken into consideration. For each case, the value in Column B is the best estimate of the magnitude of prosthesis–femur displacement between the two time points calculated according to the method described in Figure 3. Column C shows the standard error of this estimate, computed individually for each patient as described in the text above and depicted in Figure 4. On the basis of this standard error and its associated degrees of freedom, an estimate of confidence in the value shown in Column B can be determined for each individual patient. For these purposes, the number of degrees of freedom (DF) for each patient is computed as $K(N - 1)$, where K equals the number of implants in the femur and N equals the number of maps being compared. The DF for each patient are shown in Column D. The greater the DF value, the narrower will be the zone of uncertainty around the value in Column B for standard errors of any given size. Column E indicates numerically and graphically the 95% confidence interval around the best estimate of subsidence or extrusion for each patient. Those values have been computed on the basis of the patient's own standard error and degrees of freedom. For each patient, the authors can be sure at the 95% level of confidence that displacement has occurred between time points if and only if the values in Column E do not bracket zero. Conversely, if the values do bracket zero, then statistically significant subsidence has not been shown. It may be seen in Figure 5 that the only patient in this sample for whom the authors may be confident at the 95% level that subsidence has occurred is Case 7.

Table 2 abstracts the clinical records for all patients. These abstracts were prepared by a staff person unfamiliar with the SPG findings and hence can be considered to have been obtained without conscious bias. It may be noted that 12 of the 15 patients were asymptomatic, while the remaining three (Cases 7, 13, and 14) has postoperative complaints of differing severity.

DISCUSSION

Evaluation of the Clinical Findings

Subsidence of the femoral component is one of a number of parameters assessed on conventional radiographs to determine the likelihood of prosthesis loosening. Conventionally, assessment is made by comparing a current radiographic examination with an earlier one.[3,5,10] In the present study, the use of the SPG method has enabled the authors to measure subsidence with considerably greater accuracy and precision than has generally been possible previously. In addition, they have been able to compute separate and individual confidence intervals for the measurements made on each patient. These intraindividual confidence intervals fulfill a role with respect to the measurement process that is similar to that which baseline records for individual patients serve in the making of clinical judgements. In other words, they enable the authors to evaluate each patient in terms of his own measurement error distribution at each examination instead of forcing them to assume the same average condition for all patients. (The standard errors for the 15 patients in the present sample ranged from 0.21 mm to 1.51 mm, with a mean value of 0.67 mm.).

A comparison of Tables 1 and 2 reveals that none of the 12 patients in the authors' sample who were asymptomatic with respect to pain in the postrecovery period had a best estimate of subsidence exceeding 1 mm at any time during the first two years after surgery (although one patient [Case 6] had a measurement of −1.31 mm at 26 months). In general, from an examination of Tables 1

ClearCorrect Exhibit 1002, Page 1240 of 3373

TABLE 1. Femoral Component Displacement Through Time

Case No.		Months After Surgery																			
	1	*2*	*3*	*4*	*5*	*6*	*7*	*8*	*9*	*10*	*11*	*12*	*13*	*14*	*15*	*16–18*	*19–21*	*22–24*	*25–27*	*28–30*
1	0	1.08			0.35						−0.01									
2	0		1.36			0.05						−0.05								
3	0		0.15				0.48			0.40			0.13					0.26		
4	0	0.18					−0.20							−0.02						
5	0														−0.04					
6	0	−0.86				**−2.66**							**−3.01**						**−1.31**	
7	0		**−2.45**		−0.19						0.43									0.04
8	0	0.42										0.83								
9	0		0.68			0.47				−0.75										
10	0	−0.37										−0.06							−0.13	
11	0	−0.12						−0.26				0.10								
12	0			−0.19								**−1.98**							**−1.04**	
13	0		**−2.33**			**−1.20**											**−2.23**			
14	0		**−2.35**			**−1.98**										0.36				
15	0		0.36						0.15											

Raw values for femoral component displacement without consideration of measurement errors. Negative values indicate subsidence. Positive values indicate extrusion. All values are in millimeters. Each value represents subsidence or extrusion relative to the initial postsurgical weight-bearing examination. Boldface values indicate subsidence in excess of 1 mm.

ClearCorrect Exhibit 1002, Page 1241 of 3373

and 2 and Figure 5, it seems appropriate to say that there was no evidence of consequential subsidence among the asymptomatic patients.

Conversely, each of the three patients in the authors' sample who reported pain in the postrecovery period had an SPG estimate of subsidence in excess of 2 mm at one or more time points during the first year after surgery. Two of these patients (Cases 13 and 14) had best estimates of subsidence in excess of 2 mm within six months of surgery and had no estimate of subsidence less than 1.4 mm at any point within the first two years (Table 1). Estimated errors for these two patients were, however, among the larger values reported for all patients (Fig. 5). Hence, the authors cannot be sure at the 95% level of confidence that subsidence actually occurred in these cases. The third symptomatic patient (Case 7) had the largest estimate of subsidence among all patients and is the only one for whom the finding of subsidence was in fact significant at the 95% level of confidence (Fig. 5, Column E). For this patient, statistically significant subsidence was first detected on the SPG study conducted six months postoperation, and the finding was repeated on reexamination 13 months postoperation. The patient's chart reveals that he became clinically symptomatic 12 months postoperation and that a revision was performed at 18 months on the basis of persistent pain, a positive gallium study, and the growth of *Staphylococcus epidermidis* from the joint aspirate. At revision, the femoral component was found to be loose and infected—the only instance of surgically proven loosening in the authors' sample thus far.

TABLE 2. Clinical Comments

Case No.		*Months Postoperation*
1	No pain; normal function	41
2	No pain; doing well	40
3	Hip OK	49
4	No problems referable to hip; died of renal failure	33
5	No pain; doing well	19
6	No pain; good range of motion	27
7	Hip pain commenced	12
	Positive for infection on gallium subtraction study, but no evidence of loosening on arthrograms	16
	Surgical revision performed. Prosthesis loose, but not grossly so. Positive culture for *S. epidermidis*	18
8	No pain; normal function	38
9	No pain; normal function	23
10	No pain; essentially normal function and range of motion	15
11	No pain; essentially normal function	11
12	No pain; full range of motion	24
13	Vague complaints of pain since surgery	24
14	One episode of severe pain; OK now	35
15	No pain	24

Evaluation of the SPG Technique

This study represents an early attempt to introduce quantitative computer-aided technology into the evaluation of postoperative radiographs following THA. The authors consider the results to be encouraging because they have demonstrated the ability to discern smaller displacements than could previously be perceived under clinical conditions. However, three difficulties associated with the use of the method in its present form must be noted. These are:

1. The disappointingly large error intervals for many individual patients.
2. The labor intensiveness of the data acquisition process.
3. The inability thus far to quantify rotatory instabilities of the femoral component.

ClearCorrect Exhibit 1002, Page 1242 of 3373

It is possible to say on the basis of the authors' own experience that each of these problems is remediable. Earlier studies with phantoms[1] have demonstrated that more than 75% of the error that enlarges the confidence intervals is associated with patient movement between the two films of each given stereopair. Experience of others under nonclinical test conditions[14] supports the conclusion that motion artifact probably accounts for an even greater proportion of the total system error. It therefore seems reasonable to assert that intraindividual confidence intervals could be reduced at least 50% by exposing the two films of each stereopair simultaneously with twin emitters and an automatic cassette changer.[2]

The labor costs the SPG method are almost entirely associated with technician time at the digitizer. Fortunately, technologies for fully automatic digital radiology already exist and are likely to become commonplace within the next five years.[12] Once primary radiographic data become generally available in digital form (the conceptual equivalent of pairs of CT scout films), software methods that have already been developed will be able to locate discrete points, such as the centers of the metallic markers on the films, automatically and with very high precision.[11] Such procedures will also reduce technician time and improve turnaround time by at least 80%.

The authors' present inability to quantify rotatory instability is entirely a consequence of the fact that only two unambiguous landmarks are available on femoral prosthetic components of present design (namely, the center of the prosthesis head and its distal tip). Work by others aimed at attaching unambiguous markers to the prosthesis surface and/or incorporating markers of different opacities within the prosthesis has recently been reported.[13] Hence, the authors believe that routine three-dimensional measurements of the displacement of the prosthetic component with respect to the osseous femur will soon become practical with a more advanced version of the present system. This would facilitate the early detection at high precision of rotatory instability and of prosthesis displacement in any direction.

REFERENCES

1. Baumrind, S., Genant, H. K., Hunter, J., Miller, D. M.,Moffitt, F., Murray, W. R., and Ross, S.: A stereophotogrammetric system for the detection of prosthesis loosening in total hip arthroplasty. Proc. Soc. Photo-Optical Instrumentation Engineers 166: 26, 1978.
2. Baumrind, S., Moffitt, F., Curry, S., and Isaacson, R. J.: Dedicated stereophotogrammetric x-ray system for craniofacial research and treatment planning. Proc. Soc. Photo-Optical Instrumentation Engineers 361:200, 1982.
3. Carlsson, Å. S., and Gentz, C-F.: Mechanical loosening of the femoral head prosthesis in the Charnley total hip arthroplasty. Clin. Orthop. 147:262, 1980.
4. D'Aubigné, R. M., and Postel, M.: Functional results of hip arthroplasty with acrylic prostheses. J. Bone Joint Surg. 36A:451, 1954.
5. Griffith, M. J., Seiderstein, J. K., Williams, D., and Charnley, J.: Eight year results of Charnley arthroplasties of the hip with special reference to the behavior of the cement. Clin. Orthop. 137:24, 1978.
6. Harris, W. H.: Traumatic arthritis of the hip after dislocation and acetabular fractures: Treatment by mold arthroplasty. An end-result study using a new method of result evaluation. J. Bone Joint Surg. 51A:737, 1969.
7. Hunter, J., Baumrind, S., Genant, H. K., Murray, W. R., and Ross, S. E.: The detection of loosening in total hip arthroplasty: Description of a stereophotogrammetric computer-assisted method. Invest. Radiol. 14:323, 1979.
8. Korn, E. L., Baumrind, S., Chafetz, N., Curry, S., and Moffitt, F.: Establishing quantitative within-subject confidence limits for clinical stereoroentgenographs. Proc. Soc. Photo-Optical Instrumentation Engineers 361:217, 1982.
9. Larson, C. B.: Rating scale for hip disabilities. Clin. Orthop. 31:85, 1963.
10. London, R. J., and Charnley, J.: Subsidence of the femoral prosthesis in total hip replacement in relation to the design of the stem. J. Bone Joint Surg. 62B: 450, 1980.
11. Mikhail, E. M., and Thurgood, J. D.: Subpixel mensuration of photogrammetric targets. Digital Images Technical Report, School of Civil Engineering, Purdue University, No. CH-PH-82-2, 1982.
12. Rosenfeld, A., and Kals, A. C.: Digital Picture Processing, ed. 2. New York, Academic Press, 1982.
13. Selvik, G.: Roentgen stereophotogrammetry in orthopedics. Proc. Soc. Photo-Optical Instrumentation Engineers 361:178, 1982.
14. Veress, S. A., Lippert, F. G., and Takamoto, T.: An analytical approach to x-ray photogrammetry. Photogrammetric Engineering and Remote Sensing 43: 1503, 1977.

ClearCorrect Exhibit 1002, Page 1243 of 3373

Pure Posteromedial Dislocation of the Ankle Joint

A Case Report

SHANKER KRISHNAMURTHY, M.D., AND ROBERT J. SCHULTZ, M.D.

A 25-year-old man demonstrated a complete dislocation of the tibiotalar joint, caused by an axial loading injury in which he had fallen to the ground with his foot and ankle in supination. This was associated with disruption of the lateral ligamentous complex. Management consisted of immediate reduction, intravenous antibiotics, formal debridement, and ankle immobilization in a short leg cast. Early and delayed follow-up evaluations have revealed no complications resulting from the injury. Only seven cases of open posterior medial tibiotalar dislocation seem to have been reported previously in the literature.

Dislocation of the ankle joint seldom occurs in the absence of fracture. Wilson *et al.*[6] reviewed the relevant literature prior to 1939, and after adding two cases of their own, found only 16 cases of ankle dislocations without associated fracture, five of which were medial dislocations. Since that time, few other reports of medial dislocations of the ankle have appeared in the English literature.[1-4]

CASE REPORT

A 25-year-old man sustained what appeared to be a supination axial loading injury to his left ankle while playing basketball, resulting in an open dislocation of the ankle. He presented with marked deformity of the ankle and a laceration with a distally-based flap over the dislocated aspect of the foot and ankle. Visible through the wound were the fibular malleolus, ruptured fibular collateral ligament, and a lacerated extensor hallicis longus tendon. The

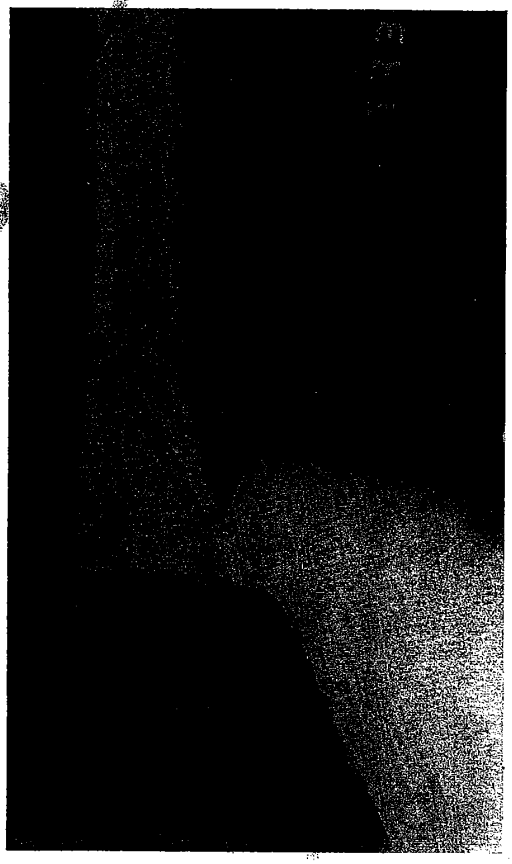


FIG. 1. Anteroposterior view of the ankle joint demonstrates a medial dislocation of the tibiotalar joint. The talus is displaced medially along with the foot. No fractures are noted.

From the Department of Orthopaedic Surgery, New York Medical College, Valhalla, New York.

Reprint requests to Shanker Krishnamurthy, M.D., New York Medical College, Department of Orthopaedic Surgery, Valhalla, NY 10595.

Received: March 24, 1983.

ClearCorrect Exhibit 1002, Page 1244 of 3373



Constructing the Gnathologic Setup and Positioner

ROBERT C. CHIAPPONE, DDS

In previous JCO articles, I described the importance of a gnathologic tooth positioner (July, 1975), adult orthodontics and how knowledge of occlusion can effect adult treatment (July, 1976), and lastly the DMR (Denar Mini-Recorder) that allows us to obtain gnathologic recordings on our patient without doing a full pantograph (October, 1977). This article describes the steps that the laboratory person takes in the construction of the gnathologic setup and the positioner.

In order for the lab person to make a gnathologic setup, certain information must be given him by the orthodontist. The models must be mounted on a semi-adjustable or fully adjustable articulator, which must be able to receive settings of protrusive path, the orbiting condyles, and the immediate Bennett side shift. This information is extremely important in determining the torque of the upper central, lateral, and cuspid complex; whether or not the case will have cuspid interference or cuspid protection; the torque of the lower cuspids; and the angulation of the lower central and lateral incisors.

The orthodontist can deliver this information in one of several ways. he can use:

1. A fully instrumented pantograph, which I feel is now outmoded with the advent of the DMR.
2. The DMR, which might be described as a "mini-pantograph", since it allows us to analyze the pertinent posterior determinants of the patient required to do a gnathologic setup (Fig. 1).
3. The check-bite technique, whereby check-bites can be taken of the patient in lateral and protrusive excursions.

The check-bite technique is the least accurate of the three, since it utilizes averages. The immediate side



Fig. 1 DMR (Denar Mini-Recorder). Used to locate hinge axis, analyze immediate side shift, measure protrusive path and orbiting condyle.

© 1980 JPO, Inc

ClearCorrect Exhibit 1002, Page 1245 of 3373
ALN006642

shift is not measured accurately but, rather, interpolations must be made. The pantograph and the DMR are by far the most accurate. The only problem with the pantograph is that it takes so much time in the setting of the articulator. The DMR, which I use, gives us the wanted angulations precisely and there really is no setting involved. The numbers are read right off the DMR and transferred onto the articulator.

The technique being presented here also assumes the following:

The orthodontist must have treated his case into centric relation occlusion. The positioner will not act like a functional appliance, seating the condyles and straightening the teeth at that position. Rather, the positioner will only maintain whatever centric relation the patient already has, or it will destroy centric relation occlusion achieved, if a hinge-axis is not done by the orthodontist in mounting the models. An average hinge-axis can be used, but this normally means more equilibration by the orthodontist after positioner wear.

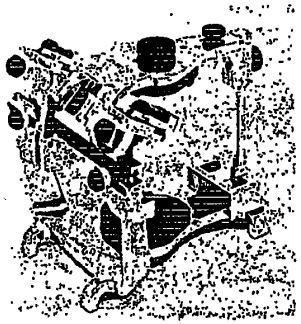


Fig. 2 D5A Articulator. (Photo courtesy of Denar Corporation.)

STEPS IN MAKING THE GNATHOLOGIC SETUP

These steps can be used with any articulator that can accept a hinge-axis and can be adjusted to the immediate Bennett side shift, the progressive Bennett side shift, and the protrusive path. The articulator used in my office is either the Denar Mark II or D5A (Fig. 2).

When the technician receives his mounted casts, he proceeds to cut off the teeth in such a way that he does not destroy the occlusal plane as it relates in space to the condyles of the articulator. To do this, all the teeth cannot be cut off at one time. The lower teeth are cut off first and then set back to the existing upper arch.

Setting the Lower Arch

I need not go into an exhaustive history of the many norms used to set the lower anteriors. Many fine orthodontic investigators have made their contributions here. All of the cephalometric evidence seems to point to the fact that the average location of the lower anteriors is somewhere near 90° to the mandibular plane. Some investigators find it 90 degrees plus or minus 3 degrees, and so on. All of these cephalometric studies give us averages. These investigators took large samples of either naturally occurring normal occlusions, or treated occlusions that were stable. From many hundreds of cases that they studied, they arrived at average measurements. But, rather than use the average, how about using something that comes directly from each individual patient?

It has been suggested to us by certain gnathologists that the proper angulation of the lower anteriors be 90 degrees to a tangent coming off of the

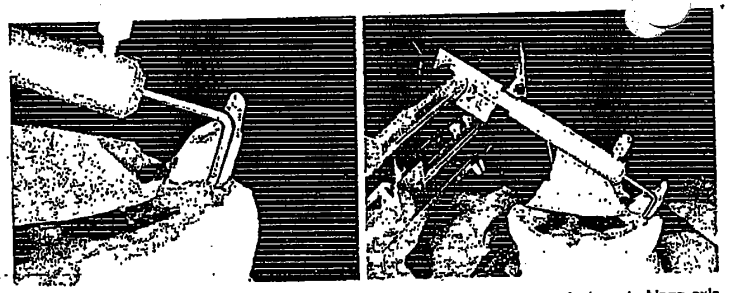


Fig. 3 Front Tooth Analyzer, developed by Dr. William McHorris, setting lower incisors to hinge-axis target.

hinge-axis (Fig. 3). This will allow the lower anteriors to be set in a position that will make the forces of occlusion truly distributed down their long axis.

Angulation of the Lower Cuspids

The lower cuspid on the right side is to be set 90 degrees to the hinge-axis on the left side, and vice versa for the left cuspid (Fig. 4). The rest of the lower arch can be set to ideal arch form that comes from the patient's mouth, with the angulations of each tooth to be refined after the "dynamic spiral" of the upper arch has been set, thereby establishing the proper curves, etc.

Setting the Upper Teeth

The upper teeth are now cut off and set to the already cut and set lower teeth. What we are trying to accomplish by this first step is to simply get the teeth in wax so that they can be moved without destroying the relationship to the condyles.

Setting the Upper Anteriors

What should be the torque of the upper anteriors? Again, pick a cephalometric source. But, all these sources give us averages that have been derived after looking at literally hundreds or thousands of head films. I say

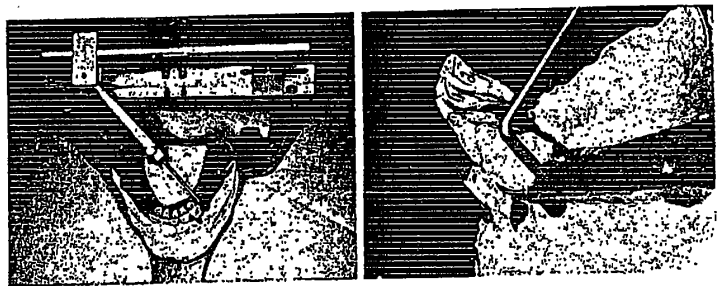


Fig. 4 Front Tooth Analyzer, setting lower cuspids 90° to opposite condyle. Setting lower incisors and cuspids properly allows forces of occlusion to be directed down long axis of these teeth during mastication.

ClearCorrect Exhibit 1002, Page 1246 of 3373

ALN006643

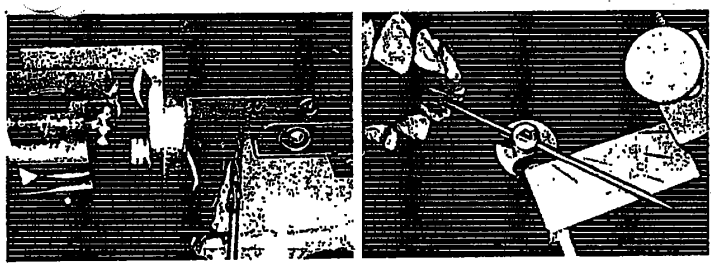


Fig. 5 Front Tooth Analyzer, setting torque of upper incisors so that lift-off during protrusive will insure no protrusive interference and be as gentle as possible for the upper anteriors. Protrusive path is 45°. Incisor torque (as measured on the lingual functioning surface) is 50°.

again, let us not be concerned with averages when we come to finding the individual patient (these averages are an invaluable help to get us close), but rather let's see what the patient can bring to us, so that an average can be translated into an absolute for the individual (Fig. 5).

As we consider torque of the upper anteriors, should we be concerned with the labial surface of the upper anteriors as certain observers would have us do? Or should we be concerned with the long axis of the upper anteriors as certain other observers would have us do?

I think as we answer the following question, it will become clear to us what part of the upper anterior should be our reference point in setting the torque. The question is this: Is it the labial surface or the long axis of the upper anterior that is functional? Neither. It is the lingual surface of the upper central and laterals that functions with the lower central/lateral complex. Since it is the lingual surface that functions, let us derive the information that the patient brings to us and apply it to the linqual surface of the central/lateral complex in setting our torque.

Our goal in setting the upper anterior is to allow it to function in protrusive without violating the protrusive path that the patient has in the glenoid fossa (Fig. 6). The protrusive path then is extremely critical in setting these upper anterior teeth. It gives us not only the torque of the lingual surfaces of the upper anteriors, but also gives us the proper overjet/overbite relationship as it relates to the occlusal plane. For example, if the protrusive path of the articulator is at 40 degrees (of course, this was read off the patient in the DMR procedure at de-



Fig. 6 Protrusive. Note lift-off with anteriors and no contact of posteriors.

banding), then the torque of the lingual surface of the upper central/lateral is set at between 42 and 45 degrees. And, if the protrusive path in its relation to the occlusal plane varies greatly away from it, then the overbite might be a very shallow one. If, however, the protrusive path comes close to paralleling the occlusal plane, then the overbite of the upper central/lateral need almost be in the deep bite category.

Setting the Posterior Teeth

(I will be discussing the setting of the upper cuspids later since these are normally done after the posterior teeth are set.)

In the setting of the upper posterior teeth, it is extremely important to remember that there is a spiral that occurs when looking down from first bicuspid to second molar. The buccal and lingual cusps of the first bicuspids are about equal in length, the lingual cusp of the second bicuspid is slightly longer, the lingual cusp of the first molar is longer than the lingual cusp of the bicuspid ahead of it, and the lingual cusp of the second molar is longer than the lingual cusp of the first molar and also longer than its own buccal cusps. This has been described as the "dynamic spiral". Many observers through the years have been warning orthodontists not to leave those lingual cusps hanging too low, as these will eventually cause balancing and protrusive interferences. However, there is equal danger in placing these cusps too high, out of centric occlusion. They will soon supraerupt and cause the interferences that you were trying to eliminate in the first place.

If the upper dynamic spiral has been properly placed, then as it occludes in centric relation occlusion with the lower arch, the proper curve of Wilson is restored in the lower arch.

Once these refinements of the lower teeth and the upper posterior teeth have been accomplished, and the case closes into a proper centric relation occlusion with no slip or slide of any kind, the case is then ready to be run through the eccentric movements to make sure that there are not protrusive working or balancing interferences. This is done without the upper cuspids in place.

Refinements of the Setup with the Upper Cuspids Out

The reason that the upper cuspids are removed, is that they are the ultimate agent for the lift-off (cuspid protection in lateral excursions). We want to refine our setup with the upper cuspids out, so that when they are placed in, their lift-off can be very gentle, in order to accomplish the desired effect.

With the cuspids out, the case is first pulled into protrusive. What we are looking for is that none of the posterior teeth will hit at this time. The lift-off is to be with the upper centrals and laterals gliding over the lower centrals and laterals. It is to be gentle though definite. The protrusive measurement is set into the articulator.

Setting the Length of the Upper Laterals

If the marginal ridges of the lower centrals, laterals and cuspids are properly placed, then one can adjust the length of the upper lateral incisors relative to the central incisors at this time. The case is pulled into full edge-on protrusive (Fig. 7). Now the length of the lateral incisors is set so that they hit the lower laterals and cuspids. Most of the time this will occur, making the up-

ClearCorrect Exhibit 1002, Page 1247 of 3373
ALN006644

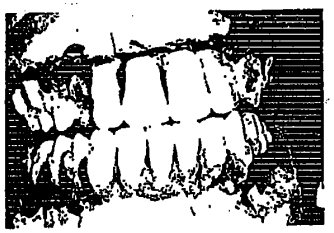


Fig. 7 Protrusive with upper cuspids cut, to set length of upper centrals and laterals.

per lateral incisors just slightly shorter than the upper central incisors. However, it is not uncommon to have them both the same length.

In going into protrusive, the lingual slope of the upper central/lateral complex (since it is nearly parallel to the protrusive path of the fossa) allows the case to very easily slip into protrusive and back again, without placing any "bang" affect on the upper central/lateral complex. It has been my observation that, many times, a diastema will establish itself after treatment when there never was one before treatment, only because the angulation of the upper central/laterals was too severe for that which was dictated by the fossa of the patient.

The amount of overbite is now rechecked. If, when the case goes into protrusive, all the posterior teeth clear, then the amount of overbite that was set is adequate. If the clearance is too abrupt or too heavy, then the overbite can be lessened. And, of course, if there is protrusive interferences of any of the posterior teeth, then the overbite must be increased.

The protrusive measurement is now replaced by the orbiting condyle measurement.

The Lateral Excursions

The articulator is now allowed to go into first a right lateral excursion and then a left lateral excursion (Fig. 8). We would like to have on the working side of the articulator (if the lower part of the articulator was moved to the right then the working side is the right side) all of the buccal cusps of the bicuspids and molars lifting off equally in what might truly be called a group working excursion.

Normally, what will be found is that a bicuspid will be lifting off earlier. The bicuspid that is the offender (that is lifting the case off before the other buccal cusps on that side) should be moved so that as to not destroy the centric contact of its lingual cusp on the opposing buccal cusp of the lower tooth, and at the same time removing lift-off. If the teeth cannot be moved in the wax so as to accommodate this while not destroying the centric relation occlusion, then an equilibration of the distal aspect of the buccal cusp of the lower bicuspid might have to be done. This is commonly called a PKT notch (Fig. 9).



Fig. 8 A. Balancing side with upper cuspids out. No balancing interferences. B. Working side. Group working.

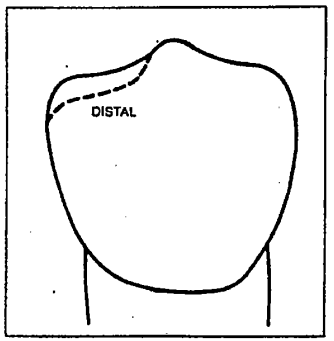


Fig. 9 PKT notch. Distal slope of buccal cusp of lower bicuspids contoured to avoid working interferences.

This is accomplished as the articulator is moved both into a right and left lateral excursion. The working side should have a group working. (Remember the upper cuspids are not in the setup.) The other side of the articulator — that is known as the balancing side — should have absolutely no contact of any of these teeth whatsoever. If an upper lingual cusp should contact a lower buccal cusp on this balancing side, then again the technician should rotate, tip or move these teeth in such a way as to remove this balancing contact, while at the same time, not destroying the centric relation occlusion contacts. Sometimes, refinement of the teeth on the working side may be needed.

Refining the Upper Cuspids

We are now ready to refine the positioner setup with the upper cuspids in their place. If the technician is working with the Denar Mark II or D5A articulator, he must be sure the protrusive measurement that he received from the patient and that he used in setting the upper central/ laterals is out and that the orbiting condyle measurement is in the articulator. This path is normally 5 to 10 degrees steeper than the protrusive path, and it is that path that the left condyle tracks in the fossa while the patient is going into a right lateral excursion and vice versa. This orbiting path is to the cuspid on its opposite side as the protrusive path was to the upper anteriors as far as setting the torque is concerned. The technician is now ready to set the torque of the upper cuspid (and I'll let the reader guess if we are talking about the labial torque, the long axis torque or lingual torque) and is ready to set the upper cuspid either tight or loose depending on the amount of the immediate Bennett movement (Fig. 10).

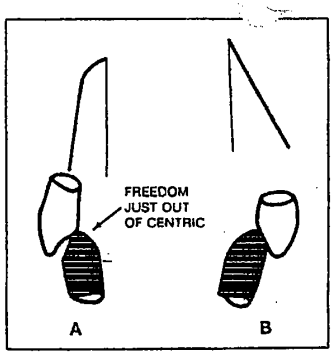


Fig. 10 A. Cuspid relationship with immediate Bennett side shift. B. Without immediate Bennett side shift.

Cuspids should have centric contact. The slope of the lingual surface of upper cuspids is dictated by the orbiting condyle on the opposite side. How tight or loose is determined by the amount or presence of an immediate Bennett side shift.

The cuspid has two condylar ele-

ClearCorrect Exhibit 1002, Page 1248 of 3373
ALN006645

ments that will control its placement: 1) the orbiting condylar path, and 2) the immediate Bennett movement.

Have you ever wondered what the difference was between cuspid protection and cuspid interference? Why can some upper cuspids be placed very tight to the lower cuspid and not cause any kind of trauma to the soft tissue of the upper cuspid nor cause the lower cuspid any excess lingual movement; and why, in some cases, placing these upper cuspids too tight causes the kind of pathology that the orthodontist is trying to eliminate with all of his treatment? The difference is the amount of the immediate Bennett side shift.*

The lab technician will be asked to set the upper cuspid into such a position that the torque of the lingual aspect of the cuspid will be approximately 2 to 5 degrees steeper than the path of the orbiting condyle on the opposite side. And if there is no immediate Bennett movement, then from the centric relation contact of the lower cuspid, the lift-off will occur immediately. If, however, there is some immediate Bennett movement, then there will need to be a slight hollow grinding of the upper cuspid from its centric relation position, into the lift-off slope. It is hoped that this gentling of the lift-off will not cause any trauma to an upper cuspid where there is looseness in the joint.

*There seems to be some evidence coming forth that an immediate Bennett movement might be indicative of a pathologic joint. Once the teeth and the condylar elements are placed "in balance", over a period of time this immediate Bennett movement will diminish. If this is as reported, then it would seem that the Bennett movement is not a "border movement" caused by hard tissue against hard tissue, but rather a ligamentous position that hopefully, like a football knee, will tighten if the trauma is removed. My advice in finishing orthodontic cases where we find a large immediate movement is to place the upper cuspids in a position that is dictated by that immediate Bennett movement, rather than hopefully waiting for the tightening of the ligaments, which may or may not occur later on

If there is any immediate Bennett movement where the upper cuspid must be hollow ground, care must be taken to see that no working interferences occur from the buccal or lingual aspect of the case. If there are, certain minor equilibrations will have to be done in the case in order to make sure that we have cuspid lift-off, rather than a group function at the beginning of the lateral excursion.

Just one comment about group function: The way group function is used properly by the Pankey-Mann people, I would have no argument against using it. In certain cases, it does work; and it would seem to me it would be extremely easy to wax into a restorative case. However, in the natural dentition with some possible settling that may occur, even though slight, I would suggest that one stick with the simplicity of a cuspid lift-off.

The Finished Setup

The finished positioner setup should exhibit the following characteristics:

1. No slides or centric prematurities. The case should open and close with the maximum intercuspation of all the posterior teeth and with no one tooth hitting prematurely, sliding or skidding the mandible into an eccentric contact. In our setups we would like to have a five ten-thousands thickness of articulating paper be able to slip through the central and lateral incisors, drag through the cuspid area, and hold tightly on each and all of the posterior teeth.

2. Lateral Excursions. On the working side there should be no contact with the posterior teeth either buccally or lingually. On the balancing side there should be absolutely no contact at all.

3. Protrusive Excursion. The upper central and laterals should slide evenly and gently against the lower central and laterals, possibly picking up the mesial slope of the lower cuspids. There should be not one of these teeth gliding any heavier than another. If easily obtainable, the distal aspect of the upper cuspid may slide against the mesial aspect of the lower bicuspid. Often, this is an impossible contact to get and there should be no extra effort placed in trying to obtain this.

The case now has been set in such

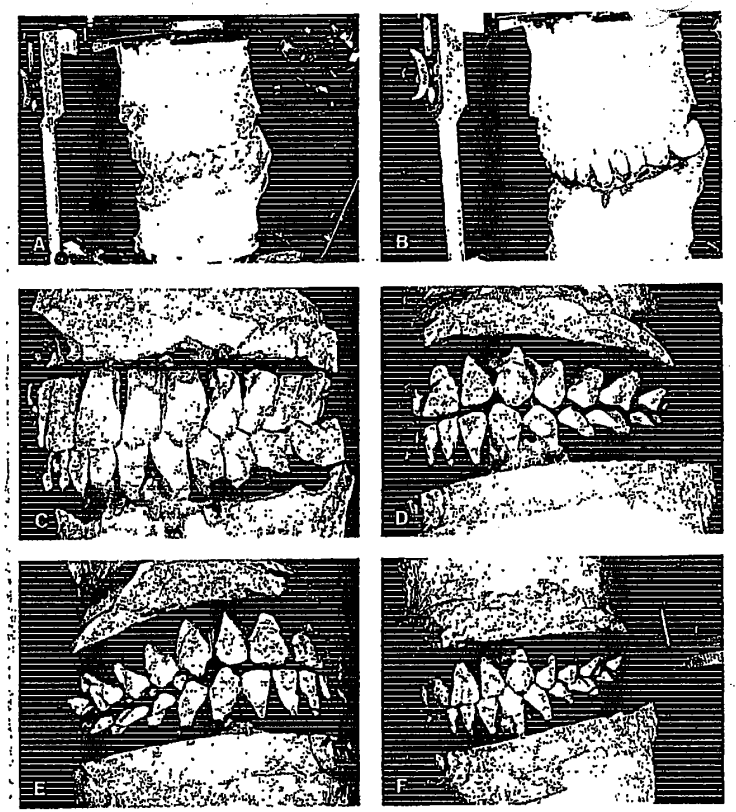


Fig. 11 Steps in setup.
A. Mounted debanded models
B. Technician cuts off lower arch. Sets lower arch to upper arch. See Figure 3 for setting of lower incisors and cuspids.
C. Technician cuts off upper arch. Sets upper arch to lower. See Figure 5 for setting of upper anteriors.
D. Setup in working, with cuspids in. See Figure 7 for cuspids out.
E. Setup in balancing.
F. Finished setup in centric.

ClearCorrect Exhibit 1002, Page 1249 of 3373
ALN006646

a way that the patient's own determinants have been used to determine the torque of the upper and lower anteriors, cuspids, and the overjet/overbite relationship. The case is now fully contoured and ready for positioner construction (Fig. 11).

Questions to Consider

1. When the case goes into the protrusive or lateral excursion, how much clearance should there be between the upper and lower posterior teeth?

If the orthodontist was doing a waxup for a restorative case, then he could make the clearances between the upper and lower posterior teeth extremely close, because these procedures are extremely precise. However, when doing a positioner setup, you have to allow for such things as:

a. Settling of the dentition that might be occurring because the patient did not wear the positioner properly.

b. The eruption of the twelve-year molars which might occur after the case is finished. For these and other reasons, I am sure we must make the lift-off a little more severe, maybe a millimeter and a half or two millimeters of separation of the posterior teeth. Almost all cases that are finished will have more than a two-millimeter overbite. This is almost always necessary because of the lack of slope of the protrusive path in the condyles.

Occasionally a patient will be found that has protrusive paths in the area of 25 degrees. If this is the case, then the above rules will be violated. The torque of the upper anterior teeth will be much steeper than will allow an even lift-off with the glenoid fossa. However, the determining factor must be no posterior contact in eccentric movements above anything else.

2. If the case has a two-millimeter side shift, does one hollow grind two millimeters off the lingual of the upper cuspid?

If the immediate side shift becomes more than .2 millimeters, then some discretion should be used in the amount of hollow grinding of the upper cuspid. The rule is simply this: Make the cuspid lift-off as gentle as possible, given the amount of the immediate Bennett, without destroying or weakening the upper cuspid by hollowing grinding.

Let us discuss cuspid lift-off. Does a patient use it?

I think it is important to realize that we are trying to develop an occlusal scheme that the patient will *never* use. If the patient used any occlusal scheme that we built in, he would destroy all of his teeth. That is how strong the muscles of mastication are. We are trying to develop an occlusal scheme that the patient will not use. Think of this example: If your wife comes home from the market with her station wagon and starts to head into the garage, does she have to hit the left side of the garage, then the right side of the garage, in order to glide her car into the garage itself? Hopefully not. She knows where the garage posts are and she simply glides in between. Let's suppose, however, her car is four feet in width and the garage posts are only three feet nine inches in width. In this situation, there is no way that she can avoid hitting the garage. This might be an analagous to setting the cuspids tight when there is an immediate side shift.

In our gnathologic setup, we are merely taking advantage of the proprioceptive nerve fibers to the anterior teeth. The front teeth have proprioceptive nerve fibers, and if you put these teeth in the right position, it allows the mouth to behave like radar — it knows where it is at all times, and will guide the mandible into closure and out of closure in such a way that the back teeth will not clash.

To summarize then, we are trying to develop an occlusal scheme that will allow the patient *not to use his teeth,* except in centric contact.



Fig. 12 A. Skull with teeth in centric, with no occlusal stent. Note seating of condyles in fossa. B. Skull in Galetti stent. Note how condyles no longer seat in glenoid fossa. C. Skull in Whip-Mix stent. Again note how condyles no longer seat in glenoid fossa. D. Skull in hinge-axis stent. Note how condyles seat!

CONSTRUCTING THE POSITIONER

The importance of the hinge-axis location is in the fabrication of the positioner. The most important thing is that the wedge of material of the positioner between the upper and lower teeth be of the proper width and size. It is imperative that when the patient closes on the positioner, the second molar and the central incisors hit simultaneously (within reason, after all we might be doing some selective extrusion of certain teeth).

If we are going to straighten teeth at an open vertical, that we hope to fit together at a more closed vertical, then a hinge-axis *must* be taken. And, of course, in a positioner we are straightening the upper and lower teeth at a vertical that may be open between two to four millimeters. As the positioner is removed and the patient is allowed to close his teeth together, we hope that the teeth will have maximum intercuspation at the centric relation vertical, with no skid or slide.

A complaint often heard in the early days was that a tooth positioner would automatically close the bite. Of course, this may happen with any positioner that is made on either a Galetti-type articulator or no articulator at all, but where the teeth are simply at all times held parallel, at the open vertical or at the closed position (Fig. 12).

ClearCorrect Exhibit 1002, Page 1250 of 3373

ALN006647

If the twelve-year molars are allowed to strike the positioner first, then two things will happen:
1. The front teeth are free to supraerupt — thereby closing the bite, and/or
2. the patient's condyles will be allowed to sublux around the first contact twelve-year molar area, thereby causing Temporomandibular Joint Dysfunction symptoms somewhere along the line.

There are three ways of constructing the positioner so that the proper opening between the maxillary and mandibular casts is not lost:
1. The first way is to make the positioner directly on the articulator to which the hinge-axis has been transferred (Fig. 13).

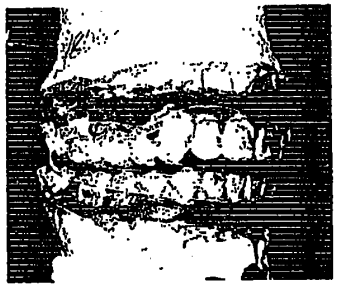


Fig. 13 Positioner on setup.

In order to do this, both casts are removed from the articulator and a Vanguard-type blank is drawn over each arch. Then the casts are placed back on the articulator and the blanks are ground so that the articulator will close, allowing a total parallel contact between the upper and lower Vanguard blanks. The vertical opening between the upper and lower casts will be such as to allow approximately one and a half to two millimeters of positioner material between the twelve-year molars.
2. The second way is to open the articulator to the vertical that you want; then take a wax bite at this opening. The cast is then removed and flasked using this wax bite and the positioner is constructed.
3. The third method is also to take a wax bite at the vertical you wish to have your positioner made, then use the Corrolator (manufactured by Denar).

Whatever the method used, it is extremely important that the wedge of material between the upper and lower casts is at the proper thickness which is determined by the path of closure on the patient's hinge-axis.

Any time dentistry is going to be done at an open vertical — and, of course, with a positioner we are straightening the teeth at a vertical that is much wider than the vertical where the teeth come together — and then the teeth are expected to function in a much more closed vertical, the hinge-axis must be taken to insure no centric slides.

Instructions to the Patient on Delivery of the Positioner

The patient is asked to wear the positioner continuously for the first three days, twenty-four hours a day. He will only remove it for eating. Over the next two months, he will be asked to wear the positioner six hours per day exercising, plus sleep wear. As the teeth begin to move into their final position, the patient is then advised to wear the positioner less and less, until only nighttime wear is required. At that point, the positioner is really acting as a retainer.

I do not go to retainers on the upper arch unless there is some specific reason to do so (i.e. cannot breathe with the positioner in his mouth; upper twelve-year molars grow in after the case is finished and will need teeth movement). However, after two months, a cemented four-to-four is placed on the lower, and the positioner is ground out so that it will be fit in place with this appliance as well (Fig. 14).



Fig. 14 Completed case. Centric (A-C). Right working with lift-off on cuspid (D). Left balancing with no balancing interferences (E).

Conclusion

In this article I have attempted to accomplish the following:
1. Give the laboratory procedures for the construction of a Hinge-Axis Gnathological positioner.
2. Give the formula whereby one can properly develop the torque on the upper and lower anterior teeth.
3. Give the rationale for hinge-axis location when using a positioner.

1036 Country Club Drive
Moraga, CA 94556

ClearCorrect Exhibit 1002, Page 1251 of 3373
ALN006648

American Journal of ORTHODONTICS

Official publication of The American Association of Orthodontists, its constituent societies, and The American Board of Orthodontics

NEW YORK UNIVERSITY
LIBRARY
421 FIRST AVENUE
N. Y. CITY
COLLEGE OF DENTISTRY

Editors

B. F. Dewel, *Editor in Chief*
708 Church Street, Evanston, Illinois 60201

Earl E. Shepard, *Assistant Editor*
225 S. Meramec Avenue, St. Louis, Missouri 63105

J. A. Salzmann, *Editor of Reviews and Abstracts*
654 Madison Avenue, New York, New York 10021

H. C. Pollock, *Editor Emeritus*
8229 Maryland Avenue, St. Louis, Missouri 63105

Constituent Society Editors

Norman D. Allen, *Northeastern Society of Orthodontists*
650 Main Street, New Rochelle, New York 10801

Charles R. Baker, *Midwestern Society of Orthodontists*
1110 Austin Street, Evanston, Illinois 60202

Arthur H. Craven, *Great Lakes Society of Orthodontists*
909 Abbott Road, East Lansing, Michigan 48823

M. Duke Edwards, *Southern Society of Orthodontists*
234 South Hull Street, Montgomery, Alabama 36104

Stephen C. Hopkins, *Middle Atlantic Society of Orthodontists*
4101 Cathedral Avenue, N.W., Washington, D. C. 20016

William R. Humphrey, *Rocky Mountain Society of Orthodontists*
1232 Republic Building, Denver, Colorado 80202

William S. Parker, *Pacific Coast Society of Orthodontists*
2430 L Street, Sacramento, California 95816

John W. Richmond, *Southwestern Society of Orthodontists*
493 Brotherhood Building, Kansas City, Kansas 66101

VOLUME 55

JANUARY—JUNE, 1969

ClearCorrect Exhibit 1002, Page 1252 of 3373

ALN006636

17. MacDowell, J., and Regli, C.: A quantitative analysis of the decrease in width of the mandibular arch during forced movements of the mandible, J. D. Res. 40: 1183-1185, 1961.
18. Cochran, G. V., Pawluk, R. J., and Bassett, C. A. L.: Stress generated electric potentials in the mandible and teeth, Arch. Oral Biol. 12: 917-920, 1967.
19. Bourne, Geoffroy H.: An introduction to functional histology, ed. 2, Boston, 1960, Little, Brown & Company, p. 34.
20. Bien, S.: Hydrodynamic damping of tooth movement, J. D. Res. 45: 907-914, 1966.
21. Bien, S., and Ayers, H. D.: Response of rat maxillary incisors to loads, J. D. Res. 44: 517, 1965.
22. Thompson, D'Arcy W.: On form and mechanical efficiency. *In* On growth and form (edited by Bonner, J. T.): London, 1959, Cambridge University Press, chap. XVI, pp. 981-985.
23. Medawar, P. B.: "D'Arcy Thompson and Growth and Form." *In* The art of the soluble, London, 1967, Methuen & Company, Ltd., pp. 23-27.

Gnathologic clear plastic positioner

Lloyd L. Cottingham, D.D.S.
San Diego, Calif.

This article presents the advantages of using a clear plastic positioner made gnathologically to complement the active orthodontic treatment of a malocclusion.

Positioners have been used for many years. Kessling described them and their use in an article published in the AMERICAN JOURNAL OF ORTHODONTICS AND ORAL SURGERY in June, 1945. Commercial laboratories have advertised them, specifying as superior products those made of rubber, vulcanite, plastics, or combinations of plastics. Many orthodontists fabricate them in their private laboratories. Some use them routinely, others use them only occasionally. A number of orthodontists have found them unsatisfactory.

The positioner provides a mechanical means for improving tooth positions following appliance treatment before retention is commenced. In some patients, it will attain a high degree of perfection, whereas in others its usefulness may be limited. It is not intended for gross treatment procedures; nor can it be expected to retain complicated tooth movements. In short, a positioner is not a cure-all or a magic wand that will produce perfect mouths for all patients. As with any other mechanical appliance, the positioner will produce the best results where it is not overtaxed. As a culmination of mechanical appliances, the positioner will close band-caused spaces, stimulate circulation in the gingivae, and place each tooth where it will be in optimum function with its opponents, the muscles of mastication, and mandibular joints. A mouth meeting these physiologic requirements will be complimentary to the patient's face.

Positioners have been a routine part of my treatment procedures since the late 1940's. At that time, a laboratory in Los Angeles was making positioners with a combination of the thermo-set plastics that was flexible but rigid enough to move teeth. The material had several advantages over pliable rubber. One advantage was that the acrylic material could be added to it to make a more rigid product. However, it had the disadvantage of wearing. Consequently, if it was used daily by the patient, the stalls in which the teeth stood would grow larger, so that the predetermined position of the teeth could not be maintained. Also, like vulcanite rubber, it retained fetid odors.

Moreover, my main objection was that I was at the mercy of the technician's ability to arrange the teeth properly. The technicians were setting up the sawed-

ClearCorrect Exhibit 1002, Page 1253 of 3373
ALN006637

off plaster teeth arbitrarily on hand-held casts, as if teeth were related in their occlusion to nothing more than the top of the table or to the palms of the operator's hands.

The technician's mistakes would be reproduced in the finished result. If he had overrotated a tooth, it would stay rotated. Worse, though the teeth were repositioned on hand-held casts, innumerable imperfections could arise. An open-bite could occur. A closed-bite could appear. Distal occlusion could develop. There could be a reversion to former orthodontic conditions, or new problems could arise. At that time I became interested in effects the mandibular articulation had on the teeth. My familiarity with jaw physiology led me to understand that undesirable occlusal relationships could inadvertently be produced when there was no appreciation of the jaw's action in the handling of the patient's casts for the fabrication of positioners. It would be necessary to fabricate a positioner on models that had been articulated on a machine, reproducing the patient's border relations, particularly the border hinge closure position, in order to avoid these unintended positioner failures.

I could see how a positioner would be corrective if made according to the principles of interjaw relations during closures. The problem was to obtain a material that would be pliable enough to fit around the teeth and yet rigid enough to move the teeth. It should be free of odor, and it would be preferable that it be clear enough that the teeth could be seen through it. It should be something that could be fabricated and available for the patient as soon as possible after his bands were removed. Most of all, it should be made to conform to the patient's physiologic jaw movements. It should at least coordinate with the hinge-axis rotation.

Impak

Mr. Horton Ely, a dental technician, agreed to help research the available products to find a material that could meet our standards. We tested many of the vulcanites and plastics that were on the market. We tried combinations of them and experimented with various curing methods, until we discovered the Impak material that was produced by the Vernon Benshoff Company in Philadelphia (which has since merged with the C. M. P. Industries, Albany, New York). This is a thermoplastic material, a powder and liquid mix, the processing of which requires cooking. We found that by varying the amount of powder in the formula mix and the duration of the cooking, we could vary the texture of the finished product from a soft, flexible material to a tough, firm material or to any degree of toughness desired. We found a 4 to 1 powder-liquid ratio and a 6-hour curing time preferable for routine patient conditions.

We found that Impak withstood abusive wear without enlarging the stalls for the teeth, and it maintained its given rigidity over months of use. It was easily shaped or cut. Moreover, its shape could be modified by the addition of cold-cure plastics. It was translucent; the teeth could be seen through it so that it was possible to determine whether or not they fully occupied their stalls. If the teeth were not descending or ascending into their stalls, whatever inhibited them, such as a bubble or too much interproximal material, could be seen.

Impak is a tough material. It has strength to grip teeth thoroughly and move them. It is also flexible enough to be molded over and engage teeth that have been rotated or repositioned, and yet its viscosity gives it elastic strength to return to its original form and put enough strain on the teeth to move them into their desired positions.

It is flexible. If molar bands with extraoral anchorage attachments are left on the teeth, or if lateral bands with antirotation spurs or a series or segment of bands (such as the lower anterior bands) are left in place to safeguard against rotations, the Impak positioner is pliable and will yield in form to adapt over these irregular surfaces.

Thermoplastic

Another desirable feature of the material was its thermoplasticity. When the thermoplastic positioner is placed in warm water, it softens and becomes moldable so that it can be easily pulled over the teeth, much like the placing of fingers in a surgeon's glove. Then, as it cools its "memory" will bring it back to the form it was given to idealize the arch forms and occlusion of the teeth.

It is nonirritant, nonporous, and noncorruptible. There is no chemical in it that will harm the tissues. It does not absorb foods and become fetid. It does not degenerate and issue sulfurous materials. It has proved to be a good stimulant to the gingivae because it increases the circulation of the blood in them. It can be cleansed readily with common detergents or by placing it for a few minutes in an ultrasonic vat.

Gingival care

It is right and proper for the orthodontist to be concerned about the arch forms and the interarch exactness of the cusps of the teeth in closing relations. However, it is equally important for him to be concerned about the health of the gingiva and the ligaments, the bone underneath, and the oral mucosa.

Active mechanical orthodontic appliances are an irritant to the gingiva. Whether these appliances are removable, made of plastic or contoured wires, or consist of the individual bands and arch wires, they inhibit the stimulation of the gingival papilla and the mucosa by the tongue, lips, cheeks, and saliva. No matter how well a band may be made to fit a tooth, it will have an edge and will give the tooth an odd shape that limits the natural surface contours that promote gingival health.

We frequently see mouths following active treatment that appear in excellent condition, but we also see mouths in which, when the bands have been removed, the gingiva has the appearance of irritated, diseased, raw meat. We see gingival tissue proliferating up between the spaced teeth. We see the rough, flat surfaces that result from faulty hygiene, fermented food, and calcified deposits that have amassed about the necks of the teeth. Orthodontic patients may have any or all of the oral pathologic manifestations known to dental pathology.

Positioner therapy is not a cure-all for all gingival pathoses, but it can help stimulate circulation in the gingivae irritated by orthodontic appliances. The

ClearCorrect Exhibit 1002, Page 1254 of 3373
ALN006638

technician should be thoroughly schooled in the gingiva contour. The wax on the setup should be considered and should be contoured, beveled, and "stippled" to simulate the healthy natural tissue.

The Impak positioner can be a therapeutic stimulant to the epithelium. It can massage and soothe the irritated gingival tissue and thus increase the circulation of the underlying capillaries to bring fresh blood to the entire periodontium.

Positioner frustration

Orthodontists have used positioners with various degrees of success. When positioners first became popular, some of my friends used them a lot and then stopped their use. I have asked them why they stopped and what success they had. Some of them had the grief that I had in previous years. They knew that their patients were using them properly. They saw the fit of the teeth ebbing away to old positions. They saw previously overlapped incisors returning to their former steep and overdeep overlaps. They saw overbites develop in some treated cases in which no overbite had existed before. They saw results gained with difficulty being concerted into malocclusions not unlike the original. They were perplexed and unable to understand what they saw. They wondered if the interocclusal space of the dentition was being changed by an improper wedge of plastic in the occlusal part of the positioner. They were concerned about the seriousness of tampering with the interocclusal space. They saw that positioners built on hand-held casts or on casts mounted without reference to the opening-closing axis of the jaw were splints that were wrecking the occlusion and the vertical corrections of the teeth.

Centriculation

For many years I have mounted the casts of incoming patients upon a "Centriculator," an articulator that duplicates the relation between the patient's teeth and his opening-closing axis. This can be used as a three-dimensional cephalometric instrument. It relates the casts to the three planes of the face and the skull, besides relating them to the physiologic centric position of the opening-closing action. Centriculated posttreatment casts record and show the new relations between the patient's teeth and his opening-closing axis. By comparing the beginning casts with the ending casts, it is easy to see and measure with a compass how far the teeth have been moved away from the axis or back toward it. The amount of vertical change can be measured from the axis-orbital plane. There is an opportunity to use "three lines of sight." When one uses just plain casts and opens them and looks at them, he is using just "one line of sight." When plain casts are put together with the occlusal plane made parallel to the table top, one is still limited to "one line of sight." It is deceiving to try to interpret the vertical dimensions. A lateral x-ray headplate provides another "line of sight," but it is difficult to measure anything except on the midsagittal plane. With articulated mounted models, it is easy to measure how the teeth are related to the Frankfort or axis-orbital plane in the beginning and at the end of treatment. It is also possible to use a third "line of sight,"

the frontal plane, to see what has been done laterally as well as vertically during the course of treatment.

Before a plastic positioner is made upon the posttreatment casts, one should study the casts in all the "lines of sight" to see how they can be corrected or improved by changing the teeth for the setup for the positioner.

Positioner effects

How well does one fare by using just mechanical appliances? By how much has he failed to gain the objective of his treatment? Centriculated posttreatment casts will tell.

A common error in most cases treated for distoclusion is that the distal occlusion has not been fully corrected. It is possible, in rare cases, to overtreat distal occlusion by carrying the upper teeth too far "rearward." In some cases what is lacking in the mesiodistal treatment may be corrected by the positioner. In many simpler cases, in which little or no distoclusion exists, the median line of the upper arch may not match the median line of the lower arch. By utilizing the band material spaces, the positioner may correct this. In treating distoclusion, we often overtip the occlusal plane. By setting up the teeth on the articulator so that the plane of occlusion is less canted, we can correct the overslant of the occlusal plane. Often, in an appliance-treated dentition, the patient cannot bite down on his canines correctly because of second molar relations on the balancing side. The positioner may correct this. In setting up the incisors on mounted models, we can use the positioner to gain the desired vertical and horizontal slant of the incisors. We can also use the positioner to hide the premolars of the upper arch behind the cuspids so that no more than a half-dozen teeth are shown in a smile. The unappreciated "toothishness" resulting from treatment can be corrected by using the positioner to close the spaces of aligned teeth into interproximal contacts and by getting the desired lip line curves to the incisal segments, the proper curves in the lateral arms of the arch, and the proper dentolabial relations.

It is usually good positioner treatment to overtreat the malocclusion, the "closed-bite," the "open-bite," the rotated teeth, or any other intra-arch or inter-arch discrepancies during the mechanical phase of treatment. Then the positioner can put the teeth into final positions so that the retainers can be much more easily made, with their sole purpose being to maintain the given position of the teeth.

Before removing the appliances in preparation for positioner therapy, the orthodontist should review the conditions present with the original diagnostic records. If he is concerned about the possible mesial migration of the upper teeth, he can leave the maxillary molar bands on to provide for extraoral retraction. If he wishes to safeguard against rotations of the maxillary lateral incisors, he may form bands with antirotation spurs, or if he is concerned about the possible rotation of the mandibular anterior teeth or any other segment or group of teeth, he may leave these teeth banded as a secure appliance to hold them in place during positioner therapy. Relief can be provided for these auxiliary bands during the wax-up preparation, so that the pliable positioner can

ClearCorrect Exhibit 1002, Page 1255 of 3373

ALN006639

pass over them without undue pressure or damage to the appliances. The toughness of the positioner may not be adequate to maintain teeth that have been severely rotated.

The waxed setup

In preparing the positioner setup, first perfect the mandibular arch. If some teeth are believed to be in good position, such as untreated second molars, leave them untouched, mark the other teeth, number them, saw them from the cast, and wax them back into place to conform to an idealized arch shape, form, and cusp height. Then the maxillary teeth are marked, numbered, removed, and waxed into place to coordinate with the occlusion of the mandibular teeth. Finally, after idealization of the dental relations to the three lines of sight and to the opening-closing axis, the occlusal wedge can be made to conform to the interocclusal space. Its thickness may come near but must not encroach upon the rest position of the mandible. The wax occlusal wedge will become the interocclusal thickness of positioner material. If this wedge-shaped amount of opening is correct, the positioner material will not impinge upon and corrupt the interocclusal space, and the teeth will close into centric occlusion in centric relation.

Duplicate stone casts are then made from the waxed setup casts. The wax wedge-shaped wafer prepared from the articulated wax setup, representing the interocclusal space separating the casts in centric occlusion in centric relation, is placed between the stone duplicated casts. Then the casts are waxed to conform to the desired shape and thickness of positioner material.

These casts are then placed in curing flasks, the wax is melted out, and the positioner is processed with the powder and liquid (4 to 1 mix of Impak material), and cured by boiling for 6 hours. The positioner can then be separated from the flasks and polished. It will appear as a milky, opaque plastic, but in a few days it will gradually clear and become translucent.

Improper positioners

It is inadvisable to use positioners at all if they are made upon hand-held or improperly mounted casts. This is emphasized when a material as tough as Impak is used as the positioner material. If you want to know how best to abuse your teeth, make a positioner for yourself. Make casts of your own dentition. Put the lower cast upon the table and lay upon it a flowable wafer of compound. Then mesh the upper cast down upon it as you guess the character of your interocclusal space. After the compound is chilled, put it into your mouth between the teeth and see if your dentition will accept it so that all the teeth close into their allotted stalls. If it does not have the same wedge shape as the interocclusal space created by a simple hinge opening, you may strike your back teeth only, you may strike only your front teeth, or you may strike only on one side.

Now mount your casts upon an articulator by guess and remake the splint of compound and see if you have improved it in any way. If your casts are set too far rearward, closer to the opening-closing axis, the angle of the wedge between your mounted teeth will not correspond to the closure of your real teeth.

The back part will be too thin. If you put the wafer in between your teeth, the front teeth will engage the wafer but your back teeth will not. If you mount the casts of your teeth too far away from the axis, the wedge of the wafer will be such that only the rear teeth will engage it when put between your arches. If you use a flat interocclusal wafer that is not wedge shaped at all but equally dimensioned from rear to front and put that between your teeth, only the rear teeth will strike. When the wedge of a positioner is made from hand-held casts or from incorrectly mounted casts, all of these faults are likely to be incorporated in the relations of the setup of plaster teeth. There is one chance in a million that you might get a single positioner ever to fit by hand-held methods or by guessed-at mountings.

Positioner "memory"

At room temperature the Impak positioner is a block of solid plastic. It is hard, like a retainer. When it is placed in hot water, 180 degrees or boiling water that has been removed from the stove, it will soften and become pliable. It has the texture of wet leather. It can easily be adapted to the teeth; it can be stretched or squeezed to fit over and around slightly malpositioned teeth. It is flexible to pass over left on bands or splinted arch segment. It loses its heat quickly and is not uncomfortable for the patient to wear.

As it cools, it regains its rigidity, and its elastic toughness has a "memory" which returns it to its fabricated setup form. It will grip the teeth and move them to the demands of the waxed setup.

Patient cooperation

The patient's cooperation in the use of the positioner is mandatory. This can usually be gained by interesting him in advance. We must not expect too little of children when we want them to grow in doing greater tasks. There are always some professional men who do not want to make innovations because they follow the flag of fear. We have heard men say that children should not wear the face-bow and neck-band appliance, and yet the modern child often wants to wear it to school. We have heard some cry out against using appliances made of multiple bands. We have heard cries against the use of rubber elastics. We hear the cries against fixed retainers as well as against the removable retainers. I suspect that every tool and every device that we use in orthodontics nowadays has had its detractors.

Children who have respiratory ailments, such as asthma, hay fever, allergies, and nasal congestions, do have difficulty in wearing positioners. Sometimes parents who "darlingize" their children discourage us from making the positioners for their children. Sometimes patients do not wear their positioners but tell us that they do.

As mentioned previously, I recommend mechanically overtreating the teeth during active treatment. Then, during positioner therapy if the patient did nothing, as the teeth settled they should come into a more favorable position than they had when the bands were removed. If a patient has a strong resistance to the positioner, it is a sign to initiate a "crash

ClearCorrect Exhibit 1002, Page 1256 of 3373

ALN006640

program" and demand a great deal of cooperation for a short period of time to accomplish as much good as possible. This would be the final endeavor to place the teeth to "look good" so that retainers can be made to hold them in this final position. It has been my experience that patients are vain. When they realize that this is their last opportunity to help themselves, they will listen, and they will want to make an effort to suit their vanity. Yes, there have been some patients who have had colds, asthma, allergies, and hay fever, but in clinical experience these have been very rare. It has been surprising to me, and to the patients, to learn that they are able to wear their positioners in spite of their asthma or nasal congestion and to find that these stomatic manifestations have waned as a result of the use of the positioner.

The importance of the positioner is first brought to the attention of the patients and parents at the consultation appointment before the beginning of active treatment. Its ability and purpose are fully discussed. Toward the latter stages of mechanical treatment, it is again brought to the attention of the patients and parents. They are made aware that active treatment time may be shortened by their willingness to cooperate by wearing the positioner, whereas their unwillingness may mean not only longer mechanical appliance therapy but also poorer results. When the appliances are removed and the positioner is made ready, they are again fully instructed in its use, purpose, and expected results. The patient is seen a few times during the period that he is using the positioner, and each time he is encouraged until finally he is ordered into a crash program for the final period before impressions are taken for the retainer.

Most patients use their positioners for 3 to 6 months, depending upon their desire to wear them and the effect the positioner is having upon the teeth. In its final phase the positioner should have expended its maximum effect and be holding the teeth in their best gained positions. After that, I prefer to use a removable and fixed retainer to hold the teeth in their acquired positions. Positioners do not retain rotations well. The patient's cooperation may wane. It is safer to use the conventional retainers so that the patient may rely upon these cribs to hold the teeth in place, rather than take a chance that the positioner might be lacking in producing what we do not know about in the influence of the other axis and the thrusts of the condyles. If the positioner is used simultaneously with a retainer, it may move the teeth in one direction during the night and the retainers may move them in another direction during the day. No tooth can serve two masters, and no dentition can become stable in serving two commanders acting in opposite directions.

Retainers

The casts made for retainers and poured from the final impressions can then be studied to see if there are any minor tooth rotations that might improve the cosmetic alignment of the teeth. These teeth can be sawed off the plaster casts below the gingival crevice and repositioned with wax. Rigid plastic may be added to the labial wires of both the mandibular and maxillary conventional retainers to crib the incisors. These retainers will have a binding, holding effect upon the teeth. They will help move them into place. Occasionally, a rotation might be severe and the retainer may not go into place at first. However, when the positioner is worn at night and the retainers during the day, they soon adapt so that within a few days the retainers can be used all of the time to secure the teeth in their anchor investing tissues. The retainers are then to be worn all the time.

If the mandibular anterior teeth have been badly rotated before treatment, I prefer the mandibular cuspid-to-cuspid banded fixed retainer; the conventional maxillary Hawley retainer is the most common form of retention for the upper teeth.

The positioner is to be kept forever by the patient in a safe place so that if a retainer is lost or forgotten and changes occur, the patient may retain the perfected results by wearing the positioner.

I do not feel that I am qualified to determine conclusively how a patient's mouth is going to react after retention. Therefore, I recommend that all patients wear their retainers for a long period of time. They should be worn all of the time for the first year or two, and then at night as a sleeping appliance for many years. I find far less objection to this now than I did 10 or 20 years ago. It is not uncommon for a patient who has worn a retainer for 5 or 10 years to return and show me that his teeth, gingival tissue, and mouth are as nice as the day he received his retainer. This is happiness for the orthodontist.

Future positioners

As idealistic as the present-day positioner may seem, it is just possible that there are plateaus of excellence to which we may yet ascend. So far, I have discussed only the importance of the opening-closing axis of the mandible. It may be that the time will come when the vertical and the sagittal axis of the mandible will become as important to our setups as the hinge axis. In recusping natural teeth, the careful restorative dentists are as much concerned about the sagittal and vertical axis as they are about the to-and-fro thrusts. As a matter of fact, they depend much upon the direction of the lateral thrusts to determine how high to reproduce the cusps and how deep to make the grooves. The character of the lateral thrusts and their timing have something to do with the kind of arc one should give to the incisors. Restorative dentists locate the rearmost position of the hinge axis so that they can find out what the lateral thrusts of the condyles are like. The posterior opening-closing hinge axis is only the starting post of mandibular centric relations.

New knowledge always leads us forward. We make progress by going from the simple to the complex. We improve art by laboring upon it intelligently. Maybe some day we will demand this knowledge for our orthodontic patients.

2850 Sixth Ave.

ClearCorrect Exhibit 1002, Page 1257 of 3373

ALN006641

CAD/CAM in the Dental Office: Does It Work?

P.R. Crawford, BA, DMD

Increased references are appearing in dental literature about computer assisted design and computer assisted manufacturing (CAD/CAM). As with all innovations, there are those (mainly the developers of the systems) who believe CAD/CAM will eventually change restorative dentistry as we know it today. But for most clinical dentists, CAD/CAM is merely an acronym of curiosity for some mechanism of the future.

The *Journal*, without taking scientific issue, paid a visit to a dental office currently utilizing CAD/CAM to evaluate its merits in a practical clinical setting.

Of the three better known dental CAD/CAM concepts – the Duret system, Rekow system and Siemen's CEREC – only CEREC is available commercially; the other two systems are still in developmental stages.

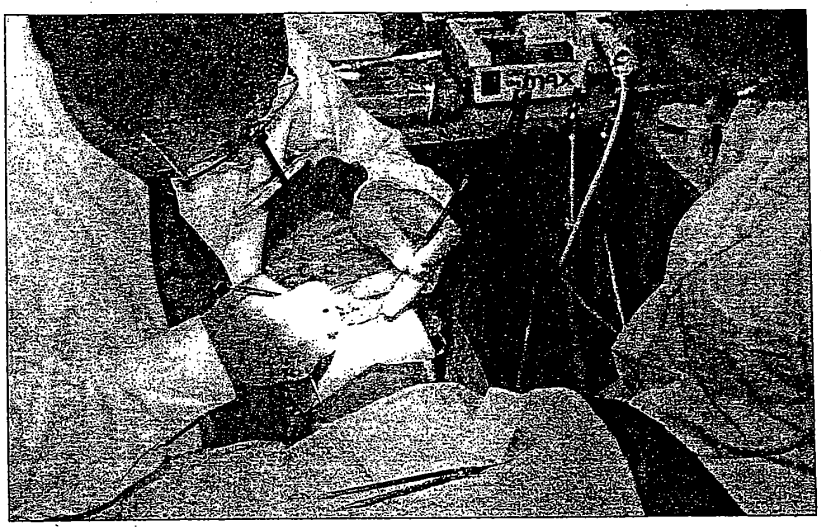
Duret System

Twenty-five years ago, the French scientist Dr. François Duret (who has a dental degree, medical degree and two PhDs) conceived the idea that a combination of physics and the computer could revolutionize dentistry. His CAD/CAM system utilizes a laser-diode scanner to produce images of tooth preparations. The restoration is "designed" with the aid of a library of tooth forms stored in the computer memory. A three-axis milling machine completes the process. The entire procedure, from preparation to final cementation, can take place in one appointment – ideally in less than one hour.

Reports indicate the complete Duret system (scanner, CAD and CAM) is priced between $150,000 and $200,000. If the CAM portion was located in a commercial laboratory and connected to a dental office by modem the costs could be reduced, but the turnaround time would be increased.

The Rekow System

Dr. Dianne Rekow is a brilliant PhD research scientist with degrees in dentistry, engineering, and business administration, plus a certificate in orthodontics. She spent years working on CAD/CAM at the University of Minnesota and has recently moved to the University of Maryland where she continues to perfect her theories.



TIME: 14:10 hours – Dr. Paul Coulombe completes the MOD inlay preparation on tooth #24.

Her CAD/CAM concept uses stereophotography to record not only the restoration requirements of the preparation but the proximal segments of adjacent and opposing teeth. The standard photographic film is exposed and the colour slides are digitized. The restoration is computer designed and milled similar to the Duret system.

One of Rekow's objectives for her optic system and design software is affordability – an investment of approximately $5,000 for the dental practitioner. The information could then be sent to another location for machining.

CEREC

Marketed by Siemens, the CEREC system is the concept of two Swiss researchers from the University of Zurich; a dentist, Dr. Werner Mormann and an electronics engineer, Dr. Marco Brandestini.

CEREC, an acronym for ceramic-reconstruction, is currently the only commercially available CAD/CAM development. Recently the *Journal* spent an afternoon with Paul J. Coulombe, BA, DDS, a 1960 graduate of the University of Toronto. Dr. Coulombe has conducted a general practice in Brampton, Ontario for 28 years. He is one of only a handful of private practitioners in Canada using a CAD/CAM system in general practice.

When asked how he became involved with CEREC Dr. Coulombe indicates several factors. "I try and look ahead at what is on the horizon," he says. "And I constantly seek out new endeavours which best serve my patients." "Dentistry is changing so rapidly," he continues. "A few years ago who would have thought we would be talking about CAD/CAM, lasers, AIDS, million dollar overheads and practices that are insurance driven. If we don't keep on top of everything we quickly fall behind."

CEREC Course In Zurich

Last year Dr. Coulombe and several other Canadian dentists joined a class of 25 dentists from around the world to take the three-day CEREC course offered at the University of Zurich. Participants pay their own travel, tuition and accommodation expenses.

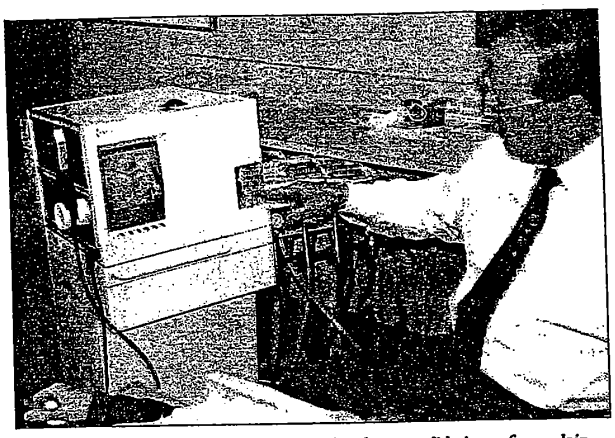
Dr. Coulombe remarks that the three days of instruction led by Dr. Mormann, CEREC's co-inventor, was extremely intensive. "Although they had us going 12 hours a day it was very well organized and the Siemen support was excellent."

Back in Brampton Dr. Coulombe continues self instruction with CEREC. He and his two associates practice on natural

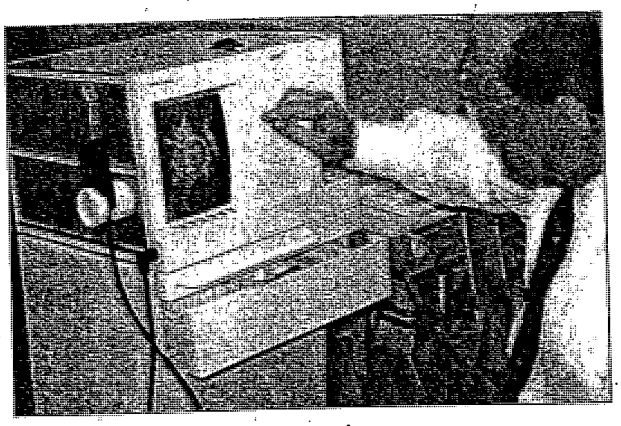
ClearCorrect Exhibit 1002, Page 1258 of 3373



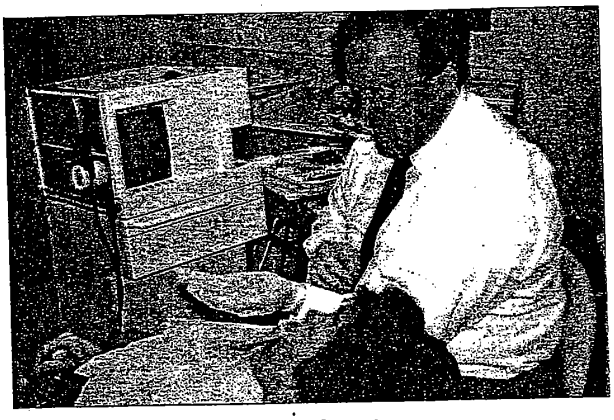
The CEREC photo-scan transmits the preparation detail to the monitor.



CEREC's milling machine cuts a precise inlay from a solid piece of porcelain.



Dr. Coulombe "designs" the inlay preparation.



TIME: 15:09 hours – the inlay is ready for try-in.

teeth embedded in plastic with the aid of a comprehensive step-by-step CEREC manual. "Like everything else," he says, "the more often you repeat a procedure the better you get at it."

The Journal Observes

The Preparation

Dr. Coulombe's patient was promptly seated at 14:00 hours. The selected tooth, a maxillary left first bicuspid, requires replacement of an old MOD amalgam. Dr. Coulombe explains a number of features during the ten minutes needed to anaesthetize, place rubber dam, remove the old amalgam and prepare the tooth for a MOD porcelain inlay.

** the inlay preparation has to be almost perpendicular with a maximum of four to six degrees divergence.

** good inlay technique is still paramount – sharpness of axial walls, floors etc.

** the gingival seat should be above the gingival line – the computer scanner cannot tell the difference between tooth and rubber dam if at the same level.

** Glass ionomer may be used if there is an undercut.

The "Impression"

Prior to the optical "impression" a contrast powder is applied to the surface of the prepared tooth. The camera system, utilizing an infra-red mechanism, is positioned over the tooth and by the flick of a foot-switch a three-dimensional preparation image instantly appears on the computer screen. The time is 14:30 hours.

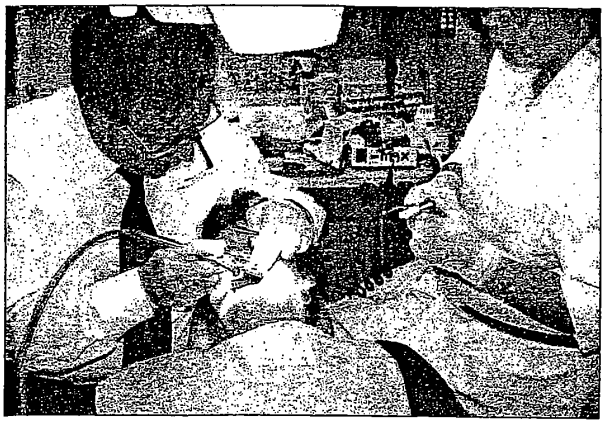
The Inlay Design

The inlay is computer designed directly on the monitor screen. Dr. Coulombe uses a "trackball" to trace a series of dots onto the monitor indicating where he wants the filling to go. In other words, he "tells" the machine how to do the milling. He arbitrarily selects the marginal ridge and the contact point. The computer tells Dr. Coulombe what size of prefabricated Dicor block is required for the particular preparation. The Dicor blocks come in a variety of sizes and shades. Dr. Coulombe and his assistant carefully select a shade to match the bicuspid. The manufacturers claim that one of the advantages of the preformed material is it's batch formulation. The process reduces porosity and guarantees colour consistency. The porcelain blocks are attached to a metal stub which is fixed to the three-axis milling machine.

Milling

At 14:41 hours the Dicor block is placed in the milling mechanism and the cutter blade is activated under a stream of water. There is a lull in the office activity while dentist, patient, staff and *Journal* watch the process through a small clear plastic door. The computer has indicated that the water-powered diamond cutter blade, about the shape of a good-size "Joe Dandy" disc, will create the inlay by making 258 cuts in 5 minutes and 37 seconds. And it does! Dr. Coulombe pronounces, "Our job is about 90% done."

ClearCorrect Exhibit 1002, Page 1259 of 3373



Following bonding, the final polish. Total elapsed time: 1 hour and 15 minutes.



The final restoration passes the Journal *test!*

The Try-In

At 14:50 hours the inlay is separated from the milling stud and tried into the preparation. Dr. Coulombe has already warned us that he may have designed the contact point a little heavy so no one is surprised when there is some preliminary adjusting. Once a tight contact is established the inlay seats well.

Bonding

An intrinsic factor of the CEREC system is the bonding. It provides not only adhesion but marginal integrity. The bonding process is similar to most systems. The enamel borders are etched for about 30 seconds and a bonding agent is applied to the inlay and cavity surfaces. All parts of the cavity are covered with a dual cure posterior composite material at which time the inlay is seated and polymerized. Total time elapsed is now 1 hour and 7 minutes. "Now the meticulous job begins," says Dr. Coulombe.

Occlusion

The meticulous (and tedious?) occlusion process is an apparent weakness of the CEREC system. The occlusion must be ground-in by a trial and error hand grinding procedure. Occlusal contouring is achieved with the use of a contour diamond (40 micometre). And tedious it is: the patient is instructed to repeatedly "tap-tap" on a piece of articulating paper.

As perfection approaches, a finer diamond (15 micrometre) is used and final polishing is achieved with flexible sandpaper discs. Interproximal areas are refined with metal strips.

A final inspection is made of all areas and when Dr. Coulombe is satisfied that marginal integrity, contours, shade and occlusal excursions are clinically acceptable, the patient is prepared for dismissal. Total elapsed time – from start to finish – is 1 hour and 27 minutes.

The Future

After the patient left the office, Dr. Coulombe candidly informed the *Journal* that although he considers the CEREC restoration to be good treatment, he certainly does not view the system as perfection. "We're at the leading edge of restorative technology. I know CAD/CAM is going to be the way of the future." he said. "But it requires investigation and research beyond what I can provide with a single unit."

Dr. Coulombe expressed a familiar comment about CEREC – one the *Journal* recognizes from several other encounters with CAD/CAM: "At this point CEREC is an elegant *Model T*. It's going to be quite a few years before CAD/CAM becomes part of everyday dentistry." Dr. Diane Rekow drew the same analogy during a recent lecture, as did Dr. Harald Heyman at North Carolina's School of Dentistry. The fact that there are only 35 or 40 CEREC units currently in use in the USA and merely a handful in Canada gives rise to the *Model T* parallelism.

Economics

Cost plays a large role in the future of CEREC and any CAD/CAM system. Dr. Coulombe paid $70,000. for his CEREC unit. His five-year lease costs $1,800. a month. "I'm not going to get my investment back very quickly at $400. an inlay," he muses. "However, I do enjoy being involved with the technology of tomorrow." △

The Journal extends sincere thanks to ***Dr. Paul Coulombe****, his staff and associates – and especially to an understanding patient – for the opportunity to observe this CAD/CAM procedure.*

Did you know?

***Megatrend's* Naisbitt Outlines 6 Major Trends**

During a speech last August, John Naisbitt, (who earned $25,000 for his 90 minutes!), told his Toronto audience the 1990s would be shaped by six major movements:

- a renaissance in the arts, literature and spirituality
- a decline of the welfare state and the emergence of free-market socialism
- the emergence of English as the first truly universal language
- a decline in importance of cities and the emergence of new "electronic heartland"
- a move toward eventual worldwide free trade, and
- a global economic boom.

(Reprinted from *Enroute* November 1990)

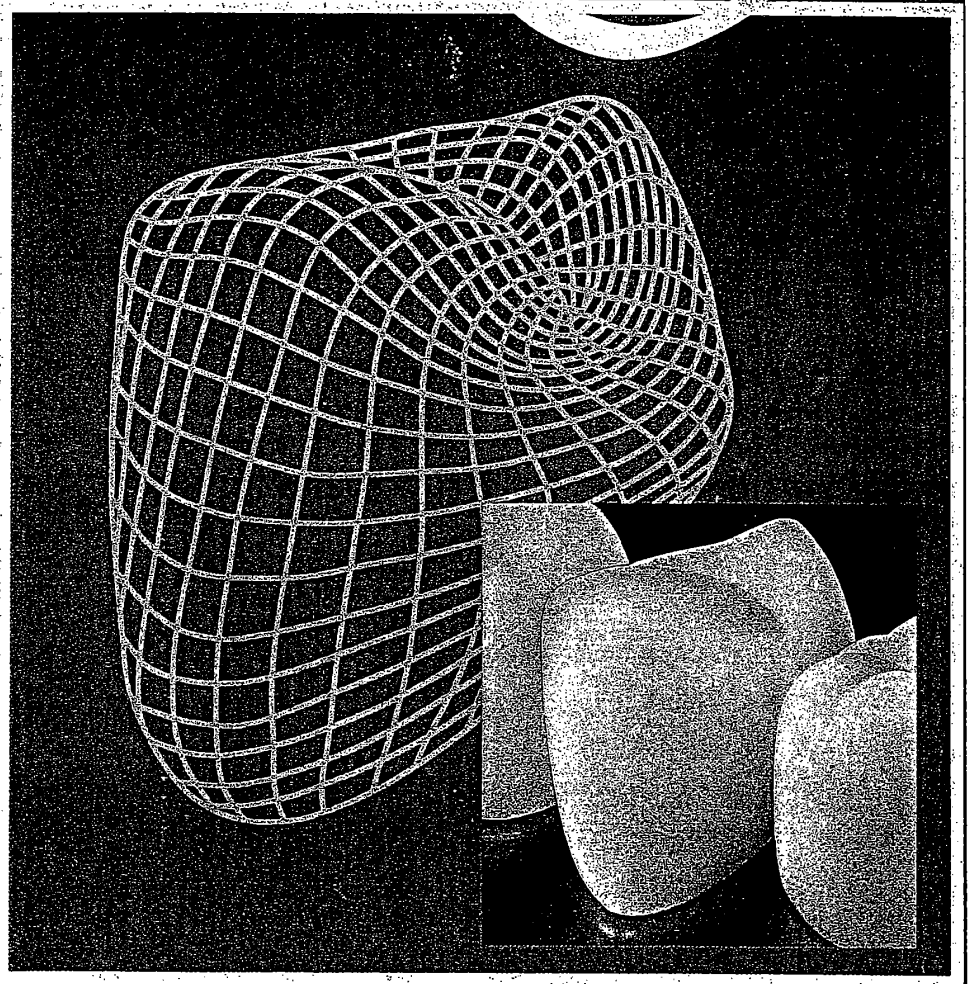
ClearCorrect Exhibit 1002, Page 1260 of 3373

JOURNAL

eptember
eptembre
988
ol. 54
o. 9

anadian
ental
ssociation

'Association
entaire
anadienne



Undeliverable
Addressee
TURN TO SENDER
turn Postage
aranteed

non livrable
destinataire
TOURNER À
EXPÉDITEUR
rt payé

▲Computers in Dentistry

▲L'informatique en médecine dentaire

ClearCorrect Exhibit 1002, Page 1261 of 3373

Specialty Features

Computers in Dentistry

Ralph Crawford, DMD

• PART ONE •

CAD/CAM: The computer moves chairside

The Computer Moves Chairside!

For years the computer has been well established in the dentist's reception area and business office. Now it has moved into the operatory.

In this issue, the Journal staff endeavors to inform its readers of some of the recent technology which undoubtedly will influence the practice of dentistry in the future.

In describing certain products and methods, the Journal does not necessarily advocate one over the other, or ascribe that it is the only one available. The Journal wishes to thank Dentsply International, York, Pennsylvania and Tekscan Inc. of Boston for their assistance in the preparation of the material. We are also grateful for the opportunity granted to attend the CAD/CAM Symposium in Vancouver and for the interview with Dr. Francois Duret.

On March 19, last, in Vancouver, a bit of history was made in Canada. For the first time, leaders in the field of CAD/CAM met in one room and presented a clinic to a group of interested dentists and technicians, outlining a system of prosthetic fabrication that will revolutionize dentistry as we know it today.

For years, dental office personnel have utilized computers at their desks and in their business offices. Now the computer is also in the operatory and directly transmitting information from the oral cavity to the computer-assisted design (CAD) and computer-assisted manufacturing (CAM) phases. A micro-milling machine will produce a finished crown or bridge of prepared teeth, ready to be cemented in less than one hour.

Dental prosthetics will never be the same again.

CAD/CAM is the first major change in technology since 1907, when Dr. Taggart demonstrated the casting of gold inlays. Certainly the lost wax technique was known to the ancients; a recent Toronto exhibition of Holy Land artifacts displayed such metal ornaments created 20 centuries before Christ. Now, however, Vancouver's March audience was told that impressions, models, wax and casting machines may well be exhibited as historic relics in the next century.

Dr. John Nasedkin, a Vancouver prosthodontist who mentors TEST, the Esthetic Study Team, arranged the one-day symposium that brought together Dr. James P. Duncan, Mechanical Engineering Professor Emeritus from the University of British Columbia; Dr. François Duret of Grenoble, France, originator of the application to dentistry of the CAD/CAM system; Dr. Diane Rekow of Minneapolis, an instructor in Orthodontics and a Post Doctoral Fellow in Biomechanical Engineering at the University of Minnesota; and Dr. Reggie Caudill, Professor of Mechanical Engineering and Director of Robotics and Computer Graphics at the University of Alabama in Tuscaloosa, U.S.A.

Dr. Duncan, who graduated in 1941 from the University of Adelaide, Australia, Mechanical Engineering and holds a Doctor of Science degree from the University of Manchester, traced the early involvement of computers in industry, particularly in the automobile sector. He has had a lifelong interest in shape reproduction, including the first uses of computers in that field back in 1954.

Dr. Duncan gave a graphic demonstration of optics engineering by displaying a perfect plaster replica of his own head – a remarkable likeness – which was computer designed and milled in minutes at a cost of $100.00.

He indicated that for dentistry there are special added concerns and problems. Industry is used to working with simple equations such as spheres and cones, but dentists are working with natural shapes where God the Creator, He alone, knows the equation. "If we want to design it (i.e. the natural shape) then we have to have some means to equate it."

Dr. Reggie J. Caudill, who began his work independently of Drs. Duret and Rekow, is involved at the University of Alabama with developing DESS, a Dental Expert Support System, where three-dimensional imaging data of the dental arch will lead the dentists through the appropriate design

ClearCorrect Exhibit 1002, Page 1262 of 3373



Left to right are: Drs. James P. Duncan, mechanical engineering Professor Emeritus, University of British Columbia; Dr. François Duret of Grenoble, France, originator of the application to dentistry of the CAD/CAM system; Diane Rekow, of Minneapolis, an instructor in Orthodontics and Post Doctoral Fellow in Biomechanical Engineering at the University of Minnesota; John Nasedkin, a Vancouver prosthodontist who monitors the Esthetic Study Team, and Reggie Caudill, Professor of Mechanical Engineering and Director of Robotics and Computer Graphics at the University of Alabama.

sequences and automatically manufacture dental prostheses utilizing computer controlled milling machines and robotics.

Dr. Caudill initially worked with robotics in industry attempting to decrease the time interval between design and production – leading to his work relating to the elimination of the dental impression phase and then automating the production stage. He emphasized that in attempting to achieve a one hour turnaround in the production of a crown, the quality must be maintained. Dentistry must take its lesson from the automobile industry. It doesn't matter what it costs, if it isn't quality it isn't going to survive. He indicated that in dentistry they are talking quality and precision in the range of 25 to 50 microns. The key, according to Dr. Caudill, falls back on the imaging system; can the computer actually get the data with the precision we need?

When questioned whether the future dentist will need an engineering degree, Dr. Caudill replied that certainly the dentists would have to be computer-oriented but the computer programs and the software would need to be developed in an "expert-friendly-interphase" manner.

Dr. François Duret, originator of dental CAD/CAM, outlined how he had toiled for 20 years to bring his system to the commercial market stage. It was in 1970 that he first conceived the idea that the combination of physics and the computer could revolutionize dentistry. (See below, "François Duret – a man with vision")

Following the preparation of the tooth, or teeth, Dr. Duret's CAD/CAM system is essentially a three-step procedure. The teeth are prepared traditionally, but feather edge margins are avoided. Chamfers and butt-edges reproduce better in the computer system. Dr. Duret is quick to point out that there is no substitute for excellent preparations. "The computer", he said, "cannot make a poor preparation better."

The first step is the Optical. The system utilizes a laser-diode scanner and a charge-coupled-device (photo receptor) to produce images of preparations and surrounding areas. As the scanner is passed over the teeth, the signals are relayed into the computer and displayed on the video monitor. A foot control allows the image to be fixed on the screen for examination, and a series of acceptable images are selected for the second step – Design. An experienced operator can complete this step in three minutes or less.

Step two, CAD, or design phase, determines the internal and external shapes of the required prostheses, right down to the exact micron space needed for the luting agent. The internal crown configuration has already been decided by the scan of the preparation. The external requirements calls upon the computer library to select a particular morphology to be placed in the optical impression. A scan of the area before the preparation can be used to 'place' the patient's own tooth morphology back into the required space. Individual, specific anatomy and contact points can be designed as required.

The success of any prosthesis is the occlusion. Intrinsic within the Duret system is a computer recording device which follows the movements of the mandible in order that the surface of the crown or the bridge is in harmony with centric occlusion and excursive movements. The complete design requirements – selection of prosthesis and its articulation – is achieved in under ten minutes. "And", says Dr. Duret, "it is not necessary for the dentist to know the physics, just be familiar with the computer software."

Step three is CAM, the manufacturing of the prosthesis. A three-axis micro-milling machine controls automatically, from a blank of pre-selected material, the internal/external shapes of the crown or bridge to a tolerance of 50 to 80 microns, all within 15 to 20 minutes. The audience was reminded that Dr. Duncan's and Dr. Caudill's lectures indicated that industry had been auto-milling for years, just in larger dimensions.

Dr. Duret's original material of choice was Dicor, and it produced quality results. Although it was possible to select the shade via the computer, the Dicor crowns have to be hand finished and glazed by a technician before insertion. He is currently working on new materials and cements specific to CAD/CAM. The micro-milling machines cut from a solid block of material and is not dependent upon the variables of chairside mixes. Thus, new vistas of material technology



Dr. Reggie Caudill of the University of Alabama.



Dr. François Duret, of Grenoble, France.

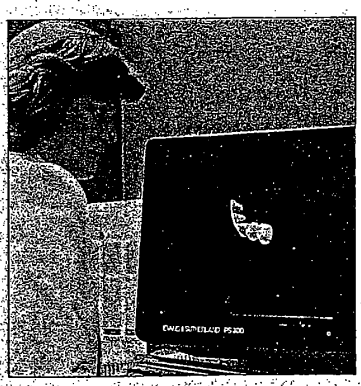
ClearCorrect Exhibit 1002, Page 1263 of 3373

are opened. Dr. Duret proposes that new material "configurations" could be aligned much like tooth substance itself.

As to integration into the dental office, there are, in Dr. Duret's opinion, three possible scenarios:

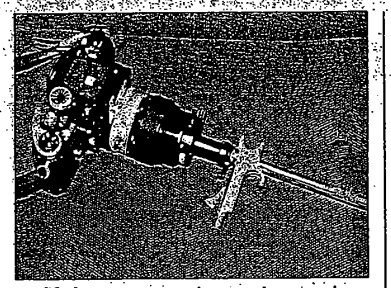
1. Complete integration: the design (CAD), and manufacturing (CAM) phases are controlled by a single dentist. A technician would be required for the CAM and subsequent color shading and polish.
2. Group office: two, three or more dentists could have an optical scanner each with one CAD and one CAM serving all.
3. Laboratory integrated: the laboratory has the CAM (most expensive component) and also the CAD which can be connected to the dentist's CAD by a modum.

When questioned as to the time frame for production, Dr. Duret said there are already systems functioning in France that are producing two crowns per day per unit. 1988 has been the target for commercial marketing. When asked about the total cost of the system, Dr. Duret replied, "I never answer this question: I am a scientific man, not a marketing man." The reported cost for the total Duret package, a scanner, CAD and CAM is said to be around $150,000 to $200,000.



Dr. Diane Rekow of the University of Minnesota

Dr. Rekow's background truly blends the knowledge of engineering and dentistry. For 12 years, she was an engineer, and at one time she headed a pacemaker development program. This was followed by a degree in dentistry, a certificate in orthodontics, a degree in Business Administration and a PhD. The wife of a dentist and mother of two children, she currently is developing a system of CAD/CAM that will construct restorations of gold, other metals, porcelain and ceramic. The impression stages will be eliminated and the finished product micro-milled to a perfection fit. "The bottom line," she said, "is you must be able to produce restorations which are the equivalent to what you can now cast. If you can't do that, then you have no business releasing the system."



Modified 35mm camera views tooth preparation three dimensionally.

Dr. Rekow's experiments, (she has not yet reached the commercial stage), are designed to create a crown by first photographing the prepared tooth with a 35 mm camera containing a specially modified lens. In order to "see" the preparation three dimensionally, stereophotogrammetry is achieved by having two cameras mounted on the same system so each half of the stereo pair view the area simultaneously . . . much as it is achieved with human vision.

The lens system needs 25 mm clearance above the tooth (about two fingers width which is similar to the distance now required for conventional dentistry). The optic system records data from the top view down onto the tooth, buccal-lingual and takes information from the cheek side to record occlusion of the upper teeth. It can take dynamic information of centric occlusion, lateral excursions and protrusive paths.

The images are recorded on standard film (Ektachrome ASA 400) and developed by commercial processing. The color slides are then digitized to produce three-dimensional computer images. When the coordinates from all the images have been reconstructed and the paths of motion of the opposing dentition established, a computer based equivalent of perfectly mounted casts on an infinitely adjustable articulator is provided.

The external surface of the crown is automatically designed, taking into consideration the actual preparation, contact points, occlusion and anatomical contours, much like the Duret system. The data base has stored within it "ideal" crown forms for all 32 teeth and these are automatically modified to fit the unique requirements of any specific case. Upon commands generated by a CAM package, the Minnesota system, using a five-axis micro-milling machine, produces a gold crown in minutes.

It is Dr. Rekow's objective that the dentist's investment will be in the neighborhood of $5,000 US, which will provide the optic system and design software necessary to obtain the prosthesis impression and design. The information will then be sent to another location for machining. Once the system is perfected to produce quality metal full-coverage crowns, then there is the potential for partial frameworks and complete denture bases.

Truly the scientist, Dr. Rekow answered her own question, "Why bother? We have a good system now. Consider," she said, "the exciting possibilities."

- one appointment crowns.
- eliminate the need for impressions.
- no need for temporaries.
- no adjustments necessary.
- exciting opportunities for materials: new alternatives. Consider stainless steel crowns that will fit like gold. What if you could use a thinner, stronger material like titanium and have to reduce less tooth substance?

Her expectation is that the clinician can sit down with the data input within the system and say:

- this is the tooth.
- this is the occlusal scheme.
- this is the material.
- Now do It!

Although not represented at the symposium, there is a third CAD/CAM system about to emerge upon the dental market. Often referred to as the Swiss system after its developers, Dr. Werner Mörmann a dentist, and Dr. Marco Brandestini, an engineer, it trades under the name of CEREC. First demonstrated in Zurich in May 1986, their CAD/CAM is designed to produce only porcelain inlays which are reported to have excellent margin integrity. Utilizing Vita porcelain blocks, an inlay can be milled in five to seven minutes. The system does not however design the occlusal surface. This must be accomplished at chairside.

What then of the dental office of the future? CAD/CAM is here. It is not a question of when or where. It is a matter of marketing and money. The participants at the symposium varied as to their "guesstimates" of practical office systems and costs – one to two years and $5,000 to $200,000 – but there was no doubt that it will eventually be a dental office routine. △

ClearCorrect Exhibit 1002, Page 1264 of 3373

• PART TWO •

FRANÇOIS DURET — a man with vision

While the symposium in Vancouver allowed an opportunity to observe, to listen and to participate in the brilliance of Dr. Duret — he has a dental degree, a medical degree and two PhDs — it was difficult to gauge the depth of the man himself rather than just his scientific knowledge. Lectures don't allow much in the way of personal glimpses. Fortunately, a lunch-time interview was arranged.

An interpreter participated in the interview. Dr. Duret is quite conscious of his ability to converse in English. It is hard to believe that until 1986, Dr. Duret had never spoken any English. One would never guess it during his lecture. Although heavily accented, the lecture was flawless and perfectly understandable. He is sensitive however to language difficulties during spontaneous question and answer episodes.

Dr. Duret was about 23 years of age when he developed the concept of applying the knowledge of computers and robotics to dentistry. He virtually laboured alone in his research but was heavily influenced by Dr. Joseph Thouvenot in 1975 and this encouragement no doubt helped overcome the "low points" during twenty years of endeavour. When asked to describe the highs and lows, he modestly replied, with a quiet smile, that probably his first low point occurred in 1979 when he was fired from the University of Lyon because his superiors felt his ideas were "crazy".

Discouraged perhaps, but not deterred, he was to enjoy his first "high" in 1983 when his CAD/CAM, a prototype, was demonstrated for the first time outside of a laboratory at La Garancière, the Dental Congress, in Paris. Possibly the second high point of achievement occurred in 1985 when for the first time in public, at the Association dentaire de France meeting in Paris, he prepared and fitted a crown for a patient (his wife! who is also a dentist). A milestone had been reached. However, modestly, Dr. Duret realized that the prototype of 1985 was far different from that which would be required for the dental office.



Dr. François Duret

That first crown required eight engineers and two and one half hours to complete. "Probably the most expensive crown in history," said Dr. Duret.

First commercial system this fall

Another milestone will be achieved this fall when the first commercially designed Duret CAD/CAM systems will be marketed and will produce for dentists crowns that will be every bit as good (or better!) than that produced by the conventional lost wax techniques.

The interview probed several parameters of the CAD/CAM system, among which was "what is the advantage to the patient?". Dr. Duret replied that probably the patient will not financially benefit from the system but will be more satisfied. He indicated how much more convenient it was to have preparations prepared and a restoration cemented in a one hour appointment rather than the two appointments (or three!) that are required today. Not only is saving time an advantage, but the patient will also be glad to circumnavigate the added inconvenience and discomfort. An added benefit could well be a more precise prosthetic appliance, better fitting and superior occlusal integrity.

Questioned how CAD/CAM would effect dental education, Dr. Duret said that the system would have little effect upon the time involvement of the dental student but increased computer skills would be necessary. Eventually there will be a decrease in student time once conventional impression making, model pouring, waxing and casting procedures are phased out. At Dr. Duret's university, CAD/CAM is already a mandatory requirement.

'Must be ready to adapt'

Dr. Duret indicated that CAD/CAM will become common place in the next five to ten years and universities must be ready to adapt and change quickly. Otherwise industry will take over. Dental companies are already closely following the project and will be involved with the dental material prospects of the future. The dental trades currently have their own agendas to follow, he implied, but as always, they are opportunistic to take advantage of innovations. Dr. Duret said, "the software of CAD/CAM is the very heart of the system and it is in this area that industry cannot easily copy."

Essentially a private practice dentist, Dr. Duret carried on his own practice for 15 years, but has little time for it now. The bulk of his time is in research and development and the necessary travelling throughout the world to demonstrate his beloved CAD/CAM. He enjoys the travel as it gives him great opportunity to associate with confrères and scientists but he does regret being away so much from his wife and three children. △

ClearCorrect Exhibit 1002, Page 1265 of 3373

• PART THREE •

THE COMPUTER GIVES NEW VISION — Literally

Computer technology and miniaturized cameras now allow new vistas and new insights for dentists and patients. Recently introduced as a first to the Canadian market, Dentsply's DENTALVISION opens new communication channels at chairside never previously realized. Now patients, for the first time ever, can see all those confusing things dentists have been talking about for years. Bewildering dental terminology can be directly associated with a photo on a TV monitor.

Dentistry in the last decade has witnessed remarkable changes. Decreasing caries ratios, greater utilization of dental plans, enhanced emphasis on prevention and increased significance of cosmetic dentistry are daily conversations in dental circles. A rising dental "IQ" for patients, and stress upon dentists for marketing has only expanded that age-old dilemma of communication.

Communication between the profession and patients relies so much upon "one-to-one" relationships. Dentistry is often referred to as the "last of the cottage industries", and its entire prevention program pivots on communication. The computer at chairside seems about to make communications just that much easier.

A tiny video camera, the size of a pencil, can go anywhere within the oral cavity normally accessed by a common mouth mirror.

The camera and screen can be used for cosmetic imaging indicating the "before and after" visuals prior to actual treatment. Any photo of the oral cavity can be "frozen" for easier viewing and discussion. Instant Polaroids may be taken for patient education and for explanation "to the folks at home".

Photos may be filed as permanent records or used for insurance purposes. The system can likewise produce dynamic video tapes and storage facilities on floppy disks.

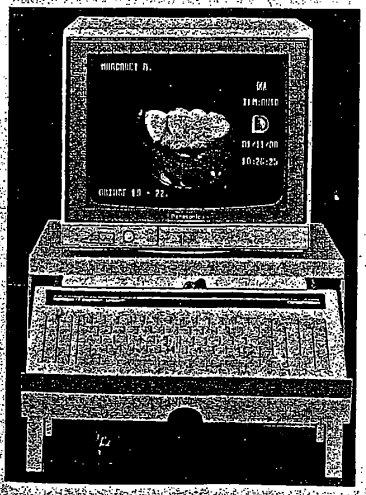
How well dentists know that patients accustomed to pictures of the complexities of the lunar surface are perplexed at root canal configurations and gingival contours. No more, say the proponents of DENTALVISION!

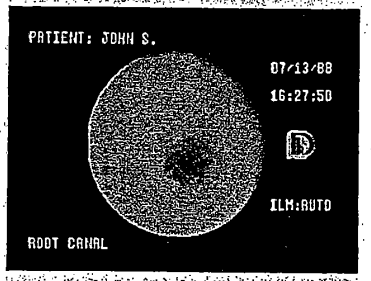
An even smaller video probe, available as an add-on, and only 1.27 mm in diameter (about the size of a #25 file), can now digitalize onto a video screen a root canal up to 200X magnification. The video probe can be inserted periodontally into any type of pocket and dramatically enhance a patient's understanding of a disease process and its prevention. Similarly, the same probe camera can project a photo of any cavity preparation onto the TV monitor.

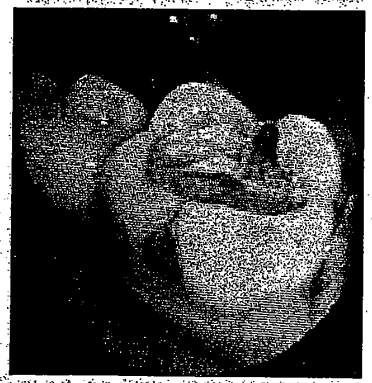
The journal was informed by Dentsply that their DENTALVISION will market at about $34,500 for the base unit of camera, processor, keyboard, monitor and footswitch.

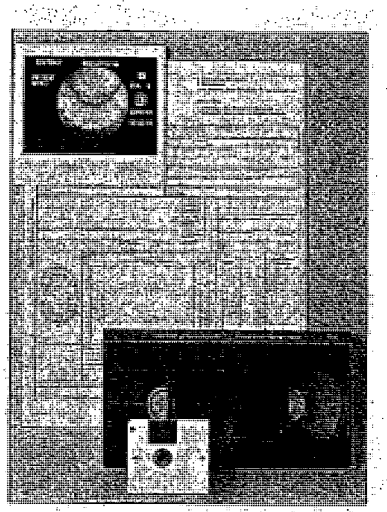
The options of Polaroid (approximately $3375), and floppy disk ($3,000–$6,000), may be purchased as add-ons. A VHS system may be obtained from any electronic store. The miniature endo/perio probe camera is estimated to cost $15,000.

It is not unrealistic to imagine that as the computer finds more and more uses in the operatory, other research and development endeavors will only widen communication channels. △









Photographs: courtesy of Dentsply/Equipment Division Dentsply International, York, PA 17405)

Prepared and written — P. Ralph Crawford, Editor JCDA

ClearCorrect Exhibit 1002, Page 1266 of 3373

• PART FOUR •

BYTES 'N BITES

The computer moves from the front desk to the operatory

Gone are the days of making occlusal records with messy carbon paper, waxes, and pastes!! A computerized system developed by Dr. William Manness of Boston not only revolutionizes an age old problem but determines occlusal accuracy never achieved previously.

Dr. Manness, an Associate Clinical Professor at Tufts University School of Dental Medicine, Division of Graduate and Post Graduate Prosthodontics took over three to years to develop "T-Scan". He now heads his own company, T-Scan Inc.

Dr. Manness reported in Tufts University Health Science News, "Dentists have been working in the dark ages when it comes to occlusal analysis, and even though the goal in much of our work is to have the maximum number of teeth touch at the same time with the same amount of force, up to now no method has allowed us to adequately do the job. The computerized method of analyzing occlusion will significantly improve the quality and effectiveness of patient care."

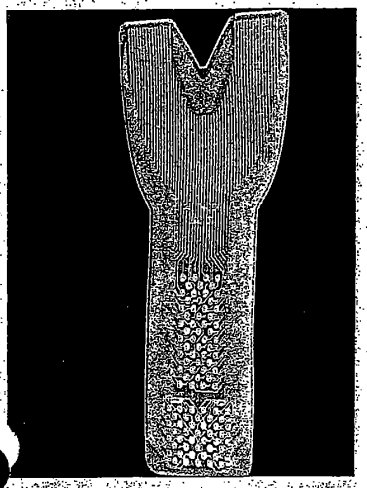
The T-Scan system is composed of a sensor, handle and cable, system unit, and software, *as illustrated*. The most important element of T-Scan is the disposable sensor, which is less than 60 microns thick (about the thickness of a credit card). The sensor consists of several layers of electrically conductive inks on a polyester film substrate. The top and bottom surfaces of the sensor are printed with thin conductive stripes which form an x-y grid of more than 1,500 sensing points. The spacing of the grid lines determines the degree of planar resolution. A separate sensor is used for each patient.

When the patient applies pressure onto the sensor, the computer automatically records, analyzes and displays – in color graphics – data about the force, sequence and timing of upper and lower tooth contacts. This is strong contrast to perforations in waxes and pastes which require qualitative interpretation by the operator.

As a clinical device the T-Scan appears to offer great potential in occlusal adjustment procedures – TMJ, restorative, periodontics, orthodontics; virtually all occlusal applications. Its proponents indicate a promise of new methods of analyzing the functional health of the muscles of mastication. An added advantage is that the recorded information can be printed or stored in disk files – occlusal histories of patients can become part of their permanent record.

Tekscan Incorporated of Boston reports that more than 200 of the T-Scan units are in the field; all in the United States. At the time of writing, the Journal was told that distribution rights were being arranged for the Canadian market. Cost of the basic T-Scan Diagnostic Package, which includes the Unit, sensors and printer paper, is about $3,000 US. The cost to the dentist for a single patient sensor is $5.00 US, and it was reported that patients were being charged from $15.00 to $50.00 for a T-Scan analysis. △

Photographs courtesy of Tekscan Incorporated, Boston.



Schematic diagram of the T-Scan system.



Visual display of distribution and timing of occlusal contact.



T/Scan sensor and handle.

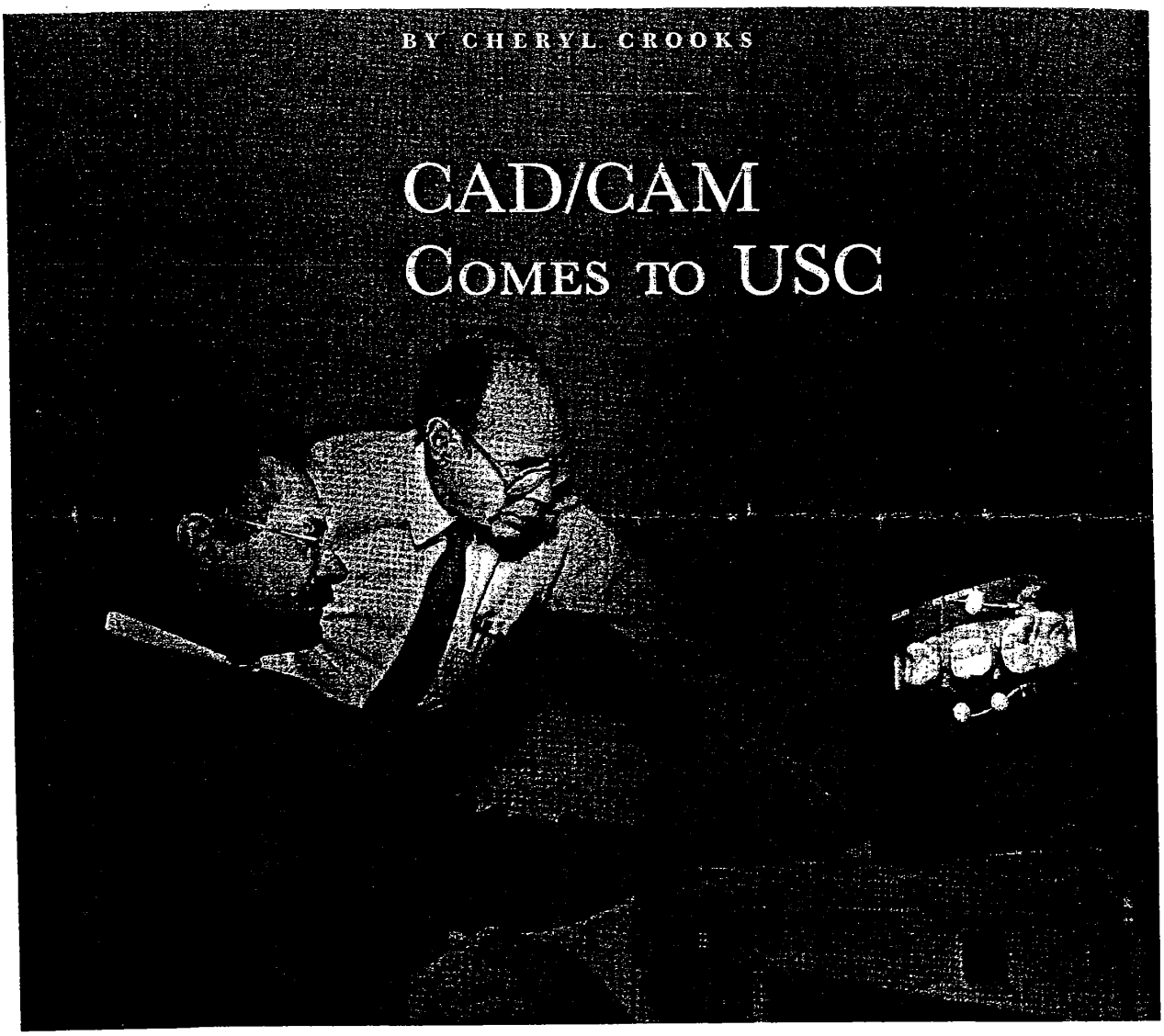


T/Scan at chairside uses time and force to quantify occlusal contact information.

ClearCorrect Exhibit 1002, Page 1267 of 3373

BY CHERYL CROOKS

CAD/CAM Comes to USC



Co-directors of the Dental Imaging Section at the USC School of Dentistry Francois Duret, D.C.D., Ph.D., research professor of dental imaging (left), and Jack D. Preston, D.D.S., the Don and Sybil Harrington Foundation Professor of Esthetic Dentistry, inspect computer image of a restoration in progress.

For the past fifteen years, a revolution has been quietly brewing in the remote country village of Le Grand Lemps, 45 kilometers northeast of Grenoble, France.

The agent of this revolution is Francois Duret, D.C.D., Ph.D., USC research professor of dental imaging, who—with his wife, Elisabeth Duret, D.C.D., and a friend—formerly conducted the only dental practice in that peaceful Alpine farming community of 2,000. His revolutionary concept constitutes a contribution to dentistry that will likely change the practice of restorative dentistry throughout the world.

Duret's objective was to assist dentists in crafting precision-fitting dental restorations, by combining the latest innovations in the realm of computer sciences with the decades-old artistry of dental reconstruction. The system he has developed makes creative use of recent technological advances in computer-assisted design/computer-assisted machining (CAD/CAM), which were initially developed for use in the tool and die industry.

Applying these techniques to the field of dentistry, however, was no

ClearCorrect Exhibit 1002, Page 1268 of 3373

simple matter. Indeed, in its earliest stages of development, Duret's notions were considered so innovative that his former superiors at the French University of Lyons dismissed them as sheer nonsense. Today, in its final stages of development, Duret's system promises to reduce or eliminate the need for many dental impressions, while enabling dentists to produce better-fitting restorations in less than half the time traditionally required.

In place of the impression customarily used to determine the shape and dimensions required for a restoration, Duret's system employs a computerized laser optical imaging device called an 'electronic moire system.' To establish the proportions of a restoration, the dentist begins by taking a series of 'snapshots' of the prepared tooth, using a hand-held laser imaging probe triggered by a foot-pedal. Typically, ten images are needed for a single crown; as many as twenty may be required for a fixed bridge.

Data gathered by the laser probe is automatically digitized—translated to a series of numerical values—and entered into the system's computer, where specially designed software selectively records only those coordinates that will accurately orient the image. "Input errors are virtually non-existent, since the computer will accept only those images that have been accurately recorded," says USC Professor of Restorative Dentistry Jack D. Preston, D.D.S., the Don and Sybil Harrington Foundation Professor of Esthetic Dentistry and co-director of the new Dental Imaging Section of the school's Department of Postdoctoral Studies.

Once the data has been recorded, the computer compiles and unifies the information of each 'snapshot' to generate a single visual representation which may be displayed on a monitor. The resulting image uses a moire information pattern to establish the surface boundaries of the tooth, following its curves and edges precisely to create a three-dimensional projection resembling a wire mesh.

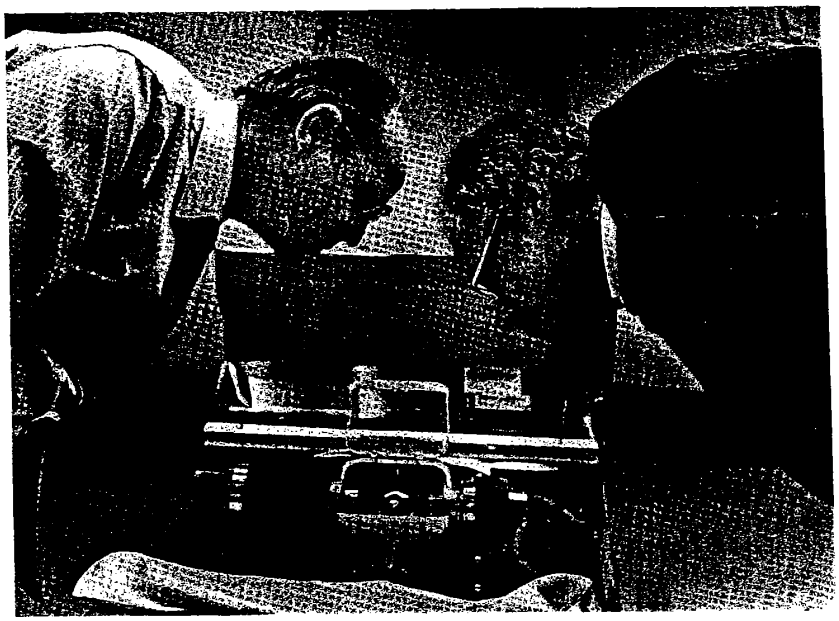
The system's software also enables the dentist to design and produce a complete restoration entirely by computer—a capability unique to Duret's system, according to Preston. By manipulating the visual image of the restoration onscreen, the dentist is able to make extremely fine adjustments in the shape and size of the eventual product. Once the image has been adjusted to allow space for cement, it is then overlaid onto the image of the proper tooth stored in the computer's memory, and is altered as necessary for contouring and contact with adjacent and opposing teeth.

When the dentist has completed creating the restoration on the computer, the information is transmitted to a computer-assisted micro-milling machine, which automatically forms the three-dimensional restoration from a block of dental material. To produce the restoration, the system's milling machine uses a series of specialized cutting tools ranging from coarse, for rapid cutting, to fine, for greater detail. Duret recently added two more tools to the machine's armamentarium, making it possible to carve even the secondary anatomy or supplemental grooves on the occlusal surface.

Although the system's micro-milling machine might have used any dental material that can be machined, Duret's creativity did not stop here. "We chose a traditional material for testing," he explains, "but with CAD/CAM, you can use any material. I decided to see what was possible."

The result of his investigations is a new prestructured organo-ceramic that is more easily fabricated than other types of materials, and yet is structured to withstand oral forces. Called 'Ariste,' and manufactured by the French firm, Spad, the new material is made of polyurethane acrylic resin using a siliceous filler. It more closely resembles the structure of a natural tooth because glass fibers running through the material are oriented in the proper direction to take the stresses of biting. "Casting methods would destroy this useful orientation; but micro-milling techniques respect the integrity of the material," notes Duret.

Duret's is one of three CAD/CAM dental systems currently under development. According to Preston, a Swiss system being developed by Mormann and Brandestini is more restrictive in what it enables the dentist to do. It is not fully three-dimensional, is meant only for porcelain inlays, and is linked to a milling machine with only a single cutting tool. This system is presently being used by dentists in the United



Drs. Preston and Duret watch the CAD/CAM's computer-assisted micro-milling machine in action. The machine uses a series of specialized cutting tools to form a complete restoration from a block of dental material.

ClearCorrect Exhibit 1002, Page 1269 of 3373

States and Europe.

Another system, under study at the University of Minnesota School of Dentistry, in Minneapolis, is still a research , and there is no projected date for its commercial availability.

Duret's CAD/CAM system is the furthest along and closest to market. In fact, 40 Duret-designed units are currently in operation in France, producing approximately 300 crowns every day.

Duret first considered the feasibility of applying CAD/CAM technology to dentistry in 1971, while he was a student at the dental school of the University of Lyons. His training in biochemistry and physiology, in addition to his dental degree, gave him the ideal broad scientific background necessary to conceive and carry out his complex invention. For the next eighteen years, Duret painstakingly shaped his idea, giving up his original notion of using holography and moire to obtain an impression in favor of laser techniques. He spent ten years refining his concept before beginning to tackle the hardware it would require.

'For me, it was better to work on concept first, because life can reduce the imagination," says Duret. "I prefer to take a more scientific approach: to develop the concept first, and solve its problems, before proceeding to try the system on patients." Finally, before a large audience at a 1985 dental congress in Paris, Duret used the CAD/CAM system to make a crown for a patient.

As Duret's idea evolved from concept to reality, he began to gain the attention of dental research schools—particularly those in the United States. Among those following his progress was Preston, who first learned of Duret's research three years ago. Through a mutual friend, the two began to correspond. Then, two years ago, they met for dinner on Thanksgiving evening at Los Angeles International Airport. They spoke several times later at professional meetings where Duret was lecturing. Finally, Preston invited Duret to visit and observe the work being conducted at USC.

Changing the practice of restorative dentistry throughout the world

"I had seen the progressive application of computer technology in the dental profession," explains Preston. "It bothered me that no one in the United States was seeking to establish policies for integrating instruction in CAD/CAM dentistry into the dental school curriculum, and there was no American work underway other than the Minnesota system—which was not clinically available."

Duret's research excited Preston. "Why should USC be second to bring it to the United States; why not first?" he wondered. At the same time, it was clear that if the USC School of Dentistry were to play a role in pioneering this new technology, it would require the talents of Francois Duret.

Much to Preston's delight, the school's administration, under the direction of Dean William H. Crawford, Jr., D.D.S., agreed to offer Duret a special appointment as research professor and co-director of the newly created Division of Dental Imaging. Duret accepted the offer, and formally signed a two-year contract with the school in November, 1988. Last August, Duret moved himself and his family to Los Angeles and began setting up his research program at USC.

Duret's first year at USC is devoted to training dental school faculty to use his CAD/CAM system, adapting the system for American use and translating its software from French, writing protocols for patient trials to begin in early 1990, and conducting bench tests of prepared teeth. Training activities in CAD/CAM applications may begin as early as the winter 1990 semester, when the Section of Dental Imaging is scheduled to offer selective courses for USC dental students. Beginning in the fall 1990 semester, the school will also offer a structured curriculum of continuing education courses in computer dentistry, through its Department of Postdoctoral Studies.

Under its agreement with Duret and Hennson International Technologies, the French company manufacturing Duret's CAD/CAM system, USC will have exclusive access to the system's equipment for educational instruction in computer-assisted dentistry. In return, USC will assist Hennson in 'Americanizing' the system and obtaining federally re-



Drs. Duret and Preston demonstrate imaging capabilities of the CAD/CAM system for Fereidoun Daftary, D.D.S., M.Sc.D., clinical associate professor and chairman of the Section of Fixed Prosthodontics at the School of Dentistry (right). Training USC faculty to work with the new CAD/CAM system is among the first challenges to be taken on by Dr. Duret as co-director of the school's new Section of Dental Imaging.

ClearCorrect Exhibit 1002, Page 1270 of 3373

quired approvals and licenses. Hennson will also pay USC to train dentists who purchase the units. The greement is, as Preston describes it, mutually beneficial."

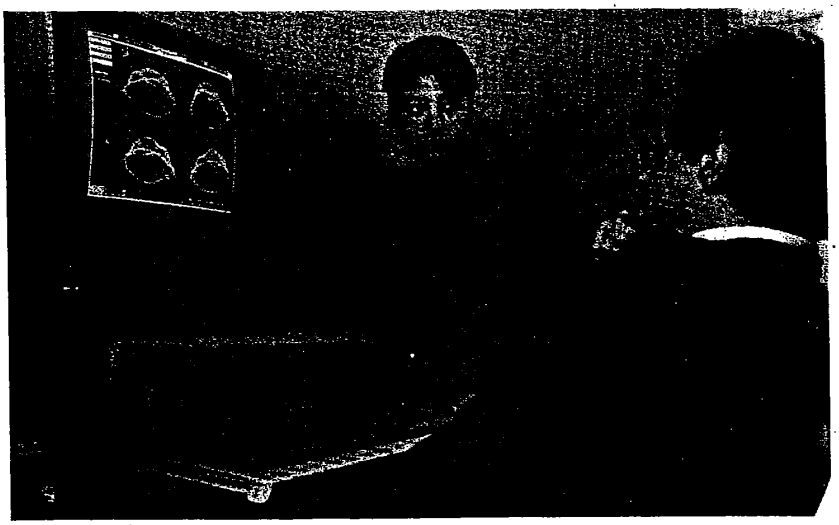
Duret's appointment and the cooperative effort with Hennson is sure to establish USC as the center for CAD/CAM dentistry in the United States, says Preston. "But the credit belongs to Francois; he's the man who has done all the work," he adds. "USC's role in completing development of this system is to help him and to facilitate other aspects of his work."

For the school, Duret's decision to continue his research at USC is a significant leap into the future. Even so, notes Preston, "We have to admit that we cannot yet envision the actual way computer technology will be best applied to dentistry, because computer application is proliferating in many, many respects. But this gets USC in on the ground floor to develop those applications."

USC's ambition to become the nation's leading center for computer pplications in dentistry, however, is not without its problems. Oddly, one of the biggest challenges is training faculty to work with the CAD/CAM system. Initially, Drs. Duret and Preston will handle the program's teaching duties. As the program grows and more faculty are trained, additional members will gradually be named to the dental imaging section.

Dental students will also experience an awkward period of transition, during which they will need to learn both the old and new technologies. "The educational system will be severely stressed to teach both at the same time," says Preston. "But it is essential that the nation's best dental schools keep pace with the latest technology. Sophisticated systems such as Duret's must be in the schools so that faculty can be trained, students can be exposed to them, and appropriate courses can be introduced into the curriculum."

In addition, dentists already in practice will have to be taught how to use Duret's system. Not everyone will readily embrace the new technology; some, undoubtedly, will prefer to stick to the older methods. "I imagine that many dentists who have been in private practice for twenty years or more aren't going to want to learn it," Preston acknowledges, "but the person who has been in practice only ten years will undoubtedly seek to overlay abilities with the new technology onto what they already know."



Francois Duret, D.C.D., Ph.D., and research technician Koitherine Pitiot, look over three-dimensional wire-mesh projections of an imaged tooth. The CAD/CAM system developed by Dr. Duret enables the dentist to design and produce a complete restoration entirely by computer.

One factor likely to inhibit dentists from switching to Duret's system immediately is the initial price tag of its equipment, expected to run as high as $150,000. Preston suggests, however, that dentists will find ways to solve this difficulty. "Individual dental practices might be physically clustered around a shared milling machine; or they might share the services of a milling machine located at a centralized laboratory to which they could telecommunicate the specifications of their restorations," he notes. "In the latter case, dentists would need to purchase only the laser probe and desk computer for their own office. These solutions may not be as far away as we think."

Either way, Duret's system is certain to increase efficiency and productivity for the dentist. Because the milling machine can work around the clock, the need for a temporary crown or bridge is eliminated, and the number of patient visits to the office is reduced.

The system also promises benefits to the patient, beginning with an imaging procedure that is less cumbersome and more comfortable than conventional dental impressions. Because the CAD/CAM system individualizes each crown, the method will dramatically improve upon traditional standards for determining a 'good fit.'

Preston thinks that Duret's imaging system will promote better communication between patient and dentist. "The dental office of the not-too-distant future will have two monitors; one for the dentist and one for the patient," Preston predicts. "It's not out of the question that dentists will one day perform the procedure by watching the monitor rather than directing it by hand."

Duret's application of CAD/CAM technology to the dental profession, dismissed as nonsense just a few years ago, is today set to revolutionize the practice of dentistry—both in concept and in the way it is physically structured. As Preston puts it: "This technology provides us with a great deal to think about. It literally takes us into a new era of practice."

ClearCorrect Exhibit 1002, Page 1271 of 3373

Correcting Malaligned Mandibular Incisors with Removable Retainers

STEVEN L. CURETON, DMD, MS

Removable spring retainers can be used to correct rotations and buccolingual malpositions. Conventional Hawley-type retainers, however, limit the direction of tooth movement, since the facial bow can only be adjusted to move or rotate the incisors lingually.

The technique shown in this article for correcting mandibular incisor positions with retainers is not new; I was first introduced to it in orthodontic residency training. Since I started using this method, however, I have become much more enthusiastic about accepting retainer patients into my practice.

In cases where I can anticipate using this technique after debonding, I make the retainer with Adams clasps on the first molars and ball clasps between the bicuspids. If bicuspids have been extracted, the Adams clasps provide sufficient retention.

Technique

Figure 1 shows the mandibular incisors of a 14-year-old finished orthodontic patient. With

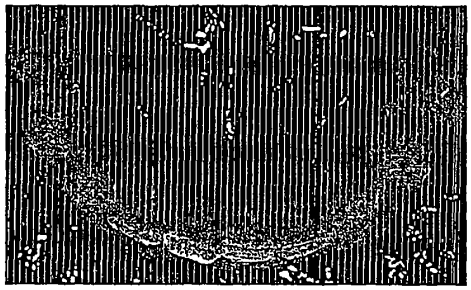


Fig. 1 14-year-old patient after orthodontic treatment.

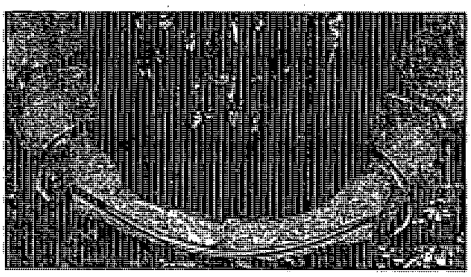


Fig. 2 With retainer in place, patient's right central incisor is rotated mesial-out and left central incisor is contacting acrylic.

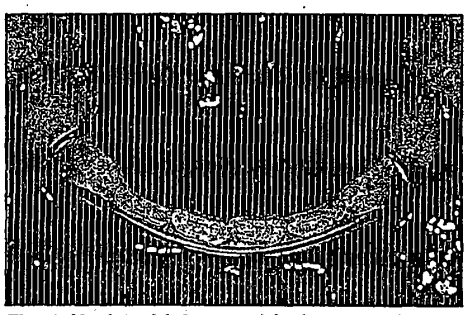


Fig. 3 Mesial of left central incisor and distal of right central marked with permanent marker.

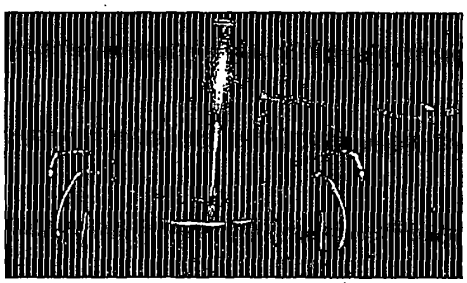


Fig. 4 Holes drilled through retainer with finishing bur.

© 1996 JCO, Inc.

ALN006630

ClearCorrect Exhibit 1002, Page 1272 of 3373

Dr. Cureton is Staff Orthodontist, Snyder Dental Clinic, Fort Gordon, GA 30905. The opinions contained in this article are those of the author and are not to be construed as official or representing the views of the U.S. Army, Department of Defense, or Government.



the standard Hawley retainer in place, the right central incisor appears to be rotated mesial-out: the left central incisor is in good contact with the acrylic, so it must have been finished in a mesial-in position (Fig. 2). To position these two teeth correctly requires a force to move the right central incisor distal-out and another force to move it mesial-in. Since the distal aspect of the left central incisor is in ideal position, a force is needed to move it mesial-out. This is accomplished as follows:

1. With the retainer in place, mark the acrylic on the mesial of the left central incisor and the distal of the right central incisor with a permanent marker (Fig. 3).

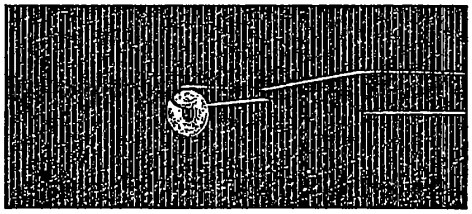


Fig. 5 Elastomeric module on ligature wire.



Fig. 6 Ends of ligature wire threaded through hole in retainer.

2. Remove the retainer, and drill small holes through the marks with a finishing bur (Fig. 4).

3. Thread a ligature wire through an elastomeric module (Fig. 5).

4. Thread both ends of the ligature wire through one of the holes in the acrylic (Fig. 6), and pull the elastomeric module about halfway through the hole (Figs. 7,8).

5. The excess elastomeric material on the lingual side of the retainer can be removed by melt-

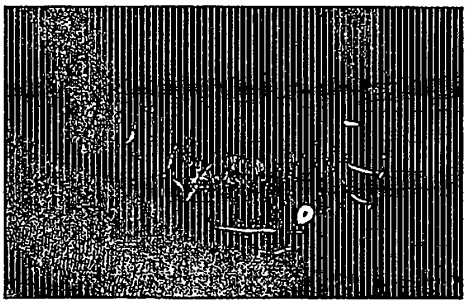


Fig. 7 Elastomeric module pulled halfway through hole.

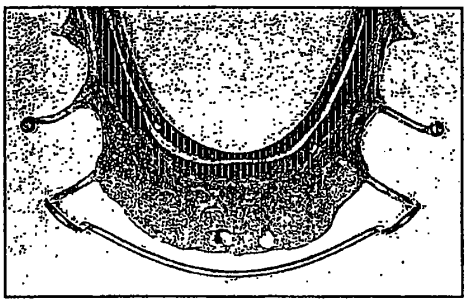


Fig. 8 Lingual side of retainer with elastomeric modules in place.

ALN006631

ClearCorrect Exhibit 1002, Page 1273 of 3373

ing it off with a heated instrument (Fig. 9), but I usually leave the excess, since patients tolerate it well. In this case, the left central incisor requires more rotation than the right incisor does, so a greater amount of elastomeric material is left on the tooth side of the retainer (Fig. 10). The modules are positioned so that they contact only the central incisors.

6. Adjust the outer bow of the retainer to allow facial movement of the incisors and to assist in the rotation and alignment (Fig. 11).

7. Instruct the patient to wear the retainers 24 hours a day. Replace the elastomeric modules about every four weeks.

8. Once the incisors are in the correct positions (Fig. 12), retain the correction by adding cold-cure acrylic to the current retainer, by fabricating a new retainer, or by bonding a lingual 3-3 retainer.

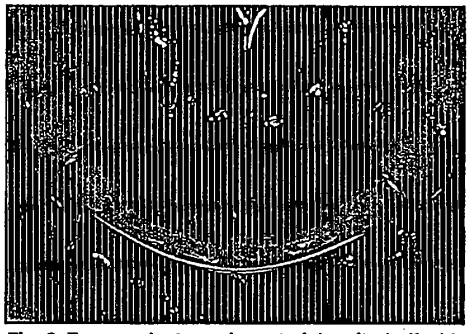


Fig. 9 Excess elastomeric material melted off with heated instrument.

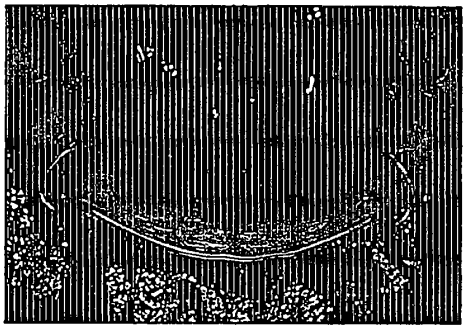


Fig. 11 Outer bow of retainer adjusted to assist in rotation and alignment.

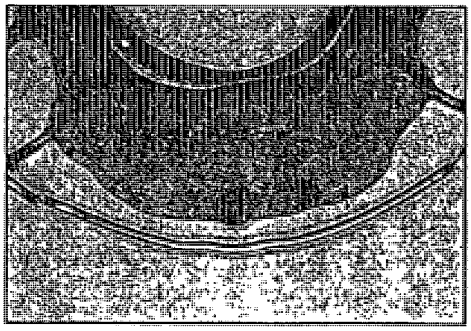


Fig. 10 Greater amount of elastomeric module left on tooth side of retainer to provide more rotation of left central incisor.

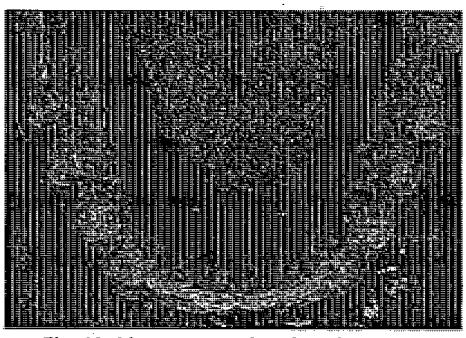


Fig. 12 After two months of retainer wear.

ALN006632

ClearCorrect Exhibit 1002, Page 1274 of 3373

Spring retainers can sometimes fail to position incisors ideally no matter how well they are adjusted. In the case shown in Figure 13, the retainer was adjusted several times, but the mandibular left central incisor remained rotated mesial-out. A small hole was drilled through the acrylic on the mesial side of the right central incisor, and an elastomeric module was pulled halfway through (Fig. 14). Acrylic was removed from the lingual surface to allow lingual rotation of the incisor (Fig. 15). After only one month, the incisor position was improved (Fig. 16), and a bonded 3-3 retainer was placed (Fig. 17).

In another case, a 41-year-old female had undergone full orthodontic treatment with four

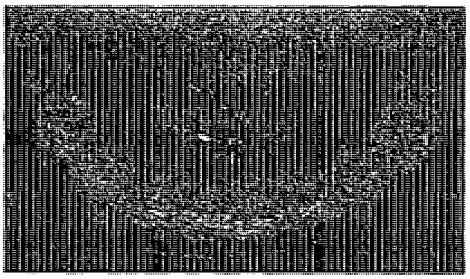


Fig. 13 After four months of stripping and spring retainer wear, mandibular left central incisor remains rotated mesial-out.

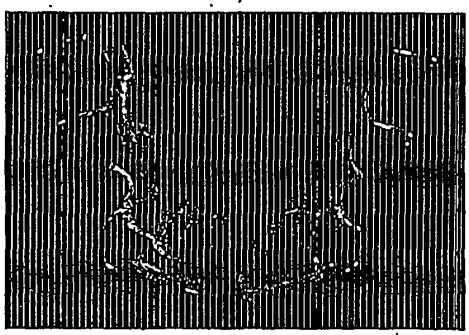


Fig. 14 Elastomeric module pulled through hole in acrylic on mesial of right central incisor.

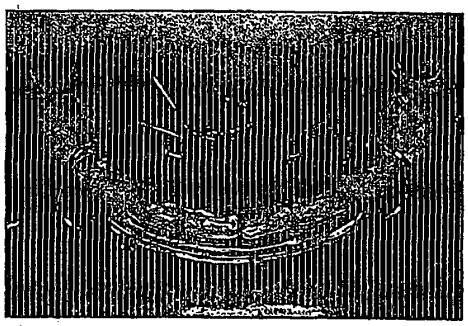


Fig. 15 Acrylic removed from lingual surface of retainer to allow lingual rotation of left central incisor.

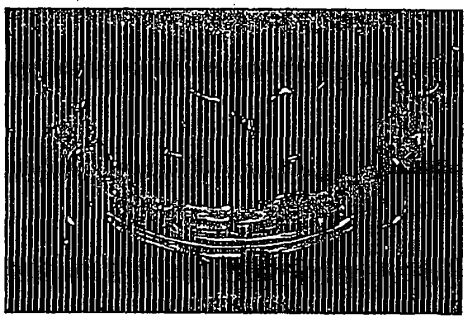


Fig. 16 After one month of retainer wear.

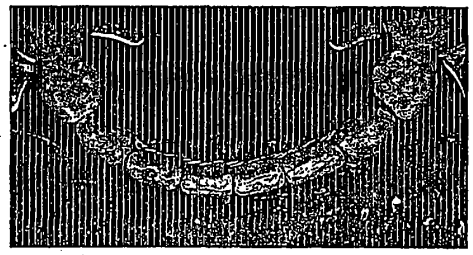


Fig. 17 Bonded 3-3 retainer in place.

ALN006633

ClearCorrect Exhibit 1002, Page 1275 of 3373

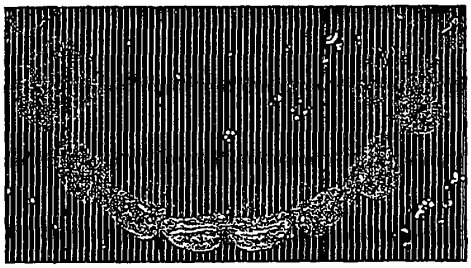


Fig. 18 41-year-old female after four-bicuspid-extraction treatment and three months of retention.

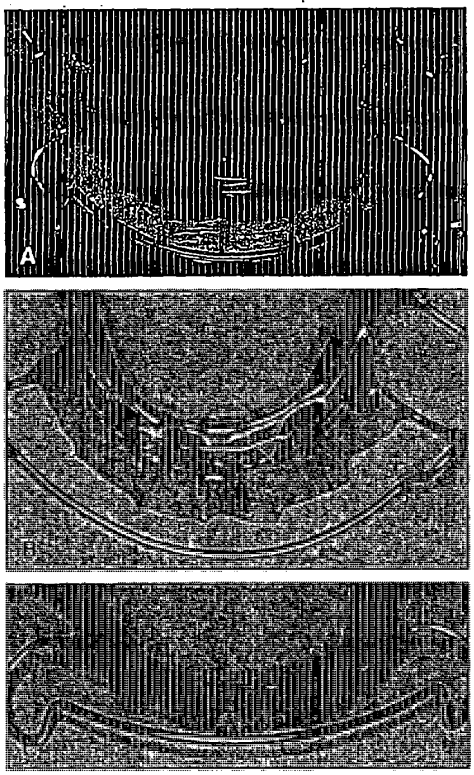


Fig. 19 A. Black mark for hole in acrylic. B. Position of elastomeric module. C. Small amount of acrylic removed distal to incisor to allow lingual rotation.

bicuspid extractions, and her appliances had been removed three months prior to her arrival in my practice (Fig. 18). Her retainers had been adjusted twice by her previous orthodontist, and she merely wanted me to readjust them periodically to prevent relapse. I commented that her orthodontic results were outstanding, but that the lower right central incisor could be rotated to

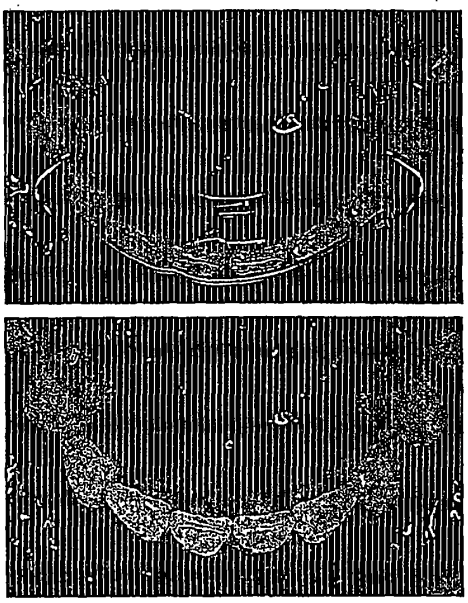


Fig. 20 After one month of retainer wear.

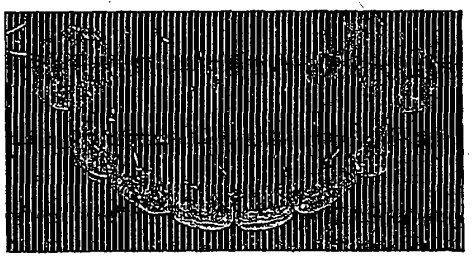


Fig. 21 Bonded 3-3 retainer in place.

ALN006634

ClearCorrect Exhibit 1002, Page 1276 of 3373

align it even better. She was treated with a Hawley-type retainer as described above (Fig. 19). A dimple was placed in the labial wire with a three-prong plier to apply a facial force against the distal of the incisor. The rotation was corrected in one month (Fig. 20), and a bonded 3-3 retainer was then placed (Fig. 21).

Discussion

Adult patients especially appreciate this technique, because the mandibular incisors become more noticeable during speaking or smiling as they grow older. In the case of the 41-year-old female shown above, the previous orthodontist treated an extremely difficult malocclusion over three years, but I became a hero by correcting a lower incisor rotation in a month.

With experience, it becomes easy to determine where to drill the holes in the acrylic and how to adjust the outer bow of the retainer. If more facial movement is required, more of the elastomeric module should protrude from the tooth side of the retainer. If significant facial movement is needed, the hole should be drilled so the module contacts the tooth more gingivally. A small reduction in gingival thickness will produce a greater facial movement of the incisal portion.

In cases of removable retainers without retentive clasps, I instruct the patients to press against the acrylic with their fingers whenever possible so the elastomeric modules can force the teeth facially. Patients usually tell me that correction occurs in four or five days. ❑

ALN006635

ClearCorrect Exhibit 1002, Page 1277 of 3373

Integrated Three-Dimensional Craniofacial Mapping at the Craniofacial Research Instrumentation Laboratory/University of the Pacific

Sean Curry, Sheldon Baumrind, Sean Carlson, Andrew Beers, and Robert Boyd

This article describes the integrated three-dimensional craniofacial mapping system that has been developed and is currently in use in the Craniofacial Research Instrumentation Laboratory at the University of the Pacific School of Dentistry, San Francisco, CA. (Semin Orthod 2001;7:258-265.) ***Copyright © 2001 by W.B. Saunders Company***

Developing practical systems for generating integrated three-dimensional (3D) craniofacial maps by merging information from x-ray cephalograms, study casts, and facial photographs has been a focus of interest of our research group since 1968.[1-3] Collaborations with the Department of Civil Engineering, University of California Berkeley, led relatively early to conceptual solutions, that analogize standard methods of topographic mapping.[4-9] A major advance was the recognition that the use of radiopaque "tie points" (removable temporary variants of the implants of Bjørk[10,11]) would facilitate the merging of information from different sources with high accuracy and precision. The conceptual basis for the use of tie points to merge 3D data from cephalometric xrays, study casts, and facial photographs is explored in this issue by Baumrind.[13]

Clinically related publications growing out of this collaboration were published in the engineering,[13-20] medical,[21-26] and orthodontic[27,28] literature. Meanwhile, investigators in other laboratories and clinics were conducting parallel investigations, only a few of which can be cited here.[29-35]

Until approximately 10 years ago, the data-acquisition and data-processing techniques available for applications of this type were very slow and labor intensive. Fortunately, three developments of the past 10 years have facilitated progress. These are (1) the increased availability of low-cost high-speed computing, (2) the availability of structured light systems for 3D facial photography,[36] and (3) the implementation of destructive scanning methods for efficient 3D mapping of study casts.[37,38] In combination, these advances have made possible the development of the general system, that is described in this study.

Creation of an Integrated Three-Dimensional Model

A major focus of the Craniofacial Research Instrumentation Laboratory (CRIL) at the University of the Pacific School of Dentistry (UOP) has been the development of instrumentation, software, and procedures for the creation of an accurate, integrated 3D craniofacial data model.

From the Craniofacial Research Instrumentation Laboratory, Department of Orthodontics, University of the Pacific, School of Dentistry, San Francisco, CA.

Development of the CRIL hardware and software systems reported in this paper were supported in part by the Align Technology Corporation and the Gendex Corporation. Earlier investigations that led to the development of the present system were supported in part by NIH-NIDR Grants #DE03598, DE03703, and DE07817.

Address correspondence to Sean Curry, PhD, Craniofacial Research Instrumentation Laboratory, Department of Orthodontics, University of the Pacific, School of Dentistry, 2155 Webster Street, San Francisco, CA 94115.

Copyright © 2001 by W.B. Saunders Company

1073-8746/01/0704-0006$35.00/0
doi:10.1053/sodo.2001.25422

ClearCorrect Exhibit 1002, Page 1278 of 3373

The model is built using data from the following sources:

A calibrated stereo x-ray device, using the DenOptix digital imaging system (Gendex Corp, Des Plaines, IL).
A calibrated stereo camera from 3DMetrics, Inc (Petaluma, CA).
Three-dimensional digital models of the upper and lower study casts, created using technology from Align Technology, Inc (Santa Clara, CA).

The resulting model contains 3D data on the facial surface, the upper and lower dentition, and the skeletal anatomy. All these data are accurately merged together in a single anatomically-determined frame of reference using a special version of Align Technology's TREAT software. Emphasis has been placed on optimizing the 3D geometric accuracy at each step of the process through the use of rigorous measurement and calibration processes, as described below.

A key feature of the CRIL system is the methodology for the accurate merging of 3D data from multiple sources using tie points. The process consists of the following steps:

1. A patient is fitted with a set of tie points, which are radiopaque markers that are attached to the teeth. The patient is also fitted with a second set of tie points that consists of radiopaque markers on the face.
2. Using CRIL's calibrated stereo x-ray machine, controlled lateral and frontal stereo x-ray image pairs are obtained.
3. Using CRIL's data collection and analysis system, 3D coordinates are computed for the tie points on the teeth, the tie points on the face, and specific anatomic landmarks visible in the stereo x-rays.
4. Using a commercially available digital stereo camera system, 3D coordinates are computed for the tie points on the face.
5. Using Align technology, 3D coordinates are computed from the study casts for the tie points on the teeth, by creating and measuring a standard Align study cast.
6. After all this processing, 3D coordinates have been gathered for the following:
   a. Skeletal anatomic features from the stereo x-ray images.
   b. Tie points on the upper and lower dentition from the Align digital model.
   c. Tie points on the face from the 3DMetrics camera model.
   d. Tie points on the face and the upper and lower dentition from the stereo x-ray images.
7. Through a series of mathematical transformations:
   a. The tie points on the teeth are transformed to the anatomic system defined by the anatomic features from the x-ray images.
   b. The models of the upper and lower dentition are transformed to the same anatomic system using the common tie points on the teeth.
   c. The facial imagery is transformed to the same anatomic system using the common tie points on the face.

Thus, the anatomic features located on stereo x-ray images act as a framework or scaffold on which data from the other sources (study cast and facial images) are hung. In this way, the study cast data and the facial image data can be visually and analytically compared with each other, though there is no direct data connection between the two. Also, all the data can be referenced to an anatomic frame of reference.

Calibrating the Stereo X-Ray System

The heart of the CRIL data collection system is the calibrated stereo x-ray machine (Fig 1). This device uses twin x-ray emitters mounted in a coplanar orientation that mimics the geometry of human vision and of conventional terrestrial mapping from airplanes and satellites. It makes possible the acquisition of high accuracy 3D coordinates of the tie points, required for the subsequent merging of data from different sources. In addition, it facilitates the capture of 3D coordinate information for key anatomical structures in the cranial skeleton. Before data collection begins, the stereo x-ray system must be calibrated.

Calibration of the x-ray system consists of the accurate determination of the two emitter locations in 3D with respect to the cassette that holds the image-recording medium, a digital DenOptics plate (Gendex Corporation). The cassette is positioned in a specialized holder that carries a series of radiopaque fiducial markers on acrylic

ClearCorrect Exhibit 1002, Page 1279 of 3373

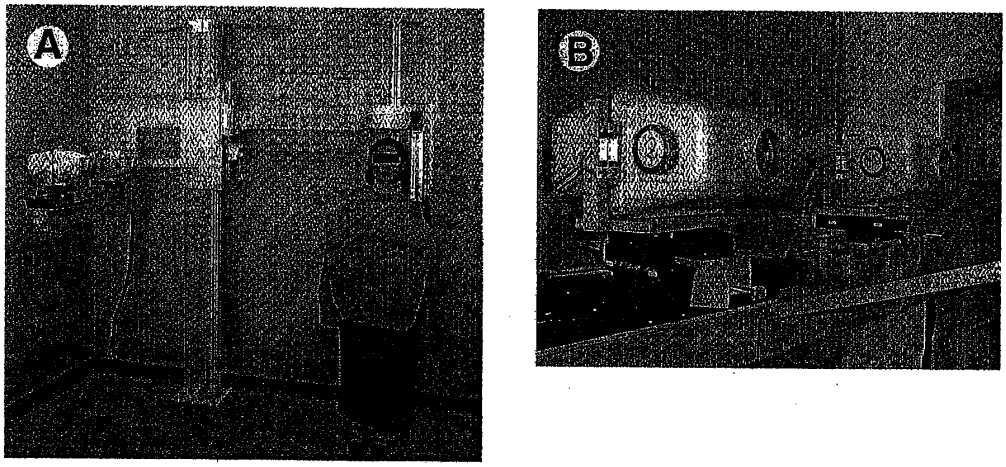


Figure 1. The Craniofacial Research Instrumentation Laboratory/University of the Pacific coplanar cephalometer. Emitter 1 generates a standard lateral or frontal cephalogram. Emitter 2 generates an offset frontal or lateral cephalogram. Overall view (A). Close-up of Twin emitters (B).

plates (Fig 2). These fiducial markers have accurately known two-dimensional (2D) coordinates, previously determined using a precision coordinate measuring machine. The images of the fiducial marks appear on all exposed plates and allow us to mathematically transform each x-ray image to a constant location with respect to the cassette holder.

A calibration array (Fig 3) has been developed by CRIL for calibration of the x-ray system. It consists of three parallel acrylic plates, each containing a series of small radiopaque markers. The 3D coordinates of the markers are known to an accuracy of ±.02 mm from prior measure-

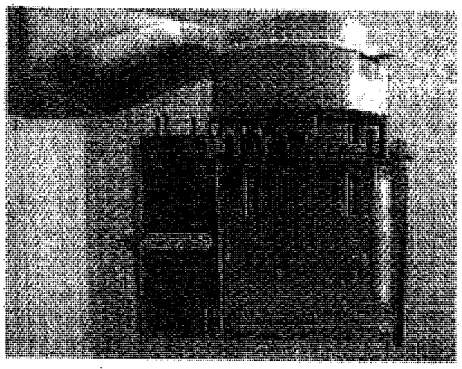


Figure 2. An array of radiopaque fiducial markers is mounted in front of the film plane. These points are projected upon each image at the time of exposure and define the precise position of the cassette. The locations of the fiducial markers on the cassette holder.

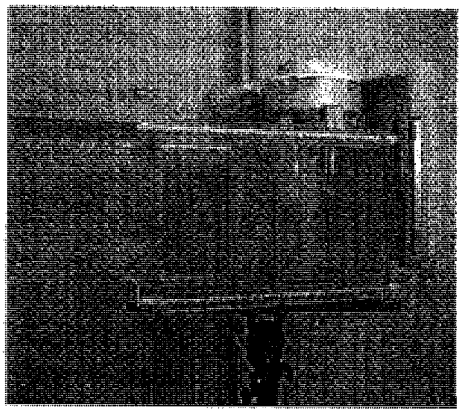


Figure 3. The calibration cage. This device has eighteen radiopaque metal markers mounted in three carefully milled plastic planes such that the maximum number of markers will be projected on the image surface at exposure from each emitter. The positions of the markers on the planes are known with great accuracy by previous measurement. Their projected images on the film plane allow us to calculate the true spatial relationships between the two emitters, the fiducial markers, and the film plane with high accuracy and precision.

ClearCorrect Exhibit 1002, Page 1280 of 3373

ment of the array with a precision coordinate measuring system. The array is placed in the x-ray field of view, and a separate exposure is obtained from each emitter. The DenOptix plates are then scanned, and both digital images are processed using CRIL software to obtain image coordinates for all of the array points.

The image coordinates are processed using a numerical analysis package called a bundle adjustment, which uses a least squares technique to compute the emitter locations. Tests of the system after calibration indicate that we can compute coordinates of unambiguously identifiable targets with an absolute accuracy of approximately ±0.1 mm in all three dimensions. Once calibration has been completed, the acquisition of an integrated 3D data set can begin. No further calibration is required so long as the system geometry remains stable.

The data acquisition procedure involves a series of steps as described here.

Step 1: Generating Three-Dimensional Digital Models of the Upper and Lower Teeth, and Creating Tie-point Bearing Aligners

Accurate and stable poly vinyl siloxane (PVC) impressions of the upper and lower teeth are obtained. Using these, Align creates 3D digital models of the upper and lower teeth for later merging with the facial and x-ray data. Align also constructs, to our specifications, upper and lower Aligners with small radiopaque spherical tie-points added to each, as shown in Figure 4. The Aligners are placed on the patient's teeth during the later x-ray imaging process.

Step 2: Placing Facial Tie Points

Another set of radiopaque tie points is placed on the patient's face. These spheres will appear in the facial 3D model as well as the x-ray images, allowing later merging of the data (Fig 5D). Their exact locations on the facial surface are not critical, but they should be fairly evenly distributed over the entire area of interest.

Step 3: Generating a Three-Dimensional Photographic Model of the Face

The subject is seated in front of the 3DMetrics camera and a series of stereo-images is collected.

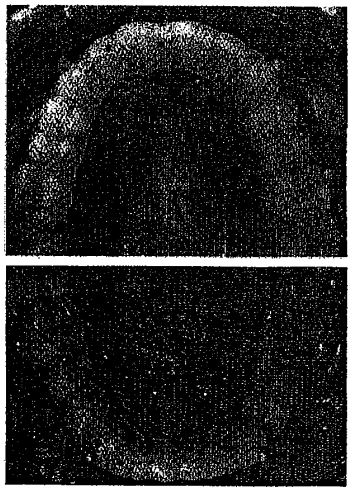


Figure 4. Upper and lower tie-point bearing Aligners positioned in the mouth.

The camera projects a color-coded light pattern onto the face before each image is acquired (Fig 5D). The pattern is displaced by the contours of the face, allowing the software to later automatically generate an accurate 3D model or stereoimage. A matching view with no projected pattern is also acquired. The 3DMetrics camera and associated software can acquire and compute a 3D surface of the face with a lateral resolution of approximately 1.0 mm, and a depth resolution of approximately 0.2 mm.

Normally, at least one frontal and two lateral oblique stereoimages are taken, to ensure complete coverage of the face. Each stereoimage is used to generate a separate 3D model. Currently, the individual facial models from the several stereoimages are "stitched" together using the 3DMetrics software, which uses only 3 common points for merging each pair of images. We are currently adapting our mathematically rigorous transformation software to allow merging the 3D information from all the patient's stereoimages simultaneously using all available facial tie points. This should result in facial reconstructions of much greater accuracy.

Step 4: Generating a Three-Dimensional X-Ray Model of the Teeth, Face, and Skull

Frontal and lateral x-ray pairs are generated using the calibrated x-ray emitters and DenOptix

ClearCorrect Exhibit 1002, Page 1281 of 3373

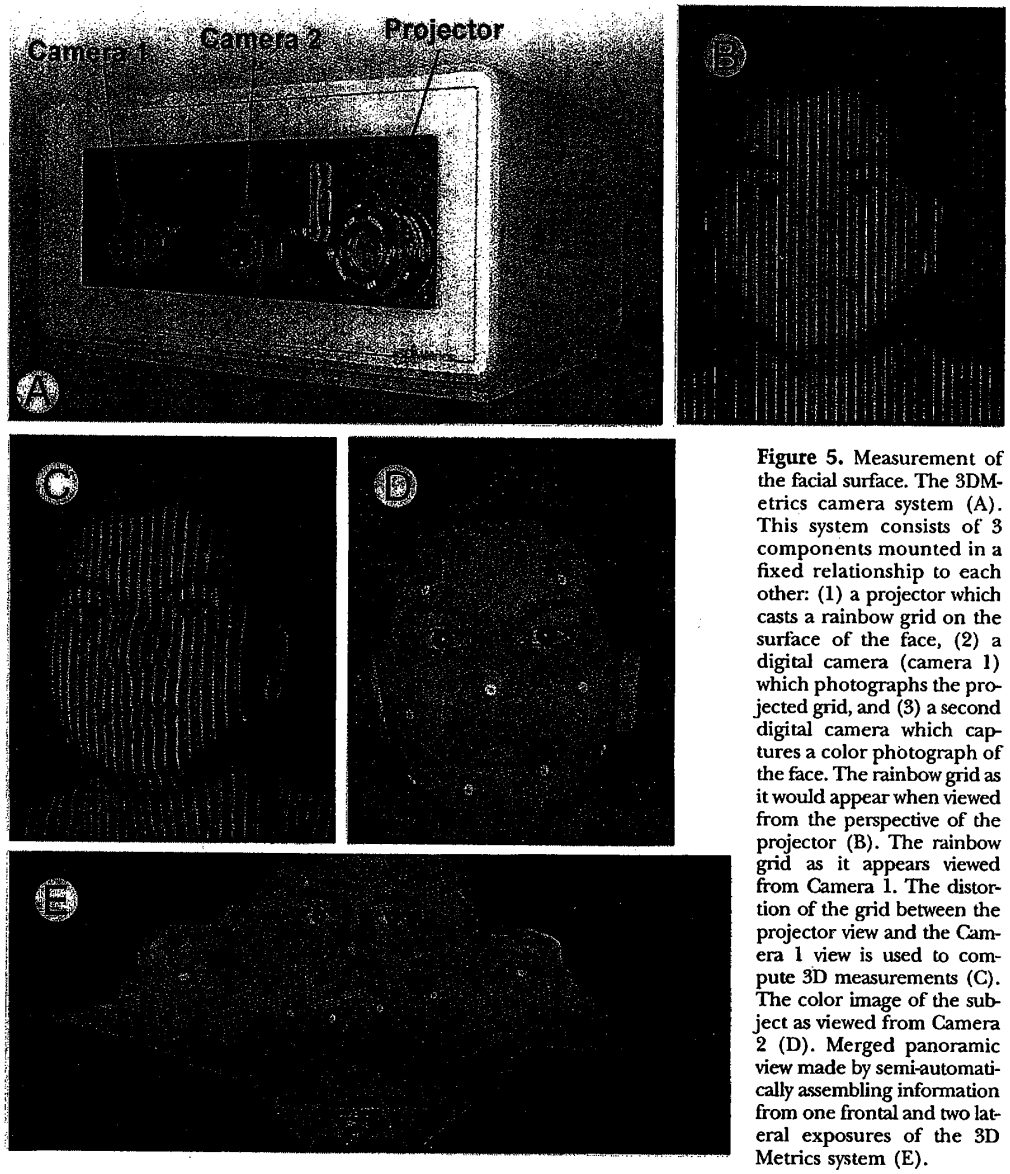


Figure 5. Measurement of the facial surface. The 3DMetrics camera system (A). This system consists of 3 components mounted in a fixed relationship to each other: (1) a projector which casts a rainbow grid on the surface of the face, (2) a digital camera (camera 1) which photographs the projected grid, and (3) a second digital camera which captures a color photograph of the face. The rainbow grid as it would appear when viewed from the perspective of the projector (B). The rainbow grid as it appears viewed from Camera 1. The distortion of the grid between the projector view and the Camera 1 view is used to compute 3D measurements (C). The color image of the subject as viewed from Camera 2 (D). Merged panoramic view made by semi-automatically assembling information from one frontal and two lateral exposures of the 3D Metrics system (E).

imaging plates (Fig 6). Fiducial marks on each film are used to reference the digital image to the calibrated x-ray system. Note also the tie points imaged on the films—both those on the face and those on the teeth. A big advantage of the DenOptix system is that it provides us with a large dynamic range in the images, making it possible to create good images for clinical evaluation while still allowing the clear identification of fiducial and tie points. The resulting digital images are analyzed using CRIL software. This analysis yields 3D coordinates for all the tie points, as well as for any anatomic features of interest.

ClearCorrect Exhibit 1002, Page 1282 of 3373

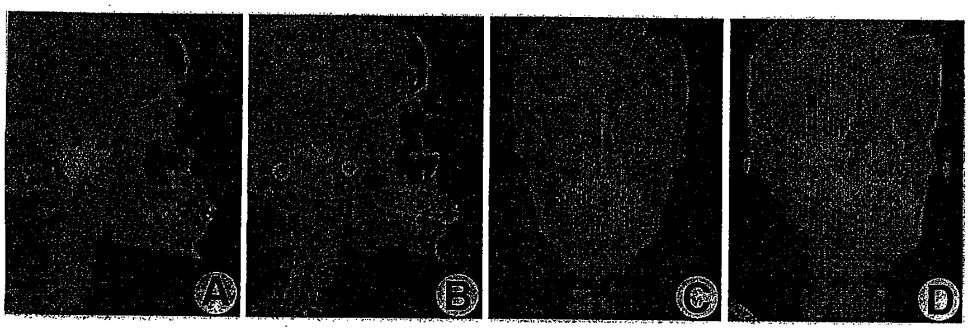


Figure 6. Lateral and frontal stereopairs showing facial and tooth tiepoints. In this figure, the left image pair (A and B), and the right image pair (C and D) are coplanar stereopairs generated using the CRIL co-planar apparatus illustrated in Figure 1 while images A and C, taken together, approximate a Broadbent bi-planar stereopair.

Step 5: Merging the Several Three-Dimensional Models

The UOP/CRIL software is used to compute the transformations between the individual 3D models so that they can be merged into a single frame of reference (Fig 7). Each model is transformed with 7 parameters (3 rotations, 3 translations, and 1 scale factor) to the common coordinate system. At least three common tie points are required in each overlapping 3D model to compute this transformation, but we use additional points to strengthen the solution and to allow error checking. The transformation is computed using a rigorous least-squares adjustment, which also produces statistics on the quality of the fit (Fig 8).

Step 6: Viewing the Integrated Three-Dimensional Model

The resulting integrated 3D craniofacial model can be viewed interactively by using Align's TREAT software. Individual components of the model can be turned on and off separately, and the transparency of each component can be varied separately. The integrated 3D model can be rotated freely around any desired axis under user control. Any surface or group of surfaces of interest can be made visible and invisible, and the transparency of each surface can be changed separately as desired. In practice, this means that the clinical orthodontist will have complete freedom to peel away the virtual layers of the face as

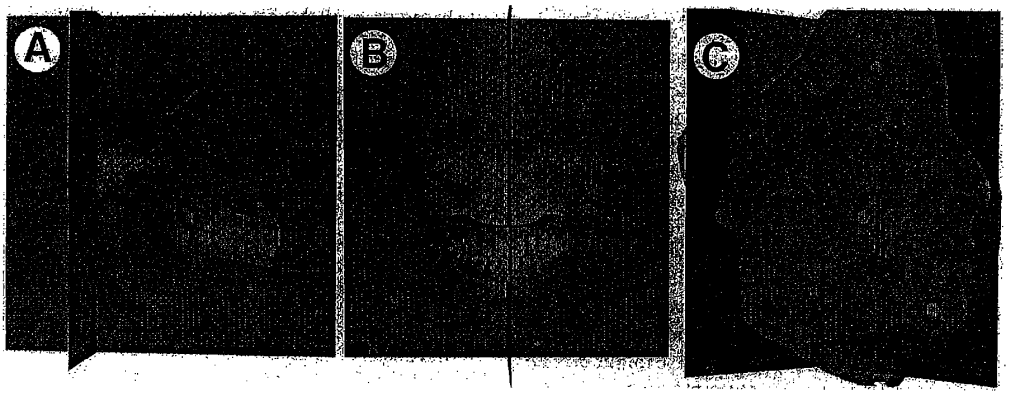


Figure 7. Representative views of the integrated three-dimensional craniofacial map. Lateral and frontal cephalograms with oriented study casts viewed from the lateral aspect (A), viewed from the frontal aspect (B), viewed from the 45 degree oblique aspect (C).

ClearCorrect Exhibit 1002, Page 1283 of 3373

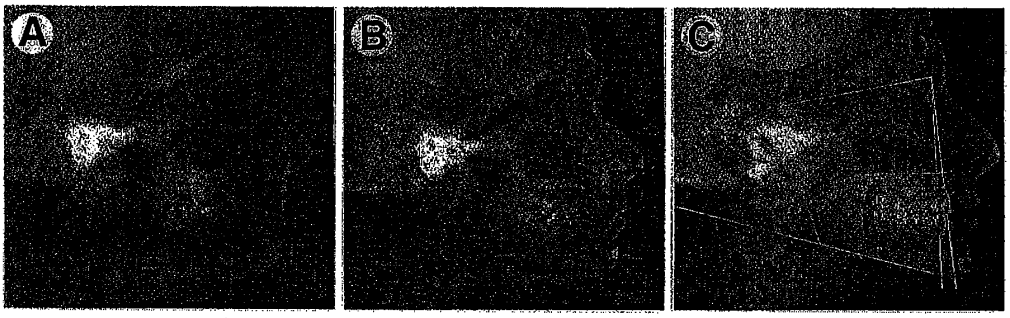


Figure 8. Representative additional capabilities. Facial wire frame surface model from 3DMetrics Camera 1 merged with Lateral Gendex/DenOptix X-Ray Image (A), facial surface model and image from 3DMetrics Camera 2 merged with Lateral Gendex/DenOptix X-Ray Image (B), representative conventional cephalometric measures overlaid on an integrated model (C).

desired and to view regions of interest from any desired angle, entirely according to his or her personal taste (Fig 8).

Conclusions

The orthodontist and maxillofacial surgeon will in the very near future, have at his or her disposal an array of information-acquisition tools to match the complexity of the clinical problem at hand. For some simple problems, the use of the current nonintegrated 2D physical records may suffice. For more complex situations, a graduated series of responses will be available. At a moderate level of complexity, existing cephalometers in clinicians' offices can be calibrated in site, making possible 3D reconstructions of acceptable accuracy from a single conventional emitter. The data source could be limited to a single lateral ceph plus a single frontal ceph, provided the system was calibrated and that the same set of tie-points could be located without ambiguity on both films. Where 3D information about the location of discrete anatomical features lying off the mid-sagittal plane is needed, stereo x-ray systems equivalent to the one at CRIL would have to be available. Where more extensive 3D information about cranial surfaces and skeletal contours is needed, low-emission computed tomographies scanners such as the Newtom[39] are becoming available. These might best be used synergistically with tie-point-based high-resolution systems, such as that described here.

Almost certainly, clinicians will wish in the near future to add to their armamentarium high-resolution information about the head in motion. For information about changes in the contours of the facial surface during speech, mastication, and deglutition, high-speed variants of the structured light camera used in our present system will soon become generally available. For studies of the changing relationships between the jaws and teeth during function, apparatus that automatically tracks active targets like light-emitting diodes attached to the face have been built and will become increasingly practical.[40,41] The use of tie-points to facilitate automatic merging of information from different sources will become progressive and more widely applied.

References

1. Baumrind S, Moffitt FH. Mapping the Skull in 3D. J California Dental Assoc 1972;48:22.
2. Baumrind S. A System for Craniofacial Mapping Through the Integration of Data from Stereo X-Ray Films and Stereophotographs. Technical Papers from the Symposium on Close Range Phtogrammetric System, American Society of Photogrammetry, University of Illinois, Urbana, IL, 1975;142-166.
3. Moffitt FH. Stereo x-ray photogrammetry applied to orthodontic measurements. Proceedings of the 12th Congress of the International Society of Photogrammetry, Ottawa, Canada, 1971.
4. Curry S, Anderson JM, Moffitt F. Calibration of a Close-Range Stereometric Camera System. Proceedings, American Society of Photogrammetry Annual Convention, Washington, DC, 1981.
5. Curry S, Moffitt F, Symes D, et al. A Family of Calibrated Stereometric Cameras for Direct Intraoral Use. Proceedings, Biostereometrics '82 (SPIE), San Diego, California 1982;7-14.
6. Isaacson RJ, Baumrind S, Curry S, et al. Semi-Real Time

ClearCorrect Exhibit 1002, Page 1284 of 3373

Monitoring of the Functional Movements of the Mandible. Proceedings, Society of Photo-Optical Instrumentation Engineers 1982;361, paper #4.
7. Baumrind S, Moffitt FH, Curry S, et al. A Dedicated Stereophtogrammetric X-Ray System for Craniofacial Research and Treatment Planning. Proceedings, Society of Photo-Optical Instrumentation Engineers 1982; 361; paper #38.
8. Moffitt FH, Baumrind S, Chafetz N, et al. A Stereoencephalographic System with Portable Calibration Cage for Use in Clinical Medicine. Proceedings, Society of Photo-Optical Instrumentation Engineers 1982;361, paper #39.
9. Korn EL, Baumrind S, Chafetz N, et al. Establishing Quantitative Within-Subject Confidence Limits for Clinical Stereogenographics. Proceedings, Society of Photo-Optical Instrumentation Engineers 1982;361, paper #40.
10. Bjørk A. Variations in the growth pattern of the human mandible: Longitudinal radiographic study by the implant method. J Dent Res 1963;42:400-411.
11. Bjørk A, Skieller V. Facial development and tooth eruption: An implant study at the age of puberty. Am J Orthod 1972;62:339-383.
12. Baumrind S: Background, principles, and perspectives. Sem Ortho 2001;7:223-232.
13. Curry S, Baumrind S. Analysis of Stereo Cranial X-Rays using Digital Images. Close Range Photogrammetry and Surveying Symposium, American Society of Photogrammetry 1984;35-46.
14. Curry S, Anderson JM, Baumrind S, et al. Stereo Camera and Stereo X-Ray Devices: Comparison of Biostereometric Measurements. Photogrammetric Engineering and Remote Sensing 1985;51:1597-1603.
15. Baumrind S, Curry S. Merging of Data from Different Records in Craniofacial Research and Treatment. Close Range Photogrammetry and Surveying Symposium, American Society of Photogrammetry 1984;35-46.
16. Curry S, Baumrind S. Real Time Monitoring of the Movement of the Mandible. Proceedings, American Society of Photogrammetry 1986;92-100.
17. Curry S, Baumrind S, Anderson JM. Calibration of an array camera. Photogrammetric Eng Remote Sensing 1986;52:627-636.
18. Curry S, Baumrind S. Digital Methods for Mandibular Motion Measurement. Proceedings DOCUMED, Amsterdam 1987.
19. Curry S, Baumrind S. Realtime Mandibular Motion Measurement. Proceedings IEEE/Ninth Annual Conference of the Engineering in Medicine and Biology Society, Boston, MA, 1987;721-722.
20. Baumrind S, Curry S. Integrated Craniofacial Data Analysis System. Proceedings IEEE/Ninth Annual Conference of the Engineering in Medicine and Biology Society, Boston, MA 1987;723-724.
21. Murray WR, Baumrind S, Genant HK, et al. The detection of loosening in total hip arthroplasty: A computer-assisted stereometric method. Proceedings of the Canadian Orthopaedic Research Society 1979.
22. Hunter J, Baumrind S, Genant HK, et al. The detection of loosening in total hip arthroplasty: description of a stereophotogrammetric computer-assisted method. Invest Radiol 1979;14:323-329.
23. Chafetz N, Baumrind S, Murray W, et al. Femoral prosthesis subsidence in asymptomatic patients: a stereophotogrammetric assessment. Invest Radiol 1984; 19:235-241.
24. Baumrind S. Integrated Surface and Deep Structure Mapping of the Human Anatomy. Proceedings, Section on Kinanthropommetry, 1984 Olympic Scientific Congress, Eugene, Oregon.
25. Chafetz N, Baumrind S, Murray W, et al. Subsidence of the femoral prosthesis: A stereophotogrammetric evaluation. Clin Orthoped Rel Res 1985;201:60-67.
26. Chafetz N, Baumrind S, Morris JE, et al. Stereophotogrammetry of the lumbar spine. Spine 1985;10:368-375.
27. Baumrind S, Moffitt FH, Curry S. Three-dimensional X-ray stereometry from paired coplanar images: a progress report. Am J Orthod 1983;84:292-312.
28. Baumrind S, Moffitt FH, Curry S. The geometry of three-dimensional measurement from paired coplanar X-ray images. Am J Orthod 1983;84:313-322.
29. Hallert B. X-ray Photogrammetry. New York: Elsevier Publishing Company, 1970.
30. Rune B, Jacobson S, Sarnas KV, et al. Roentgen stereophotogrammetry applied to the cleft maxilla of infants. I Implant technique. Scand J Plast Reconstr Surg 1997;11:131.
31. Rune B, Sarnas KV, Selvik G, et al. Posteroanterior traction in maxillonasal dysplasia (Binder's syndrome): a roentgen stereometric study with the aid of metallic implants. Am J Orthod 1982;81:65-70.
32. Selvik G. Roentgen stereophotogrammetry in Lund, Sweden: applications of human biostereometrics. Proceedings, SPIE 1978;166:184-191.
33. Burke PH, Beard LFH. Stereophotogrammery of the face. Am J Orthod 1967;53:769.
34. Berkowitz S, Prusansky S. Stereophotogrammetry of several casts of cleft palate. Angle Orthod 1968;28:136.
35. Berghagen N, Ronnerman A, Adolfsson B. Determination of the movement of impacted upper canines by x-ray photogrammetric methods. Acta Odontol Scand 1964;22:4.
36. Image-Based Rendering: Structured Light, The Graphics and Visualization Center, National Science Foundation Science and Technology Centers. Available at: http://www.cs.brown.edu/stc/resea/rendering/research_R6.html.
37. Destructive Physical Analysis, ORS Labs. Available at: http://www.ors-labs.com/DPA.html.
38. CAIP Rutgers, The State University of New Jersey, Introduction to Stereolithography. Available at: http://www.ciap.rutgers.edu/~kbhiggin/VDF/SLA.html.
39. Mozzo P, Procacci C, Tacconi A, et al. A new volumetric CT machine for dental imaging based on the cone-beam technique: preliminary results. Eur Radiol 1998;8:1558-1564.
40. Baumrind et al, Mandibular motion monitoring system. United States Patent #4,836,778 June 6, 1989.
41. Miyakawi S, Tanimoto Y, Inoue M, et al. Condylar motion in patients with reduced anterior disc displacement. Dent Res 2001;80:1430-1435.

ClearCorrect Exhibit 1002, Page 1285 of 3373

Three-Dimensional Computer-Assisted Design of Craniofacial Surgical Procedures: Optimization and Interaction with Cephalometric and CT-Based Models

Court Cutting, M.D., Fred L. Bookstein, Ph.D., Barry Grayson, D.D.S., Linda Fellingham, Ph.D., and Joseph G. McCarthy, M.D.

New York, N.Y., Ann Arbor, Mich., and Mountain View, Calif.

A computer program is described which aids the clinician in planning craniofacial surgical procedures. It operates on a three-dimensional landmark data base derived by combining posteroanterior and lateral cephalograms from the patient and from the Bolton normative standards. A three-dimensional surgical simulation program based on computerized tomographic (CT) data is also described which can be linked to the cephalometrically based program. After the clinician has selected the number and type of osteotomies to be performed on the patient, an automated *optimization* program computes the postoperative positions of these fragments which best fit the appropriate normal cephalometric form. The clinician then interactively modifies the design to account for such variables as bone-graft resorption, relapse tendency, occlusal disparities, and the condition of the overlying soft-tissue matrix. Osteotomy movement specifications are easily transferred between the CT-based and the cephalometrically based surgical simulation programs. This allows the automated positioning step to be performed on the cephalometrically based model while the interactive step is performed using the superior image provided by the CT-based model.

In current practice, the planning of craniofacial surgical procedures involves simultaneous evaluation of cephalograms, photographs, dental models and clinical examination along with tabulated "normative standards."[27,34-36] This laborious process requires considerable experience and is accurate only for symmetric deformities. Asymmetric problems—truly three-dimensional problems, such as hemifacial microsomia—are not apprehended effectively by these two-dimensional cephalometric modalities. Recently, Marsh and Vannier,[20] Marsh et al.,[21] and Merz[22] introduced three-dimensional imaging of skeletal deformities based on computerized tomographic (CT) data. This technique is quickly becoming accepted as a valuable tool in the preoperative evaluation of craniofacial patients.

In this paper, two-dimensional cephalometric data are used to create a three-dimensional data structure that supports a morphometric analysis and surgical simulation program. As a first step, the computer automatically positions the osteotomy fragments so that they "best fit" the normal form. Results of this program are displayed as a line drawing. Alternately, the specified movements may be displayed using synthetic images created from computerized tomographic data. The clinician then modifies the surgical design using interactive computer graphic techniques.

From Two Dimensions to Three

The computer programs to be described operate on three-dimensional landmark points taken from the facial skeleton. This three-dimensional data set is derived by correlating points found on conventional posteroanterior and lateral cephalometric films, as shown in Fig. 1. A

From the Variety Club Center for Craniofacial Rehabilitation, Institute of Reconstructive Plastic Surgery, at New York University Medical Center, the Center for Human Growth and Development at the University of Michigan, and Contour Medical Systems, Inc. Received for publication June 17, 1985; revised October 7, 1985.

Presented at the Annual Meeting of the American Society of Plastic and Reconstructive Surgeons, in Las Vegas, Nevada, in October of 1984 and at the First International Congress of Cranio-Maxillofacial Surgeons in September of 1985 in La Napoulle, France.

ALN116331

ClearCorrect Exhibit 1002, Page 1286 of 3373

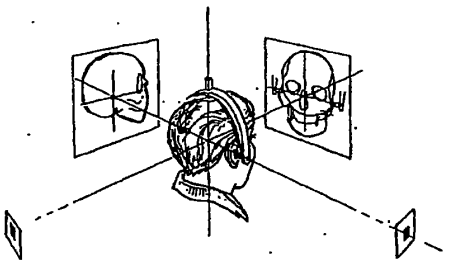


FIG. 1. Method of finding three-dimensional point locations from posteroanterior and lateral cephalograms. For each view a line is formed between the x-ray source and the location of the landmark on the film. The three-dimensional position of the landmark lies at the point where the two lines intersect.

number of conventional anatomic landmarks located in one view can be identified with more or less accuracy in the other. Such pairs of two-dimensional locations may be converted to a single three-dimensional location by a variant of the ray intersection method commonly used in stereophotogrammetry.[3,31] This method is also used for the location of metallic implants from two x-ray views.[29]

Briefly stated, any point on a single cephalogram represents all locations along a line in three-dimensional space. This line connects the x-ray source with the corresponding location on the film plane at the moment of exposure. To a single three-dimensional landmark correspond two such lines, one from the lateral and the other from the posteroanterior cephalogram. If these lines were measured with infinite precision, they would intersect in space at the actual location of the landmark in question. In the presence of measurement error, we take their "intersection" to be the midpoint of their common perpendicular segment, the average location of the two points, one on each line, each of which is closest to the other line. Landmarks locatable in this fashion are cusps of teeth and other such landmarks clearly seen on both views.

For landmarks that are not seen with equal clarity in both cephalograms, spatial information is restored by a slightly different construction. We take the lateral coordinate of the landmark from the corresponding coordinate on the posteroanterior film and the posteroanterior coordinate from the lateral view. (Each "coordinate" is in fact slightly corrected for beam spreading.) We extract the third Cartesian coordinate, height, from the view in which the landmark is more clearly seen. The net procedure amounts to the intersection of a plane with a line perpendicular to it. Most landmarks (e.g., gonion, pogonion, nasion, anterior nasal spine, etc.) are located by this approach.

This simple method of combining two conventional two-dimensional representations into a three-dimensional representation is susceptible to some inherent flaws and errors. These include positioning changes during the rotation of the head by 90 degrees from the lateral to the posteroanterior exposure, discrepancy in geometric identification of "corresponding" landmarks, and other more minor sources of error.[9,13,14,23,24,30] From the method of construction used, it is apparent that several of the points will not actually touch the skeleton, but will lie close to it in a consistent fashion. This is analogous to the use of the gonial intercept landmark, familiar from two-dimensional cephalometrics. This landmark is defined as the intersection of a line through the posterior mandibular ramus border with a line approximating the inferior mandibular border. Although this "landmark" is not actually on the skeleton, many clinicians prefer its use to the gonion because the latter is more subject to the judgment of the individual doing the tracing. The three-dimensional gonion will always lie consistently lateral to the skeleton. This does not prevent it from being useful. Further, this definition permits access to a large normative data base because it leaves two-dimensional landmark definitions undisturbed.

For each patient, the correlation of points between posteroanterior and lateral cephalograms yields a reconstruction of his or her anatomy in three dimensions in the form of a constellation of points. Using standard computer graphic methods,[12,28] these reconstructions are visualized with the aid of a line drawing connecting the landmark locations computed. A similar process may be carried out on the published tracings of Bolton,[6] resulting in a similar construction of the Bolton-preferred "ideal" constellation for every age and sex. The patient's landmark constellation also may be linked to his or her three-dimensional computerized tomographic data for the purposes of interactive surgical simulation.

SIMULATING SURGERY

Once these point constellations have been computed, they are subjected to shape analysis

ALN116332

ClearCorrect Exhibit 1002, Page 1287 of 3373

with automated fragment repositioning followed by interactive three-dimensional surgical simulation. The landmarks may be divided into skeletal subsets which are specific to each type of osteotomy. For example, all the maxillary landmarks as well as both inferior orbital rim landmarks would move together if a Le Fort III osteotomy were to be simulated. The specific locations of the cuts are not modeled by the cephalometric program. Simulating surgery is therefore reduced to deciding which subsets of landmarks are to move together (choosing the osteotomies) and then specifying a rigid motion for each of these subsets of landmarks.

As the first step in a surgical simulation, the osteotomy fragments are positioned based on an *optimization principle.* Optimization algorithms automatically adjust the free variables in a numerical problem until the minimum value of the computed result is obtained. At this stage, it is the algorithm, not the user, which relocates the mobile skeletal fragments. The algorithm computes displacements and reorientations of all fragments as a set so as to minimize the mean-squared distance between the corresponding landmarks in the normal Bolton form and the patient's postoperative form—i.e., to have the surgical outcome most closely approximate the normative form. Because the landmarks are linked together in rigid fragments, this computation is a constrained optimization that compromises failures to fit the normal anatomy in all the different aspects and regions of the form. Should the surgical designer feel that landmarks ought to vary in their relative importance for the assessment of this fit, he or she may assign different weighting factors to different landmarks. The optimization strategy employed is of the coordinate search type.[8,19]

The user then interactively alters the orientation and position of each osteotomy fragment. Following Euler,[5] reorientation is specified by a series of separate rotations about the x, y, and z axes (see Fig. 4), followed by displacement of the reoriented piece in x, y, and z directions (see Fig. 5). These six degrees of freedom (three rotations and three translations) must be specified for each osteotomy segment which is to be moved. After repositioning a fragment, the clinician may examine the three-dimensional result graphically and further alter the plan. At the end, the program generates a numerical printout which precisely summarizes the final displacements and reorientations for each skeletal fragment (Table I). This printout, the "surgical blueprint," may be referenced directly at the time of the actual surgery.

TABLE 1

Typical Printout Reporting the Amount of Movement of the Right (RMT) and Left (LMT) Maxillary Tuberosities and the Anterior Nasal Spine (ANS) Used to Specify the Three-Dimensional Position Change of a Le Fort I Osteotomy Fragment at the Time of Surgery

RMT moved superiorly 8.12 mm
RMT moved left −1.34 mm
RMT moved anteriorly 2.04 mm
LMT moved superiorly 4.06 mm
LMT moved left −1.06 mm
LMT moved anteriorly 2.04 mm
ANS moved superiorly 6.09 mm
ANS moved left −1.20 mm
ANS moved anteriorly 2.04 mm

This interactive phase of surgical planning also may be performed on three-dimensional CT-scan reconstructions of the patient's facial skeleton. A program has been developed which allows these osteotomy fragments to be created in full three dimensions and surgery simulated much as it would be in the operating room. An example of this kind of visualization is given in Fig. 6. The three-dimensional CT-scan visualization may be linked directly with the cephalometric data so that the surgical simulation is done in a conjoined way.

Fusion of the cephalometric and CT-based models gives the user the advantages of both forms of three-dimensional representation. The cephalometric form provides access to a large normative data base necessary for the optimization and measurement operations, while the CT-based model provides superior visualization for the interactive surgical simulation. This linking of classical cephalometrics with CT will be necessary until a comprehensive three-dimensional cephalometric representation, based on a normative data base of CT scans, is developed.

Materials

The resources required for the input and display of the three-dimensional cephalogram are relatively inexpensive. The program used to produce Figs. 3 to 5 was executed on a microcomputer (8086 CPU with 8087 numeric coprocessor; DPC/OS Action Computer, Inc.) interfaced to a Houston Instruments hipad digitizer and a Vectrix graphics output device. This hardware

ALN116333

ClearCorrect Exhibit 1002, Page 1288 of 3373

environment is comparable to several currently available personal computers. Programming was done by the senior author (Cutting) using the C computer language.[17]

The surgical simulation programs based on computerized tomographic data were produced in cooperation with Contour Medical Systems, Inc. A Cemax 1000 three-dimensional imaging device was used to load CT tapes from the patient and preprocess all the skeletal data into contour files. These data may be viewed directly on the device, which produces high-quality three-dimensional images. These preprocessed data are then downloaded to a Silicon Graphics Iris 2400 workstation. Using another program (Cutting), the data may be cut into several osteotomy fragments which are then freely moved in three dimensions in a manner similar to that described previously for the three-dimensionalized cephalogram. Movements specified by the three-dimensional cephalogram program and by the CT-based program are easily transferred from one to the other. This allows optimized surgical planning based on Bolton's standards to be transferred directly to the CT-based image for further modification and display. Work is currently in progress to integrate the entire surgical planning process into a single software package.

Clinical Examples

Figure 2 demonstrates the preoperative and postoperative appearance of a patient with mild hemifacial microsomia. Figure 3 illustrates the surgical design for this patient. The left column shows the patient's preoperative line drawing, while the right column shows the computed postoperative result. The three-dimensional landmark locations for this result were reconstructed from pairs of cephalograms taken at the Institute of Reconstructive Plastic Surgery at New York University Medical Center. The simulation involves a Le Fort I osteotomy, a sagittal split of the mandible, and a horizontal osteotomy (genioplasty). In arriving at this design, the user began by allowing the program to lead the way in an automatic (distance-optimizing) mode followed by user intervention to modify the computed surgical plan (see also Figs. 4 and 5). Figure 6 illustrates this same operative plan using the CT-based interactive surgical simulation in another patient with hemifacial microsomia. In this example, the geometrically optimal positions of the bone fragments have been modified by the clinician to account for bone-graft resorption, tendency to relapse, and the differing soft-tissue state on the two sides of the face. Note the overcorrection of the Le Fort I, the sagittal split of the mandible, and the genioplasty.

Discussion

The use of computers in the analysis of cephalometric data has a long history.[1,2,7,10,18,25,26] Description of population differences[15,16] and growth prediction[26,32] are active research areas at present. Two-dimensional preoperative planning of surgical procedures with computer assistance has recently been described.[4]

Three approaches to three-dimensional surgical simulation have been reported by Marsh et al.[21,33] In the first approach, mirror-image techniques project the normal side over the midsagittal plane to the abnormal side, allowing precise measurements to be taken of the deformity. We feel this approach is the best one for planning surgery in unilateral trauma and rapidly growing tumor cases. Unfortunately, the slow-growing tumors (e.g., fibrous dysplasia and hemangiomas) frequently produce compensatory changes on the "normal" side. Similarly, for most of the congenital anomalies (e.g., plagiocephaly and hemifacial microsomia) there is no normal side to mirror. For these problems, comparison of the patient with a large normative data base is desirable.

A second approach involves model making using computer-controlled milling machines based on CT data. This approach is particularly useful for teaching, since a large number of pathologic skulls could be made from a single mold. Although necessarily destructive, this type of surgical simulation is the most realistic. Computer-milled models have several disadvantages. They are relatively expensive and time-consuming to produce on a per-patient basis. More important, however, is that the surgical simulations produced are not in digital electronic form. If the surgery is modeled directly on the computer, the resulting shape may be readily analyzed numerically. If automated shape analysis and/or positioning of the fragments is to be carried out, the modeling must be done directly on the computer.

The third approach taken by Marsh et al. involves preoperative planning of procedures directly on the computer terminal using commercially available computer-assisted design (CAD) software. They have reported modeling of a hypertelorism correction and a midface advance-

ALN116334

ClearCorrect Exhibit 1002, Page 1289 of 3373



FIG. 2. Preoperative (*above*) and postoperative (*below*) photographs of a patient with hemifacial microsomia involving correction with a Le Fort I osteotomy of the maxilla, sagittal split of the mandible, and a horizontal osteotomy (genioplasty). Computer-assisted preoperative plan for this patient appears in Fig. 3.

ALN116335

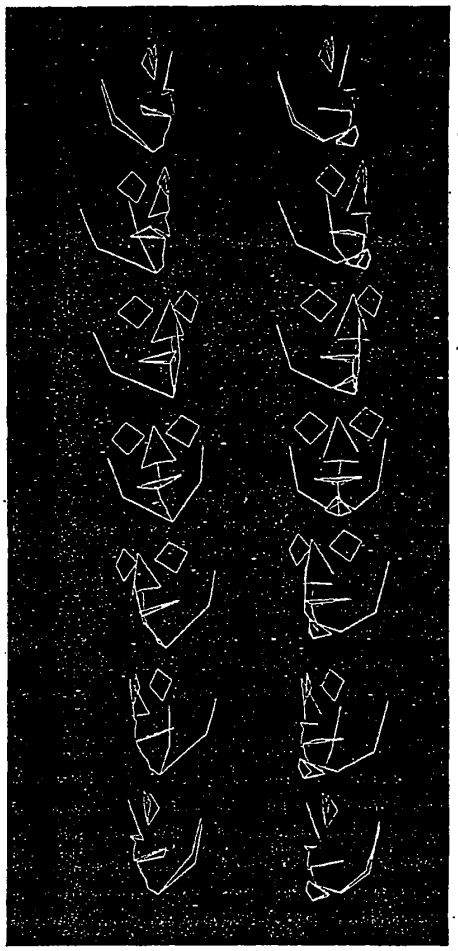


FIG. 3. Line drawings of patient with hemifacial microsomia. The left-hand column is a rotation sequence prior to manipulation. The right-hand column displays an optimized computer-generated surgical plan involving simulation of a Le Fort I (*red lines*) sagittal split of the mandibular rami (*magenta lines*) and a genioplasty (*yellow lines*). The blue lines represent the orbital rims and the upper piriform aperture. Each row is a step in an animation sequence from right lateral to left lateral.

ment using this approach. Our experience with currently available CAD packages suggests that they will be difficult to use in common clinical practice. Cutting a piece from a very complex object that already exists and moving it to another location is not an operation that is frequently done in commercial applications. Also, the horizontal line format of CT data is not easy

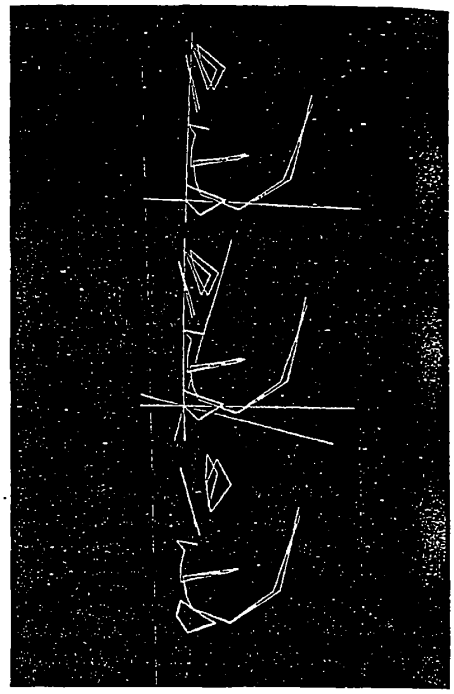


FIG. 4. Method of specifying a rotation of a horizontal osteotomy fragment from the lateral view. (*Above*) A cross (*blue*) is drawn through the center of rotation. (*Center*) The user has specified a rotation of the cross (*red lines*). (*Below*) The image is rotated as directed (*yellow lines*). Similar rotations must be carried out from the posteroanterior and basilar views to completely define the rotational orientation of the fragment.

to work with directly. It is for these reasons that we have chosen to produce a custom program based on CT data which closely approximates the surgical situation. This program may be quickly learned by a clinician with no computer experience. Also, it operates on a shaded-surface representation rather than on a line drawing, which is a more natural form for clinical use. Hopefully, general-purpose CAD software for solids modeling will develop such that it may be custom altered for this clinical application. This would greatly reduce programming time and facilitate distribution and service.

Precise planning of orthognathic surgical procedures is currently the standard of practice. If the procedure is a Le Fort I osteotomy in a patient with long-face syndrome, one needs to know the number of millimeters of bone to be removed at the piriform aperture, the number

ALN116336

ClearCorrect Exhibit 1002, Page 1291 of 3373

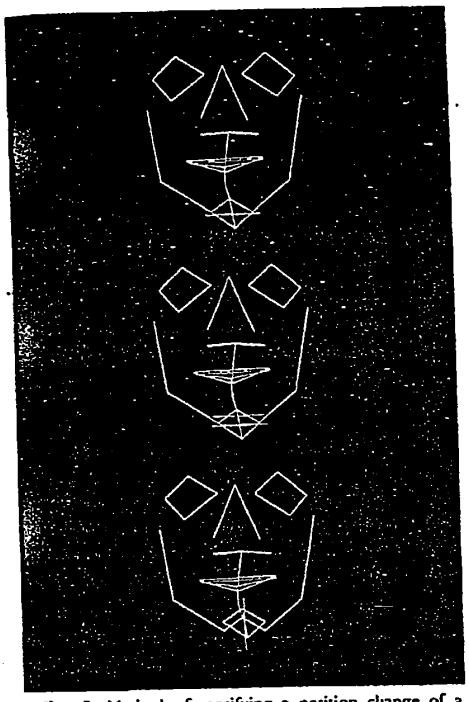


FIG. 5. Method of specifying a position change of a horizontal osteotomy fragment. (*Above*) A horizontal line (*blue*) is drawn through the fragment. (*Center*) The user has specified the amount of vertical position change desired (*from blue line to red line*). (*Below*) The fragment is moved appropriately to its new vertical position. Similar movements are required to specify the lateral and posteroanterior position changes of the fragment.

of millimeters to be removed at the maxillary tuberosity, and the amount of horizontal motion of the palatal segment. This "surgical blueprint" greatly facilitates the performance of the procedure and usually results in a predictable, consistent outcome.[34-36]

The extension of this process from two to three dimensions, which is necessary in planning more complex craniofacial surgical procedures, is ideally suited to computer methods. The program described in this paper uses optimization methods and interactive graphics to facilitate this task. Optimization software is applied to the three-dimensional cephalogram in order to automatically move the osteotomy fragments into a geometric "optimum" compared with the Bolton normative standards. The movement specifications which arise from this optimization program are transferred to either of the interactive surgical simulation programs. Interactive movement of simulated osteotomy fragments may be performed on both the three-dimensional cephalogram using a line-drawing image format or the computerized tomographic data using more sophisticated imaging hardware. The "surgical blueprint" which arises from the simulation may be derived from either of the interactive programs.

Despite the optimized computer-generated surgical plans, evaluation and modification by the clinician are mandatory. Such variables as bone-graft resorption, relapse tendency, unique occlusal problems, and a variety of soft-tissue considerations usually force the clinician to modify the computer-generated design. For example, the computer may suggest a 20-mm advancement of a Le Fort I segment in a cleft palate patient. Clinical experience with postoperative relapse tendencies should prompt the modification of such an impractical design. In the future it may be possible to integrate these clinical factors into an automated surgical program. At present, clinical experience with facial osteotomies and their biological behavior must be used to modify any computer-generated plan.

The present system is a prototype. One obvious deficiency lies in the three-dimensional cephalogram. This is too small a data set to plan upper craniofacial surgery accurately. Much more information is present in the CT scan. Mathematical methods of incorporating CT data into the optimization routine are required. Further, alternative measures of "best fit" in the computation of the "optimal" surgery are currently being explored. We believe that in the near future the planning of reconstructive surgery will be carried out within computer environments, rather than using pencil and paper at a desk, and that the computer will almost literally generate the "first cuts" of a geometric surgical plan. It cannot compute the best surgical strategy, but it can reject a vast number of flawed possibilities much faster than the most conscientious surgical designer.

Court B. Cutting, M.D.
Institute of Reconstructive Plastic Surgery
New York University Medical Center
550 First Avenue
New York, N.Y. 10016

ACKNOWLEDGMENT

This work was supported by NIDR Grant No. DE03568.

REFERENCES

1. Baumrind, S., and Miller, M. D. Computer-aided head film analysis: The University of California San Fran-

ALN116337

ClearCorrect Exhibit 1002, Page 1292 of 3373

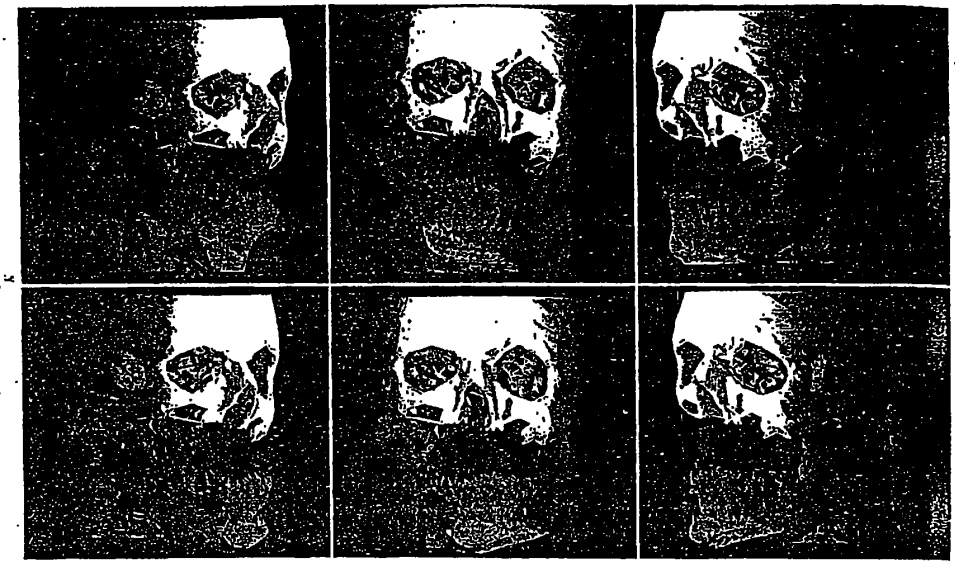


FIG. 6. (*Above*) Three preoperative views of a patient with hemifacial microsomia using the CT-based surgical simulation program. (*Below*) The corresponding views following simulation of a Le Fort I sagittal split of the mandible and genioplasty.

cisco method. *Am. J. Orthod.* 78: 41, 1980.
2. BeGole, E. A., Cleall, J. F., and Gorny, H. C. A computer system for the analysis of dental casts. *Angle Orthod.* 51: 252, 1981.
3. Berkowitz, S., and Cuzzi, J. Biostereometric analysis of surgically corrected abnormal faces. *Am. J. Orthod.* 72: 526, 1977.
4. Bhatia, S., and Sowray, J. A computer-aided design for orthognathic surgery. *Br. J. Oral Maxillofac. Surg.* 22: 237, 1984.
5. Borisenko, A., and Tarapov, I. Vector and Tensor Analysis with Applications. Trans. by R. Silverman. New York: Dover Publications, 1968. Pp. 45–47.
6. Broadbent, B. H., Broadbent, B. H., and Golden, W. *Bolton Standards of Dentofacial Development Growth.* St. Louis: Mosby, 1975.
7. Burke, P. H., Banks, P., Beard, L. F. H., Tee, J. E., and Hughes, C. Stereophotographic measurement of change in facial soft tissue morphology following surgery. *Br. J. Oral Surg.* 21: 237, 1983.
8. Caceci, M., and Cacheris, W. Fitting curves to data. *Byte* 9: 340, 1984.
9. Chawla, S. D., Glass, L., Freiwald, S., and Proctor, J. W. An interactive computer graphic system for 3-D stereoscopic reconstruction from serial sections: Analysis of metastatic growth. *Comput. Biol. Med.* 12: 223, 1982.
10. Faber, R. D., Burstone, C. J., and Solonche, D. J. Computerized interactive orthodontic treatment planning. *Am. J. Orthod.* 73: 36, 1978.
11. Farkas, L. G., Bryson, W., and Klotz, J. Is photogrammetry of the face reliable? *Plast. Reconstr. Surg.* 66: 346, 1980.
12. Foley, J., and Van Dam, A. *Fundamentals of Interactive Computer Graphics.* Reading, Mass.: Addison-Wesley, 1982.
13. Garrison, J. B., Ebert, W. L., Jenkins, R. E., Yionoulis, S. M., Malcolm, H., Heyler, G., Shoukas, A. A., Maughan, W., and Sasawa, K. Measurement of three-dimensional positions and motions of large numbers of spherical radiopaque markers from biplane cineradiograms. *Comput. Biomed. Res.* 15: 76, 1982.
14. Goitein, M., and Mento, D. An optical scanner as an aid in simulating treatment with CT data. *J. Comput. Assist. Tomogr.* 6: 1201, 1982.
15. Grayson, B. H., Boral, S., Eisig, S., Kolber, A., and McCarthy, J. G. Unilateral craniofacial microsomia: I. Mandibular analysis. *Am. J. Orthod.* 84: 225, 1983.
16. Grayson, B. H., McCarthy, J. G., and Bookstein, F. Analysis of craniofacial asymmetry by multiplane cephalometry. *Am. J. Orthod.* 84: 217, 1983.
17. Kernighan, B., and Ritchie, D. *The C Programming Language.* Englewood Cliffs, N.J.: Prentice-Hall, 1978.
18. Leonard, M. S., Johnson, G. W., Starfield, A. M., and Speidel, T. M. Computer graphics in facial morphology analysis. *Int. J. Oral Surg.* 10(Suppl. 1): 273, 1981.
19. Luenberger, D. *Linear and Non-Linear Programming.* London: Addison-Wesley, 1973.
20. Marsh, J. L., and Vannier, M. W. The "third" dimension in craniofacial surgery. *Plast. Reconstr. Surg.* 71: 759, 1983.
21. Marsh, J. L., Vannier, M. W., Stevens, W. G., Warren, J. O., Gayou, D., and Dye, D. M. Computerized

ALN116338

ClearCorrect Exhibit 1002, Page 1293 of 3373

imaging for soft tissue and osseous reconstruction in the head and neck. *Clin. Plast. Surg.* 12: 279, 1985.
22. Merz, B. Computer guides facial reconstruction (News). *J.A.M.A.* 249: 1409, 1983.
23. Nagurka, M. L., and Hayes, W. C. An interactive graphics package for calculating cross-sectional properties of complex shapes. *J. Biomech.* 13: 59, 1980.
24. Prothero, J., and Prothero, J. Three-dimensional reconstruction from serial sections: I. A portable microcomputer-based software package in Fortran. *Comput. Biomed. Res.* 15: 598, 1982.
25. Richardson, A. A comparison of traditional and computerized methods of cephalometric analysis. *Eur. J. Orthod.* 3: 15, 1981.
26. Ricketts, R. M., Bench, R. W., Hilgers, J. J., and Schulhof, R. An overview of computerized cephalometrics. *Am. J. Orthod.* 61: 1, 1972.
27. Riolo, M. L., Moyers, R. E., McNamara, J. S., and Hunter, W. S. *An Atlas of Craniofacial Growth.* Monograph No. 2, Craniofacial Growth Series, Center for Human Growth and Development. Ann Arbor, Mich.: University of Michigan Press, 1974.
28. Rogers, D., and Adams, J. A. *Mathematical Elements for Computer Graphics.* New York: McGraw-Hill, 1976. Chap. 3.
29. Rune, B., Sarnas, K.-V., Selvik, G., and Jacobsson, S. Roentgen stereometry with the aid of metallic implants in hemifacial microsomia. *Am. J. Orthod.* 84: 231, 1983.
30. Savara, B. S. A method of measuring facial bone growth in three dimensions. *Hum. Biol.* 37: 245, 1965.
31. Savara, B. S., Miller, S. H., Demuth, R. J., and Kawamoto, H. K. Biostereometrics and computer graphics for patients with craniofacial malformations: Diagnosis and treatment planning. *Plast. Reconstr. Surg.* 75: 495, 1985.
32. Schulhof, R. J., and Bagha, L. A statistical evaluation of the Ricketts and Johnston growth-forecasting methods. *Am. J. Orthod.* 67: 258, 1975.
33. Vannier, M. W., Marsh, J. L., and Warren, J. O. Three-dimensional CT reconstruction images for craniofacial surgical planning and evaluation. *Radiology* 150: 179, 1984.
34. Zide, B., Grayson, B., and McCarthy, J. G. Cephalometric analysis: Part I. *Plast. Reconstr. Surg.* 68: 816, 1981.
35. Zide, B., Grayson, B., and McCarthy, J. G. Cephalometric analysis and preoperative planning: Part II. *Plast. Reconstr. Surg.* 68: 961, 1981.
36. Zide, B., Grayson, B., and McCarthy, J. G. Cephalometric analysis for mandibular surgery: Part III. *Plast. Reconstr. Surg.* 69: 155, 1982.

ALN116339

ClearCorrect Exhibit 1002, Page 1294 of 3373

DCS PRODUCTION

DCS Dental AG POB 104 Gewerbestrasse 15 CH-4123 Allschwil 3 Switzerland
Telefon 061 482 06 06 Fax 061 482 06 22

THE CAD/CAM "DCS TITAN SYSTEM" FOR PRODUCTION OF CROWNS/BRIDGES

* USA Patent number 4 997 369 (issued March 5, 1991)
* Development of the System by DCS Dental AG
  (5 years starting in 1985)
* Production of the System by DCS Production AG
* Guidance and dental support
  Prothetics Department - University of Basel under the
  supervision of Prof. Graber
  Dr. A. Tavor - dentist
  J. Zaborsky - dentist

FUNCTION OF THE SYSTEM

Production of infrastructures of crowns/bridges momentarily out of Titan (and in the near future also out of ceramics) from a plaster model through a milling process instead of the conventional casting method in dental labs.

BENEFITS OF THE SYSTEM

1. enormous savings of technical manpower to produce infrastructures of crowns/bridges. Anybody that is trained on the job for a few days can operate the System. (remark: bridge-planning as well as covering infrastructures with ceramics still has to be carried out by the dental technician)

2. production increase of crowns/bridges per work-day in a dental lab (up to 50% more than today) without enlarging the staff.

3. savings on material-costs to produce crowns/bridges (in comparison with the casting procedure approx. SFr. 18.00 per crown on material, cutters, electricity and yearly service costs for the machine)

4. preciser fitting of the end-product (accuracy crown to ground tooth 30 $\pm 20\mu$) due to computerized production

5. making of crowns/bridges out of new materials like Titanium, in the near future also out of ceramics.

6. Amortisation of investment for the entire system within 1,5 years (Germany and Switzerland)

7. the system does not ask for an increase of pay-roll, 13th salary, sick-leave etc. and can be used on a 24 hour basis

8. the system is based on a modular-design-principle

ClearCorrect Exhibit 1002, Page 1295 of 3373

ADVANTAGES OF TITAN

a) cheaper than gold
b) bio-compatible
c) but extremely robust
d) possibility to X-ray through Titan
e) doesn't create electrical potentials
f) life-span 3 times longer than conventional crowns

OF CERAMICS

a) simple to handle by milling (prior to burning-process)
b) extreme hardness (after burning-process)
c) very aesthetical (no metal inside mouth)
d) many more benefits

UNITS OF THE SYSTEM

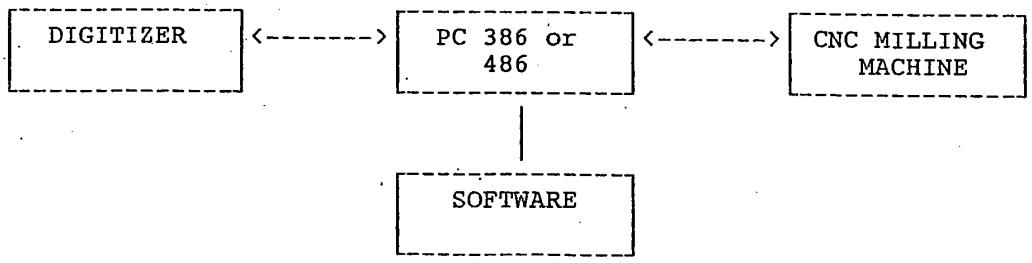
1. DIGITIZER — to take 3 dimensional data of the ground tooth from the impression (accuracy 3μ)

2. AN IMPROVED PC 386/486 COMPUTER as well as software

   a) that collects and processes the 3-dimensional data
   b) that can be used as CAD/CAM for change as well as planning of the outer wall (if needed in 3 different elevations)
   c) to plan the bridge construction (up to half a jaw in one piece)
   d) that prepares the automatic milling programm
   e) that controls the CNC-machine

3. COMPUTERIZED CNC-MACHINE

   3 axes CNC machine to mill crowns/bridges
   precision 5μ
   spindle speed 15'000 rpm
   220V - 1 phase



CAPACITY OF THE SYSTEM

within a normal work-day ± 20 single crowns can be made with the CNC milling machine, and in the future with changes of the milling process and software even 24 to 26 crowns per day - actual work of user per crown approx. 15 minutes.

BRIDGE - CONSTRUCTION UP TO HALF A JAW IN ONE PIECE

Investment of time for a bridge is calculated as follows: single crown multiplied by amount of elements needed e.g. infrastructure consisting of 2 crowns built on teeth and one element without tooth means 3 elements therefore invested time today approx. ±1½ hours - starting with digitizing the model, planning the bridges with CAD/CAM and milling the bridge (infrustructure) with the CNC-machine.
In the future the same procedure will be terminated within 1 hour.

The actual time investment of the operator/technician for this bridge amounts to 30 minutes and is divided up as follows:

20 minutes for digitizing the plaster model, planning the bridge by CAD/CAM
and
10 minutes for operating the CNC machine

DIFFERENT POSSIBILITIES OF CROWNS/BRIDGES SUPPORTED BY THE CAD/CAM SYSTEM

1. Change of inner fittings of crown to ground tooth (enlarged/reduced friction)
2. Change of thickness of crown
3. Change of thickness of outer wall in 3 different elevations
4. Planning of different versions of elements between the crowns of a bridge
5. alot more possibilities

A SYSTEM FOR SMALL/MEDIUM SIZED DENTAL LABS

The System is based on the following units:

1 digitizer
1 computer 386 or 486 + software
1 CNC milling machine
(see diagramm page 2)

WORKING PROCESS BY USING 1 COMPUTER ONLY IN AN 8,5 HOUR DAY
(production of 15 crowns or as an example 2 "three-element" bridges and 9 crowns)

---

method in general:

a) tracing a tooth from a plaster model by using digitizer
b) processing 3-dimensional data via computer and producing an automatic milling programm simultaneously
c) computerized automatic milling process permits to produce crowns/bridges by CNC-machine

"production line" method:

a) at the end of each work day (1 hour before closing) 13 ground teeth are being digitized and then produced the following day
b) all data will be collected and processed throughout the night by the computer
c) all crowns or a combination of crowns and bridges will then be prepared by the CNC machine the following morning

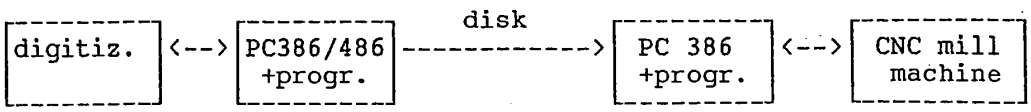
Actual time investment of the operator on our System throughout one normal work-day is ± 3½ hours.

USING THE SYSTEM BY RUNNING 2 COMPUTERS (386)

This enables the operator to digitize and plan bridges as well as work the CNC machine simultaneously.

By taking this step one can produce on a normal work-day more than 20 crowns/bridges instead of 15 crowns/bridges and, as said before, in the future even 24 to 26 crowns/bridges.

1 computer will always be connected to the digitizer while the other computer will serve the CNC milling machine



ASSETS OF THIS VARIATION IN COMPARISON TO THE ALREADY MENTIONED VERSION

1. Full utilization of the CNC-milling machine throughout the entire work-day just by purchasing an additional computer
2. Possibility of bridge-planning while CNC-machine operates
3. Increase of production (number of crowns/bridges per day)
4. Many other advantages

AN EXPANDED SYSTEM FOR LARGE DENTAL-LABS

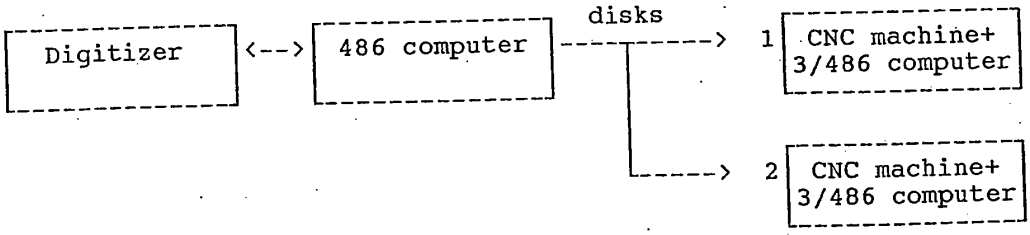
1. One digitizer working in connection with its own computer can trace up to 50 teeth per day

   OR

   digit e.g. 30 teeth to produce single crowns in addition to tracing and planning 7 bridges each one consisting of 3 separate elements.

2. For this operation one needs 2 milling machines

This shows, a system can be combined using 1 digitizer equiped with a computer which operates 2 CNC-milling machines provided also with a computer



production of 50 crowns per day
or e.g. 30 crowns + 7 bridges
(3 elements)

We are of the opinion that the above mentioned combination should be easily manageable by 2 employees:

a) 1 worker trained on the job

b) 1 dental technician for bridge-planning
time investment for the above mentioned job is
± 12 hours for both employees together per day.

ClearCorrect Exhibit 1002, Page 1299 of 3373

Additional possibilities to use our DCS "TITAN" System

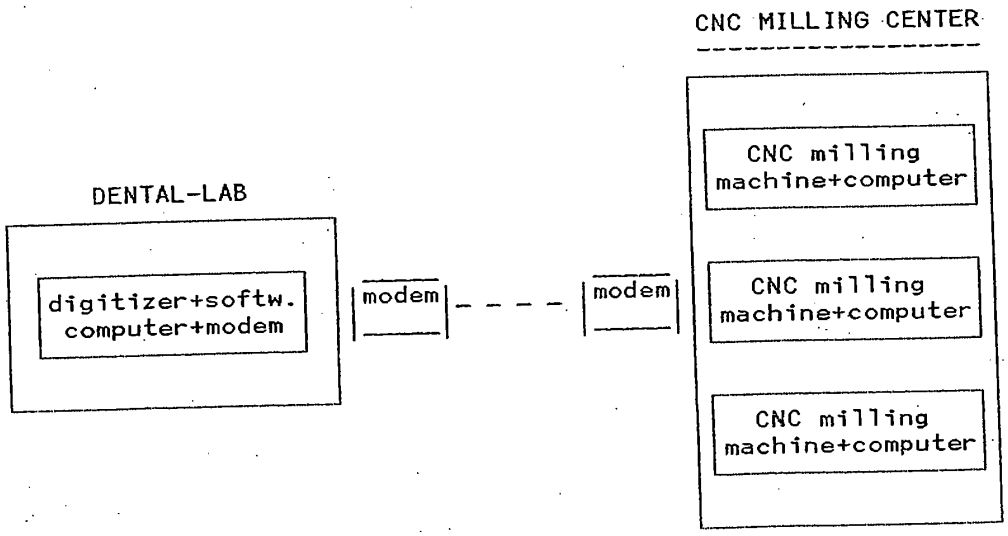
The sketch below shows another possibility to work with the DCS "TITAN" System.

1. The Dental Lab is equiped with
   1 digitizer
   1 computer/software
   1 modem

2. Someplace a milling-machine-center will be installed.

   The Dental Labs will digitize the needed tooth/bridge, transmit the data to the milling-center by modem (or postal service) and the milling-center will produce the tooth/bridge and send the finished product either by mail or any other transport company back to the dental lab.

   This arrangement will help the dental lab to make use of the entire DCS "TITAN" System by only investing partially into it.



ClearCorrect Exhibit 1002, Page 1300 of 3373

FURTHER DETAILS CONCERNING THE DCS TITAN SYSTEM:

* As of the middle of 1991 the Systems are being sold to dental-labs in Germany

* Our calculation here is based on an average milling-time of 20 minutes per crown

* It is possible to plan and manufacture a bridge-construction up to a half a jaw in one piece

* It has to be taken into consideration that small and simple crowns need less milling-time than a complicated one which is more time consuming.
An improvement will enable us to reduce the approx. milling time to 10 to 15 minutes per crown.

* gross-weight of the system without packing material approx. 450 kg

* System functions with 220V 1 phase - for USA also on 60 Hz.

* For the milling process 2mm and 3mm hardmetal cutters are needed, working with 15'000 rpm.

* The CNC-machine is packed in a specially closed cabinet which includes all the electrical parts as well as the coolant system. (computer and digitizer come separately)

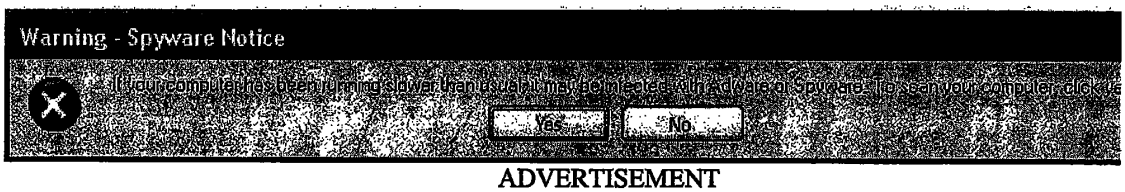
* No programming of the CNC-milling machine has to be done, this is taken care of automatically by the computer.

* The work-pieces are especially manufactured for this system and therefore an additional income for the distributer.

DCS Production AG
January, 1992

ClearCorrect Exhibit 1002, Page 1301 of 3373

Dictionary.com
gingiva
Dictionary Thesaurus Web
Home
Premium: Sign up | Login



ADVERTISEMENT

Dictionary - Thesaurus - Web

Get the Most Popular Sites for "gingiva"

5 entries found for *gingiva.*

ADVERTISEMENT

gin·gi·va Pronunciation Key (jĭn'jə-və, jĭn-jī'-)
n. pl. **gin·gi·vae** (-vē')

See gum².

[Latin gingīva.]

[Download or Buy Now]
Source: *The American Heritage® Dictionary of the English Language, Fourth Edition*
Copyright © 2000 by Houghton Mifflin Company.
Published by Houghton Mifflin Company. All rights reserved.

gin·gi·va (jĭn'jə-və, jĭn-jī'-)
n. pl. **gin·gi·vae** (-vē')

See gum.

---

gin'gi·val (jĭn'jə-vəl, jĭn-jī'-) *adj.*

Source: *The American Heritage® Stedman's Medical Dictionary*

Copyright © 2002, 2001, 1995 by Houghton Mifflin Company. Published by Houghton Mifflin Company.

Main Entry: **gin·gi·va**
Pronunciation: `'jin-j&-v&, jin-'jI-`
Function: *noun*
Inflected Form: *plural* **gin·gi·vae** /`-"vE`/
: GUM —**gin·gi·val** /`'jin-j&-v&l`/ *adjective*

Source: *Merriam-Webster Medical Dictionary, © 2002 Merriam-Webster, Inc.*

gingiva

n : the tissue (covered by mucous membrane) of the jaws that surrounds the bases of the teeth [syn: gum]

Source: *WordNet ® 2.0, © 2003 Princeton University*

gingiva

gingiva: in CancerWEB's On-line Medical Dictionary

Source: *On-line Medical Dictionary, © 1997-98 Academic Medical Publishing & CancerWEB*

Ads by Google

Medical Dictionary
$34.95
Medical Dictionary/Bibliography on Hyperhidrosis by ICG
Affiliate
www.icongrouponline.com

English Dictionary
Search for Collectibles
Cultures, Ethnicities. Aff
www.ebay.com/collectibles

Palm Dictionary
Discount Palm Dictionary
Check out the deals
now! aff
www.ebay.com

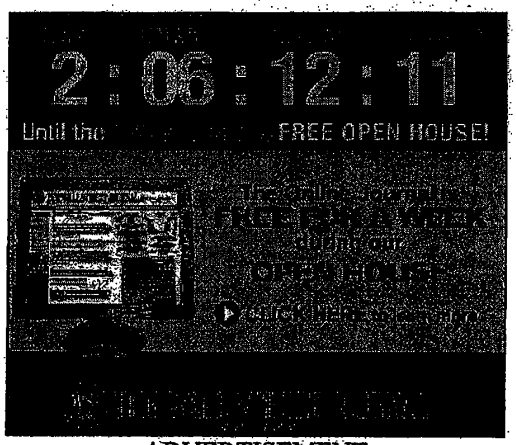
Legal Medication Online
Order prescription drugs online. FDA approved,
100% legal purchase.
www.LegalMedsOnline.com



Perform a new search, or try your search for "gingiva" at:

- Amazon.com - Shop for books, music and more
- HighBeam Research - 32 million documents from leading publications
- Merriam-Webster - Search for definitions
- Reference.com - Web Search powered by Google
- Thesaurus.com - Search for synonyms and antonyms

ClearCorrect Exhibit 1002, Page 1303 of 3373



ADVERTISEMENT

Get the **FREE Dictionary.com Toolbar** for your browser now!
From the makers of Dictionary.com

Copyright © 2004, Lexico Publishing Group, LLC. All rights reserved.
About Dictionary.com | Privacy Policy | Terms of Use | Link to Us | **Help** | Contact Us

J. Biomechanics. 1976. Vol. 9. pp. 793–801. Pergamon Press. Printed in Great Britain

THREE-DIMENSIONAL LARGE DISPLACEMENT ANALYSIS OF ORTHODONTIC APPLIANCES*†

JOSEPH C. DEFRANCO, HERBERT A. KOENIG and CHARLES J. BURSTONE‡

Department of Mechanical Engineering, The University of Connecticut, Storrs, CT 06268, U.S.A.

Abstract—An incremental technique for predicting the nonlinear load–displacement characteristics of orthodontic appliances is developed. The analysis is based upon a three-dimensional finite-difference formulation which permits the treatment of appliances that have arbitrary configurations and non-uniform material and cross-sectional properties. The effects of intermediate loading and attached springs may also be studied.

The results show the activated configurations and the associated force–couple systems for three appliances that are activated to the yield point. The incremental analysis results are compared to those of the linear solution for each case.

INTRODUCTION

In order to develop orderly procedures for the design of orthodontic appliances, a precise engineering analysis is required to predict the force systems that appliances will deliver when they are subjected to clinical activations. Although a number of analyses have been developed (Waters, 1970 and 1972; Yang and Baldwin, 1974; Koenig and Burstone, 1974), the method that is presented here is of greater generality since it is based upon a three-dimensional formulation which permits the treatment of spatial configurations and activations. Also, an incremental procedure is used which gives the analysis a large displacement capability.

The equations of equilibrium are derived in a manner which includes the shear force contributions to the bending moments. The spatial curved beam deformation and load–deformation equations are those that are used by Koenig (1974) for the three-dimensional linear analysis.

FORMULATION

In deriving the governing equations (See Appendix A), the appliances are treated as beams since their cross-sectional dimensions are small when compared to their lengths and since the lateral strains of the wire are not significant. In addition, the stresses and strains are within the elastic range, the cross-sectional dimensions are small compared with local curvatures and twists, and the principal axes are at an angle θ with respect to the local coordinate axes. The appliances are idealized as a series of beam elements whose centerlines are connected by node points. Any internal stresses that act at the lateral cross-sections are represented by their force and moment resultants which are defined as being located at the cross-sectional area centroids. If the appliance is subjected to external loads, they are assumed to act at the nodes rather than on the elements. As the appliance deforms under loading, the nodes may translate in three dimensions. In the formulation, the stress resultants and the displacements at each node are represented in component form. The components are expressed in a local right-hand reference frame (t,n,b) which consists of the tangent, normal, and binormal directions of the centerline at the node point. The global reference frame used is a cartesian right-hand system (x,y,z) and defines the locations of the nodes and the orientations of the local coordinate systems. The local coordinate frame is shown in Fig. 1. The geometric relationships which govern the local unit vectors are given in Appendix C.

A typical wire element, isolated from its two end nodes (which are designated as m and m-1), is illustrated in Fig. 2. The nodes are numbered in ascending order in the direction of increasing centerline arc-length and the indices R and L refer to the right and left sides, respectively, of the end nodes for an element which is viewed as in Fig. 2. The equilibrium equations for an element are derived with respect to the local coordinate directions of the higher-numbered node. The six vector equations of equilibrium are listed in Appendix A. In order to obtain moment

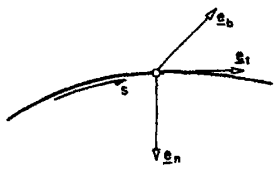


Fig. 1. Local unit vector triad.

* *Received* 3 *May* 1976.

† This investigation was supported by Grant DE-03953 from the National Institute of Dental Research National Institutes of Health, Bethesda, MD.

‡ Department of Orthodontics, The University of Connecticut.

ClearCorrect Exhibit 1002, Page 1305 of 3373

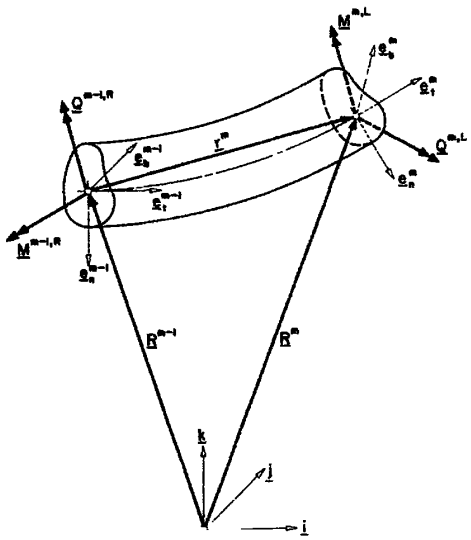


Fig. 2. Free-body diagram of a wire element.

calculations which are more exact than a linear formulation, the relative position vector, $\mathbf{r}^m$, in equations A.4, A.5, and A.6, is expressed as a function of the node coordinates and the node displacements. This results in cross products of displacement and force terms. These cross products are eliminated with an approximation technique in order to preserve the linearity of the equations (DeFranco, 1975).

The deformation equations and the load–deformation equations for the elements are also listed in Appendix A. These are converted into algebraic equations by expressing them in finite-difference form. The twelve governing equations are then arranged as a single matrix equation which expresses the load–displacement characteristics of each element. This equation may be written in the form

$$\pi_{m-1}\,\mathbf{b}_{m-1,R} = \eta_m\,\mathbf{b}_{m,L}, \tag{1}$$

where

$$\mathbf{b} = \begin{vmatrix} M_t \\ M_b \\ M_n \\ Q_t \\ Q_b \\ Q_n \\ \phi_t \\ \phi_b \\ \phi_n \\ w_t \\ w_b \\ w_n \end{vmatrix} \tag{2}$$

The relationships between the loads and the displacements of one element to those of an adjacent element are established with the conditions of equilibrium and continuity which exist at the intermediate node. The free-body diagram of such a node is shown in Fig. 3. For the sake of clarity in the illustration, the linear and torsional springs have been omitted. The equations are listed in Appendix B and may be expressed in matrix form as

$$\gamma_m\,\mathbf{b}_{m,L} = \mathbf{b}_{m,R} + \mathbf{p}_m.$$

Or

$$\mathbf{b}_{m,L} = \gamma_m^{-1}\,(\mathbf{b}_{m,R} + \mathbf{p}_m). \tag{3}$$

Substituting equation (3) into equation (1), and defining

$$\xi_{m,m-1} = \pi_{m-1}^{-1}\,\eta_m\,\gamma_m^{-1}, \tag{4}$$

yields the equation

$$\mathbf{b}_{m-1,R} = \xi_{m,m-1}\,\mathbf{b}_{m,R} + \xi_{m,m-1}\,\mathbf{p}_m, \tag{5}$$

which relates the loads and displacements that exist at one node to those at the preceding node. By applying equation (3) to the first node (node 0) of the model and equation (5) to each of the remaining nodes yields (after combining the results) the system matrix equation

$$\Omega\,\mathbf{b}_{N,R} = \gamma_0\,\mathbf{b}_{0,L} + \lambda. \tag{6}$$

where N designates the last node. Solution of equation (6), together with the given boundary conditions, yields the loads and displacements at each end of the appliance. The solutions at the intermediate nodes can be determined with equation (5).

INCREMENTAL SOLUTION

Prior to actually solving the system matrix equation (6), the boundary conditions of the problem (which are expressed in the local reference frames of the end points of the preactivated appliance), are divided into equal increments. Then, the local unit

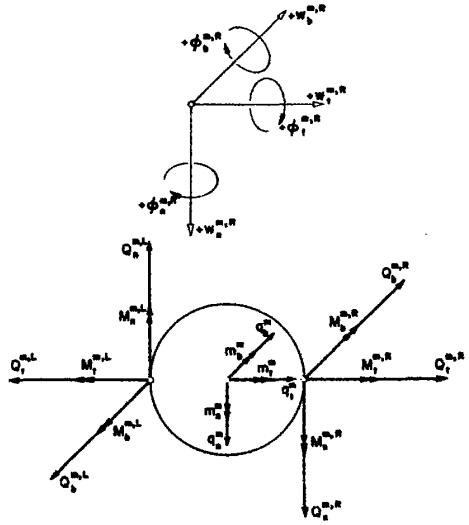


Fig. 3. Free-body diagram of a node.

ClearCorrect Exhibit 1002, Page 1306 of 3373

vectors, internodal distances, curvatures and geometric torsions are computed for the configuration. The first solution step begins by applying the incremental boundary conditions and solving the system matrix equation for the unknown values of the stress resultants and displacements that exist at the appliance end points. Then, by applying equation (5), which relates the loads and displacements of successive nodes, these quantities are determined at each of the intermediate nodes of the appliance. They are then transformed into the global reference frame and the global coordinates of the deformed appliance are calculated along with the associated geometric properties. The new geometry serves as the initial geometry for the second step. It may be noted that at this point in the analysis, the solution that is obtained in the first step is the linear solution to the problem for a small increment of the actual activation.

The second step begins by transforming the incremental boundary conditions into the new local reference system prior to their application. The solution is obtained as before but, this time, the local forces and displacements that were determined in the previous step are used as the values for the approximation terms that appear in the moment equilibrium equations. Again, the resulting stress resultants and displacements are transformed into the global reference frame and the global coordinates of the deformed appliance are calculated along with the associated geometric properties. The new geometry serves as the initial geometry for the following step.

The procedure which is followed in the second step is repeated for as many times as is necessary to allow the complete application of the boundary conditions of the problem. The global coordinates that are obtained in the final step define the fully activated appliance configuration. The stress resultants for the fully activated appliance are determined by adding the global stress components that are produced in each step. Any external loads that may be applied to the system are incremented and transformed in the same manner as the boundary conditions are. The directions of all applied forces remain constant throughout the analysis as do the axes about which all applied moments act.

The computer program, which performs the analysis, requires as input data, the preactivated node coordinates, the material and cross-sectional properties, the boundary conditions, and the selected number of increments. Any external loads or spring constants which act on the nodes are also included in the input.

Three orthodontic configurations have been studied to demonstrate the differences between the results that are obtained with the incremental analysis and those that are obtained with the linear analysis. The results show the activated configurations and the associated force-couple systems for two vertical loop retraction springs and a Burstone rectangular loop. Each appliance is brought to the yield activations that are predicted by the linear analysis and by the incremental analysis.

The configurations which are presented are representative of appliances used in orthodontics. Orthodontic appliances deliver a force and a couple at an attachment on the crown of a tooth, have relatively large deflections and operate in three dimensions. The predictive model of load–displacement characteristics of orthodontic appliances allows the clinician (1) to determine the force system from an appliance that he currently uses. (2) To identify undesirable aspects of the force system and to eliminate these by altering the activation or redesigning the appliance. The predictive model offers great potential in the development of new appliances minimizing the trial and error approaches of the past. Complete details of the incremental solution are given by DeFranco (1975).

RESULTS

The appliances that are analyzed here are constructed of 0.016 in. round, steel wire whose yield moment is 1860 g-mm.

Retraction spring

The ends of the retraction spring are subjected to lateral deflections that cause the appliance to reach its yield point at the top of the loop. The force systems that would be delivered as a result of this activation are predicted with the linear analysis and the incremental analysis and are illustrated in Figs. 4 and 5, respectively. The required activation for yielding is indicated to be 2.4 mm by the incremental analysis which is completed in 5 steps. The linear results are obtained by performing an analysis in a single step. The linear solution indicates that the critical activation is 2.648 mm. By scaling the linear results, a comparison can be made to show that, for identical deflections, the incremental analysis predicts higher end forces and lower end moments than does the linear analysis. In addition, less activation is possible when the nonlinear analysis is considered. Since the activation force is higher, the force/deflection rate is considerably higher than that which would be predicted from the linear analysis. This higher rate is clinically undesirable in orthodontics.

20° Retraction spring

The 20° retraction spring is activated by displacing its end points so that they move parallel to the appliance's axis of symmetry. Prediction of the end force systems due to the yield activation are shown in Figs. 6 and 7 which illustrate the linear and the nonlinear results, respectively. The maximum bending moments in this appliance occur in the vicinities of the bends that join the extended legs of the appliance to the loop section. To attain the yield moment in these regions, both solutions indicate very similar activations (the nonlinear solution is slightly smaller). A comparison of the force systems shows that the

ClearCorrect Exhibit 1002, Page 1307 of 3373

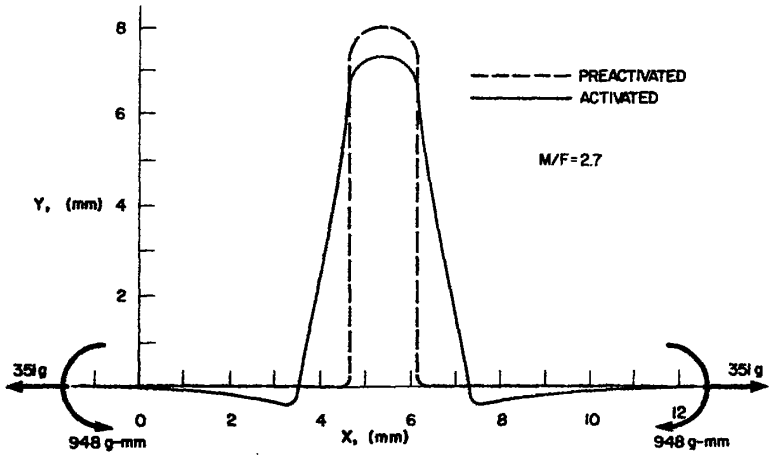


Fig. 4. Retraction spring (linear solution).

incremental analysis predicts higher moments and higher forces than does the linear analysis at the yield activation. Since this type of appliance is used to try to achieve high moment/force ratios for tooth translation, it is desirable to note that the nonlinear (and the more accurate) analysis predicts higher ratios. However, the force/deflection and moment/angle ratios also increase. The difficulty of producing this activation also increases.

The nonlinear analysis was performed in ten increments.

Rectangular loop

The Burstone rectangular loop is an asymmetric configuration which is activated by deflecting its rightmost (in Figs. 8 and 9) endpoint downward while restraining it from rotation. The maximum bending moment occurs at the leftmost endpoint and, according to the incremental analysis (Fig. 9), attains the yield value of 1860 g-mm at an activation of approx. 4.112 mm. The linear solution (Fig. 8) predicts the activation that is required for yielding to have the somewhat greater value of 4.244 mm. At a deflection of 4.112 mm, both methods predict similar vertical end forces. However, the nonlinear, large-deflection analysis predicts a higher end moment in addition to predicting a horizontal end force which does not appear in the small deflection theory results. A significant difference is obtained in the moment-to-force (M/F) ratio at yield which is obtained for the rightmost end. The high M/F ratio at the left appliance bracket could produce a significant undesirable side-effect on the tooth if this value is ignored. Since the orthodontist usually desires a M/F ratio of zero at the right bracket for this configuration, the geometric relationship of the loop arms must be altered to produce this effect or the configuration must be redesigned with more wire placed to the right.

Five steps were taken for the nonlinear analysis.

Numerical results for the cases shown in Figs. 4–9 are listed in Appendix D.

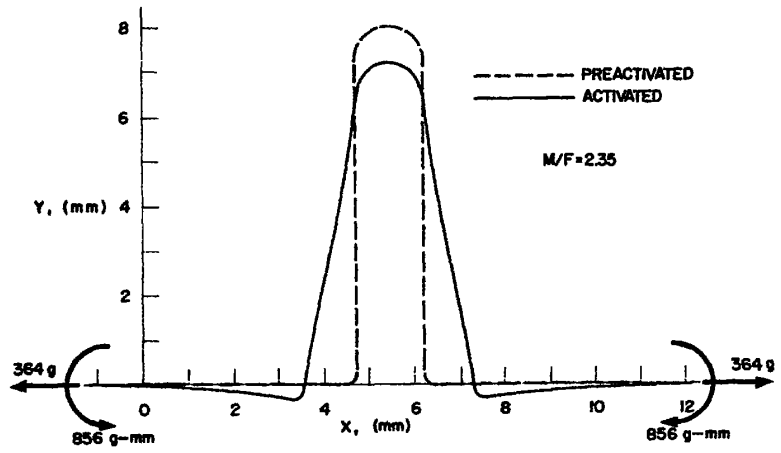


Fig. 5. Retraction spring (nonlinear solution).

ClearCorrect Exhibit 1002, Page 1308 of 3373

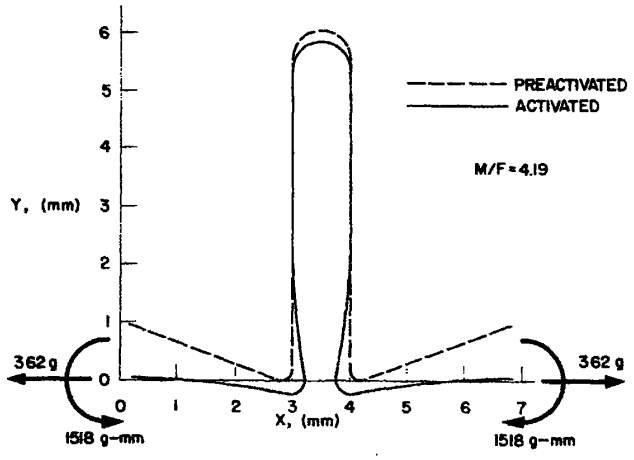


Fig. 6. 20° retraction spring (linear solution).

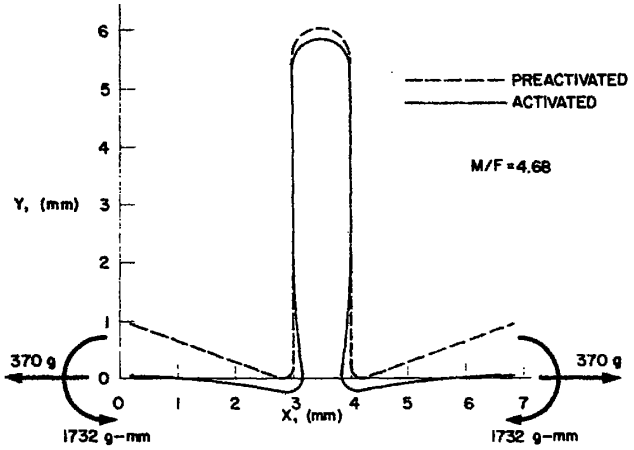


Fig. 7. 20° retraction spring (nonlinear solution).

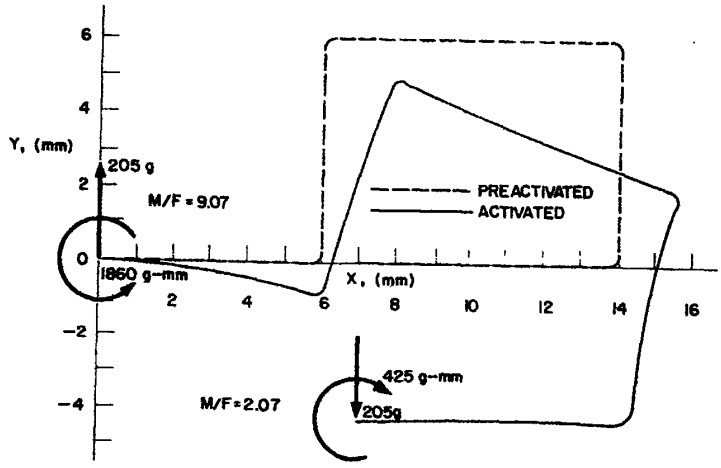


Fig. 8. Rectangular loop (linear solution).

ClearCorrect Exhibit 1002, Page 1309 of 3373

APPENDIX A

$$Q_t^{m-1,R} = Q_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_t^{m-1}) + Q_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_t^{m-1}) + Q_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_t^{m-1}) \quad (A.1)$$

$$Q_b^{m-1,R} = Q_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_b^{m-1}) + Q_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_b^{m-1}) + Q_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_b^{m-1}) \quad (A.2)$$

$$Q_n^{m-1,R} = Q_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_n^{m-1}) + Q_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_n^{m-1}) + Q_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_n^{m-1}) \quad (A.3)$$

$$M_t^{m-1,R} = M_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_t^{m-1}) + M_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_t^{m-1}) + M_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_t^{m-1}) + (\mathbf{r}^m \times \mathbf{Q}^{m,L}) \cdot \mathbf{e}_t^{m-1} \quad (A.4)$$

$$M_b^{m-1,R} = M_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_b^{m-1}) + M_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_b^{m-1}) + M_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_b^{m-1}) + (\mathbf{r}^m \times \mathbf{Q}^{m,L}) \cdot \mathbf{e}_b^{m-1} \quad (A.5)$$

$$M_n^{m-1,R} = M_t^{m,L}(\mathbf{e}_t^m \cdot \mathbf{e}_n^{m-1}) + M_b^{m,L}(\mathbf{e}_b^m \cdot \mathbf{e}_n^{m-1}) + M_n^{m,L}(\mathbf{e}_n^m \cdot \mathbf{e}_n^{m-1}) + (\mathbf{r}^m \times \mathbf{Q}^{m,L}) \cdot \mathbf{e}_n^{m-1} \quad (A.6)$$

$$\phi_n = -(\mathrm{d}w_b/\mathrm{d}s + \tau w_n) \quad (A.7)$$

$$\phi_b = \mathrm{d}w_n/\mathrm{d}s + \kappa w_t - \tau w_b \quad (A.8)$$

$$\mathrm{d}w_t/\mathrm{d}s - \kappa w_n = Q_t/E_3 A \quad (A.9)$$

$$\mathrm{d}\phi_t/\mathrm{d}s - \kappa\phi_n = Z' + Z + \kappa(B + B') \quad (A.10)$$

$$\kappa\phi_t + \mathrm{d}\phi_n/\mathrm{d}s - \tau\phi_b = X + X' - (\tau N + B'' + \tau N' + B''') \quad (A.11)$$

$$\mathrm{d}\phi_b/\mathrm{d}s + \tau\phi_n = Y + Y' + N'' - \tau B + N'''' - \tau B', \quad (A.12)$$

where

$$X = \left\{\left(\frac{\cos^2\theta}{E_3 I_1} + \frac{\sin^2\theta}{E_3 I_2}\right)M_n + \left(\frac{\sin\theta\cos\theta}{E_3 I_1} - \frac{\sin\theta\cos\theta}{E_3 I_2}\right)M_b\right\} \quad (A.13)$$

$$Y = \left\{\left(\frac{\sin\theta\cos\theta}{E_3 I_1} - \frac{\sin\theta\cos\theta}{E_3 I_2}\right)M_n + \left(\frac{\sin^2\theta}{E_3 I_1}\frac{\cos^2\theta}{E_3 I_2}\right)M_b\right\} \quad (A.14)$$

$$Z = \left(\frac{1}{G_{e\pi} J_3}\right)M_t \quad (A.15)$$

$$X' = \left\{\left(\frac{h_2\cos\theta}{E_3 I_1} + \frac{h_1\sin\theta}{E_3 I_2}\right)Q_t\right\} \quad (A.16)$$

$$Y' = \left\{\left(\frac{h_2\sin\theta}{E_3 I_1} - \frac{h_1\cos\theta}{E_3 I_2}\right)Q_t\right\} \quad (A.17)$$

$$Z' = \left\{\left(-\frac{[\chi_2\cos\theta + \chi_1\sin\theta]}{G_{e\pi} J_3}\right)Q_n + \left(-\frac{\chi_2\sin\theta}{G_{e\pi} J_3} + \frac{\chi_1\cos\theta}{G_{e\pi} J_3}\right)Q_b\right\} \quad (A.18)$$

$$B = \left\{\left(\frac{\sin\theta\cos\theta}{\alpha_1 G_{13} A} - \frac{\sin\theta\cos\theta}{\alpha_2 G_{23} A}\right)Q_n + \left(\frac{\sin^2\theta}{\alpha_1 G_{13} A} + \frac{\cos^2\theta}{\alpha_2 G_{23} A}\right)Q_b\right\} \quad (A.19)$$

$$N = \left\{\left(\frac{\cos^2\theta}{\alpha_1 G_{13} A} + \frac{\sin^2\theta}{\alpha_2 G_{23} A}\right)Q_n + \left(\frac{\sin\theta\cos\theta}{\alpha_1 G_{23} A} - \frac{\sin\theta\cos\theta}{\alpha_2 G_{23} A}\right)Q_b\right\} \quad (A.20)$$

$$B' = \{[(\mu_1\sin\theta + \mu_2\cos\theta)M_t]\}^{\cdot} \quad (A.21)$$

$$N' = \{(\mu_1\cos\theta - \mu_2\sin\theta)M_t\}^{\cdot}. \quad (A.22)$$

$$B'' = \left(\frac{\sin 2\theta}{2}\right)\left(\frac{1}{\alpha_1 G_{13}} - \frac{1}{\alpha_2 G_{23}}\right)\frac{\mathrm{d}}{\mathrm{d}s}\left(\frac{Q_n}{A}\right) + (\cos 2\theta) \times \left(\frac{\mathrm{d}\theta}{\mathrm{d}s}\right)\left(\frac{1}{\alpha_1 G_{13}} - \frac{1}{\alpha_2 G_{23}}\right)\left(\frac{Q_n}{A}\right) + \left(\frac{\sin 2\theta}{2}\right) \times \left(\frac{Q_n}{A}\right)\left[\frac{1}{(\alpha_2 G_{23})^2}\frac{\mathrm{d}(\alpha_2 G_{23})}{\mathrm{d}s} - \frac{1}{(\alpha_1 G_{13})^2} \times \frac{\mathrm{d}(\alpha_1 G_{13})}{\mathrm{d}s}\right] + \left(\frac{\sin^2\theta}{\alpha_1 G_{13}} + \frac{\cos^2\theta}{\alpha_2 G_{23}}\right)\frac{\mathrm{d}}{\mathrm{d}s}\left(\frac{Q_b}{A}\right) + \frac{Q_b}{A}\left[\left(\frac{1}{\alpha_1 G_{13}}\right)\sin 2\theta\frac{\mathrm{d}\theta}{\mathrm{d}s} - \frac{1}{(\alpha_1 G_{13})^2}\frac{\mathrm{d}(\alpha_1 G_{13})}{\mathrm{d}s} \times \sin^2\theta - \left(\frac{1}{\alpha_2 G_{23}}\right)\sin 2\theta\left(\frac{\mathrm{d}\theta}{\mathrm{d}s}\right) - \left(\frac{1}{\alpha_2 G_{23}}\right)^2 \times \frac{\mathrm{d}(\alpha_2 G_{23})}{\mathrm{d}s}\cos^2\theta\right] \quad (A.23)$$

$$N'' = \left(\frac{\cos^2\theta}{\alpha_1 G_{13}} + \frac{\sin^2\theta}{\alpha_2 G_{23}}\right)\frac{\mathrm{d}}{\mathrm{d}s}\left(\frac{Q_n}{A}\right) + \left(\frac{Q_n}{A}\right)\left[-\left(\frac{1}{\alpha_1 G_{13}}\right) \times \sin 2\theta\left(\frac{\mathrm{d}\theta}{\mathrm{d}s}\right) - \frac{1}{(\alpha_1 G_{13})^2}\frac{\mathrm{d}(\alpha_1 G_{13})}{\mathrm{d}s}\cos^2\theta + \left(\frac{1}{\alpha_2 G_{23}}\right)\sin 2\theta\left(\frac{\mathrm{d}\theta}{\mathrm{d}s}\right) - \left(\frac{1}{\alpha_2 G_{23}}\right)^2\frac{\mathrm{d}(\alpha_2 G_{23})}{\mathrm{d}s} \times \sin^2\theta + \left(\frac{\sin 2\theta}{2}\right)\left(\frac{1}{\alpha_1 G_{13}} - \frac{1}{\alpha_2 G_{23}}\right)\frac{\mathrm{d}}{\mathrm{d}s}\left(\frac{Q_b}{A}\right) + \cos 2\theta\left(\frac{\mathrm{d}\theta}{\mathrm{d}s}\right)\left(\frac{1}{\alpha_1 G_{13}} - \frac{1}{\alpha_2 G_{23}}\right)\left(\frac{Q_b}{A}\right) + \left(\frac{\sin 2\theta}{2}\right)\left(\frac{Q_b}{A}\right)\left[\frac{-1}{(\alpha_1 G_{13})^2}\frac{\mathrm{d}(\alpha_1 G_{13})}{\mathrm{d}s} + \frac{1}{(\alpha_2 G_{23})^2} \times \frac{\mathrm{d}(\alpha_2 G_{23})}{\mathrm{d}s}\right] \quad (A.24)$$

$$B''' = (\mu_1\sin\theta + \mu_2\cos\theta)\frac{\mathrm{d}M_t}{\mathrm{d}s} + M_t\left[\mu_1\cos\theta\frac{\mathrm{d}\theta}{\mathrm{d}s} + \sin\theta\frac{\mathrm{d}\mu_1}{\mathrm{d}s} - \mu_2\sin\theta\frac{\mathrm{d}\theta}{\mathrm{d}s} + \cos\theta\frac{\mathrm{d}\mu_2}{\mathrm{d}s}\right] \quad (A.25)$$

$$N''' = (\mu_1\cos\theta - \mu_2\sin\theta)\frac{\mathrm{d}M_t}{\mathrm{d}s} + M_t\left[-\mu_1\sin\theta\frac{\mathrm{d}\theta}{\mathrm{d}s} + \cos\theta\frac{\mathrm{d}\mu_1}{\mathrm{d}s} - \mu_2\cos\theta\frac{\mathrm{d}\theta}{\mathrm{d}s} - \sin\theta\frac{\mathrm{d}\mu_2}{\mathrm{d}s}\right] \quad (A.26)$$

APPENDIX B

The equations of equilibrium and continuity for a node are

$$M_t^{m,L} + C_t^m\phi_t^{m,L} = M_t^{m,R} + m_t^m \quad (B.1)$$

$$M_b^{m,L} + C_b^m\phi_b^{m,L} = M_b^{m,R} + m_b^m \quad (B.2)$$

$$M_n^{m,L} + C_n^m\phi_n^{m,L} = M_n^{m,R} + m_n^m \quad (B.3)$$

$$Q_t^{m,L} + c_t^m w_t^{m,L} = Q_t^{m,R} + q_t^m \quad (B.4)$$

$$Q_b^{m,L} + c_b^m w_b^{m,L} = Q_b^{m,R} + q_b^m \quad (B.5)$$

$$Q_n^{m,L} + c_n^m w_n^{m,L} = Q_n^{m,R} + q_n^m \quad (B.6)$$

$$\phi_t^{m,L} = \phi_t^{m,R} \quad (B.7)$$

$$\phi_b^{m,L} = \phi_b^{m,R} \quad (B.8)$$

$$\phi_n^{m,L} = \phi_n^{m,R} \quad (B.9)$$

ClearCorrect Exhibit 1002, Page 1310 of 3373

$$w_t^{m,L} = w_t^{m,R} \quad \text{(B.10)}$$

$$w_b^{m,L} = w_b^{m,R} \quad \text{(B.11)}$$

$$w_n^{m,L} = w_n^{m,R}. \quad \text{(B.12)}$$

APPENDIX C

The equations which govern the geometric characteristics of the center-line of an appliance having a spatial configuration are

$$\mathbf{R}(s) = x(s)\mathbf{i} + y(s)\mathbf{j} + z(s)\mathbf{k} \quad \text{(C.1)}$$

$$\mathbf{e}_t = d\mathbf{R}/ds \quad \text{(C.2)}$$

$$\kappa = |d\mathbf{e}_t/ds| \quad \text{(C.3)}$$

$$\mathbf{e}_n = (1/\kappa)\, d\mathbf{e}_t/ds \quad \text{(C.4)}$$

$$\mathbf{e}_b = \mathbf{e}_t \times \mathbf{e}_n \quad \text{(C.5)}$$

$$\tau = |d\mathbf{e}_b/ds| \quad \text{(C.6)}$$

$$d\mathbf{e}_t/ds = \kappa\mathbf{e}_n \quad \text{(C.7)}$$

$$d\mathbf{e}_n/ds = \kappa\mathbf{e}_t + \tau\mathbf{e}_b \quad \text{(C.8)}$$

$$d\mathbf{e}_b/ds = -\tau\mathbf{e}_n. \quad \text{(C.9)}$$

These equations are also known as the Serret–Frenet equations.

APPENDIX D

Table 1. Standard retraction spring

	Deactivated			Activated					
				Linear solution			Nonlinear solution		
PT.	X	Y	Z	X	Y	Z	X	Y	Z
1	0	0	0	0	0	−1.325	0	0	−1.20
5	0		2.6	−0.114		1.276	−0.107		1.398
10	0		4.05	−0.276		2.726	−0.260		2.841
15	0		4.3	−0.312		2.976	−0.293		3.090
20	0		4.55	−0.384		3.241	−0.335		3.342
25	0.148		4.743	−0.365		3.489	−0.257		3.545
30	0.4		4.75	−0.189		3.569	−0.071		3.627
35	0.65		4.75	0.061		3.612	0.177		3.669
40	1.962		4.75	1.374		3.861	1.47		3.911
45	4.9		4.75	4.311		4.433	4.365		4.472
50	7.444		4.776	6.833		4.835	6.791		4.97
55	8.00		5.5	7.352		5.49	7.225		5.48
60	7.444		6.224	6.85		6.196	6.841		6.119
65	4.9		6.25	4.311		6.567	4.351		6.551
70	1.962		6.25	1.374		7.139	1.452		7.089
75	0.65		6.25	0.061		7.388	0.157		7.321
80	0.4		6.25	−0.189		7.431	−0.088		7.361
85	0.148		6.257	−0.365		7.511	−0.278		7.446
90	0		6.45	−0.39		7.757	−0.328		7.642
95	0		6.7	−0.312		8.024	−0.298		7.901
100	0		6.95	−0.277		8.274	−0.244		8.158
105	0		8.4	−0.114		9.724	−0.1		9.602
109	0	0	11.0	0	0	12.325	0	0	12.2

Table 2. 20° retraction spring

	Deactivated			Activated					
				Linear solution			Nonlinear Solution		
PT.	X	Y	Z	X	Y	Z	X	Y	Z
1	0.946	0	0.166	0.026	0	0.166	0.028	0	0.166
5	0.572		1.192	−0.031		1.308	−0.021		1.262
10	0.106		2.475	−0.194		2.702	−0.188		2.62
15	0.004		2.840	−0.227		3.086	−0.188		3.039
20	0.074		2.955	−0.138		3.191	−0.098		3.145
25	0.2		3.000	0.011		3.231	0.068		3.191
30	2.850		3.000	2.647		3.006	2.691		2.991
35	5.5		3.000	5.297		3.013	5.341		3.007
40	5.854		3.146	5.650		3.148	5.694		3.147
45	6.000		3.500	5.796		3.500	5.84		3.500
50	5.854		3.854	5.65		3.853	5.694		3.853
55	5.500		4.000	5.297		3.987	5.341		3.993
60	2.850		4.000	2.647		3.994	2.691		4.009
65	0.200		4.000	0.011		3.769	0.067		3.809
70	0.074		4.045	−0.138		3.809	−0.098		3.855
75	0.004		4.160	−0.227		3.914	−0.188		3.961
80	0.106		4.525	−0.194		4.298	−0.188		4.380
85	0.572		5.808	−0.031		5.692	−0.021		5.738
89	0.946	0	6.834	0.026	0	6.834	0.028	0	6.834

ClearCorrect Exhibit 1002, Page 1311 of 3373

Table 3. Rectangular loop

PT.	Deactivated X	Y	Z	Activated Linear solution X	Y	Z	Activated Nonlinear solution X	Y	Z
1	0	0	0	0	0	0	0	0	0
5	1.657		0	1.657		−0.085	1.655		−0.085
10	3.729		0	3.729		−0.396	3.707		−0.399
15	5.428		0	5.428		−0.779	5.37		−0.787
20	5.583		0	5.583		−0.818	5.52		−0.827
25	5.738		0	5.738		−0.858	5.671		−0.868
30	5.891		0.022	5.9		−0.873	5.831		−0.864
35	5.990		0.138	6.036		−0.783	5.956		−0.79
40	6.000		0.293	6.09		−0.634	6.028		−0.658
45	6.000		0.448	6.132		−0.479	6.062		−0.507
50	6.000		0.760	6.218		−0.167	6.153		−0.206
55	6.000		3.560	7.085		2.633	7.037		2.481
60	6.000		5.459	7.763		4.532	7.702		4.286
65	6.000		5.614	7.821		4.687	7.753		4.428
70	6.000		5.769	7.874		4.823	7.826		4.585
75	6.038		5.918	7.933		4.883	7.886		4.636
80	6.169		5.998	8.068		4.881	7.981		4.642
85	6.324		6.000	8.197		4.776	8.088		4.577
90	6.479		6.000	8.352		4.715	8.26		4.546
95	7.720		6.000	9.593		4.22	9.441		4.097
100	11.52		6.000	13.393		2.710	13.065		2.809
105	13.49		6.000	15.362		2.027	14.955		2.271
110	13.64		6.000	15.513		1.977	15.06		2.226
115	13.80		6.000	15.588		1.894	15.1		2.16
120	13.94		5.941	15.583		1.752	15.06		2.035
125	14.00		5.800	15.51		1.553	15.063		1.897
130	14.00		5.645	15.389		1.366	14.991		1.76
135	14.00		5.49	15.345		1.211	14.869		1.541
140	14.00		4.12	15.00		−0.16	14.641		0.182
145	14.00		1.32	14.517		−2.96	14.372		−2.611
150	14.00		0.479	14.428		−3.801	14.256		−3.455
155	14.00		0.324	14.409		−3.857	14.2		−3.615
160	14.00		0.169	14.27		−4.112	14.09		−3.769
165	13.92		0.038	14.106		−4.234	13.951		−3.895
170	13.77		0	13.812		−4.282	13.762		−3.952
175	13.61		0	13.615		−4.273	13.613		−3.953
180	13.46		0	13.46		−4.264	13.457		−3.953
185	11.99		0	11.987		−4.213	11.986		−3.976
190	9.72		0	9.72		−4.217	9.72		−4.054
195	7.453		0	7.453		−4.246	7.452		−4.113
196	7.00	0	0	7.000	0	−4.247	7.000	0	−4.115

ClearCorrect Exhibit 1002, Page 1312 of 3373

Table 3. Rectangular loop

	Deactivated			Activated Linear solution			Activated Nonlinear solution		
PT.	X	Y	Z	X	Y	Z	X	Y	Z
1	0	0	0	0	0	0	0	0	0
5	1.657		0	1.657		−0.085	1.655		−0.085
10	3.729		0	3.729		−0.396	3.707		−0.399
15	5.428		0	5.428		−0.779	5.37		−0.787
20	5.583		0	5.583		−0.818	5.52		−0.827
25	5.738		0	5.738		−0.858	5.671		−0.868
30	5.891		0.022	5.9		−0.873	5.831		−0.864
35	5.990		0.138	6.036		−0.783	5.956		−0.79
40	6.000		0.293	6.09		−0.634	6.028		−0.658
45	6.000		0.448	6.132		−0.479	6.062		−0.507
50	6.000		0.760	6.218		−0.167	6.153		−0.206
55	6.000		3.560	7.085		2.633	7.037		2.481
60	6.000		5.459	7.763		4.532	7.702		4.286
65	6.000		5.614	7.821		4.687	7.753		4.428
70	6.000		5.769	7.874		4.823	7.826		4.585
75	6.038		5.918	7.933		4.883	7.886		4.636
80	6.169		5.998	8.068		4.881	7.981		4.642
85	6.324		6.000	8.197		4.776	8.088		4.577
90	6.479		6.000	8.352		4.715	8.26		4.546
95	7.720		6.000	9.593		4.22	9.441		4.097
100	11.52		6.000	13.393		2.710	13.065		2.809
105	13.49		6.000	15.362		2.027	14.955		2.271
110	13.64		6.000	15.513		1.977	15.06		2.226
115	13.80		6.000	15.588		1.894	15.1		2.16
120	13.94		5.941	15.583		1.752	15.06		2.035
125	14.00		5.800	15.51		1.553	15.063		1.897
130	14.00		5.645	15.389		1.366	14.991		1.76
135	14.00		5.49	15.345		1.211	14.869		1.541
140	14.00		4.12	15.00		−0.16	14.641		0.182
145	14.00		1.32	14.517		−2.96	14.372		−2.611
150	14.00		0.479	14.428		−3.801	14.256		−3.455
155	14.00		0.324	14.409		−3.857	14.2		−3.615
160	14.00		0.169	14.27		−4.112	14.09		−3.769
165	13.92		0.038	14.106		−4.234	13.951		−3.895
170	13.77		0	13.812		−4.282	13.762		−3.952
175	13.61		0	13.615		−4.273	13.613		−3.953
180	13.46		0	13.46		−4.264	13.457		−3.953
185	11.99		0	11.987		−4.213	11.986		−3.976
190	9.72		0	9.72		−4.217	9.72		−4.054
195	7.453		0	7.453		−4.246	7.452		−4.113
196	7.00	0	0	7.000	0	−4.247	7.000	0	−4.115

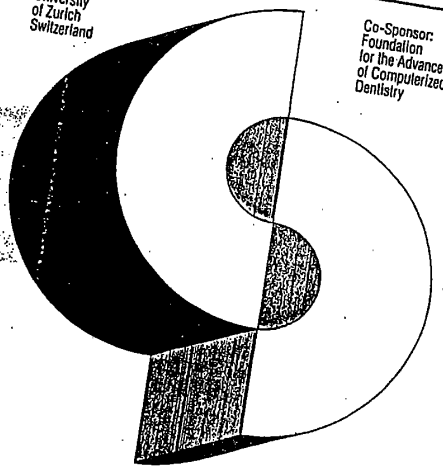
ClearCorrect Exhibit 1002, Page 1313 of 3373

Dental Institute
University of Zurich
Plattenstrasse 11
CH-8028 Zürich, Switzerland
Phone 01-257 32 72
Fax 01-252 32 88

May 1991

Dental Institute
University
of Zurich
Switzerland

Co-Sponsor:
Foundation
for the Advancement
of Computerized
Dentistry



INTERNATIONAL SYMPOSIUM ON COMPUTER RESTORATIONS

State of the Art of the CEREC-Method

3 – 4 May 1991
Hotel Mövenpick
Regensdorf-Zurich
Switzerland

Program and Abstracts

ClearCorrect Exhibit 1002, Page 1314 of 3373

Friday, 3 May 1991:

SCIENTIFIC PROGRAM

ESSION III B: :30 - 6:15 pm	*SHORT COMMUNICATIONS: Experience with the CEREC-Method in Private Practices in Five Countries*	
Chairman: Co-Chairman	B. Reiss S. Carlsen	
resentation Time: 10 min;	Discussion Period: 5 min	
:30 - 4:45 pm	F. Geiger Switzerland	The Cerec-Method in a Swiss Private Practice
:45 - 5:00 pm	R. Schwärzler Switzerland	Experience with Cerec Restorations in a Zurich Private Practice.
:00 - 5:15 pm	S. Carlsen Denmark	A practice specialized on Cerec-Restorations in Denmark
15 - 5:30 pm	R. Siervo & S. Siervo Italy	Cerec Veneers on Natural Teeth and Prosthetic Elements: Italian Experiences.
30 - 5:45 pm	J. M. Leobold France	Experience with Cerec in a Mulhouse Private Practice.
45 - 6:00 pm	B. Reiss/ W. Walther Germany	Life-Time Analysis and Clinical Evaluation of Cerec-Restorations
00 - 6:15	R. W. Nash & USA J. Beutell USA	a) The use of the Cerec in an all-cosmetic Practice b) The Change from Gold-Inlays (Metallics) to Cerec-Ceramics.
5 pm	End of Afternoon Session	

Location: Hotel Mövenpick, CH-8105 Regensdorf/Switzerland
Phone 41-1-840 2520
Fax 41-1-840 2941

Time:
Scientific Program:
Friday, 3 May 1991, 1:30 pm - 6:15 pm
Saturday, 4 May 1991, 8:00 am - 1:30 pm

Course Directors Meeting:
Friday, 3 May 1991, 10:00 am - 12:00 pm

Registration: Hotel Mövenpick
Friday, 3 May 1991, 9:00 am - 1:00 pm

Slide Review Room: Friday, 3 May 1991, 8:00 am - 7:00 pm
Saturday, 4 May 91, 7:00 am - 1:30 pm

Registration Fees:
Scientific Program including coffe, Aperitif, Get-Together-Party 3 May SFr. 480.--
Get-Together Party on 3 May 1991 for accompanying person(s) each SFr. 50.--

Accommodation

A block of rooms has been reserved at the following three Hotels:

Hotel Mövenpick, CH-8105 Regensdorf (phone 41-1-840 2520, Fax 41-1-840 2941)
Hotel Trend, Eichwatt, CH-8105 Regensdorf (phone 41-1-870 0040, Fax 41-1-870 0255)
Hotel International, Am Marktplatz, CH-8050 Zurich-Oerlikon
(phone 41-1-311 4341, Fax 41-1-312 4468)
Transport to Regensdorf provided.

For further hotel reservations please contact Zurich Tourist Office, Bahnhofplatz 15, CH-8001 Zurich (phone 41-1-211 40 00, Fax 41-1-211 3981).

Transportation

There is free shuttle bus service from the Airport to both hotels (Mövenpick and International). Parking lots are available at both hotels. Free shuttle from 'International' Hotel to Mövenpick, Regensdorf.

Information:

Dental Institute
ISCR Office
Plattenstrasse 11
CH-8028 Zurich/Switzerland

Tel. 41-1-257 3272
Fax 41-1-252 3288

ClearCorrect Exhibit 1002, Page 1315 of 3373

1 TABLE OF CONTENTS

Contents

1 TABLE OF CONTENTS 4

2 Identification and Significance of the Innovation 5

3 Phase I Technical Objectives 8

3.1 Improvement of Prototype Hardware 8

3.2 3-D Modeling of Dental Surfaces 8

3.3 Integration of X-Ray Data with 3-D Models 8

3.4 Design Specification of Fabrication Machine 9

4 Phase I Research Plan 9

5 Commercial Potential 10

6 Company Information and Management Team 12

6.1 Dentrac Patents 12

6.2 Management Team 14

7 Consultants and Subawards 17

8 Equipment, Instrumentation Computers and Facilities 20

9 Equivalent or Overlapping Proposals to Other Federal Agencies 20

11 Summary Proposal Budget 20

11.1 Budget Justification 20

12 Prior SBIR/STTR Phase II Awards 22

13 References 22

ClearCorrect Exhibit 1002, Page 1316 of 3373

2 Identification and Significance of the Innovation

Dentistry has yet to capitalize on the many advances in computer and sensing technology that have become pervasive in other disciplines such as Medicine and Engineering. A visit to the dentist today is little changed from 40-50 years ago, particularly with respect to equipment and procedures. The tools are still hand operated, and much of the critically accurate work on tooth surfaces is done by visual observation and reliance on the dentist's own expertise.

DenTrac Corporation, through the efforts of its founder Dr. David Mushabac, a practicing dentist with 4 decades of experience in the field, has pursued a strategy of inventing, patenting and exploiting sensor and computer technology to allow the dentist to take the guess work out of critical metric measurements on teeth, and to create a fully digital model of the teeth, gums, and other intra-oral surfaces that can be used for patient treatment, diagnosis and continuing care.

The most important piece of this innovation is the DenTrac Probe Stylus (DPS), shown in Figure 1. This is a unique, multi-patented dental instrument for determining coordinate measurements inside the mouth that takes advantage of advances in computer technology, laser positioning, and 3-D imaging. The hand-held dental digitizer has a stylus that operates with an integrated contact tip that reads coordinate X, Y, Z positions with 5-30 micron accuracy at 30 Hz using a unique amorphous silicon sensor. While there have been other devices built to perform contact measurement, none are as accurate and as potentially inexpensive as the DPS. For example, the Microscribe, a well known 3-D digitizer, has resolutions of only hundreds of microns, which is too coarse for dental and many other applications. Further, the DPS has an integrated design that is consistent with many current dental devices, and can be retrofitted and integrated to an existing dental tool suite in a Dentist's office.

The DPS hand instrument traces tooth, gingiva and intra-oral surfaces, capturing the dental surface contact point and displays each point of contact in 3-D. By visualizing the points, the operator can determine which areas need to be scanned, and the proper scanning resolution. Because the points are extremely accurate, on-line metric measurements of distances on the teeth are possible, and are part of the proposed integrated software that will be developed in Phase I. This software will allow integration of the shape of the instrument in the operator's hand into the visualization screen. This can be viewed with the instrument's full position-orientation as trace-contacts are made over dental surfaces. Such "live" surface records can inform the dentist of where and how the instrument is oriented in relation to the dental volume area and to the operative task performed intra-orally. One can observe the instrument's motions and graphic positions, both in time and in perspective, as the operator moves the stylus or drill over surfaces of teeth or gingiva. The instrument will be pictured within its full dimension and precise shape in real-time as the operator scans over surfaces of teeth or gingiva. In parallel, while operating on the patient, the dentist can view all instrument positions and relative locations, even of subsurface digitized X-rays of such related areas. The complete, animated, on-line operative process with precise dimensions will appear in any selected perspective, one that is graphically displayed as part of the 3-D programs. A record of all 3-D data can be kept along with

[illegible] with all the original scan dimensions, the operator can pause/halt at any procedure and use the DenTrac System Resources to proceed in a Virtual Mode. This means a preparation form (e.g. a crown or inlay), can be performed in a virtual setting, testing designs and creating custom fit inlays, consistent with the patient's own teeth. In addition, the virtual mode of operation serves as a powerful learning tool for educating practitioners. Instructions can be utilized and programmed from prior resourced information in files, creating a library of forms to be used by the dentist.

The probe unit and its contact stylus has been designed to fit and satisfy the Dentist's usual work-practice requirements. For example, the tip end, or stylus of the Probe unit is a piece out of every practitioner's everyday instruments inventory. The DPS is designed to accept common tools such as drills, explorers, curettes, root-canal files, perio-charting measurement probes as add-on end-effector tooling. Given the dimensions of these end effectors, the 3-D positions of the new tools can be read out with a simple transformation to the new tooling endpoint. A Dentist's inventory of every day instruments can be scanned and the dimensions recorded for later use with the DenTrac ssytem. The graphics visualization will also include this new tooling on the operator screen for visualization of the procedure. Whatever instrument is handled by the dentist is what appears and moves in replicated pictures, as a graphic animation of the user's hand motions. A related application for use of such technology is as a teaching platform, where the operative methods can be animated for viewing and teaching of dental procedures, DenTrac has a hierarchy of patents applicable for Distance Instruction of Dentistry and General Surgery, and can make the idea of virtual dental training a reality (see section 6.1).

ClearCorrect Exhibit 1002, Page 1317 of 3373

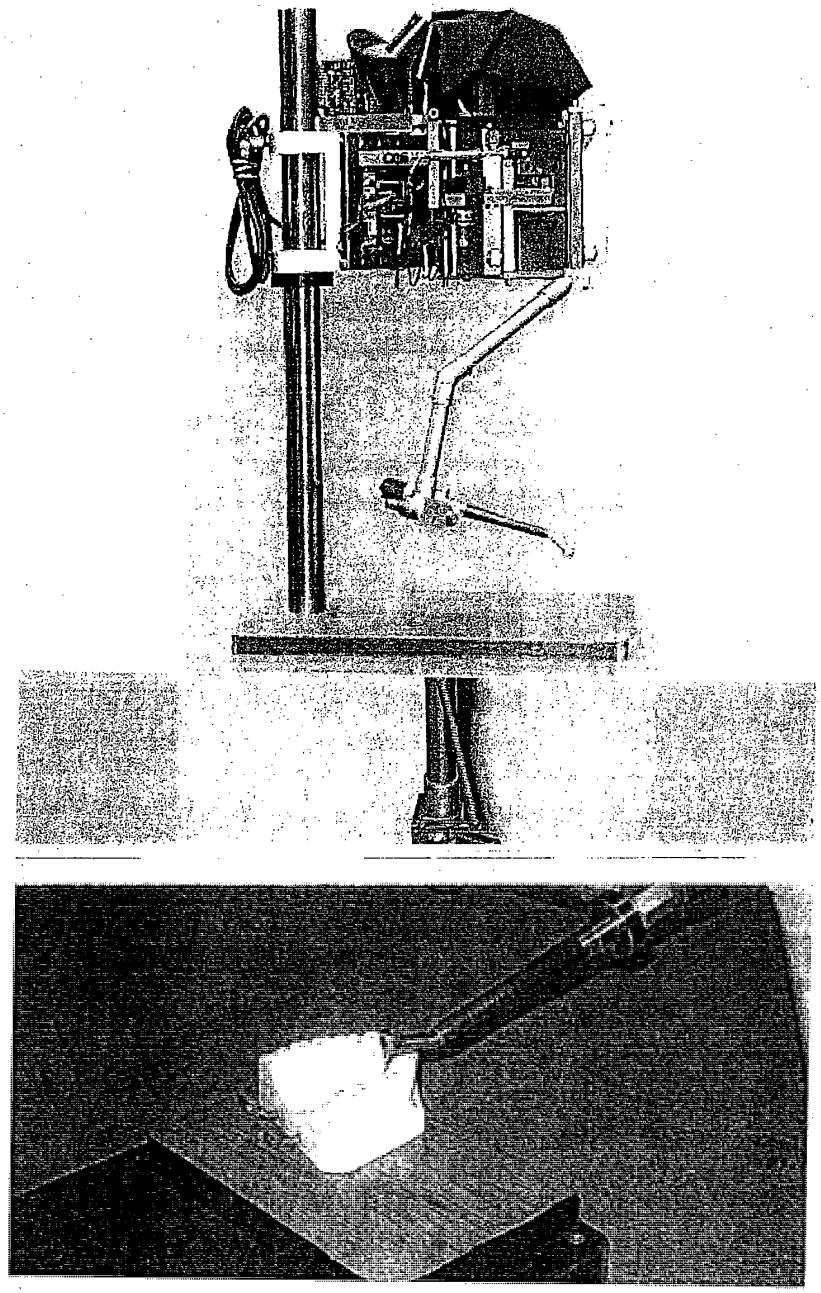


Figure 1: DenTrac Probe Stylus with position sensing apparatus.

ClearCorrect Exhibit 1002, Page 1318 of 3373

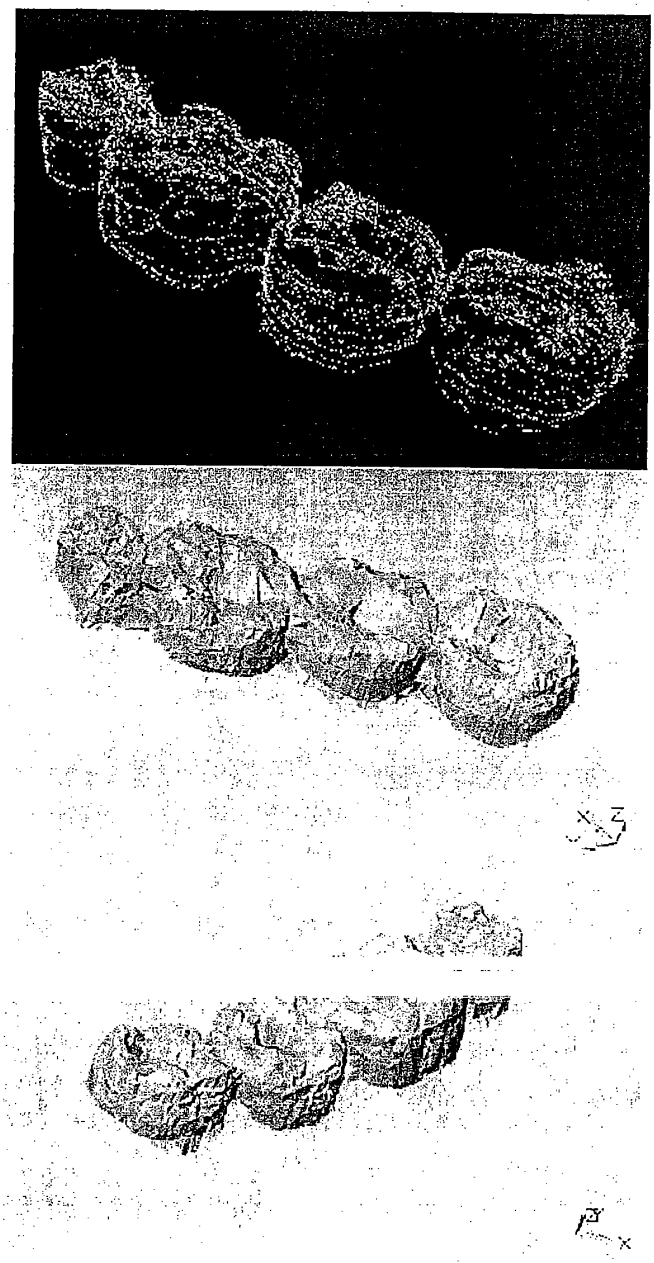


Figure 2: Top: Visualized contact points from DenTrac Probe Stylus. Bottom: 3-D Surface models built from acquired points

ClearCorrect Exhibit 1002, Page 1319 of 3373

3 Phase I Technical Objectives

The present prototype state of the DenTrac instrument development has given us a bench mark position for bringing the DenTrac unit to the commercial market as a working unit for every dental practitioner. Currently, we have designed, tested and built a working prototype unit of the patented DPS unit providing 5 to 30 micron accuracy data points of any traced surface. The working prototype (see Figure 1) has been built by Dr. Mushabac, and is being used as a beta test machine for the applications discussed above.

We propose to build an integrated system as discussed above around this unique device that exploits 3-D computer visualization and geometric modeling techniques to create highly accurate models that can be visualized and manipulated by the dentist, using the DPS as the input source. We are also interested in designing the most useful operator interface to assist the dentist in a variety of procedures that create 3-D models of intra-oral structures. Once the models are completed, we can then add X-Ray data to the models to create a 3-D viewing environment with surface transparency to allow the dentist to visualize the interior surfaces of the teeth in a true 3-D surface model. As part of the research, we will also investigate methods to directly machine these models on a dental mill which DenTrac is also developing. The DenTrac system can replace slow, and inaccurate plaster casting with a fully digital, on-line, fast method of creating restorative builds. From the patient's perspective, this method is also much more appealing.

3.1 Improvement of Prototype Hardware

While the prototype has shown it can record data at the resolutions necessary, the device design needs to be improved to make it a user-friendly, hand-held practical dental tool. Redesign criteria includes refining linkage lengths, improving ease of handling and hand instrument approaches for reading dental structures. The unit currently reports data coordinates at 30 Hz. While this is entirely adequate for most dental operations, we would like to increase the update rate to 60 Hz.

We have also been investigating parallelizing the unit so that more than one contact point can be read at a time. One can envision a multifingered probe that can report multiple contacts at once. We expect to do the preliminary design of such a device in Phase I. We have a prior issued patent on a multi-stylus scanning unit which we can exploit.

The final designs for the unit will advance to market stage the prototype that we have been testing. It will provide valuable add-ons consistent to its dental functions, both intra-orally and on models.

3.2 3-D Modeling of Dental Surfaces

3-D modeling of these point sets presents some challenging research questions. In particular, we need to create highly accurate surface models that can be used to model and render the teeth and intra-oral surfaces. Simple triangular mesh polyhedral models can be built from the data points (see Figure 2). However, these models need to be smoothed and a NURBS based model may be preferable to provide a more accurate surface. We will explore a number of different modeling techniques to find the most accurate method.

Data filtering can also be performed on-line to filter out noise and outliers that can affect the modeling process. The models will be fully functional CAD surface models, allowing rendering, transparency, and boolean set operations to merge intra-oral surface models with prostheses models.

3.3 Integration of X-Ray Data with 3-D Models

A major advance that DenTrac is proposing is to merge X-Ray data with the models acquired using the DPS. This poses a difficult registration problem that includes merging 2-D X-ray data with the 3-D models for a live overlay of the 2 sensing modalities. This will involve finding appropriate registration points on both the model and the X-ray to compute the appropriate transforms from each coordinate system. In previous research [1, 6, 5, 7], Professor Allen (consultant on project) has worked extensively on registering 3-D data sets for reconstruction. These methods will be extended using 2-D edge finders on the X-Ray data and 3-D curvature features on the modeled data. A set of candidate 2-D and 3-D

ClearCorrect Exhibit 1002, Page 1320 of 3373

features will be matched, and then these matches will be further refined using a RANSAC process to complete the match and compute the appropriate coordinate transforms. Once the transforms have been computed, we can then overlay the data sets during the real-time visualization process. What the dentist will see is an actual live 3-D model of the patient overlaid on the X-Ray data.

The method to derive the registration transformation between 2-D and 3-D images is to find features in each image. Using these features, transformation parameters are gradually updated and refined until the views are precisely registered. A feedback function measuring the quality of the registration is used. This has been an active research area over the last few years; a recent paper [4] gives an overview of different methods in this category. These methods can break the hardware limit and enable us to register different views scanned from arbitrary view points.

Our method is a 2-step feature-based registration algorithm. In step 1 we derive the initial transformation from the features in the range data, such as points, edges and curvatures. Features in the 2-D images will be generated from edge detectors and linking programs that create chains of ede pixels. Then, in step 2, we apply our modified Iterative Closest Points (ICP) algorithm[2, 3]. We note that the second step is optional, since with objects with salient features, the output of step 1 may be accurate enough.

In the 3-D data, we will choose edge points that have a gradient over a threshold. Because points with a high gradient usually belong to the edges or contour of the object, they can form salient feature points. These points can then be joined by curves to get a highly structural description of the range data. Further, these characteristic curves are stable with respect to rigid transformations, and can tolerate partial occlusion due to their local nature - this is very important in our case.

The curvature-based method is not guaranteed to converge if there are no salient features on the surface of the object. In these cases, we can place fiducial marks on the intra-oral surfaces. These marks provide very good visual checkpoints to see how good the registration is, and they can be contacted by the DPS as well as seen on the X-Rays. Using fiducial marks, the registration becomes easy. We have experimented with special lead, inter-dental wedges which can be used for X-Ray coordinate references. These lead wedges can also be contacted by the stylus, making the point association for the registration. [1]

3.4 Design Specification of Fabrication Machine

One of the major benefits of the DPS is the ability to create highly accurate 3-D models of intra-oral surfaces. Once these models are created, they can be sent to a milling machine to create restorations, bridges and splinted copings, based on the DenTrac data collected in the probe read out. In phase I we expect to be able to do the initial design of the fabrication machine, including motor specification and cutter head design. We also will begin to develop the software to translate

quality, working efficiency and dental office work delivery time.

4 Phase I Research Plan

The Phase I project will result in: 1) A working DPS unit for the dental office which will provide 3-D readouts of a patient's dental data for charting and perio pocket recording, 2) 3-D digital models of intra-oral surfaces 3) integration of X-Ray data with the generated 3-D models, 4) specification for a machine fabrication unit to mill restorations based on data acquired via step 1 above.

The phase I research plan is divided among Dr. Mushabac, Mr. Polichi and Professor Allen. Each will be working on a coherent focused part of the proposal, with Dr. Mushabac and Ms. Konrad providing integration of each piece and further clinical testing.

The current hardware prototype will be upgraded and redesigned for a clinical setting. Our objective is to make a device that meshes with the current methods of the dentist, in both instrumentation and visualization. It is essential that the

[1] This registration method is DenTrac proprietary information

ClearCorrect Exhibit 1002, Page 1321 of 3373

system fits in with a dentist's current practices and procedures. We expect that this will take most of the 6 month period, but a working unit will be available at that time for clinical trial.

Professor Allen will initially focus on developing accurate, noise free 3-D surface models using NURBS. Once this is done (about 1-2 months into the contract period), the integration of X-Ray data into the models will begin. The registration procedure will be developed, and registration accuracy will be quantified. The final piece of software is the integrated viewing/user environment for these models. We expect this to take up the remaining time in the contract.

Dr. Mushabac will initially begin to create a design specification for the milling unit, which will be based upon prior DenTrac prototypes. This part of the proposal is somewhat ambitious, but the market potential for a fully integrated system from data acquisition to lab fabrication is compelling. By performing the design spec now, we can be in a position in phase II to actually create the machine. Dr. Mushabac will also be the lead clinical tester of the devices and software from a dentist's perspective.

5 Commercial Potential

The U.S. dental market is an estimated $45 Billion market, To exploit this market, DenTrac has developed and owns a patent hierarchy (see section 6.1) estimated in its present state value as a $12 million dollar intellectual property 'consortium". These are the DenTrac inventions, products, and generalized enabling tools for nearly all dental uses and types of treatments. The DenTrac instruments benefit each of the other products presently used by the profession, and can be easily integrated into the current practitioner's office. The Phase I funding will be instrumental in turning this intellectual property into a set of marketable and useful tools and procedures that can bring dentistry into a new digital era.

DenTrac's instruments and methods are tools for the generalist and the specialist, and they serve as an effective communication/transfer method for sharing of patient data and treatment protocols. DenTrac brings the fractionalization parts of the Dentist's present practice modes into an integrated advanced coherence, by linking all phases of dentistry to accurate 3-D models of teeth, gingiva, prostheses and other intra-oral surfaces. From the Dentist's perspective there are innate pleasures in the actual use of the tool as well as in the functions that allow proficiency for the users skills, and with profits and prestige from their work which is now far more accurate and precise.

The motivations and profits begin with use of the hand held DPS probe which digitizes shapes, contours and structures of the teeth. It records 3-D graphics and 3-D models, products the dentist uses in producing his/her own patient preparation forms, models, transfer data, outlines, etc. The dentist now has permanent easily retrievable models, which also provide an important time/change history for detecting patient problems and response to treatments. These models in each patient's

The uses of this system include:

- All charting information in 3-D, as seen, understood and traced by dentist
- 3-D record of perio conditions, again observed and trace-recorded by dentist.
- 3-D record of tooth forms, prior to any work on patient
- Original condition, and subsequent traces, maps of all conditions prior to treatment
- Upper and lower arches
- Output map following treatment, including perio conditions.
- Output map, during treatment which includes preparation forms for restorations, and comparisons of prior work.
- Graphic simulations of procedures appended to a case analysis
- X-Ray inclusion and integration as part of diagnostic models
- Tutorials using similar models in comparative teaching

ClearCorrect Exhibit 1002, Page 1322 of 3373

- Case planning, using stored models and prior work; tutorials
- Consultant participation, exploiting DenTrac's resources

All of the above become part of the dentist's marketing presentation to the patient. From a business perspective, all business analysis, records, modeling, charting consulting, transfer of records going to insurance carriers can be done based on the digital analysis and patient treatment with electronic routines.

The first market penetration can be classified as the preliminary work-up/analysis. Patients will have 3-D models recorded by the DenTrac system, and the electronic record of procedures can begin. This business management and recording data phase produces efficiency and work output that triples present modes, there by adding a significant overall gross income increase. This can be valued as a 25% income profit from the first set of applications.

The next platform benefits are for treatment, restorations and lab work delivery with patient insertion. The great income benefit after the initial setup in the practitioner's office is that it sets up and enables the fabrication process to take place easily as a natural extension of the DenTrac system. Thus the fractionated and distributed dental office/specialist/lab model becomes an easily integrated and more accurate and efficient delivery system to the patient, while incurring cost savings.

Besides general practitioners, the DenTrac system can be used by most other specialists to enhance their own business. Some examples follow.

Orthodontia: DenTrac teaches positioning in a tooth by tooth simulation; correlation between animated instruction and the dentist's actual work. Animated motion captures can be created as models are built over time during the movement of teeth. This can be a powerful marketing, teaching and treatment tool.

Periodontia: DenTrac records all stylus tip and instrument position motions, corresponding to actual treatments as the dentist provides for each patient's requirements. For perio treatments there are also important enhancements available. Simulation/instructions through animation of the "lesson" for each patient requirement. This is on the screen with the visualized hand motion unit. There is the individual case analysis demo, customized for each patient. This is interactive. As a result the dentist's treatment of the patient is observable on line and in 3-D graphics. There is a connective integration where each instrument used on patient is monitored, its output recorded and overlaid. The animation of the treatment is evaluated by a trace out of pocket "contours" and comparative overlays in 3-D, with color defining depths.

Endodontia: The graphics display can utilize the root canal tools as a stylus entering the canal. From that position/analysis an online display of all root canal work is monitored through DenTrac's integration of the prior images (including X-Rays) with the successive broach/file insertions. The picture on monitor is of the original X-Ray image

Full/Partial Prosthesis Dentistry: DenTrac's stylus can perform contact mapping directly on the patient's dentition/edentelous areas and provide measured details for the parameters of all framework contours. This readout is for both the contact side and the outer form of the restorative partial.

Operative Dentistry: The processes of preparation of tooth forms is significantly improved and graphically advanced. Blueprinted graphics of the optimum final preparation form, and virtual rendering is available through animated presentation of wrist motion/process for achieving the "classic" preparation and/or any modifications. Drill cut-offs to avoid faulty steps can also be provided with visual displays reinforcing the operative processes. This position feedback (DenTrac patented) means that display, motion and routes of operative contours that shape teeth can be integrated with displays of instrument positions. Boundary and depth can be displayed in color, informing the operator of drilling distances required for anticipated ideal forms. Integrated auditory feedback related to drilling actions and drill positions can improve clinical work.

Implant Dentistry: DenTrac enables the following to be integrated into delivery of optimum selection, position and build up for the implant. This includes selection of the best anchor site from 3-D graphics/position analysis and selection of ideal implant dimension for that particular patient site. This will enable selection of an available match from all manufacturer's inventory in program data base. It will also provide virtual animation of the process of doing implant delivery for each/any selected case. The process of anchorage site drilling is accompanied with graphic display of burr position related to optimum pre-selected "tunnel" path, for insertion of the implant. DenTrac also has patented drill cut off,

ClearCorrect Exhibit 1002, Page 1323 of 3373

with warning signal, to maintain path accuracy.

Dental Education: The DenTrac system can revolutionalize the teaching of dentistry. All tool positions are continuously monitored, and can be replayed with 3-D graphics, along with graphical renderings of the mouth and intra-oral surfaces. Students can visualize procedures before they need to work on real patients, as well as simulating treatments and designing new forms of treatment by interacting with the models.

We have projected the cost of the initial DPS unit to be in the $25-$30K range. At this pricing, a dentist can expect a payback in less than 2 years which is within normal equipment purchase parameters.

6 Company Information and Management Team

DenTrac Corporation was formed in March 1994 to commercialize unique and significant technology based on patents by its Founder and President, Dr. David R. Mushabac. This patent portfolio is owned jointly by DenTrac Corp and Dr. Mushabac and has an assessed valuation of over $12 million dollars, an amount projected by a licensed evaluation group (documents available).

Dr. Mushabac has been engaged since 1948 in the private practice of dentistry and has long served on the faculty of a number of leading Dental Schools and Institutions including New York University, College of Dentistry and Suny Computer Center at Stony Brook. In addition, he has served as a consultant to many major American companies including IBM, ITEK, Raymond Lowey Co. and the Cincinnati Milling Machine Co., Inc. The DenTrac products are based on original designs for 3-D systems and motion control technologies. The presently planned motion unit based on the issued patents has an outlet market through a major global dental supplier.

DenTrac has designed and built a unique dental product which is a 3-D hand held scanning unit. This technology enables 3 dimensional objects to be scanned into a computer, complete with XYZ coordinates by employing a proprietary combination of a hand held touch scanning probe with electro-optical scanning technology. This technology opens up many areas in almost every industry where individual and customized CAD/CAM solutions are required, enabling them to be easily and economically managed. However, our major and first market is the 45 Billion (U.S.A.) dental market, with 3x that globally.

The Company has a strategic alliance for ongoing development with EG&G (a Fortune 500 Company) to exploit a novel sensor they have developed which is ported into DenTrac's working product, one that fills a unique niche in DenTrac's patented technology. DenTrac Corp has a strategic alliance with EG&G for exploitation of the unique combination

and mechanical configurations which are specifically

ing know-how, capacities and their interest in adapting for manufacturing has motivated their dedication to and cooperation with DenTrac.

6.1 Dentrac Patents

Below is a listing of the Patent hierarchy developed at Dentrac. This set of patents is unique in its coverage of all aspects of the dental process including hardware/sensing, 3-D modeling, data acquisition, hand instrumentation, and application methods. It establishes DenTrac as the sole provider of a fully integrated "solution" to the advancement of digital dentistry. Further, the range of patents means that DenTrac can develop this market carefully, from initial use of the DPS probe to more and more extensive applications in dentistry.

U.S Patent #3,971,133 The patent covers the fabrication method for the manufacturing of dental crowns and bridges by use of ultrasonic material removal drills. The prototype on this unit has been designed, built and tested. It is presently operational and used as the building unit for the next generation in office instrumentation system. In this method a porcelain prefab is shaped by a metal model of the prepared tooth. The new upgraded model will function as an advanced fabrication unit, an improved "universal" system for manufacturing of crowns, bridges, full dentures, partial framework, partial and hybrid implants. This unit is customized to operate in the dental office in an integrated manner with new hardware designs.

ClearCorrect Exhibit 1002, Page 1324 of 3373

U.S. Patent #4,182,312 This patent covers the hand-held probe unit for scanning dental surfaces. It is the first of a continuous upgraded technology capturing operator's motions during use of hand held tools, surgical and otherwise.

U.S. Patent #5,017,139 This is a generic patent for the hand held probe for the scanning of dental intra-oral, head, neck and face structures. This probe unit can function within various size cube envelopes, from a tooth size to face dimensions. As such it has applications for continued education, and for teaching and monitoring surgery and for operating room assisting.

U.S. Patent #5,257,184 This patent delivers upgrades and innovations to the prior probe unit #4,182,312 and expands original design from mechanical connection to non-physical and optical sensor input thereby providing the operator with full manual freedoms and 3-D read outs in measured displays. It also teaches novel means for turnaround surface scanning of full anatomic/dental areas with recorded clouds of information of the desired dental/facial areas. Also, in this patent proprietary designs for multi-stylus scanning has been granted.

U.S. Patent #5,343,391 This patent continues the processes of interactive analysis for treatment and clinical care. An instrument scans and records 3-D contour data of intra oral and facial/head/neck structures.

U.S. Patent #5,347,454 This patent teaches a turnaround one visit means for the fabrication and insertion of prosthesis and restorations or replacements in dentistry such as dental implants, crowns, bridges and hybrid combinations of both. The patented designs include means for automated, robotic productions of crowns, bridges, prosthesis as the digitized output obtained from each patient's individual scan data. This is implemented through an automation process based on making models used in forming the restorations and bridges.

U.S. Patent #5,448,472 This patent provides an easy ergonomic approach for quick scanning of dental surfaces to obtain 3-D data by exploiting the invented techniques of placing an adhering fiducial mark to teeth and oral surfaces. Through use of tape-strips with slots and through probe traces, the surface data is available. The patent teaches an easy on-line means for digitization of tooth structure through a probe sweep and recording of that data. This is an add-on upgrade and improvement to the original probe patent.

U.S. Patent #5,545,039 This patent teaches means and the method for analysis and feedback of 3-D data for use in operative dentistry and other surgery. The system projects coded, light structured information onto a scanned operative field. The projected patterns reinforce and aid the surgeon's work task by defining surfaces and providing intelligent analysis. The hand-held instrument projects light structured patterns based upon an integrated analysis of hand instrument positions, structured anatomy and clinical data. The results are optimum surgery procedures aided with directional guidance through the light patterns, which can be multi colored and so coded.

U.S. Patent #5,562,448 This patent is directed to a series of methods for facilitating dental diagnosis and treatments. By combining the probe unit now improved with multi stvli inputs. and with surface images of anatomic structures. dentists'

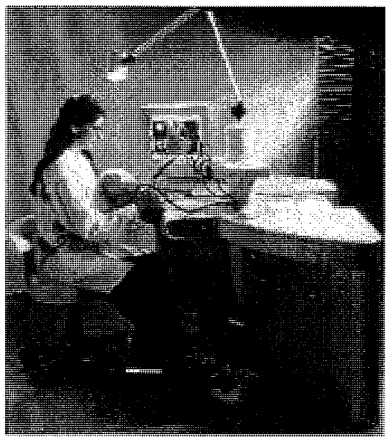
3-D Models 3-D Charts, perio scans 3-D Data of X-ray with electronic models. These study models become integrated with pre-programmed dental information resources for diagnostic instrumentations and analysis. Once this has been generated the systems enables: 1) Teaching and instrumentation processes through computer controls of virtual rehearsed and practice modes for performing: a) Surgery b) Implantology c) Tooth preparation forms. Modifications, shaping of tooth forms and intra osseous sites for implants. These are routine functions through the methodologies of this patent.

U.S. Patent #5,569,578 This patent has a method and apparatus for affecting physical changes in shape of pre-existing objects.

The current product development status is that the remote sensor has been developed and manufactured into an operating unit. The fabrication unit has been assembled in prototype forms and has been tested at Dr. Mushabac's office/clinic.

ClearCorrect Exhibit 1002, Page 1325 of 3373

DentSim... Dent-X's virtual reality 3-D training simulator...A revolution in dental education.



Dental knowledge has exploded over the last several decades. In order to keep pace with the growing challenges, an effective change in the education and training of tomorrow's dental practitioners is vital. DentSim enables dental education to take the great leap forward that the times demand.

Much more than a teaching tool, DentSim is a comprehensive information management system that merges the synergies of advanced simulation technology with established teaching and practice.

DentSim is manufactured by DenX Ltd.

Dent-X is a marketing partner.

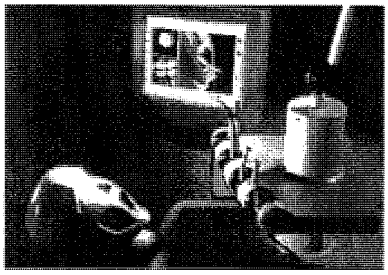
DentSim's Training Solution.

The ultimate learning experience.

DentSim's sophisticated simulation techniques and "touch-sensitive" feedback enable users not only to perform real dental procedures, but via computer models that behave in life-like ways, to experience the "look" and "feel" of dental performance. This training also prepares the user for interaction with the displays and techniques of the dental clinics of the future.

A complete hardware

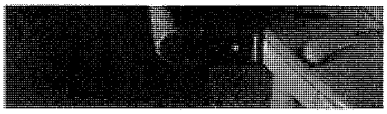
and software solution



Optic technology, data, graphic visuals, mannequin, dental instruments, ergonomic positioning; all are linked in an interactive loop that provides instruction, guidance, correction,evaluation and above all, practice. Case-based learning programs enable students to repeatedly

ClearCorrect Exhibit 1002, Page 1326 of 3373

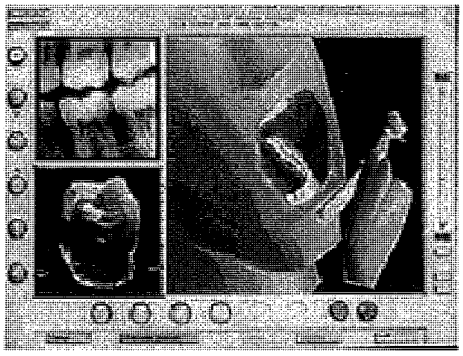
practice such procedures as cavity and crown preparations on a mannequin head while viewing the procedure on a monitor in real time.



The computer interface enables instructor follow-up and control.

DentSim's database comprises images and texts selected in collaboration with the teaching faculty. Procedures are based on the school's academic resources, thus enabling DentSim to create an objective, standardized body of knowledge.

Singular individual training capabilities



The learning process is structured to provide consistent feedback of all movements, including a sensation of tooth layers (healthy or carious tooth matter).

Treatment information

Lessons provide full patient information including patient case history, radiographic presentation, diagnosis, treatment plan and prognosis.

Treatment process

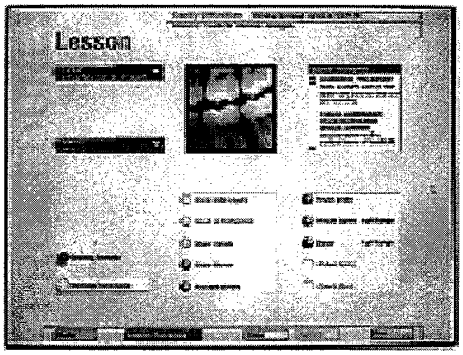
During the treatment process, the user benefits from full interaction both with the real mannequin and the virtual screened mannequin. All models can be illuminated, zoomed and rotated for closer inspection and comparison. Error and correction alerts are displayed in real time.

Error analysis

While working, students receive real time

ClearCorrect Exhibit 1002, Page 1327 of 3373

feedback and explanations. Detailed, color-coded comparisons with a pre-defined optimal solution are screened as well as cross sections of teeth. DentSim also provides an error report and grade that assure objective, standardized evaluation. This is based on the comparison of performance with the parameters determined by the dental institution during DentSim's customization. Work related information is stored in a large scale video database and is available for review by users and instructors. The treatment record can also be retrieved via network connections within the teaching facilities, as well as in other locations. The movement and articulation functions of the mannequin approximate real-life conditions and enable perfect simulation of a multitude of treatment situations. Also included, high quality handpieces with triple syringe, suction/dust extraction, as well as mirror and illumination. Planning includes secured personal work areas. All fittings are recognized, high quality and construction is rugged for years of continuous training.



Standard Dental Procedures:

Cavity preparations for amalgam

Cavity perparations for composite

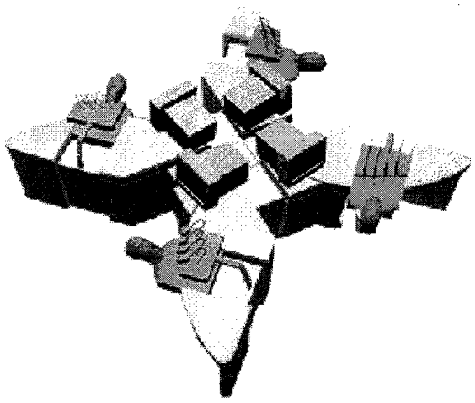
Crown preparations

Other customized procedures - optional

ClearCorrect Exhibit 1002, Page 1328 of 3373

DentSim's optional

"Quad" space configuration



DentSim's "Quad" space configuration is distinguished by a remarkably efficient utilization of teaching and training resources. It replaces the conventional linear workbench with a single, highly sophisticated station that enables four students to work simultaneously, yet secures the privacy of each individual. Instructor involvement is optimized via centralized control and instant access.

Perfect treatment

ergonomics

The integrated visual display enables correct positioning according to ergonomic principles and facilitates eye-screen contact. Modular workstations are adaptable for left and right hand use.

ClearCorrect Exhibit 1002, Page 1329 of 3373

The equivalent of round the clock, chairside instructor.

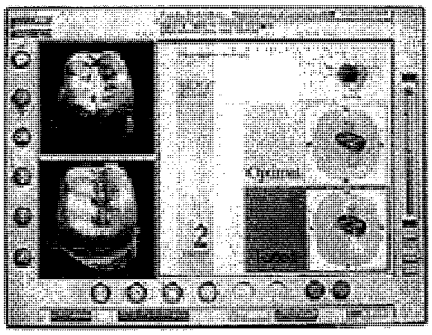
DentSim encompasses a comprehensive practical training solution that includes interactive theoretical content. Students learn on their own and proceed at their own pace. DentSim's specially developed multimedia kit allows them to continue practicing lessons at home on PC's. With DentSim, students can take all the time they need to achieve exellence.

Reduced instructor workload

DentSim saves instruction time and enables more instructor control via centralized display and software. An objective tool for student competency testing, DentSim gives highly effective assessment and evaluation of learned procedures and methodology. It is also invaluable for teachers in essential research related to the effectiveness of the dental education curriculum and student skills.

Increased benefits for the dental school

In addition to initial applicant screening, DentSim raises student potential and performance during the pre-clinical stage, effectively reducing the cost and duration of training and increasing the productivity of dental school clinics. DentSim can play a major role in continuing education and certification.



Advantages to benefit a broad spectrum of needs.

> Sophisticated 3-D simulation

> Real-time, interactive display

> "Touch sensitive" feedback

> Presentation of tooth layers and caries

> Demonstration of various treatmen modalities

> Case-oriented teaching and learnin

> Round the clock self training

> Optimized instructor performance

> Objective evaluation

> Enhanced research capabilities

> Cost saving benefits

> Customization to school needs

ClearCorrect Exhibit 1002, Page 1330 of 3373

E-mail:market@dent-x.com

Tel: 914-592-6100

Fax: 914-592-6148



Please visit DenX for more information:
http://www.denx.com/

Please visit our parent company:
http://www.afpimaging.com/

DENTX

Home Page

ClearCorrect Exhibit 1002, Page 1331 of 3373

DIGITAL DENTISTRY

DOCTORS USE CAD/CAM TO TAKE THE PAIN OUT OF EXTENSIVE DENTAL PROCEDURES

BY AUDREY DOYLE

Patients visiting Dr. Carl Boscketti have a reason to smile. The co-owner of a small dental practice in Exeter, New Hampshire, Boscketti uses a new CAD/CAM system that saves his patients the time and discomfort traditionally associated with repeat visits to the dentist's office for restorative dental work. It also frees up Boscketti's time so that he can see more patients on a daily basis. "This is one of the best things to come along for the dental profession in a long time," he enthuses. "My patients love it, and I love it. It's an integral part of my practice. I use it for 80 percent of the restorations I do."

The system to which Boscketti is referring is the Cerec 3, a modular, Windows NT-based CAD/CAM system from Sirona Dental Systems (Bensheim, Germany). Originally developed at the University of Zurich by professor Werner Mörmann and Dr. Marco Brandistini, the Cerec methodology has evolved from creating single- and dual-surface inlays to one that can produce multisurface inlays, single onlays, veneers, and posterior and anterior crowns. And perhaps the most innovative aspect of the Cerec system is the fact that the restorations are digitally designed and built by the dentist in his or her office within a matter of minutes, rather than by hand at an off-site laboratory over the course of a few weeks. That means patients can have restorative work done on their teeth in just one appointment, rather than the usual multiple visits.

Traditionally, dental restorations are created by hand at laboratories by skilled dental technicians. Although dentistry is a nontraditional market for CAD/CAM, the use of CAD/CAM tools and technologies in dentistry isn't limited just to the Cerec system. For instance, Atlantis Components (Cambridge, MA) has developed a method that uses 3D CAD software and computer numerically controlled (CNC) milling machines to create custom abutments, pieces of metal that connect a full crown to a fixture (the part that anchors the crown to the patient's jawbone). Another company, Align Technology (Sunnyvale, CA), has developed a procedure that combines 3D modeling and animation software and stereolithography machines to design and manufacture customized orthodontic appliances for adults. (For more information on these technologies, see "Making an Impression," pg. 52.)

Although Atlantis and Align offer their systems in the form of a service they provide to dentists, Sirona's Cerec system is actually used by the dental practitioner. "We're putting the CAD tools into the hands of the dentists," says Steve Sutton, director of Cerec support in North America. He estimates that thousands of dentists worldwide are using a version of the Cerec system.

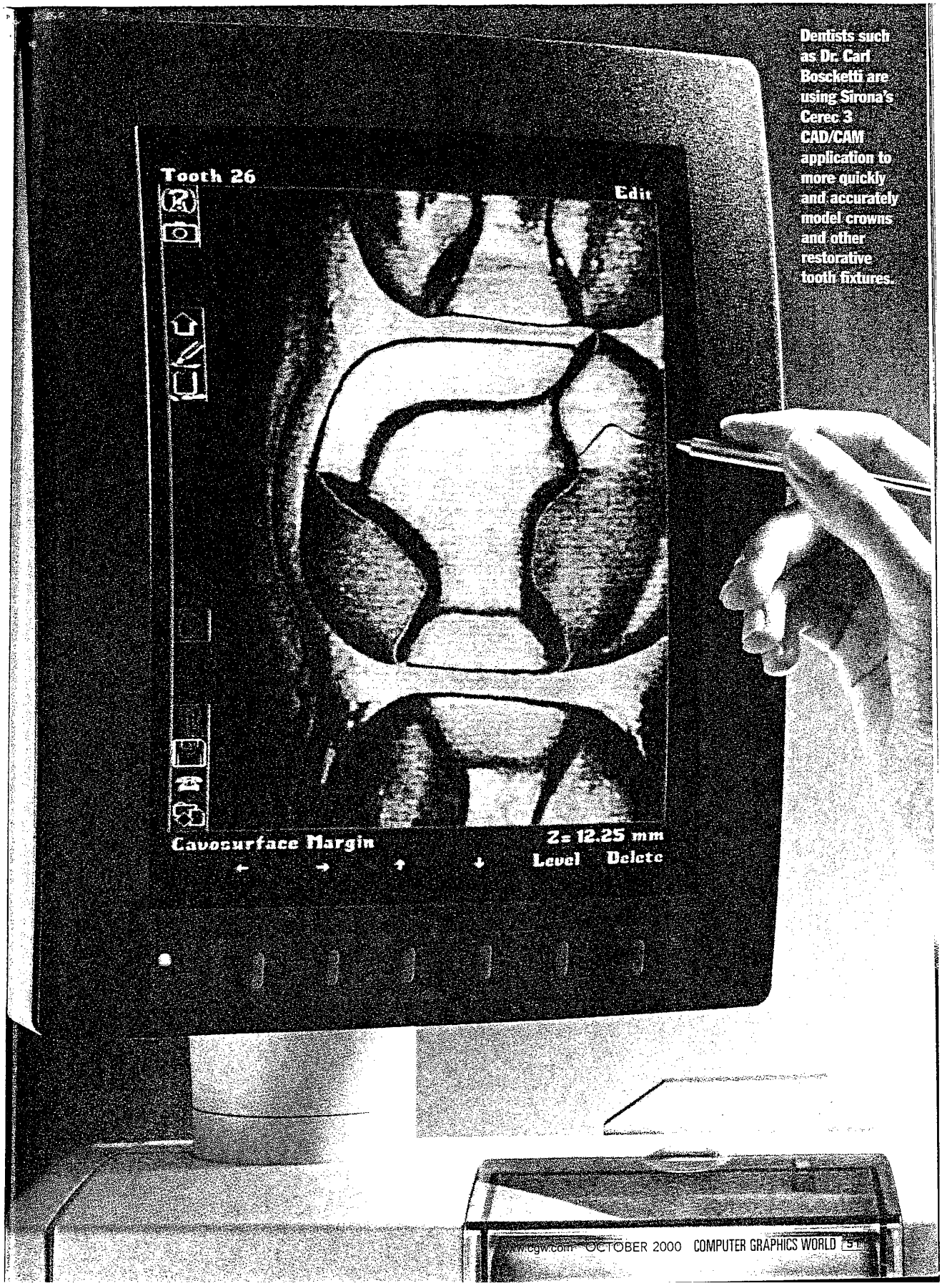
Creating a Crown

The term "Cerec" is derived from ceramic reconstruction, or the replacement of missing tooth substance with ceramic material. The Cerec 3 system incorporates a mobile PC that's equipped with a flat-panel monitor; a proprietary, high-precision intraoral measuring camera connected to the PC via cable; and an Intel microprocessor-controlled image capture card. In addition to displaying the grayscale images generated by the camera, the proprietary card also processes the images in real time. The PC runs proprietary, Windows NT-based Cerec 3 CAD software that has been optimized for dental applications and does not require any special computer knowledge. The final component, the proprietary six-axis Cerec 3 milling unit, is a tabletop device that communicates with the camera via a wireless RS connection and features cylindrical and conical diamond burrs for speedy and precise milling. The SiroCAM 2, an intraoral color video camera, is available as an option.

Use of the system is relatively straightforward. Let's say a patient needs a crown placed on his or her tooth. After administering anesthesia to the patient, the dentist drills away any decay remaining on the tooth, and preps it by painting it with an imaging liquid and then covering it with a special opaque powder. The dentist then positions the small, handheld camera above the tooth and simply takes a picture of it. Within a few seconds the 3D image appears on the computer screen. "The imaging process replaces the impressions everybody hates in dentistry," says Boscketti. "That whole process of obtaining an impression of the tooth—putting the gunk in your mouth and then letting it sit there for a few minutes to harden—is eliminated."

Next, the dentist or dental assistant uses the CAD software to design the crown on the computer screen. Using a trackball and simple CAD commands, the operator defines the equators of the neighboring teeth as well as a baseline on the tooth that needs restoration. The 3D software then determines the size of the required crown based on the size, height, and orientation of the

ClearCorrect Exhibit 1002, Page 1332 of 3373



Dentists such as Dr. Carl Boscketti are using Sirona's Cerec 3 CAD/CAM application to more quickly and accurately model crowns and other restorative tooth fixtures.

ClearCorrect Exhibit 1002, Page 1333 of 3373

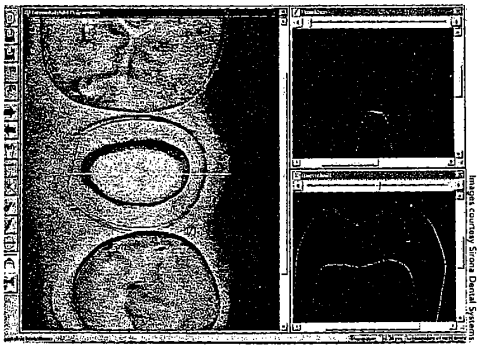
neighboring teeth. "The software is really easy to use. It's like using a big Etch-a-Sketch," notes Boscketti.

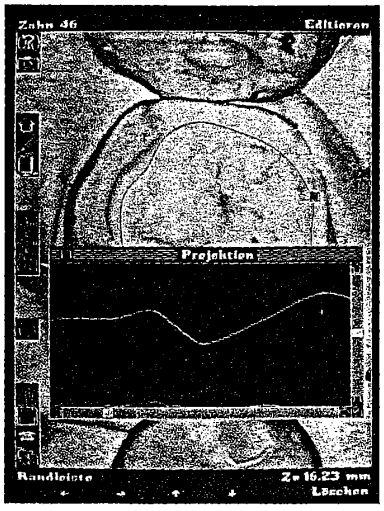
After the crown is designed, it is ready for milling, a fully automated process that takes from 10 to 15 minutes, depending on the crown's size and complexity. The Cerec 3 CAD software tells the operator what size ceramic block is required. After inserting the corresponding block into the milling unit, the operator clicks an icon on the screen to initiate the milling process. When the milling is complete, the crown is bonded into place using conventional ceramic bonding techniques and then polished.

According to Boscketti, the Cerec method offers numerous advantages over traditional techniques. Dentists usually administer novocaine to the patient, drill away the decay, take the impression, and fit the person with a replacement crown. The impression would then be sent to a lab, and a few weeks later the dentist would replace the temporary crown with a permanent one. "With the Cerec system, I can service my patient in just one visit that lasts a little over an hour," says Boscketti. "He doesn't have to worry about temporary crowns that crack or fall out."

The system also has other benefits. Traditionally, Boscketti says he would have to drill away the decay and build up the tooth again using core material—metal pins, or plastic which he would then have to drill down so that he would have something stable to attach the crown to. "All that drilling weakens your teeth," he points out.

With the Cerec system, dentists can digitally design and build tooth restorations within minutes right in their offices.





But with the new system, Boscketti is milling the crown out of solid ceramic that works well with today's strong bonding adhesives. Therefore, he doesn't need to use pins to secure the crown in place, nor does he have to drill as much of the original tooth. "This not only saves the patient discomfort, but also it reduces the chance of fracturing neighboring teeth," Boscketti says.

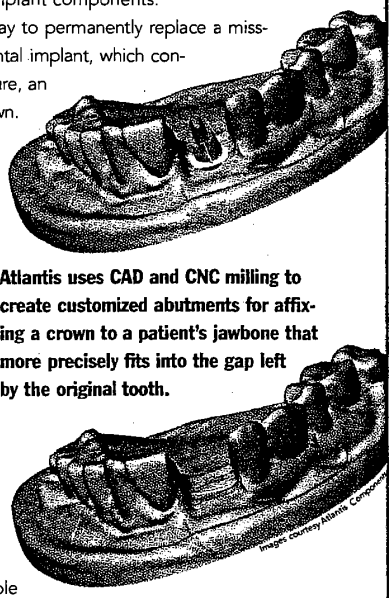
Of course, there are a few limitations to the Cerec system. "At this point, it can't do bridges, or multiple-tooth restorations with a connection piece between the teeth," comments Sutton. The company, however, is planning to release a CAD package next year that will accomplish such a procedure.

Another limitation is the Cerec 3's $90,000 price tag, which includes "everything

MAKING AN IMPRESSION

In addition to Sirona, other companies are capitalizing on CAD/CAM technologies for dental applications. Atlantis Components, founded in 1996 by a Boston prosthodontist, uses CAD/CAM software and hardware to develop customized restorative implant components.

Usually, the best way to permanently replace a missing tooth is with a dental implant, which consists of an implant fixture, an abutment, and a crown. A hole is drilled in the patient's jawbone, and the implant fixture is placed in the hole. After the bone heals, or osseointegrates, around the implant, the abutment is mounted on the implant, mimicking the natural shape of a tooth emerging from the soft tissue. The crown, which replicates the contour and appearance of the visible portion of the replaced tooth, is then mounted on top of the abutment. The abutment is a crucial component of a dental implant because it determines the fit, form, and functionality of the total implant.



Atlantis uses CAD and CNC milling to create customized abutments for affixing a crown to a patient's jawbone that more precisely fits into the gap left by the original tooth.

According to Atlantis, currently available off-the-shelf abutments present some limitations. First, they're cylindrical in shape and, therefore, bear little resemblance to the contours of the natural teeth they replace. Also, stock abutments are available only in standard sizes and shapes, requiring modification by the dentist or a dental lab.

As an alternative to stock abutments, dentists can order custom abutments from dental labs. With this process, after the bone osseointegrates, the dentist cuts open the soft tissue and mounts a temporary "healing abutment" on the fixture to provide the correct soft tissue emergence. Then, using impression material, the dentist takes an "index" locating the implant with respect to the neighboring teeth and sends this information to the dental lab. Using this as reference, a skilled technician builds a wax model of the abutment by hand, and then casts it in metal using the lost-wax casting technique.

However, this process also presents limitations. Not only does it take several weeks to complete, but also, creating dental implants by hand is a highly specialized skill.

With the Atlantis abutment, the index can be taken when the implant is first placed, and the abutment can be placed when the soft tissue is first opened, eliminating a visit to the dentist's office and providing the patient with a tooth weeks earlier. This is possible because the shape of the Atlantis abutment is very close to the shape of a natural tooth, so the gum tissue looks natural as it heals. *continued on pg. 54*

ClearCorrect Exhibit 1002, Page 1334 of 3373

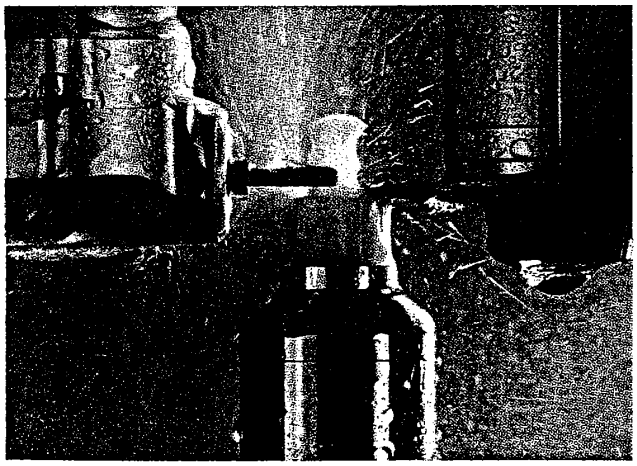
the dentist needs to begin using the system," Sutton says. Although Sutton admits that some small dental offices might find the price high, he claims that the return on investment is typically less than two years. Indeed, Boscketti notes that he achieved an ROI within a year after making his purchase.

Expanding Possibilities

According to Sutton, dentists and their patients aren't the only people excited about the Cerec technology. "Other software companies have approached us with proposals that could make the system work even faster and more efficiently," he says. "And because Cerec is NT-based, a platform that's fairly common in the industry, the Cerec PC could be used to also run different off-the-shelf technologies—commercial imaging programs or programs that can morph teeth to show the patient a before and after image before the work is done."



Even without these capabilities, the Cerec system is still an innovative use of CAD/CAM technology, and it shows how CAD tools are becoming easier to use by people in non-traditional markets.



After the dentist digitally designs a crown using Cerec, a CNC milling machine automatically creates the new dental piece from a ceramic block.

"We took existing optical imaging, 3D CAD, and CNC milling technologies—which have been used in other areas for years—and simplified and miniaturized them for use by dentists so that they can design and build restorations themselves," Sutton concludes. "So now, dental visits no longer have to be feared or dreaded, or thought of as a long, drawn-out process. Instead, they can be pleasant, convenient experiences that let people receive the proper necessary dental treatment but in a less painful and more efficient way."

Audrey Doyle, a contributing editor to Computer Graphics World, *is a freelance writer and editor based in Boston. She can be reached at audreyd@mediaone.net.*

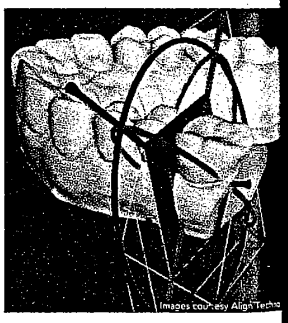
continued from pg. 52

The process begins with a plaster model of the teeth created by the dentist from an impression of the patient's mouth. To re-create the exact location of the fixture in the plaster model, a separate impression also is taken of the implant itself. Atlantis scans the plaster models using an off-the-shelf optical 3D scanner and then imports the resulting point cloud of data into Raindrop Geomagic's (Research Triangle Park, NC) Studio software, running on an NT-based PC, where the data is turned into a 3D surface model representing the teeth. Atlantis then digitally modifies a 3D abutment-model template so that the abutment model fits the 3D surface model of the patient's mouth precisely. "The surface model we create in Geomagic Studio is used only as reference geometry so that we can modify our 3D abutment model to fit it," explains Bethany Grant, Atlantis engineering program manager.

The final step involves creating a tool path and machining the abutment in titanium on a CNC milling machine. Atlantis then delivers the abutment to the dentist. Although the process currently takes about a week today, Grant says Atlantis is working to reduce the turnaround time to hours.

Aligning Teeth

For adults who require orthodontic work on their teeth but don't relish the thought of wearing metal braces, Align Technology offers Invisalign, a system that uses a series of customized plastic "aligners." The aligners exert enough pressure on the patient's teeth so that the teeth are gradually repositioned. Nearly invisible, the aligners fit snugly over the teeth and are replaced every other week with new, recalibrated aligners until the patient's teeth are in the final desired position.



Using digital design techniques, Align Technology creates customized orthodontic devices for adults.

The Invisalign treatment begins with an orthodontist taking an impression of the patient's mouth. The orthodontist sends the impression, along with a diagnosis and treatment plan, to Align, which casts a mold from the impression and, using a 3D scanner, scans the mold into an NT-based workstation. From there, the company uses proprietary software called Treat to generate a 3D animation that represents the patient's teeth moving from their original state to their final, treated state. After the orthodontist approves the treatment based on the animation, Align uses 3D Systems' (Valencia, CA) SLA-7000 stereolithography machine to produce a series of customized, clear polymer orthodontic aligners.

The patient wears each aligner for about two weeks before switching to the next one in the series. Because the desired tooth movement is built into each customized aligner, patients need to revisit the orthodontist only once every six weeks to make sure the aligners are working properly. With traditional braces, patients must visit the orthodontist once every two weeks to have the braces tightened. —*A.D.*

ClearCorrect Exhibit 1002, Page 1335 of 3373

AOA is proud to introduce our new Red, White & Blue material - **DuraClear™**! Since the introduction of Red, White & Blue, we have fabricated the appliance with commercially available materials. In the past several months, we have recognized the need for a material with enhanced durability without additional thickness. **DuraClear™** does this! **DuraClear™** also offers more resilience for tooth moving efficiency. This proprietary blend of resins even allow you to warm the appliances with hot tap water for more flexibility when seating appliances on complex cases.

The enclosed Red, White & Blue appliances are fabricated in our **DuraClear™** material. The development of **DuraClear™** is yet another example of how AOA is striving to meet the ever demanding standards of the profession!

DuraClear™ is a registered trademark of Allesee Orthodontic Appliances, Inc.

AOA
Allesee Orthodontic Appliances

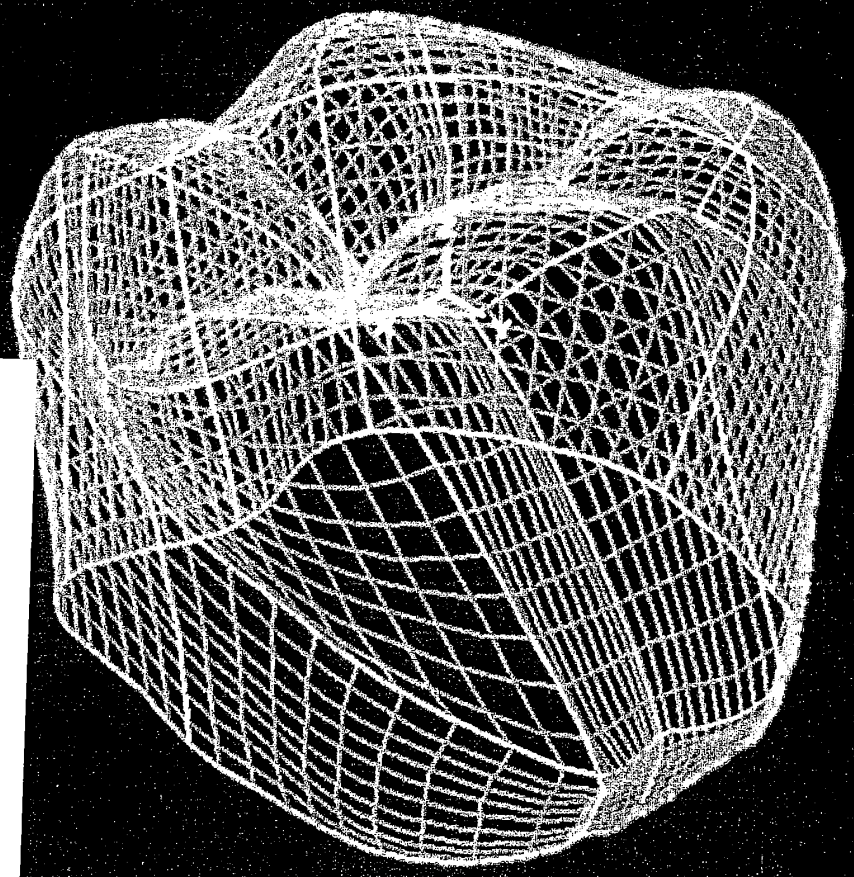


AOA000097

AOA000097

THE JOURNAL OF THE AMERICAN DENTAL ASSOCIATION NOVEMBER 1988

JADA



********** CAR-RT SORT ** CR31
MBR 07370066[illegible] 11/01/88 3362

CAD CAM in dentistry

After a long period of research, computer-aided design and computer-aided manufacturing (CAD-CAM) in dentistry has become clinically applicable. This article is exclusively aimed at the clinical practice of dentistry. Setting aside scientific considerations, the practitioner will learn, through this paper, how the system is used.

CAD-CAM in dentistry

Francois Duret, DCD, DSO, MS, PhD
Jean-Louis Blouin
Bernard Duret, CD

A series of closely linked steps are required to make a fixed dental prosthesis. After any preparation, the dentist must take an impression of the prepared tooth, together with adjacent and opposing teeth, using elastic impression material. This impression is used to obtain a hard stone model, and a wax pattern of the crown or inlay is carved. The actual cast restoration is obtained by using the "lost wax method."

Regardless of the advanced state of this 300-year-old technique, information must still be transferred by hand from the impression to the finished crown via a series of materials, each of which may induce error in the final castings. This system of casting does not allow us to take advantage of tremendous advances in computers and robotics. For these reasons, we introduced CAD-CAM technologies to the dental profession in 1971.

Early studies have been more experimental and theoretical than clinical.[1-4] Although these outstanding works have been consulted, we have stressed the clinical aspects of application rather than the fundamental.[5,6]

In 1979, Heitlinger and Rodder,[7] followed by Moermann and Brandestini[8] in 1980, began to share this approach. The former researchers milled the equivalent of the stone model used by a dental technician to make the crown, inlay, or pontic, while the latter team took a single picture and milled only the internal surfaces of the inlay. During the next 5 years, little was heard. The first dental CAD-CAM prototype was presented at the Garanciere conference (France) in 1983,[9] and the first crown was publicly milled and installed in a mouth without any laboratory involvement in 1985.[10] Though 1985 was a decisive year for computer-aided dentistry, there was still a long way to go. Several engineers took 2 hours[5] to operate the first usable system in a dental office. Nevertheless, this demonstration at the French Congress[11-13] vindicated principles established 14 years earlier.

Two new names appeared at this time, the Aoki team in Japan[14] and Diane Rekow at the University of Minnesota.[15,16] Dr. Rekow chose a photogrammetric method to acquire the third dimension and used the principle of the theoretical tooth, which we had established earlier,[5] for her second and third steps. It should also be mentioned that Reggie Caudill, at the University of Alabama,[17] started a project aimed in the same direction.

In this paper, a system that is already functional in dental offices in France—the Duret system, developed by Hennson International (Los Angeles) under our direct supervision—is described.

Equipment needed in dental office

Instead of using a physical model (die) to acquire and transmit information, the CAD-CAM system uses a three-dimensional probe system, surface modeling, and screen display, and an automatic

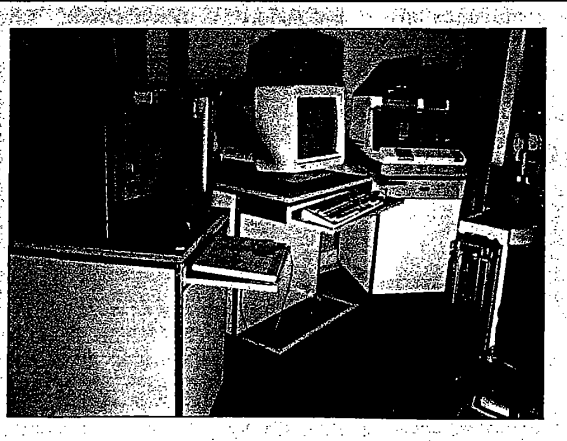


Fig 1 ■ Presentation of a dental CAD-CAM (Duret) system in a private dental office.

ClearCorrect Exhibit 1002, Page 1338 of 3373

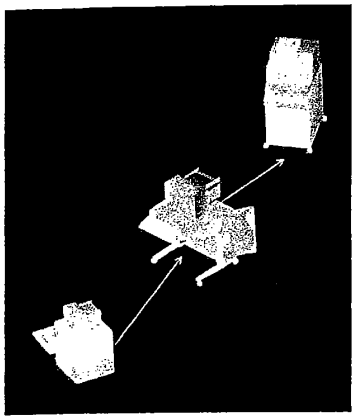


Fig 2 ■ Drawing of a system consisting of, left to right, a probe, a CAD system, and a machine tool.

milling machine. Exchanges and transformations of information from one material to another during which precision may be lost, are thus limited.

An electro-optical method is used to obtain the "impression" (that is, the necessary three-dimensional information).[18] This method combines holography[19] and Moire[20]: the light carries volumetric information, which is digitized by camera and fed into the computer. The resulting data are stored by the computer. Because all of the variables contained in a single impression (more than 1 million values for three teeth) cannot be measured, dentists had to use visualization. They understood quickly that measuring and reproducing with a model are identical functions. The only difference between an optical and a traditional impression is that the former uses numerical values in place of a physical model. The stone model or die is thus analogous to a memory system in which information is stored, as on a computer disk.

The CAD system (hardware and software) uses encoded information to allow the operator to visualize an impression on a graphic screen, and to design a prosthesis. This step is equivalent to the creation of the wax pattern on the stone model. Modifying the surface of a crown or inlay as displayed on the screen is equivalent to adding or removing wax material to or from the die.

In the last step of the process, the lost wax technique is replaced by the milling of a preformed cubical block of material. Although traditional materials may be used, this new technology encourages the development of new dental materials.

The CAD-CAM system includes three parts, which correspond to the three basic steps of the process:

—First, a device is used to input the existing dental shapes into the system. This device includes a laser source (diode) which, through the first endoscope, projects light on the desired picture area. A second endoscope, adjacent to the first, allows a camera to take pictures in the mouth. This camera is connected to a system that digitizes the information and correlates the different views (Fig 1).

—Next, the CAD system, including all necessary hardware and software, allows the operator to create an electronic model of the impression, display it on the screen, and use it to design the prosthesis. The CAD system is linked to a proprietary articulator, called the Access Articulator, which provides the data relating to the dynamic movements of the jaw.

—Third is the CAM system, which includes a numerically controlled machine tool with four-axis capability. This machine will automatically mill the prosthesis from conventional or special materials.

These three parts can be linked in several different ways. Three possible configurations are presented:

—A complete system may be used in a dental office with a single operating room. The optical probe system should be located near the dental chair; the CAD-CAM parts should be placed in another room. This configuration allows for immediate milling of the prosthesis while the patient is still under local anesthesia. It is possible to reduce costs if several practitioners share the system (Fig 2), which could be installed in a specified area, as was done in the past with X-ray equipment.

—A dental office with several operating rooms may have one CAD-CAM system installed in a separate room, whereas each chair would have its own optical probe system. Although somewhat more expensive, this configuration eliminates the necessity of moving the patient to the equipment or of waiting to use the system. It is also possible to connect a second machine tool to the system, thereby greatly increasing the number of prostheses that can be done in a single day (Fig 3).

A dentist who is equipped with an optical probe in a remote location could have access to the CAD-CAM system either through the phone line (with a modem) or by sending a picture-containing floppy disk to the home base of the computer and the micro-milling machine, whether a dental office or dental laboratory.

A dental laboratory may be equipped with one or several CAD-CAM systems, and dentists are equipped with the optical probe system. Data between the two are transferred as described (Fig 4).

In all cases, the dentists can personally handle all the operations of the system after a training period of only a few days. A large dental office equipped with several probe systems may find it logical to have an assistant responsible for the CAD-CAM operations. In fact, different office setups and procedures may easily be envisioned, depending on the interests and preferences of staff members. As a

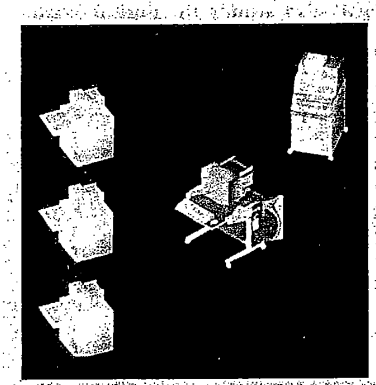


Fig 3 ■ Configuration for a dental office equipped with several probe systems; probes (left), CAD (center), CAM (upper right).

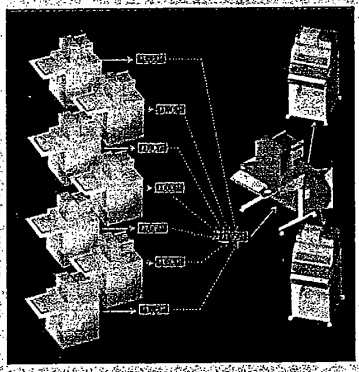


Fig 4 ■ Mixed configuration showing dental offices linked via modem to a production center (laboratory).

ClearCorrect Exhibit 1002, Page 1339 of 3373

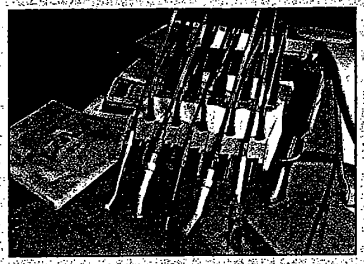


Fig 5 ■ Optical probe (right).



Fig 6 ■ Tracing of the margin on the video screen.

production tool, the CAD-CAM system will thus offer greater internal flexibility to the dentist.

Clinical production of crown

The production of a fixed prosthesis with a CAD-CAM system, regardless of its configurations, includes a series of simple and precise steps that are the same for crowns, inlays, or bridges. The process may be divided into seven steps—some clinical, others theoretical.

Preparation of the tooth

The preparation of the tooth for a CAD-CAM crown does not require methods and rules that are different from those used today. The traditional rules of sparing dental tissue, retention, and stability of the future crown to maximize the life span of the prosthesis are still followed. It is wise to avoid proximal surfaces that are too vertical when the space between teeth is small, and occlusal planes containing deep grooves that will cause projected shadows on the video screen. For a clear continual view of the finish line of the crown preparation on the video screen, some operators prefer to use a chamfer with or without a shoulder.

Preparation of the impression area

For optimum visibility of the sulcus, the impression area must be cleaned of all debris, water, blood, or saliva, as required for a conventional impression, even if a light source is developed that is capable of penetrating the buccal fluids and selectively reflecting on the tooth surface. Moreover, drying and gingival retraction with conventional methods are desirable. Retraction must be routinely used if the crown finish line is more than 1 mm below the free margin of the gingiva. Retraction will allow a proper view of the sulcus during the impression; an adequate angle of incidence is necessary between the plane of the tooth and the axis of projection of light from the probe, to obtain three-dimensional acquisition.

The tooth must be dry before any impression is taken with the probe, so that a thin coating of white, nontoxic material can be sprayed on the tooth to enhance the quality of the picture. Light that strikes the uncoated tooth is reflected in part, while the remainder penetrates the structure, thus considerably reducing the quality of the three-dimensional acquisition. It is advantageous to have a regular (lambertian) reflection on the tooth, as the natural tooth reflection would blind the camera. Special clamps, which include certain references that are recognizable in each view, have been designed to help achieve a good correlation between views. These clamps are placed around the preparation, much like rubber dam clamps, after the tooth has been dried and coated.

The impression

The dentist or an assistant starts the laser and the camera controls. The operator holds the probe like a handpiece, and places it in the patient's mouth to take the pictures. Some operators use a suspension arm for more comfort. Several views are taken of the preparation, including one buccal view, one lingual view, two proximal views, and one view of the occlusal surfaces of the opposite teeth (Fig 5).

To take these pictures, the dentist moves the probe around the preparation, controls the positioning of the probe on a TV monitor facing him, and activates a foot switch to record the picture.

A final, important view must be taken with the teeth in occlusion. The patient's masticatory apparatus is placed in an occlusal position of reference, according to the dentist's preference. It could be, for example, either the centric relation or the maximal intercuspal position. Considering that the preceding views have led, like the models of the maxilla and the mandible, to the creation of two objects, the view in centric occlusion will enable the practitioner to determine the relative position of these two objects with a minimum risk of error. It is possible to make this correlation process entirely automatic without taking the view in centric occlusion. But today, it is faster and less costly to keep the process interactive by requiring input from the operator. It must be noted that this last view is also a starting reference point for the analysis of the dynamics of the occlusion.

This third step takes 2 to 3 minutes, depending on the case. After recording each view, the camera is immediately available to take a new view, which ensures the comfort of the dentist and the patient. (The storage of views in the computer's memory is rapid.) After all views have been taken, the probe must be sterilized.

Work on the video model

All views taken are stored in the memory of the computer, as a stone model would be stored in a tagged laboratory pan. Before figuring the computations needed to develop the three-dimensional shape of each view and to correlate the views to obtain two objects in a correct relative position, additional information must be given to the computer.

The complete set of pictures is first displayed on a high-resolution video screen, and each is recalled one by one from the memory so that characteristic zones, such as the contact areas, certain cusps, and the alignment of grooves and cusps of the upper and lower arch, can

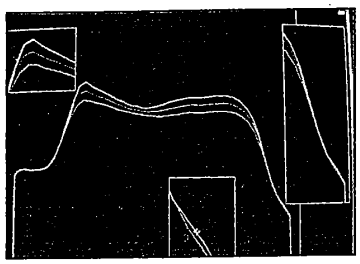


Fig 7 ■ The cement space is created only beyond the margin.

ClearCorrect Exhibit 1002, Page 1340 of 3373

be identified. Identification takes place on the video screen with the help of a mouse and a tablet—input devices that are user-friendly.

One of the more interesting operations is the tracing of the margin. Using a view of the preparation on the screen, the dentist defines a series of points along the desired position of the margin, thereby tracing the line as would be drawn with a fine pencil on the stone die (Fig 6). After completion of this step, the computer automatically calculates the three-dimensional shapes of the impressions and transfers them to the CAD system to design and build the computer model (also called the "virtual model") of the crown.

Design of the crown

The design of a crown with a CAD system is an interesting operation in that it clearly shows the superiority of the CAD-CAM approach over medical imaging techniques such as magnetic resonance imaging or scanners. Three-dimensional medical imaging does not go beyond the development in space of an observed image. As early as 1973, we were explaining that such a representation was of limited interest, and that the power of a medical application for CAD-CAM would be in its ability to design a piece that would replace what was being observed. In dental CAD-CAM, there is a big difference between the initial object (the preparation) and the final object (the prosthesis). It is possible to go beyond the stage of a mere reproduction because prosthetic rules can be integrated in the software. Therefore, a form of creativity called artificial intelligence exists in the dental application as defined in the early 1970s.

The design of the crown includes four stages: design of the interior of the crown; design of the buccal, lingual, and proximal surfaces of the crown; build-up of the occlusal surface; and modification of the shape of the crown.

Design of the interior of the crown. The optical impression is defined by a large number of small picture elements (called "pixels"), as would be seen in a highly magnified photograph. Together, these elements form a mosaiclike representation of the surface. Although only certain elements are useful in designing the crown, it is desirable to show the operator a complete model on the screen, including the preparation and the margin.

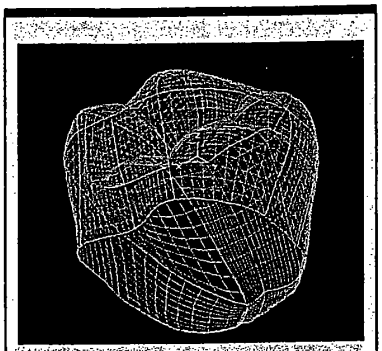


Fig 8 ■ Mandibular right first molar retrieved from the library of theoretical teeth.

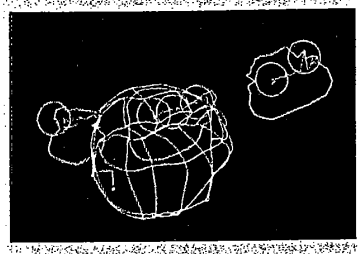


Fig 9 ■ Optical wax-up evaluation of the occlusal surface.

A computer (virtual) model may be viewed from different angles, just as a physical model. Buccal, lingual, or perspective views may be displayed instantly on the screen. Among the latter, the axonometric view will be widely used, as it is the easiest to understand.

The operator can recall to the screen, at any time, the views of the adjacent and opposite teeth, although there is no need to do so at this stage of the procedure.

The system displays a menu of actions that may be executed. The menu is executed from top to bottom in a simple, strict order; it is impossible to skip over an operation. Although a short procedure exists to design a crown without any intervention, it is more interesting to describe the interactive method, because it is more precise and provides better control over the successive operations.

The operator checks the impression and the margin, which may be modified if an error or imperfection is detected. The display of one of four points is sufficient. As the hidden lines and surfaces have been automatically removed by the system, it is possible to work as with a stone model (Fig 7).

When the display is deemed correct, a value is entered for the desired cement space, and the interior of the crown will be automatically generated, starting with the margin line. No cement space enlargement is applied to the margin (Fig 7).

Design of the buccal, lingual, and proximal surfaces of crown. The crown to be designed is first retrieved from the memory bank of theoretical teeth stored in the computer. A special program builds a set of contours that will allow for esthetic modification of the shape of the theoretical tooth (Figs 8, 9).

The program first modifies the theoretical shape to fit the existing morphology while respecting the buccal and lingual curvatures, the alignments of the grooves and cusps, and the contact areas of the arch. The operator may make additional modifications; for example, change the shape of the lingual or buccal surfaces, or create a diastema between adjacent teeth. Any contour line may be moved to achieve the desired result.

Use of a theoretical library of teeth allows the anatomy recognized by anatomists to be respected. With the interactive editing capabilities, the practitioner can personalize anatomy as desired. The deformation of the tooth, taken from memory in the environment of the patient, results in a custom crown. This operation may be compared with the development of a wax pattern in which the technician uses the shape of the tooth that he has, from experience and memory, to sculpt it on the physical model (die).

Build-up of the occlusal surface. This operation could justify a separate article. We describe it briefly without expanding on the dynamic analysis.

The term "build-up" is used to emphasize that the CAD design is much like the "wax-up" technique used in the laboratory. The occlusal surface is roughly aligned according to the opposite grooves and cusps, after the wax-up technique of Lundeen,[21] or according to the adjacent teeth. The choice is defined by the operator. To have a correct "build-up" of the centric points of the crown on the opposite centric points, their positions are first proposed to the operator on the basis of a theoretical arch corresponding to the opposite arch. These points can be freely moved to obtain a cusp-to-fossa or cusp-to-marginal ridge occlusion. In addition, the choice between functional and gnathologic options allows the morphology of the contact (centric freedom or tripodic blockage) to be defined. The CAD system

ClearCorrect Exhibit 1002, Page 1341 of 3373

does not impose a concept but leaves choices open to the practitioner.

When these elements have been defined, a program projects the cusps and the grooves of the crown onto the opposite teeth, according to Lundeen's technique. Functional occlusion is achieved with the use of a specially designed articulator.

Modification of the shape of the crown. If the shape is not satisfactory, the practitioner may modify the shape by moving a point or retracing a contour. It is also possible to raise a cusp (although care should be taken with the resulting occlusion) or to create a diastema (Fig 10).

In all cases, it is sufficient to indicate which point must be moved and to show its new position. The software reshapes the tooth while respecting the rules of esthetic dentistry. For this operation, a specific interactive program was developed that does not require computer experience. The result compares to the work on the wax pattern of the physical model. Adjacent and opposite teeth may be displayed at the same time, and their presence on the screen is often helpful.

Milling the prosthesis

The milling of the prosthesis is performed on a robot. This robot is a micro-milling machine (28 × 20 × 20 in) with four-axis machining, coolant, and automatic tool-change capabilities. All fixed prostheses can be milled with eight tools placed on a rotating disk near the spindle.

The machine retrieves them automatically according to the machining program. Before starting a cycle, the condition of the tool is checked automatically (Figs 11, 12).

To start the milling process, the block of material must be installed in the machine and the start button must be pushed. The process is automatic and delivers a crown that is ready to be polished and colored, with an accuracy of fit that meets accepted dental standards in the United States. The operation includes two phases: computation of tool paths and execution of milling.

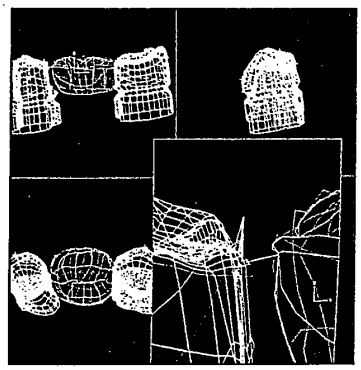


Fig 10 ■ The dentist can create a diastema on the model.

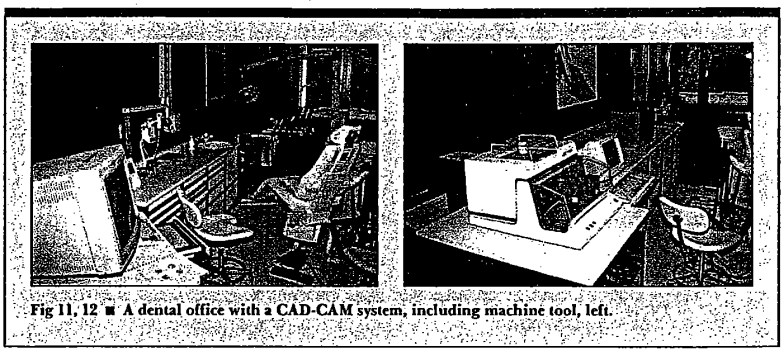


Fig 11, 12 ■ A dental office with a CAD-CAM system, including machine tool, left.

Computation of the tool paths. Each tool is basically a cylinder or a sphere, removing material progressively to shape the exterior and interior of the crown. The software computes the path that must be followed by each tool, the feed and spindle speed, and the machining sequence, to permit a smooth, efficient operation.

The software controls not only the tool movements but also technological factors such as coolant, tool changes, or checks for wear. Instructions are read sequentially and translated into electrical impulses that drive the moving parts of the machine tool.

Execution of the milling. This second phase automatically follows the preceding one. After a surfacing operation is completed to take into account manufacturing tolerances of the preformed block of material, the material is rough-cut in the form of a prism corresponding to the line of greatest circumference of the crown. Several tools are used successively to obtain a precise occlusal surface, which is completed by the fine milling of the secondary grooves. A realistic occlusal morphology results. All tool paths are calculated in three-dimensional space.

After the occlusal surface is completed, the material is automatically rotated for the milling of the interior and base of the crown. The interior is milled first to keep a maximum amount of material at the level of the margin. The portion of the exterior buccal, lingual, and proximal surfaces below the margin is milled last (Fig 13).

A precise tool is used to finish the margin because it is obviously the area of the crown that requires the most precision. When this step is completed, the machine removes all waste material, except for two attachment pieces (that may be compared with a sprue) located below or above the proximal contact areas. The operator then removes the crown from the machine.

Coloration

The last step in the production of a CAD-CAM crown is a quick polishing, followed by coloration of the inside and surface of the crown.

Coloration principles defined 20 years ago and recently reintroduced by Dentsply for their Dicor crowns are followed. Although CAD-CAM can mill all traditional dental materials, appealing alternatives exist with Dicor (Dentsply), and Aristee (Spad)—a new ceramic composite with an oriented fiber structure specially designed for CAD-CAM.

A preformed cube of Dicor is placed in the milling machine. After it is milled, coloration is applied as is currently done in the United States.

With Aristee, cement provides the basic color (type A, B, C, or D), whereas surface coloration accounts for local effects. Blue colors, for example, increase translucency at the incisal edge; yellows increase color density of the cervix. More intense



Fig 13 ■ Milling of a three-unit prosthesis.

ClearCorrect Exhibit 1002, Page 1342 of 3373



Fig 14 ■ Inlay entirely made with CAD-CAM on mandibular left first molar (Dicor).



Fig 15 ■ Crown with CAD-CAM on a first molar (Aristee), colored and cemented.

colorants have been added to these base colors to simulate grooves or imperfections in the enamel. To maintain this added color for wear resistance, the crown, bridge, or inlay must be fired at 200 C. To facilitate the coloration process and better control the results, a proprietary spectrocolorimeter (Bertin) can be integrated into the CAD-CAM system.

All that remains is to cement the crown, following standard practice (Figs 14, 15).

Discussion

Great progress in dentistry appears possible with CAD-CAM technology, which uses the most advanced scientific concepts. It is nevertheless necessary to answer practical questions concerning, for example, the accuracy of user-friendliness of the system.

In systems that use CAD-CAM technology, the number of points defining views varies between 50,000 (Moermann) and 16,000,000 (Rekow).

Clinical experience has shown, contrary to intuitive beliefs, that a high number of points is no guarantee of accuracy. Overall accuracy of the object is considerably reduced when different views are correlated. This phenomenon is visible on high-resolution stereoscopic images of small objects.[22] On the other hand, it is possible to compensate for the limitation because of the number of points by increasing the number of views (provided the correlation is correct). By working with these two factors, better accuracy can be obtained than is normally achieved in most dental offices and laboratories (the prepared tooth is defined by 200,000 to 400,000 points). The quality of the restoration does not require accuracy greater than 40 μm.[23-25] In addition, it must be noted that during the CAD and CAM stages, precision cannot be guaranteed beyond 5 μm because of the smoothing of curves and the positioning of tools in the milling process. It is therefore necessary to be cautious in terms of precision (not to be confused with resolution) and to realize that to reach a level of precision equivalent to 10 μm, although technically feasible, an uneconomical investment of human, material, and financial resources would be required.

The interaction between the operator and the system has been simplified as much as possible, to a level comparable to the user-friendly aspect of a Macintosh computer, which allows for complete training of the user in less than a week.

Conclusion

The introduction of CAD-CAM in dentistry will influence the direction of clinical practice and research at universities. Results achieved must be analyzed with caution, but the extraordinary speed of development of this technology in industry affirms that it will be rapidly and definitively accepted in the dental profession. Its future evolution could be spectacular considering its numerous possibilities.

JADA

Information about the manufacturers of the products mentioned in this article may be available from the authors. Publication of the names of products or manufacturers does not imply endorsement by the American Dental Association. Because of the French origin of this paper, not all products may be available in the United States.

Dr. Francois Duret is director of the CAD-CAM laboratory and professor, University of Marseilles School of Dentistry, Marseilles, France, where Mr. Blouin is a robotics engineer, and Dr. Bernard Duret is a clinician and researcher in biomaterials. Address requests for reprints to Mr. Jean C. Haas, Hennson International, 11444 W Olympic Blvd, Suite 1050, Los Angeles, 90064.

1. Altschuler, B. Holodontography: an introduction to dental laser holography. School of Aerospace Medicine AD-758.191:1-29, 1973.

2. Swinson, J. Dental fitting process, US Patent no. 3.861.044, 1973.

3. Garnick, J., and McGivern, R. Error in the photogrammetric determination of volume of small object. J Dent Res 2(53):495, 1974.

4. Schmidt, R., and others. Automated crown replication using solid photography. US Army Contract no. DAMD 17.77.C-7041, 1977.

5. Duret, F. Empreinte optique these: 2c cycle, no. 231, 1973.

6. Duret, F. Analyse d'images holographiques dentaires en vue de la commande des systemes automatiques. Congres IRIES, Tours, France, Bois des Hates, 1976.

7. Heitlinger, P., and Rodder, F. Verfahren zur Herstellung von Zahnersaltz und Vorrichtung zur Durchfuhrung des Verfahrens. De Patent no. 25911, 1979.

8. Moermann, W.H., and Brandestini, M. Verfahren zur Herstellung medizinischer und zahntechnischer alloplastischer, endo und exoprothetisher Passkorper. European patent no. 0 0054 785, 1985.

9. Duret, F., et coll. Demonstration pratique de l'empreinte optique, 9e. Entretiens de Granciere. Paris, 21 Septembre, 1983.

10. Duret, F., et coll. Realisation d'une couronne par ordinateur. Congres A.D.F., Paris, 25 Novembre, 1985.

11. Duret, F. Vers un nouveau symbolisme pour la realisation de nos pieces prothetiques. Cah Prothese 50:65-72, 1985.

12. Duret, R., et coll. Principes de fonctionnement et applications techniques de l'empreinte optique dans l'exercise de cabinet. Cah Prothese 50:73-110, 1985.

13. Duret, F.; Duret, B.; et Blouin, J.L. Bases fondamentales dans la conception et fabrication assistees par ordinateur des prostheses dentaires. QOS 39:197-215, 1985.

14. Fujita, T., and others. Preliminary report of construction of prosthetic restorations by means of computer aided design (CAD) and numerically controlled (NC) machine tools. Bull Kenagowa Dent Coll 12:79-80, 1984.

15. Williams, A.G. The Switzerland and Minnesota developments in CAD/CAM. J Dent Pract Adm 4(1):50-54, 1987.

16. Rekow, D. Computer-aided design and manufacturing in dentistry: a review of the state of the art. J Prosthet Dent 58(4):512-516, 1987.

17. Caudill, R. Computer-integrated dentistry. New Harbor, Academy of Dentistry, 1988.

18. Williams, A.G. Dentistry and CAD/CAM: another French revolution. J Dent Pract Adm 4(1):2-5, 1987.

19. Gabor, D. Microscopy by reconstructed wavefront. Proc Roy Soc 197:437-457, 1949.

20. Rayleig, L. On the manufacture and theory of diffraction gratings. J Science (4e Serie) d(310):81-93, 1874.

21. Lundeen, H.C. Introduction to occlusal anatomy: teaching manual for dental students. Earleton, FL, L and J Press, 1969.

22. Duret, F. Letters to the editor. J Dent Pract Adm 4(3):132-133, 1987.

23. McLean, J.W., and others. The estimation of cement film thickness by an in vivo technique. Br Dent J 131:107-111, 1971.

24. Belser, U.C.; MacEntee, M.I.; and Richter, W.A. Fit of three porcelain-fused-to-metal marginal designs in vivo: and a scanning electron microscope study. J Prosthet Dent (53):24-34, 1985.

25. Allan, D.N. A macroscopic study of filled teeth. Br Dent J (21):386-390, 1970.

ClearCorrect Exhibit 1002, Page 1343 of 3373

CAD/CAM imaging in dentistry

Francois Duret,* DCD, PhD and Jack D. Preston,† DDS

Section of Dental Imaging* and The Don and Sybil Harrington Foundation,†
University of Southern California School of Dentistry, Los Angeles, California, USA

CAD/CAM (computer-assisted design/computer assisted manufacturing), although devised 20 years ago, has only been available for routine dental practice for 2 years. As a supplement to the conventional methods for making dental prostheses, CAD/CAM will have profound effects on the dental profession. CAD/CAM will improve versatility, accuracy, and cost effectiveness and will be a part of routine dental practice by the beginning of the 21st century.

Current Opinion in Dentistry 1991, 1:150–154

A dental prosthesis is designed to reconstruct, partially or totally, the portions of the oral-facial complex using manufactured products. For over 200 years, the fabrication process has undergone constant evolution leading to progressively more excellent results, but requiring rather awkward operations. Traditional methods, such as making the impression, pouring the cast, waxing, and casting, remain rather fundamental. Dental CAD/CAM (computer-assisted design/computer-assisted manufacturing) offers an extraordinary opportunity to introduce into dentistry the most modern techniques from physical science and mathematics. Although devised 20 years ago, CAD/CAM has only been available for routine dental practice for 2 years. A review of the evolution of dental CAD/CAM will indicate how this new technology has grown and demonstrate some of its capabilities. Although CAD/CAM currently has daily application, the first results indicate substantial future development that will have a profound effect on the dental profession.

Description of CAD/CAM

Dental CAD/CAM is the application of computer-assisted design and manufacture to dentistry. To this has been added a first step of capturing information, analogous to making an impression. CAD/CAM systems are technically complex instruments whose operation involves three distinct steps: gathering information, designing the restoration, and fabricating the restoration.

The first step: collection of information

The first step, which for a long time has been the specialty of dental CAD/CAM, is the collection of the maximum amount of intraoral information in association with certain diagnostic and therapeutic elements. This guarantees correct software function and the creation of an individualized prosthesis.

After preparation of the area to be treated, the dentist makes the optical reading or measurement using an electromechanical or electrooptical capture device, either directly in the mouth, or indirectly on a cast. Most CAD/CAM methods use the metrological properties of the laser beam for measuring, and those of the charged coupled device camera for reading. Even though some methods substitute the use of a micropalpation device for the camera, or use a second charged coupled device instead of the laser, these systems remain quite similar for the most part. The laser or "structured" lights [1] can be represented by the projection of a fine fringe or one of several screens whose superimposition allows one to obtain particular physical phenomena, such as Moire, and assures three-dimensional recognition of the object. Irrespective of the method of imaging, this measurement leads to the three-dimensional capture of a cloud or pattern of points representative of the object and referenced in space. This does not differ much from the traditional method, in which the stone cast serves as a storage of information, and does not require any prior knowledge of the relative position of each point that constitutes the surface. The second part of this first step consists of indicating on the digitized object and reconstructing on the video screen a certain number of points and information whose specific identification is crucial to the fabrication of the prosthesis (contact areas, physical boundaries, identification of occlusal determinants, and others). This operation, conducted by the practitioner, will be followed by calculation of the surface topography and correlation of multiple views if more than one image has been made.

Abbreviations
CAD—computer-assisted design; CAM—computer-assisted manufacturing.

© 1991 Current Science ISSN 1046–0764

ClearCorrect Exhibit 1002, Page 1344 of 3373

The second step: design of the prosthesis

The second step is the creation step derived from classical industrial CAD, but whose software uses concepts unique to dentistry. One of its most important fundamental properties is that a functionally and artistically satisfactory restoration will be created from the oral impression and some additional information with no prior knowledge of any forms or volumes. The process is far more advanced in this area than methods of x-ray scanning or imaging using magnetic resonance, wherein an object is only visualized, but cannot be produced. This ability requires a creative and evolving expert system capable of responding to all of the situations that might be encountered. This also requires a very professional interactive instrument. One may return at any time to the preceding interactive step during the process of modeling and constructing both the internal surface (allowing consideration of needed cement space) and the external surface (providing development of the desired occlusal morphology) of the prosthesis. Only one of the systems presented here has this capability, and it remains reserved for the most sophisticated. Some systems merely reproduce the negative of the preparation, requiring a manual finishing of the unknown external surfaces. Only the systems completely modeling all surfaces and creating them truly merit the name *dental CAD/CAM.*

The third step: manufacture of the prosthesis

The third [2•] and final step corresponds to the manufacturing of the prosthesis created during the preceding steps. This is usually a classic milling procedure using various degrees of technological sophistication ranging from a simple pantographic device that copies a manually created model to the true four-axis milling center with automatic tool changing. In all instances, dental CAD/CAM is completed using traditional manual finishing procedures.

Various systems for creating dental prostheses using a computer

At this writing, there are two commercially available systems that can be called *dental CAD/CAM.* Perhaps some are about to be presented for distribution, but some information is contradictory, and discretion is advised. Systems will be discussed in ascending order of complexity.

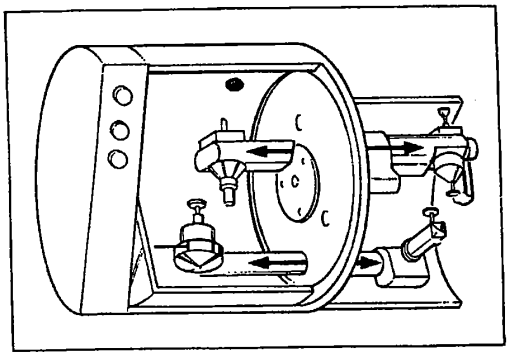


Fig. 1. Sketch of the CELAY system. Tracing of the pattern on the left side of the unit provides information for the machining of the ceramic restoration.

The CELAY system

The CELAY system [3•] (Mikrona Technologie, Spreitenbach, Switzerland) is a micropalpation system and uses a four-axis micromilling device. It is used only for inlays and onlays. The dentist must first develop the desired restoration using hard resin that can resist deformation while being read by the palpation tracing device. This resin restoration is placed under the tip of a tracing device (Fig. 1) whose form is exactly like that of the milling tool. The material for the finished restoration is placed under the machining head. These reading and milling units are linked by a pantographic arm. The cutting tool follows the profile indicated by the reading head that traces the resin model. This method allows the creation of an inlay, including the occlusal surface, in approximately 20 minutes without having to use a casting technique or an optical impression. However, it requires the fabrication of an intermediary unit in the mouth or on a cast, a time-consuming and delicate procedure. The method is limited insofar as the type of prosthesis that can be created, and is relatively expensive.

The Procera system

The first publications on the Procera (Nobelpharma Inc., Göteborg, Sweden) system date from 1987 [4 ••]. It is a simple copying and milling system using a pantograph and electroerosion system. The system is designed for the fabrication of titanium copings through the following process: a die of the preparation is made using classic impression-and-cast proce-

ClearCorrect Exhibit 1002, Page 1345 of 3373

dures. The die must be hard enough to resist abrasion by the pantographic tracing point. The die is placed under a reading point connected to a milling system by a pantographic arm. A carbon graphite duplicate die is made that is uniformly slightly dilated to provide space for cement. Usually, three carbon dies are created in this manner. The original die is also used to guide the milling of titanium, using greater uniform expansion adequate to allow the desired thickness of metal in the finished coping. This creates a titanium coping shaped as an expanded form of the original preparation. The internal surface of this piece of titanium is then formed using an electroerosion process. The titanium piece is placed upside down on an electroerosion plate, while the carbon die, acting as the milling electrode, is progressively inserted into the internal part. Inasmuch as some of the integrity of the carbon die is lost during the process, one or more new rods are used to refine the machining. Following the electromilling process, the titanium coping is veneered with resin or porcelain.

This system has been the object of a clinical study and shows interesting results. A number of patients have been treated in Sweden using crowns produced by the this method [5•], and acceptable results have been reported. The cost has not yet been announced. The process takes approximately 1 hour and is limited to the production of a coping. The advantage is that the coping is fabricated from titanium, a very biocompatible material.

The Titan system

The Titan system [6•] is a composite procedure that has not yet been completed. It involves reading by micropalpation tracing, a CAD station, and a CAD milling unit. This device is produced by the Swiss firm, DCS Dental in Allschwil, and should be introduced in 1993. Even though the information available is still contradictory, it appears that the manipulation principle is as follows; The tooth preparation is made in the conventional manner. Information is gathered either directly from the tooth or from a die, using the micropalpation tracing device in either instance. This information is transferred to a CAD computer. The CAD system is not yet fully developed but appears to resemble that of the Duret system. The milling of a titanium form is accomplished from data issued by the software, using a professional-type machine tool and numerical commands. This system is still in the preproduction stage, so it is impossible to provide any information on the quality of the restorations created. The system allows the creation of titanium restorations and has an announced cost of between $300,000 and $350,000.

The Cerec system

The Cerec system uses data that is gained from an optical method taken either from a stone die or directly intraorally. The Cerec system was developed by an engineer (Marco Brandestini) and a dentist (Werner Mörmann) of Zurich, Switzerland [7]. This system is manufactured by the Siemens Dental Corp. (Benshein, Germany). The first professional publication dates from 1985, and approximately 250 systems have been sold throughout the world. There are several scientific studies done by various university teams [8•] that give a precise idea of the characteristics of this device.

The Cerec equipment is a compact assembly [9 ••] enclosing an image-treatment station with screen, and a micromachine tool using two and one half axes. A camera using a 256 X 256 charged coupled device allows the capture of information about the inlay or onlay preparation. Only one view can be made. The absence of the CAD stage means that the machine tool can only mill the interior of the inlay or the laminate veneers. The external or occlusal portion must be created manually in the mouth or on the die. This restoration is created using Dicor glass-ceramic (Dentsply International, York, PA) or Vita porcelain material (Vita Zahnfabrik, Bad Sachingen, Germany).

Although the method is limited in its applications, its precision of marginal adaptation is within approximately 100 μ [10•]. At $35,000, it is cost effective. Its compactness, simplicity, and maneuverability make it practical to use. Approximately 45 minutes are necessary to complete an inlay.

The Duret system

The Duret system is the result of 20 years of research and development by Duret [11•,12] and his team of engineers. It is the first known CAD/CAM system. It is in use in 30 dental offices in France and at an American Dental School (USC) [13 ••].

This system unites the three basic components of dental CAD/CAM: optical reading, CAD, and milling (Fig. 2). The optical impression is made from a cast or directly in the mouth by a 512 × 512 charged couple device camera using an interferometric method derived from electronic Moire patterns. It allows the taking of a view and the correlation of up to 16 different images. The CAD station allows the creation of all the classic prosthodontic elements: coping, crown, inlay, and soon, fixed partial dentures, including the external and occlusal surfaces. In particular, the connection of this device with an electronic articulator (Access Articulator, under contract development) assures an incorporation of the kinematic mandibular movements into the design of the occlusal surfaces. The milling, in metal, ceramic, composite resin, or organo-ceramic (Aristee, Spad, Dijon, France) materials is accomplished using a 3.5-axis machine tool custom designed for this application. The fabrication of a crown requires approximately 1 hour [14]. The system remains in limited distribution with a price that is quite expensive ($200,000). However, the variety of restorations possible, along with a precision of less than 50 μ at the marginal junction, leads one to believe that it will remain the spearhead of the new technology. Its effectiveness in routine dental practice remains to be seen.

ClearCorrect Exhibit 1002, Page 1346 of 3373

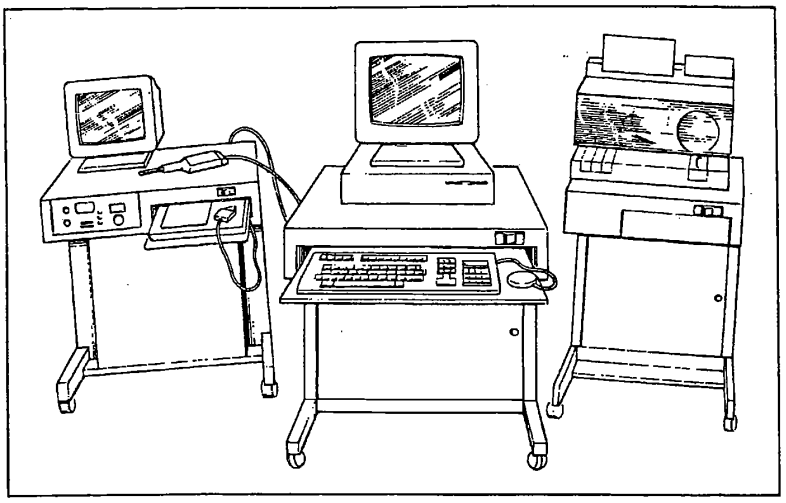


Fig. 2. Sketch of the Hennson system showing the imaging station (*left*) with laser camera, mouse, and display monitor. The CAD station (*center*) is primarily mouse-driven and has a high-resolution monitor. The CAM unit (*right*) is a small, self-contained complete machining system.

Systems under development

A number of systems are being developed, but have yet to be publicly displayed, and it is difficult to know their actual level of advancement. Their developers are respected and dedicated in their work. The two systems most well known and apparently technically close are those of Rekow (Baltimore, Maryland) [15•,7] and Tsutsumi (Kyoto, Japan).

The Rekow DentiCAD system

Rekow (unpublished data, 1991), is developing a system that she has stated will produce crowns, inlays, and eventually, fixed partial dentures. Now working at the University of Maryland in Baltimore, Rekow recently moved from intraoral photogrammetry and laboratory laser imaging to a form of micropalpation. A tracing probe resembling a periodontal probe relays intraoral information on the form of the tooth preparation that is used with the CAD system to create the desired form. The milling machine is intended to work with resin, ceramic, or metal materials. Single crowns fabricated from a laboratory cast using the previous CAD/CAM system design have been presented by Rekow. This system was recently licensed to BEGO GmbH (Bremen, Germany).

The Kyoto Project

Tsutsumi of Kyoto University heads a team of scientists working to produce a CAD/CAM system based on optical recording [16•]. The system uses the projection of a light structured by a laser fringe and stereoscopic recording. The level of the CAD system is not known. A conventional CAM unit operated using numerical commands is used.

Until these systems are actually in use and the costs and relative accuracy are known, any other statements would be conjecture.

Conclusions

While the first dental CAD/CAM machine was presented in 1983 and the first crown created in 1985, 4 more years were required before the first systems were built and used in dental offices. It is the opinion of the authors that the systems will continue to improve in versatility, accuracy, and cost effectiveness, and that they will be a part of routine dental practice by the beginning of the 21st century.

Annotated references and recommended reading

Papers of special interest, published within the annual period of review, have been highlighted as:

- • Of interest
- •• Of outstanding interest

1. BIEMANN A: **Three-dimensional machine vision.** *Photonics Spectra* 1988, 22:81–92.

2. • DUNCAN J, LAW K: *Computer-Aided Sculpture.* Cambridge ed. Cambridge University Press, 1989, pp 162.
An excellent book on the modeling and milling of awkward forms, written by one of the pioneers of CAD/CAM.

3. • *CELAY System Catalog* Mikrona Technologie, Spreitenbach, Switzerland, 1990, pp 1–4.
The only known document on the CELAY system (Mikrona Technologie Spreitenbach, Switzerland).

4. •• ANDERRSON M, BERGMAN B, BESSING C, ERICSON E, LUNDQUIST P, NILSON H: **Clinical results with titanium crowns fabricated using duplication and spark erosion.** *Acta Odontol Scand* 1989, 47:279–286.

ClearCorrect Exhibit 1002, Page 1347 of 3373

Description of the method with very good figures. Presents the first clinical results.

5. • BERMAN B, BESSING C, ERICSON G, LUNDQUIST P, NILSON H, ANDERSSON M: **A follow-up study of titanium crowns.** *Acta Odontol Scand* 1990, 48:113–117.

The authors present clinical results of the Procera (Nobelpharma Inc, Göteburg, Sweden) system and provide a very in-depth study.

6. • *Unser DCS Titan System Catalog*: DCS Dental 1990, pp 2.

The only known document on the Titan (DCS Dental, Allschwil, Switzerland) system.

7. WILLIAMS AG: **The Switzerland and Minnesota developments in CAD/CAM.** *J Dent Pract Adm* 1987 4:50–54.

8. • HEYMANN HO: **CAD/CAM: exploring the Cerec system.** *Dentistry Today* 1990, 9:6–54.

The author presents results of the use of the Cerec system in the United States. However, some errors are noted.

9. •• MÖRMANN WH, BRANDESTINI M: *Die CEREC Computer Reconstruction: Inlays, Onlays, and Veneers.* Quintessenz Verlags-GmbH 1989, pp 250.

An excellent work that must be read. It offers a complete description of the Cerec system (Siemens Dental Corp. Benshein, Germany).

10. • MOERMANN WH, BRANDESTINI M: **Chairside computer-aided direct ceramic inlays.** *Quintessence Int* 1989, 20:329–339.

The authors give their opinion of Cerec (Siemens Dental Corp., Benshein, Germany) and present the clinical results. It is a good classification of FDA standards.

11. • CATANEO P: **Special informatique.** *Dent Hebdo* 1991, 197:13.

The author gives a resume of the use of a computer in a dental office and offers an opinion on the Hennson system in France.

12. WILLIAMS AG: **Dentistry and CAD/CAM, another French revolution.** *J Dent Pract Adm* 1987, 4:2–5.

13. •• CROOKS C: **CAD/CAM comes to USC.** *USC Dentistry* 1990, Spring:14–17.

A good description of Hennson's CAD/CAM as seen by University of Southern California.

14. DURET F, BLOUIN JL, DURET B: **CAD/CAM in dentistry.** *J Am Dent Assoc* 1988, 117:715–720.

15. • REKOW D: **Computer-aided design and manufacturing in dentistry: a review of the state of the art.** *J Prosthet Dent* 1989, 58:512–516.

An older paper, but it is one of the basic articles on CAD/CAM.

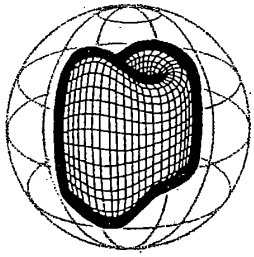
16. • KIMURA H, SOHMURA T, WATANABE T: **Three-dimensional shape measurement of teeth. Part 3: on the measurement by the newly developed laser displacement meter with double sensors.** *J Osaka Uni Dent* 1990, 2:295–300.

One of the numerous articles written by this team. It is a good description of reading by laser fringe.

F. Duret, DCD, PhD, Section of Dental Imaging, and J.D. Preston, DDS, The Don and Sybil Harrington Foundation, University of Southern California, School of Dentistry, Los Angeles, CA 90089-0641.

ClearCorrect Exhibit 1002, Page 1348 of 3373

DURET

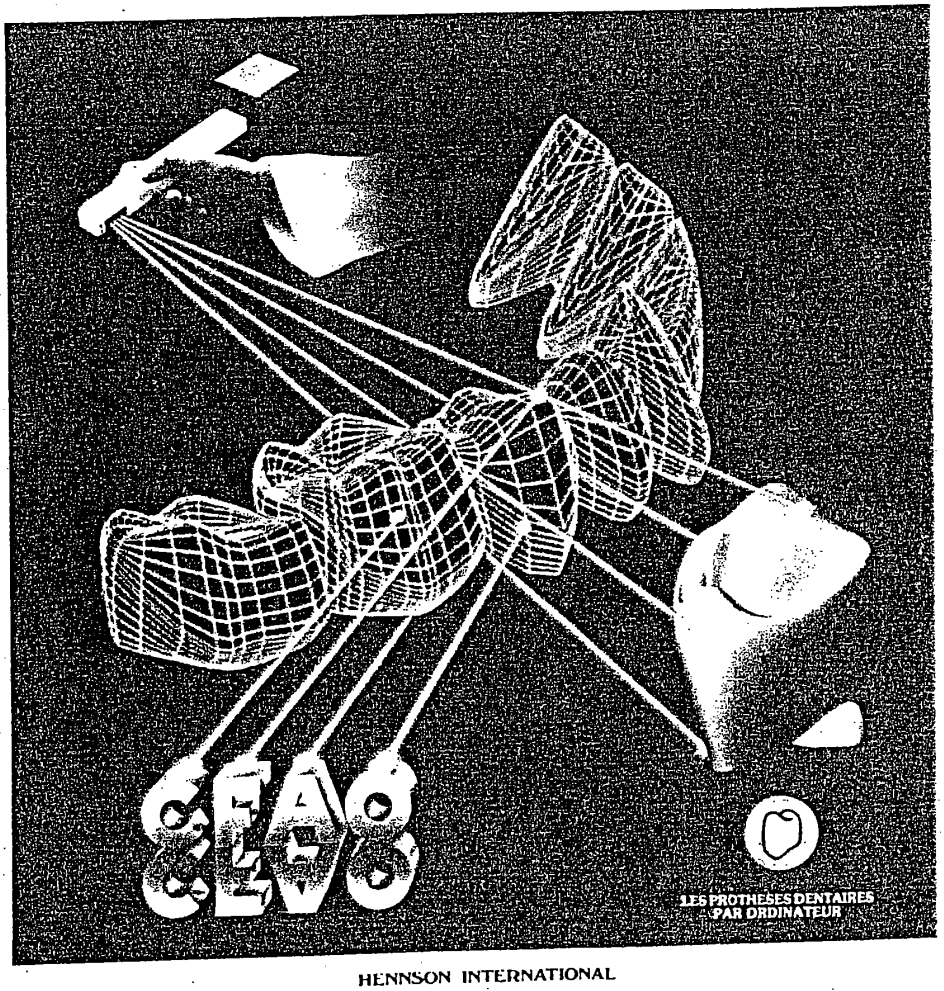


HENNSON

INTERNATIONAL

CHÂTEAU DE MALISSOL - F-38200 VIENNE - FRANCE
TÉL. (74) 57.23.70

HENNSON



HENNSON INTERNATIONAL

THE DENTAL CAD/CAM

GENERAL DESCRIPTION OF THE PROJECT

January 1986

DENTAL CAD / CAM

SUMMARY

HISTORY

INDUSTRIAL AND COMMERCIAL STATE

1) What is CAD / CAM ?

2) How did CAD / CAM take form in the dental field ?

3) What is Dental CAD / CAM ?

4) State of industrial development

5) State of commercial development

6) Cost of the equipment

7) Composition for the prosthesis

HISTORY

For the first time the CAD/CAM process enabling design and manufacture of a dental crown in less than one hour without neither paste nor moulds was created and fitted, in a single sitting inside the "Palais des Congrès" during the International Congress of the French Dental Association. It is on his wife that *Doctor DURET*, the inventor, tested the first prototype made by a French company : *HENNSON International* .

The operation attended by a very large number of French and foreign dental specialists with much enthusiasm, took place in PARIS on Saturday afternoon November 30. 1985. It thoroughly demonstrated the complete feasibility of a revolutionary system of which people had the opportunity to discuss during the Garancière meeting in September 83.

This is the result of fifteen years of research and of a partnership rarely met between and extremely outstanding firm a subsidary of *the OCE Group* in LYONS and a totally independant researcher *Doctor DURET*.

Let us review the highlights of the evolution of this project.

It was precisely at Christmas 1971 when *Doctor DURET* invented this complex association between the three-dimensional optics, the design by computer and the manufacture of crowns by a digitally controlled machine-tool.

Thanks to the support of outstanding professors such as J. DUMAS from LYONS, J. EXBRAYAT (currently Dean of Nice University) M. MARTY from the LYONS INSA (National Institute of Applied Science) he realized this line of research could be envisaged in odontology , i.e. in the Science of dental surgery.

From 1976 until 1981, he pursued this work under the direction of the Professor Y.THOUVENOT whose works are authoritative in medical imagery. The latter gave him his total support and widely helped him to counter the reticenses of many sceptics.

From 1981, the project took a positive step thanks to the work in collaboration with his friend Ch. TERMOZ of the THOMSON and MATRA DATAVISION Companies.

This collaboration enabled the presentation of a first feasibility model on September 25. 1983 inside the Parisian School of Garancière under the professor VIGNON 's presidency.

However, everything was still to be done. If the feasibility was partly demonstrated, it still had to be proved and particularly it was necessary to assemble all the pieces together to make and fit a crown in the patient's mouth.

Above all, it is the meeting of two men : *J.L. BLOUIN* and *F. DURET* followed by the commitment of a company, managed by *Jean-Pierre HENNEQUIN, HENNSON INTERNATIONAL*, that enabled to reach this objective. This demonstration, the result of a close collaboration is an essential step, unique in the world.

It is unique for several reasons :

- the demonstration took place in a congress, on a patient and in real time, i.e. a transportable equipment therefore perfectly adaptable to a dental operatory will be used to define the shape of the mouth, design a fixed prosthesis and permit the manufacture and insertion in the patient's mouth.

- at every level, the methods used are leading technologies. Particularly, the method of taking and reconstruction of the impression are extremely original.

- since its origin, the dental CAD/CAM method differs from the scanner or the N.R.M. Actually, if the last two ones only make an analysis of the organs and visualize them, the CAD/CAM goes on to carry out an automatic diagnosis and therapeutic treatment.

ClearCorrect Exhibit 1002, Page 1354 of 3373

- in spite of this, the specialist retains full capability to intervene and make best use of his knowledge. We can see it is the first complete medical system combining diagnosis and therapy.

It is a CAD/CAM process combined with the artificial vision which can be directly used in everyday life, everyone can benefit from it at any time of his life.

This demonstration shows, once more, if it were necessary, the high quality of the cares and the research in an area often overlooked : the French Dental Surgery.

We can only be proud to state that a dentist is at the origin of anaesthetia and again a dentist is at the origin of the Medical CAD/CAM.

---oOo---

ClearCorrect Exhibit 1002, Page 1355 of 3373

INDUSTRIAL AND COMMERCIAL STATE

1) What is CAD/CAM ?

As its name indicates, the Computer Aid Design and Computer Aid Manufacture (CAD/CAM) is a process which consists in using the modern computer power for a wide automation of the manufacturing process.

Almost non existent fifteen years ago, the CAD/CAM market passed the two billion dollars with an annual growth over 35 %, it will be about 20 billion dollars in 1990.

The CAD/CAM evolution has several common points with the computerized management evolution which is very close as regards to technique and strategy point of view.

2) How did CAD/CAM take form in the dental field ?

From 1971, a young dentist surgeon of GRENOBLE, Doctor DURET, imagined the computer would enable the specialists to design and manufacture automatically dentures of high quality, so quickly that in a single visit the dentist could perform the design, the shape and the fitting of a prosthesis.

But for this, the machine had to be equipped with an "eye" so that it could see in relief in the patient's mouth and with a mechanical instrument immediately ensuring the manufacture of the prosthesis under its control.

For twelve years, Doctor DURET, who has a wide science education, worked with different colleagues to elaborate a process of three-dimensional optical imprint and to conceive a dental CAD/CAM process. In 1983, he presented the results of his work to the Dental Profession during the Garancière Dental Surgery meeting in PARIS.

3) What is Dental CAD/CAM ?

The innovation consists in using the CAD/CAM for the design and the manufacture of fixed prosthesis.

The actual method of design and manufacture of dental prosthesis has the disadvantage of being lengthy and expensive. This method used for over 300 years has not received any fundamental modifications in its operation.

It includes the following steps :

- taking of impressions in the mouth with impression material in the dentist's operatory

- sending of this impression to the dental technicien who manufactures a cast and fabricates the prosthesis following the method called "lost wax"

- testing and modifications of the prosthesis at the dentist's (sometimes they are numerous and unpleasant)

The new process combines a method of optical imprint-taking with a complete system of CAD/CAM including an automatic manufacturing micro-milling procedure for the prosthesis.

- **the optical probe** enables an image capture in relief (i.e. in three dimensions) in the patient's mouth, showing the preparation intended to receive the prosthesis and of the nearby teeth (upper and lower jaws).

- this image is converted in digital data and transmitted to a **CAD computer** which enables to restore the missing teeth on the screen, following a very accurate dental method from theoretical memorized shapes.

- then, this computer guides a **digital controlled micro-milling machine** which carves the prosthesis from a little block (preshapes) of the chosen material (metal-composites or ceramics).

The new process offers many advantages :

- suppression of the use of impression material which is lengthy, unpleasant and relatively inaccurate

- significant reduction of the dentist's operation time.

- very significant reduction of the time of design and manufacture of the fixed prosthesis, which limited to a single visit, offers conditions of care much more comfortable for the patient from the physical and psychological point of view.

- better quality both in shape and fitting of the fixed prosthesis

- possibility of using new and better adapted, more aesthetic and cheaper materials.

REMARKS :

. Simplifying the dentist's working methods this new process gives them an independence a better quality and much more rapid ease of execution.

. The use of the process can be directly extended to applications in the orthodontics, the conservative odontology and the paraodontology fields ; with applied software, it can give the specialists a power of considerable diagnosis.

4) State of the industrial development ?

In 1984, an industrial group of LYONS OCE chaired by Mr. Jean-Pierre HENNEQUIN, signed a contract of sole rights licence for the operation of the Doctor DURET's invention and for the industrialization of the process, created its subsidary HENNSON INTERNATIONAL, the head office of which is in VIENNE, in ISERE.

The HENNSON INTERNATIONAL company is composed of very highly qualified ingineers working in close collaboration with a "dental team" supported by Doctor DURET. This "dental team" includes specialists as well as dental professors.

In 1983, Doctor DURET has presented a model of feasibility of his process to the Dental Profession. The manufacturer's role is to transform it into a feasible, reliable apparatus in thousands of copies that can be easily used and profitable for its users.

This work is even more important because the requirements are those of a market of an international dimension . To succeed, as quickly as possible, HENNSON calls on some firms well known for their high level of competence such as BERTIN, MATRA DATAVISION and THOMSON CSF.

On November 30 th 1985 at the International Congress of the French dental Association, Doctor François DURET presented "in world premiere" the manufacture of a dental crown with an optical imprint on a patient, followed by the design and the manufacture assisted by computer of a prosthesis.

5) State of the commercial development ?

The launching of the manufacture of the first production equipments is planned in the second half of 1986, because, before the apparatus will be subjected to an extensive clinical testing.

The professional demand is already very strong for this truly revolutionnary equipment.

This demand comes from two different sources :

- the one coming from French and foreign specialists and dental mechanics wishing to equip themselves. It is more and more urgent with the development.

- the other one which comes from large industrial and commercial companies involved in the industrial dental market. They wish to have exclusive distribution or even manufacture for the product rights. Negociations are in progress.

6) Cost of the equipment ?

Notibly, there will be more than one model of apparatus on the market, but there will be several possible configurations, for instance, several specialists working in the same surgery can equip each of their operating theatre with an apparatus of optical imprint-taking , connecting them to a single manufacturing machine.

The price of the various configurations varies from 150 000 to 500 000FF (tax free) but to be realistic, one must compare its cost of depreciation and use with the actual cost of purchase of prosthesis. For many dental procedures, it will be immediately profitable, the more so because the fixed prosthesis are feasible within a single visit.

7) Compositions for the prosthesis ?

Many people thought that since the apparatus manufactures the prosthesis by machining it could only make metallic fixed prosthesis. It is not the case, and for a long time Doctor DURET and his team have worked on the manufacturing of much more aesthetic materials such as composites and ceramics.

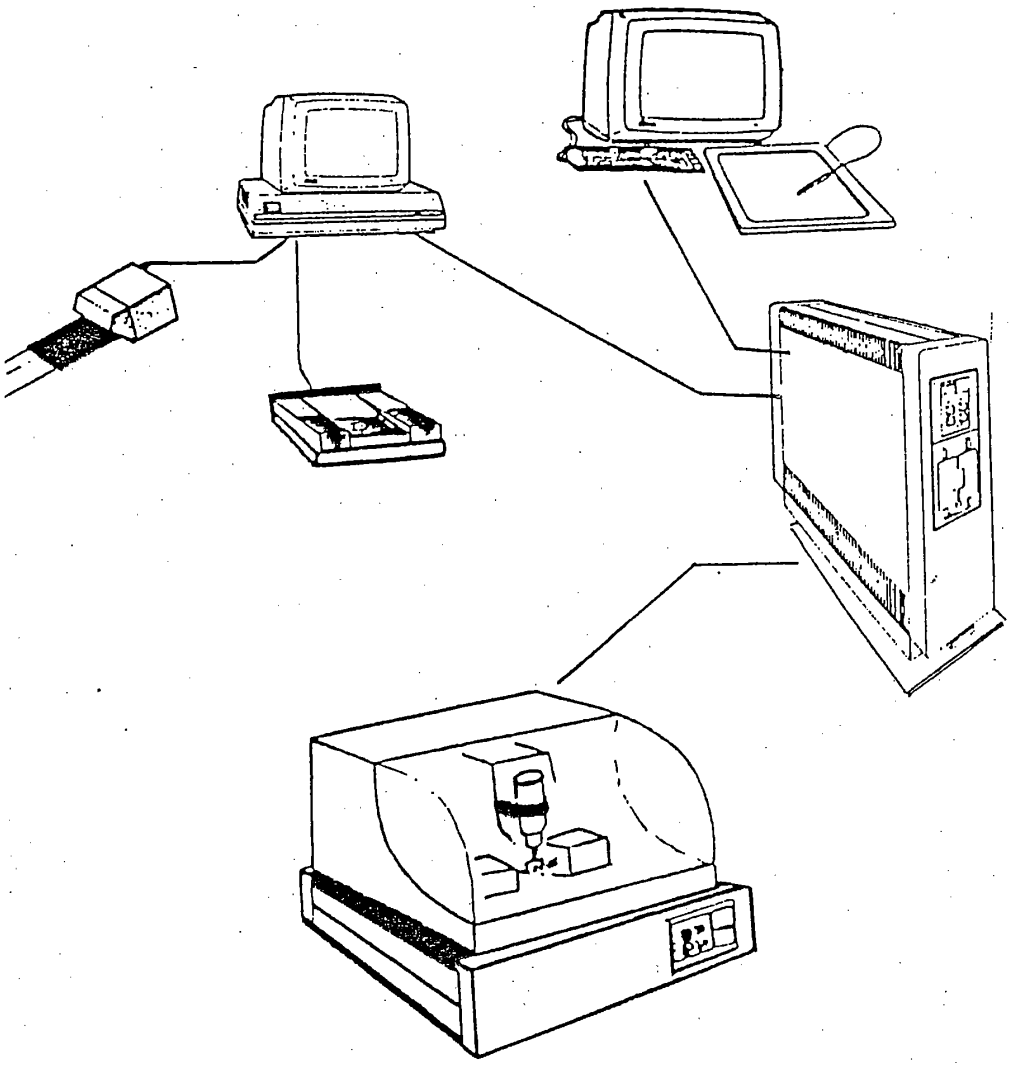
Actually, it is undeniable that these "aesthetic materials" will come into general use, for today, what makes the high price of the so made prosthesis is much more the cost of the actual manufacturing process than the material cost.

The CAD/CAM fundamentally changes these facts.

Today, thanks to the lightning development of composite materials , we can envision the production of high quality mechanical and aesthetic prosthesis.

HENNSON INTERNATIONAL

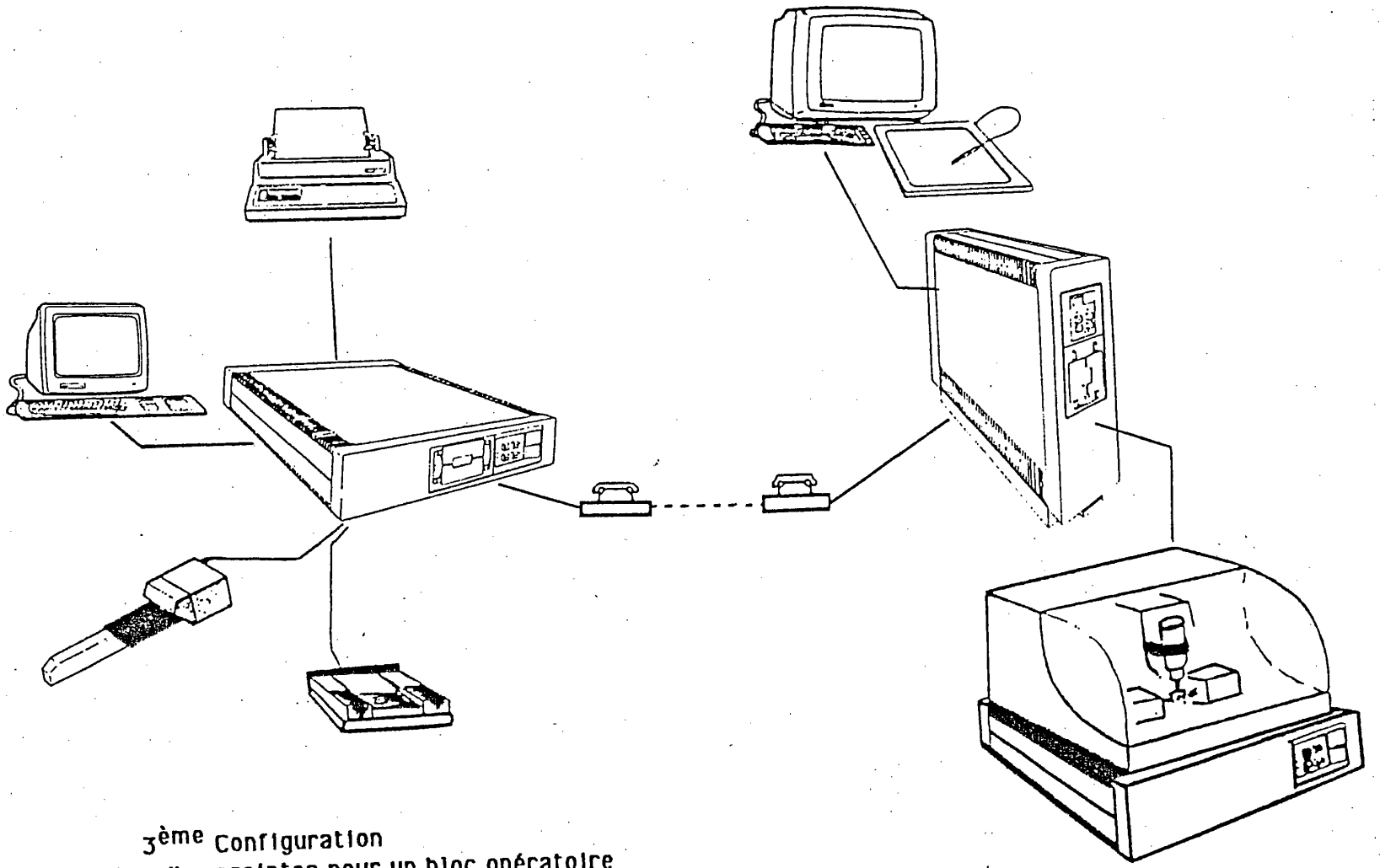
Legal Form	:	public company
Capital	:	5 600 000 F
Head Office	:	Château de Malissol 38200 VIENNE
APE Code	:	3406
Trade Register Nr.	:	VIENNE B 329 107 056
Financial year's closing date	:	31st December
Established	:	1st January 1984
Company's aim	:	conceipt and manufacturing of CAD/CAM devices for dental prosthesis.
Staff on 1st January 1986	:	9
Company's management	:	
Chairman of the Board	:	Mr. Jean-Pierre HENNEQUIN
General Manager	:	Mr. Gilles DECHELETTE
Directors	:	Mr. François DURET
Address	:	Château de Malissol 38200 VIENNE
Tél.	:	74 57 23 70



1ère Configuration
Equipement complet pour un seul bloc opératoire.

ClearCorrect Exhibit 1002, Page 1362 of 3373

2ème Configuration
Equipement complet pour cablnet de trois blocs opératoires



3ème Configuration
Equipement de prise d'empreintes pour un bloc opératoire
avec transmission par modem.

ClearCorrect Exhibit 1002, Page 1364 of 3373

François DURET
Draye des vignes
38 690 le grand Lemps
(76) 55 87 86

Né le 8 décembre 1947 à Chalon sur Saône (71)
marié-2 enfants

DIPLOMES

1. - UER des Sciences Odontologiques
   - 1973 Diplôme de Chirurgien Dentiste
   - 1974 Docteur en Chirurgie Dentaire
   - 1975 Certifié d'études supérieures en Parodontologie
   - 1976 reçu au concours des Assistants Odontologiques
   - 1980 Docteur en Sciences Odontologiques
   - 1981 Equivalence du DERSO

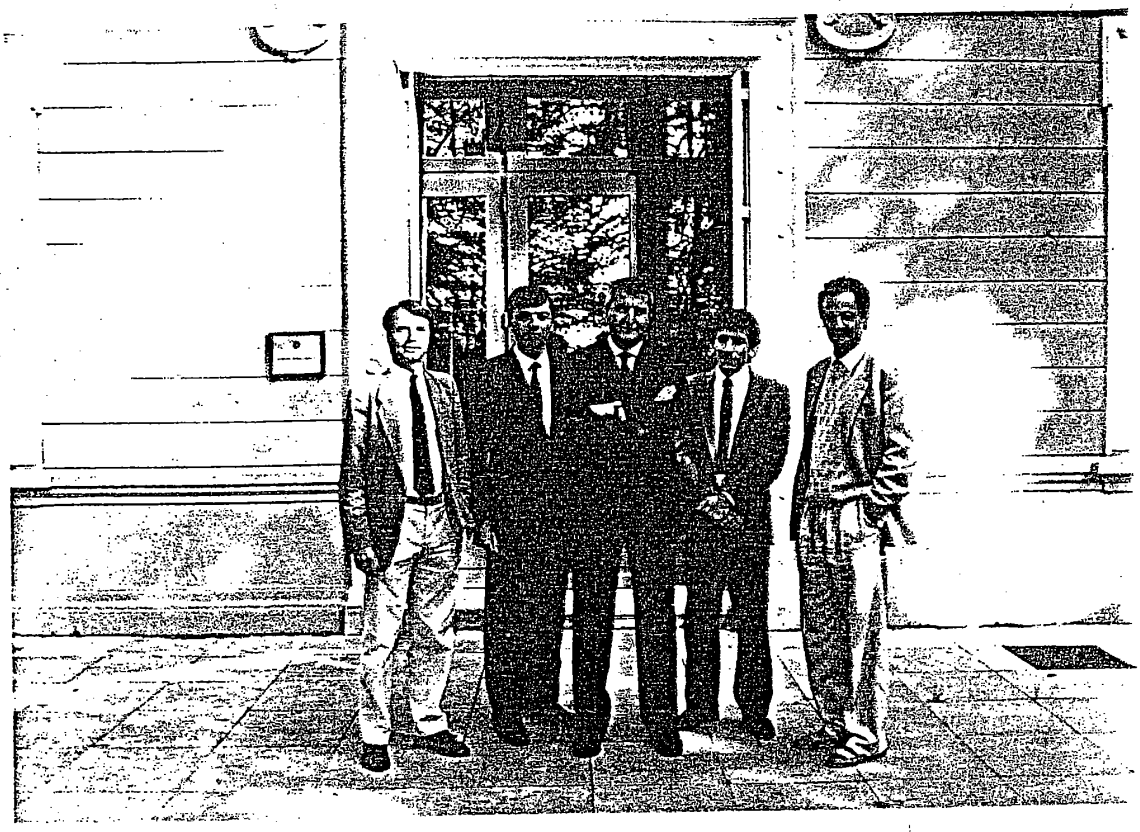
2. - UER des Sciences
   - 1969 Diplômé d'études Scientifiques (Chimie-Biologie)
   - 1971 Certifié d'études supérieures en Physiologie Animale
   - 1973 Certifié d'études Supérieures en Biochimie
   - 1974 Licencié es Sciences
   - 1976 Certifié d'études supérieures en physiologie des régulations
   - 1976 Maître de recherches en Sciences

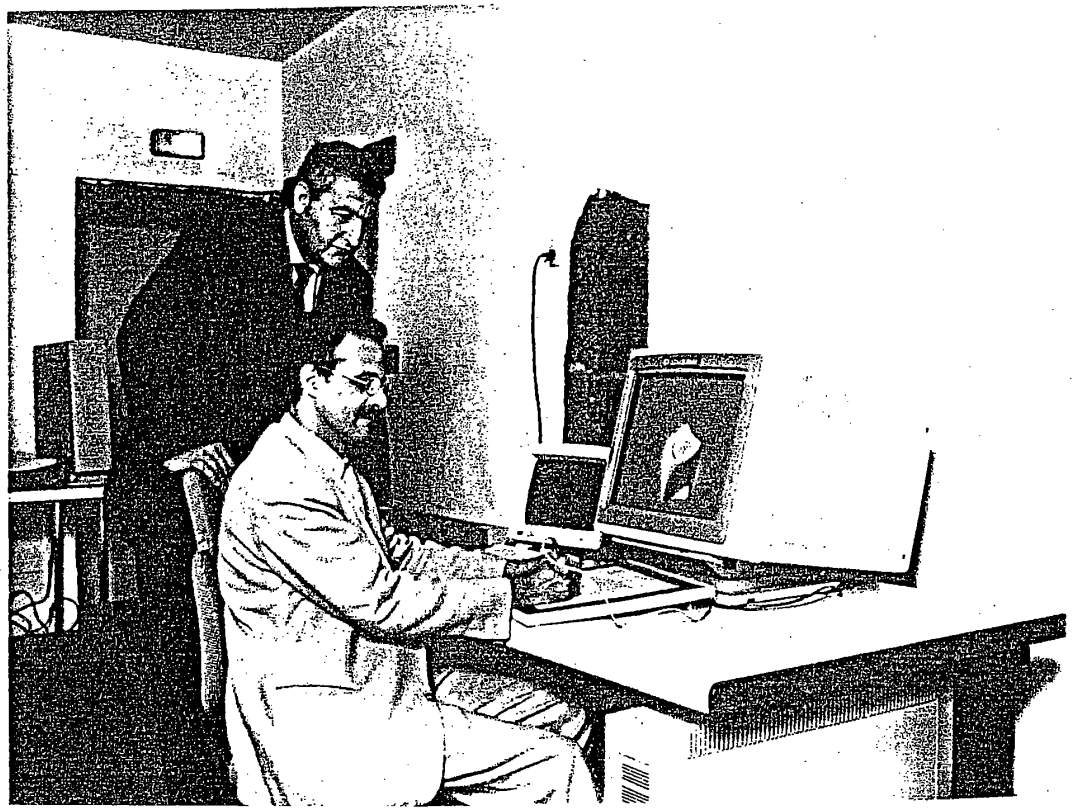
3. - UER de médecine/Biologie Humaine
   - 1975 Certifié d'études supérieures en méthodes de Biochimie
   - 1976 Maître de recherches en Biologie Humaine
   - 1978 Attestation d'études approfondies en Biologie Humaine
   - 1981 Diplômé d'études et de recherches en Biologie Humaine
   - 1983 docteur d'Etat

* premier prix d'encouregement à la recherche pour ses travaux sur les cultures cellulaires. (Paris 1981)

Résumé:

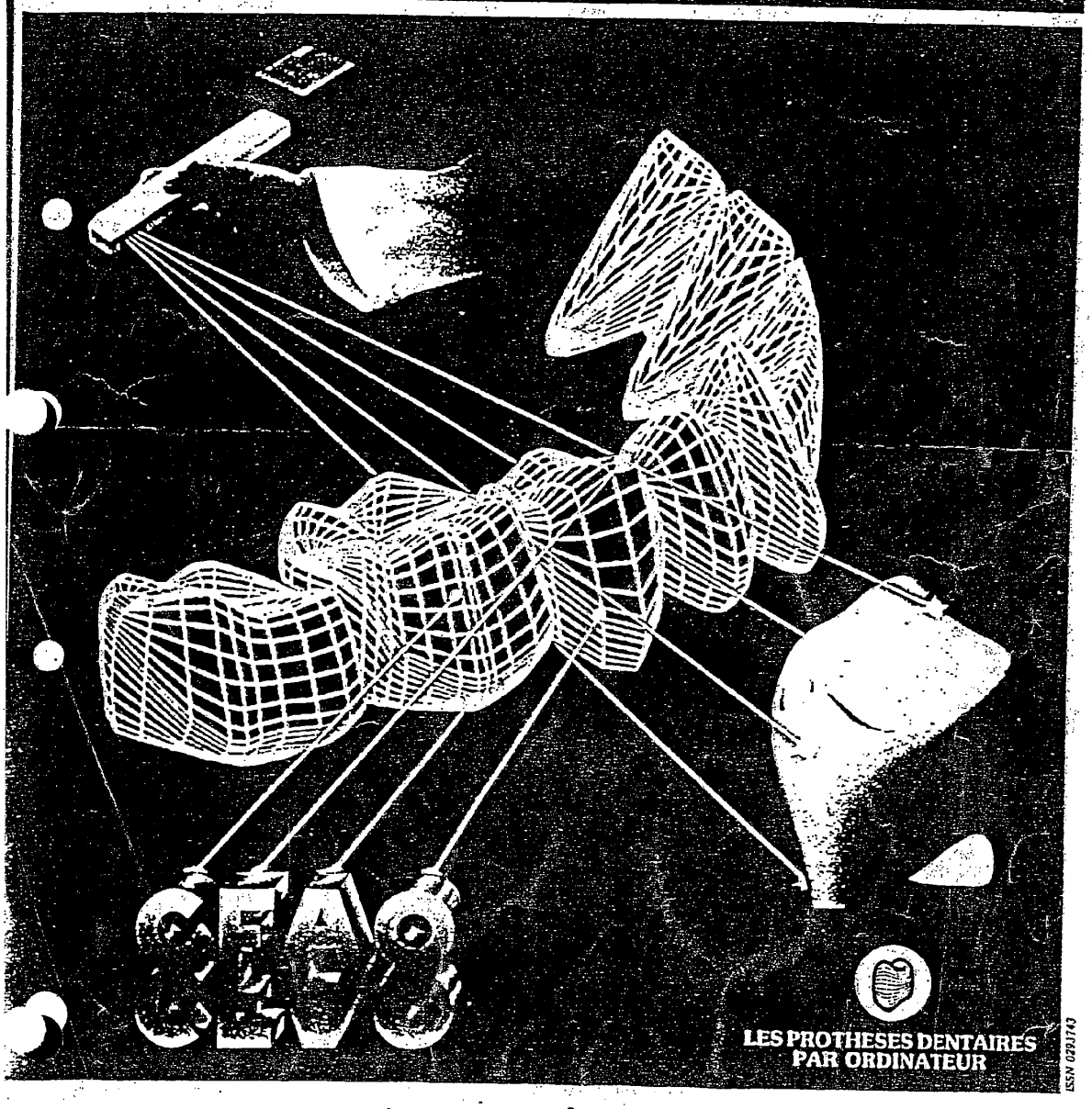
docteur en chirurgie dentaire et Sciences Odontologiques
Licencié et maitre de recherches en Sciences
Maitre et Docteur d'Etat en Biologie Humaine





tonus

ANNÉE SABBATIQUE :
RÉSULTATS DU SONDAGE
TONUS-CDPV (page 58)



LES PROTHESES DENTAIRES
PAR ORDINATEUR

ISSN 0293743

ClearCorrect Exhibit 1002, Page 1367 of 3373

Vers une prothèse informatisée

La réalisation actuelle des prothèses dentaires fixées comprend une succession d'étapes étroitement liées les unes aux autres. L'insuffisance de l'une d'entre elles peut amener l'échec de la reconstruction entreprise par le praticien. Au cours de cet acte thérapeutique, le transfert de l'information de corps en corps, support du relief étudié (empreintes, modèles...) et de la forme de la future prothèse (cire, revêtements...) constitue la règle de base d'une technique actuellement unique et vieille de plus de trois siècles. Si des progrès importants ont été réalisés dans la qualité de ces actes et en particulier dans la fidélité du transfert de l'information, il est incontestable que peu de modifications fondamentales ont marquées l'évolution de cette partie de notre travail. Mais tout risque de changer dans les mois qui viennent...

EN effet, la CFAO (conception et fabrication assistées par ordinateur des prothèses dentaires) indique un nouvel axe de travail et il n'est pas déraisonnable de prévoir son large développement dans un proche avenir au sein de nos cabinets dentaires et de prothèses comme ce fut le cas dans d'autres secteurs techniques. L'aspect inventif du concept nous oblige à parler plus de révolution dans la méthode que d'évolution dans la conduite de l'acte.

Il ; arait comme nécessaire de faire une description du matériel mis au point dans les laboratoires de la société Hennison et qui doit être présenté pour la première fois à l'ADF de 1985. Si en 1983, lors des entretiens de Garancière nous annoncions qu'il nous faudrait deux années pour développer prototype et trois années la sortie des premiers pareils (Antenne 2), nous ne savions pas les difficultés techniques que nous allions rencontrer. En revanche aujourd'hui, cette première étape respectée, il ne nous paraît nullement absurde de prévoir la sortie des premiers appareils au 3e ou 4e trimestre 1986.

COMPOSITION DU SYSTEME

Le système se compose globalement d'une sonde optique, d'un logiciel de traitement du signal, d'un ensemble microprocesseur + logiciel de CAO, d'une commande numérique et d'une microfraiseuse.

La **sonde optique** (dessin n° 1) mesure les dents selon les trois axes de l'espace, c'est-à-dire en trois dimensions. L'aspect très innovant du mode utilisé nous oblige à une extrême réserve dans le descriptif de la technologie suivie. Proche parente du Moiré optique tel que décrit par les anciens (CdP n° 50), elle offre l'avantage de respecter un cahier des charges particulièrement sévère, à savoir surtout moins de 20 µm d'incertitude absolue dans la détermination d'un point dans l'espace de la dent étudiée.



DR

Schéma 1 - La sonde optique.

Photo 2 - Logiciel de création et microprocesseur 32 Bits.

Connecté à la sonde et très dépendante de celle-ci se trouve le **système de traitement d'image** - QOS n° 39 - il doit répertorier de manière numérique les éléments transmis par le DTC (dispositif à transfert de charge) et trier les informations, pour éviter une surcharge au niveau de l'ordinateur. Le DTC (CCD pour les anglo-saxon) est une sorte de microcapteur matriciel remarquable par la fidélité de sa lecture et la rapidité de son « balayage » (3 à 6 Méga hertz). Il permet entre autre d'avoir une image sur une surface plane et ce plusieurs fois par seconde. Il générera une information fidèle et précise de l'environnement appréhendé par la sonde et les valeurs en résultant, traitées par un processeur cablé ou non, seront aptes à être digérées par le logiciel d'exécution de la prothèse. Le processeur de traitement d'image à donc pour fonction de numériser, simplifier puis transmettre les zones d'appui du calcul de la future prothèse.

Utilisant un **microprocesseur 32 Bits**, léger, puissant et rapide le **logiciel de création de la prothèse** (photo n° 2) a pour fonction première de générer la future prothèse respectant l'identité du patient traité. Il ne s'agit pas de refaire n fois le même élément mais de générer une forme intérieure et extérieure respectant les impératifs de la bouche à reconstituer. C'est réellement une conception assistée par ordinateur réalisée par des dentistes pour des dentistes et utilisant un noyau classique de CAO (ici Euclid de Matra Datavision). La création de l'intrados n'est pas une croissance spécifique et calculée mais le résultat d'un triple souci lié au dynamisme d'écoulement des fluides, la minimisation de l'espace et la résistance à la désinsertion. L'extrados, forme et volume créés par le logiciel, s'appuit sur ce qui sera identifié comme des zones privilégiées à savoir les zones de contact, courbures vestibulaires et linguales et espace de l'articulé. Il y a donc création d'une dent théorique originale et idéale que le dentiste pourra garder ou modifier.

Au-delà de cette création se trouve la **commande numérique** (CNC) de la machine outil. Ce logiciel spécifique, mixte cablé/écrit, doit générer non pas une forme mais un trajet d'outil. Ce trajet est en rapport d'une part avec la définition exigée pour une prothèse dentaire et d'autre part avec les caractéristiques géométriques de l'outil de taille. Mis au point spécifiquement pour notre application elle permet de diriger la machine outil dans l'exécution d'un usinage des parties internes et externes de la future prothèse selon un déplacement en trois axes.

La machine outil à commande numérique ne fait qu'exécuter les ordres transmis par la CNC.

obligé sonde

ClearCorrect Exhibit 1002, Page 1368 of 3373

Elle a plusieurs outils et plusieurs supports de forme, respectant en celà les exigences d'un bon usinage automatique exécuté par des moteurs à déplacement pas à pas lissés ou linéaires. Le rendu final peut exiger une finition semi automatique pour permettre le scellement immédiat (préformes à couleurs prédéterminées) ou le maquillage pour les praticiens plus exigeants.

Les matériaux utilisés dans cette technologie sont nouveaux et ont des caractéristiques mécaniques et biologiques proches de celles de la zone de la dent qu'ils doivent remplacer. Le fait qu'ils soient préparés industriellement et qu'ils ne subissent aucune transformation structurale avant leur insertion en bouche explique l'importance de cette évolution et la qualité du respect des valeurs physiques du milieu buccal.

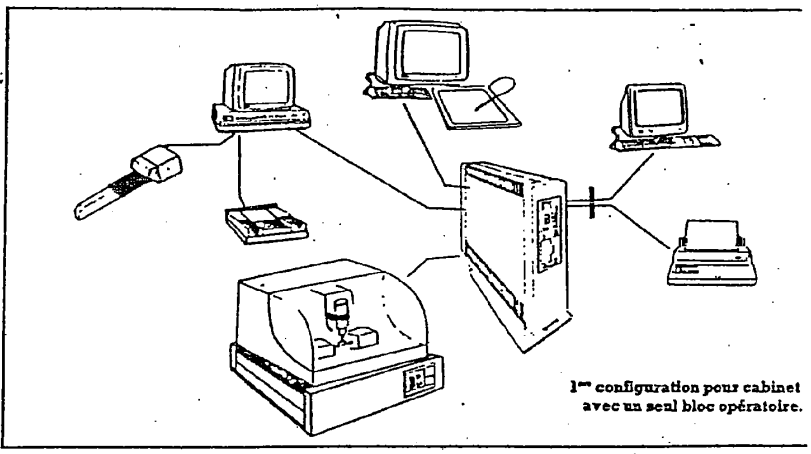
CONFIGURATION DU SYSTEME

Cette brève représentation de l'ensemble des composants de base fait ressortir un aspect modulaire qui permet son insertion dans les cabinets dentaires quelque soit leur configuration.

Les cabinets dentaires n'ayant qu'un seul bloc opératoire (1ère configuration) il est possible d'utiliser un système complet ou seulement une sonde et un système de transmission (modem). Tous ces systèmes de transmission respectent la qualité de l'information comme son secret (codage d'accès aux données) et permettent des modifications de logiciels spécifiques. Ils offrent enfin au praticien la possibilité de suivre l'évolution des programmes dans le temps.

Dans un **cabinet à plusieurs fauteuils** (2e configuration), le partage de certains éléments est parfaitement compatible avec la structure modulaire de l'ensemble. Ainsi le microprocesseur, le logiciel de CAO ainsi que la microfraiseuse et sa commande numérique peuvent être reliés à plusieurs sondes optiques comme l'est le compresseur pour les units. Cette structure n'empêche nullement l'utilisation d'un modem de transmission vers les laboratoires de prothèses équipés. Tous les avantages de la première configuration se retrouvent ici dans leur intégralité.

Dans **les laboratoires de prothèses** (3e configuration) dans la mesure où le chirurgien-dentiste sera équipé d'un système de saisie, soit l'information sera traitée par le logiciel de CAO du laboratoire et l'usinage aura lieu dans le laboratoire soit l'information de la commande numérique sera retransmise à une machine outil située dans le cabinet dentaire demandeur. Dès aujourd'hui, un certain nombre de prothésiste attache à leur formation de base celle de la CAO pour être prêt à répondre à cette nouvelle demande.



1ère configuration pour cabinet avec un seul bloc opératoire.

LA METHODE D'UTILISATION

Nous pouvons schématiser l'acte de réalisation d'une couronne esthétique ou non par plusieurs étapes. Ces étapes dépendent essentiellement du mode de configuration adoptée.

Dans **la première configuration** (cabinet entièrement équipé) nous effectuons les opérations suivantes :

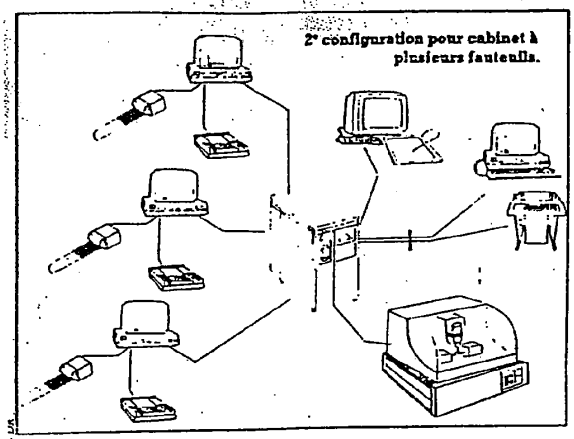
— Prise d'empreinte : le praticien, après avoir effectué sa taille comme à son habitude, devra nettoyer sa zone de lecture et la sécher. L'utilisation des modes de rétraction gingivale classique est souhaitable pour parfaire la lecture dans le sulcus. L'utilisation d'un produit spécifique déposé sur la gencive, voir même sur la dent, peut augmenter la qualité du codage. A ce stade, le praticien prend la sonde, sorte de micro caméra endoscopique, et effectue une succession de prise de vue sous le contrôle d'un moniteur vidéo classique attenant à son unit. Une pédale permet de figer l'image pour un examen attentif, de valider ou de rejeter la vue. Il est possible de relire certaines zones particulièrement inaccessibles. Une main exercée met moins de 3 mn pour faire la lecture de la dent taillée, de ses voisines et la surface antagoniste.

— Un temps relativement court (entre 2 et 4 mn) est nécessaire pour le traitement de l'image et la corrélation des différentes vues. Celà permet au patient de se rincer et au praticien de nettoyer et ranger la sonde. C'est la seule intervention à effectuer dans la bouche d'un patient pour qui l'on prépare un élément unitaire ou de faible étendue.

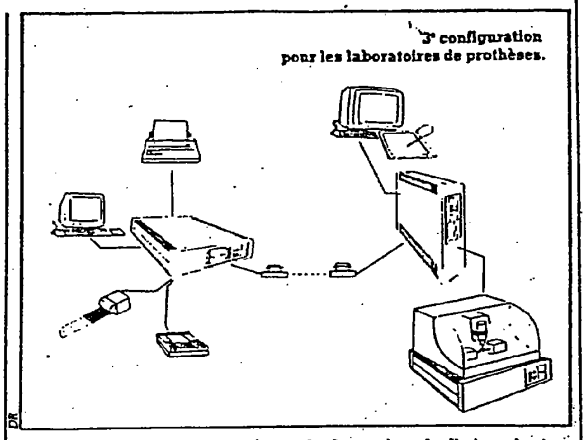
— La suite du travail s'effectue avec l'aide du logiciel de CAO et peut avoir lieu dans le cabinet dentaire ou dans son laboratoire de prothèse. Il nécessite un minimum d'apprentissage qui fera l'objet d'une formation spécifique et obligatoire lors de l'acquisition du système. Ce type de formation est classique pour l'informatique. Elle est aujourd'hui bien acceptée et donne lieu à des échanges d'informations fructueux. Les dents traitées par la sonde apparaissent sur l'écran CAO et peuvent être orientées selon un angle choisi. On procède à la vérification de la taille et à son acceptation ou son refus. Dans ce dernier cas la reprise d'empreinte est nécessaire après retouche du moignon. Si il y a acceptation du travail, le logiciel lissera les contre-dépouilles éventuels et dilatera le moignon pour permettre l'espace du ciment de scellement (Intrados de la couronne).

La réalisation de l'extrados sera par la proposition d'un modèle au praticien. Celui-ci peut accepter ou modifier la forme en utilisant un certain nombre de fonction interactive. Ainsi un effet de loupe (effet zoom) lui permettra de modifier la forme d'un angle, de rapprocher des zones de contact. Il est possible aussi de modifier un sillon, le bord cervical, la position des cernes ou la pointe des cuspides. Dans tout état de cause le langage sera simple et utilisera des termes spécifiquement dentaires. Par exemple : il ne sera

ClearCorrect Exhibit 1002, Page 1369 of 3373



2e configuration pour cabinet à plusieurs fauteuils.



3e configuration pour les laboratoires de prothèses.

question « d'agir sur un vecteur de déformation » mais de « mésialiser la cuspide vestibulolinguale » de la molaire du... Les mouvements occlu... pourront être étudiés se... plusieurs théories et le choix de ces dernières conduira à la modification du relief occlusal spécifique. Nous voyons que l'action permise par le logiciel de CAO s'apparente totalement à la création de la maquette de cire et à la modélisation de la surface occlusale.

L'usinage et le scellement con...ue la dernière phase de l'op...tion. Si la modélisation sur l'écran CAO peut durer entre 2 et 10 mn, la phase d'usinage sera d'autant plus longue que l'élément est complexe, que le matériau est dur et que l'on souhaite avoir un bon état de finition. Cette phase de travail doit être abordée avec le plus grand soin car elle représente l'étape ultime et surtout l'instant de la matérialisation des données chiffrées. Il y a lieu donc de veiller à sa bonne exécution et même si elle est entièrement automatisée (y compris le changement d'outil et le retournement de pièce) il est essentiel de vérifier régulièrement son bon dé...ment. Après avoir choisi ...éforme dans une couleur ...que adaptée à la bouche (Zp, 4A...), la pièce à usiner est posée sur le plateau, fixée automatiquement et le cycle d'usinage lancé par l'intervention sur un seul bouton (marche-arrêt). Le cycle dure aujourd'hui entre 15 et 20mn par élément pour un excellent fini mais celui-ci peut être réduit en usinant l'intrados pendant la création de l'extrados en CAO et en perfectionnant la machine de coupe.

Un polissage, maquillage de surface (détails) et un vernissage ou glaçage (suivant le matériau) est souhaitable. Il est possible de contrôler l'exactitude de la pièce en la relisant avec la sonde optique et en comparant ce résultat avec celui qui avait servi de base de travail à la commande numérique.

Il a donc fallu entre 20 et 25 mn pour réaliser une couronne esthétique prise d'empreinte comprise et ce en une séance. Il est possible durant l'usinage d'effectuer un soin de bouche afin de ne pas bloquer le patient trop longtemps sur le fauteuil sans raison thérapeutique. Dans la configuration avec modem seuls l'empreinte, son contrôle et une partie du traitement d'image ont lieu dans le cabinet dentaire (entre 5 et 7 mn). Le reste du travail pourra être exécuté rapidement dans le laboratoire de prothèse, dans la journée si nécessaire.

DEVELOPPEMENTS ULTERIEURS

La présente explication concerne les éléments unitaires ou de faible portée. Il est prévu de développer dans les 6 mois à 9 mois les bridges de grande étendue ainsi que l'analyse occlusale directe. Il en sera de même pour les inlays, les dents à tenon et les attachements. Il ne s'agit à ce stade que de compléter l'étude CAO et le mode d'usinage.

Pour 1987 sont ciblés l'aide au diagnostic en ODF et parodontologie ainsi que l'usinage des brackets et des attelles, première porte ouverte sur la prothèse adjointe...

Le logiciel de gestion fera partie très certainement des premières versions. Il faut dire que la puissance des moyens informatiques mis en œuvre permet d'espérer déboucher vers un programme puissant, rapide et simple de manipulation.

Les logiciels seront évolutifs et seront disponibles comme c'est aujourd'hui le cas pour la micro-informatique individuelle. Il sera possible de se procurer tel ou tel logiciel de telle ou telle école dans la mesure où cette dernière aura collaboré efficacement au développement correspondant à la ligne des travaux de notre laboratoire. Il en sera de même de la formation qui, sous le contrôle d'une équipe strictement dentaire, assurera l'apprentissage théorique et pratique de la CFAO en prothèse. N'est-ce pas une bonne méthode pour, marier les moyens industriels et la formation de l'odontologiste par les odontologistes.

Fin 1983 nous annonçions qu'il nous fallait deux ans pour sortir un système prototype, nous tenons parole. Nous arrivons aujourd'hui en phase d'expérimentation clinique. Elle permettra de modifier et de rendre de plus en plus compatible un système aujourd'hui au stade du prototype. C'est ainsi qu'une équipe dentaire de plus de 50 chirurgiens-dentistes et médecins, dont j'ai la responsabilité, œuvre autour des éléments pour apporter leurs expériences pour le développement du système.

L'objectif reste pour la société d'exploitation des licences de commercialiser les premiers équipements de série dans le courant du deuxième semestre 1986. Parallèlement nous menons des travaux très importants sur de nouveaux matériaux dont certains seront présentés au cours du premier semestre 1986.

Des cycles de formations à la nouvelle méthodologie débuteront dès avril 1986 dans des structures spécialement étudiées pour les prothésistes et pour les chirurgiens-dentistes. Reste à expliquer le coût et les conditions d'amortissement d'un tel matériel. Cela fera l'objet d'un prochain article dans les colonnes de Tonus.

Dr François Duret

ClearCorrect Exhibit 1002, Page 1370 of 3373

Toward a computerized prosthesis

The actual accomplishment of fixed dental prosthesis embraces a succesion of stages closely related to one another. The deficiency of one of them can cause the failure of the reconstruction undertaken by the practionner. During the therapatic act , the transfer of the information from body into body, the support of the designed relief(prints, models...) and of the shape of the future denture(wax, coatings) constitutes the basic rule of a technic actually unique and more than threecenturies old.If a great progress has been accomplished in the quality of these proceedings and in particular in the accuracy of the processing of the information, it is undisputable that few fundamental modifications have marked the evolution of the work. But everything might change in the coming months...

As a matter of fact, the CFAO(conceptions and products assisted by dental c-prosthesis computer) shows a new axis of work and it is not unreasonable to forsee its large development in the near future in dental and dentures surgeries as the case in other technical sectors. We are bound by the inventive aspect of the concept to talk more of the revolution in the conduction of the process.

It would have been necessary to make a description of the material devised in the laboratories of the Hennson Company and which has to be presented for the first time at ADF(Association of French dentists) of 1985.If in 1985, during the meetings of Granciere we announced that it would take two years to develop a prototype and three years for the first

years for the first apparatus to be out(chanel 2) we were not aware of the technical difficulties we were going to encounter. On the other hand, today, this first step accomplished, it is not at all absurd to forsee its coming out in the third or fourth quarter of1986.

COMPOSITION OF THE SYSTEM

The sytem is globaly composed of an optical probe, a log. data processor, a microprocessor set + log of CAO, a numerical control and microdrillsrs.

The optical probe (diagram : #1) mesures the teeth according to the three axes of space (that is in three dimensions). The highly innovative aspect of the method used puts us in an extreem reserve in the description of the continuous technology.Closely related to Moire optic as described by the ancients (CDP #50), it offers the advantage of keeping a particularly strict record, less than 20µm of absolute in incertitude indetermining a point in the space of the teeth that is being studied.

Connected to the probe and very dependent on the latter is found the data processing system-QOS #39- it must repertorize in a numerical manner the elements processed by the DTC(dispositive that processes image) and especially distributes the information to avoid an overload in the computer. The DTC (CCD for the anglosaxons) is a sort of ~~irrceptor~~ matricial microcaptor noted for its accurateness of its scanning and the rapidity of its pendulume (3 to 6 megaherz), It permits among other items to have an image on a plane surface and this several times a second. If will generate an accurate and precise

information of the enviroment apprehended by the probe and values in resulting, guided by cabled processor or not, it will be apte to be analyzed by the denture execution log. THe function of the processor of image analyzing is to numerize , simplify and then transmit the supporting zones of calculation of the future denture.

Using a 32bits microprocessor, light, powerful and fast the denture log creation(photo# 2) its foremost function is to generate the future denture while respecting the identity of the patient being treated. It is not to remake a million times the same element but to generate an interier and exterior form respecting the imperatives of the mouth to be treated reconstituted..It is really a conception assisted by computers devised by dentists for dentists and using a classical core of CAO(here Euclid of Mata Data-vision). The creation of Entrados is not a specific groth and calculated but the result of a triple preoccupation related to the dynamism of the floww of fluids, the minimisation of space and the resistance disinsertion. The extrados , the form and volume created by the log, leans on what will be identified as privileged contact zones, vestibular and lingual curves and space of the articulated. There is then a creation of a theorical, original and ideal teeth that the dentist could keep or modify.

Beyond this creation is found the numerical control (CNC) of the tool# machine. This specific log., mixed cabled/written, must generate , not a form but a tool track. This track is in relation on one hand with the requisite defination for a denture and on the other hand with the geometric caracteristics of the surgical

tool . This is specifically devised for our application; it allows us to guide the tool machine in the execution of the tooling of the internal and external parts of the future prosthesis according to the movement in three axes.

The numerical control tool machine only executes orders processed by the CNC. It has several tools and several form supports, not interfering in the demand of a good automatic finish tooling executed by moving engines. step by step glossy or linear. The final product can demand a semi-automatic finish to permit the immediate sealing(preformed in predetermined colors) or the make-up for more practitionners.

The material used in this technology are new and have mechanical and biological caracteristics close to the zone of the teeth they are to replace. The fact that they do not undergo any structural transformation before their insertion in the mouth explains the importamce of this evolution and the quality of the respect of the physical values of the buccal cavity.

CONFIGURATION OF THE SYSTEM

This brief representation of the set of the basic components bring out a modular aspect which permits its insertion in the dental surgeries no matter their configuration.

Dental clinics with only one surgery(# 1 configuration) it is possible to use a complet system or only a probe and a transmission system(modem). All these transmission systems respect the quality of the information as its secret (access code to a given information and permits modifications

ClearCorrect Exhibit 1002, Page 1374 of 3373

of specific log. They offer, at last, to all practitionners the possibility to follow the evolution of the programs.

In a clinic with several chairs (#2 configuration) the division of certain elements is perfectly compatibble with the modular structure of the set. So the microprocessor , the CAO log. , the microdriller and its numeric cntrol could be connected to several optical probes like the cmpressor for the units. This structure does not prevent the use of a transmission modem in equiped denture surgeries. All the advantages of the first cnfiguration here in their complete form.

In the denture surgeries(#3 configuration) unequiped with a seizing system , the information will either be processed by the laboratory CAO log. and the tooling will take place in the laboratory or the information of the numeric control will be retransmitted to a tool machine situated in the demanding dental clinic. From today a certain number of prosthesists include in their basic training ,that of the CAO,so as to be ready to reply to this new demand.

THE UTILIZATION METHOD

We can schematize the act of development of an artificial crown or not by several stages. These stages depend essentially on the type of configuration adopted.

In the first configuration(surgeries entirely equiped) we apply the following operations :

- prints taking : the practitionner, after having made the size as he ussually does, should his scanning zone and dry it. The use of methods of classical gingival retraction is necessary to perfect the reading in the sulcus. The use of a specific product on the gencive,

ClearCorrect Exhibit 1002, Page 1375 of 3373

on the tooth, could increase the coding quality. At this stage, the practitionner takes the probe, sort of micro-endoscopic camera, and takes a succession of shots under the control of a classical monitor video attaining its unit. A pedal permits to fix the image for an attentive examination to validate or reject the shot. It is possible to reveal certain zones, particularly innacessible. A expert hand takes less than 3mn. to make the reading of the prepared tooth, of its neighbors and antagonist surface.

A relatively short time (between 2&4 mns) is necessary for the processing of the image and the correlation of different views. This permits the patient to rinse his mouth and the practitionner to clean and put away the probe. This is the only intervention done in the patient's mouth for whom is prepared a unitary element or of a small dimension.

The continuation of the wofk is done with the help of the CAO log. and could take place in the dental surgery or in his denture laboratory. It will take a minimum apprenticeship that would be the object of a specific and compulsory trainning when the system is aquired. This type of trainning is classical for computer work. It is always well accepted and gives way to exchanges of fructuous identities. Teeth treated by probe appear on the CAO screen and could be orientated according to a chosen angle. One to the verification of the size and to its acceptance or refusal. In the latter case, it is necessary to retake the print after patcing up the stumps. If there acceptance of the work, the log. will dilate the stump to permit the sealing of ciment space(Intrados of the crown.)

The development of the extrados will pass by the proposition of a model to the practitionner. The latter can accept or modify the form using a certain number of interactive function. So a magnifying glass effect(zoom effect) will permit him to modify the shape of an optical angle to draw the contact zones closer. It is also possible to modify a groove, the cervical , the position of the centers, or the tip of the cusps.

In any case the language will be simple and will use specifically dental terms. For example: it will not be a question of "manupulate the deformation vector but mesialize the vestibular-lingual cusp" of the bottom mollar. The occlusal mouvements could be studied according to several theories and the choice of the latter will lead to the modification of the relief of the specific occlusal. We can see that the action permited by the CAO log. is totally connected to the creation of the wax model and to the modelling of the occlusal surface. The and the sealing constitutes the last phase of the operation. If the modelling on the CAO screen can last between 2 & 10 mn, the tooling phase will be so much as longer as the element isc complex , than the material is hard , and that one wishes to have a good finishing state. This phase of work must be appreached with the greatest care for it represents the ultimal stage and especially the instant of the materialisation of the figured results . It is necessary to watch it is well executed , and even if it is entirely automatic(including the change of tool and the returning of of the parts) it is essential to verify regularly that it

functions well. After having chosen a preform in a classical coloradapted to the mouth(2B, 4A..) the part to be tooled is placed on a tray , fixed automatically and the tooling cycle is set in motion by pressing on one knob.(on - off) The cycle lasts today between 15 & 20 mn. by element for an excelent finish but the latter can be reduced in tooling the Intrados during the creation of the extrados in CAO and in perfectionning the cuting machine.

A polishing, a surface make-up(details) and varnishing or icing(depending on the material) is recommended. It is possible to control the exactitude of the part on rereading with the optical probe and on comparing this result with the one that had served as the base of the numeric controlled work.

It took between 20 & 25mn. to develop an artificial crown including print, and this was in one session. It is possible during the tooling to clean the mouth in order to not to block the patient too long in the chair without any therapatic reason. In the configuration modem, only the print, its control and a part of the image processing take place in the dental surgery(between 5 & 7mn.).The rest of the work could be executed rapidly in the prosthesis laboratory, the same if necessary.

ULTERIOR DEVELOPMENTS

The present explanation concerns unitary elements of feeble range. It is planned to develop , within 6-9 months, wide bridges and direct occlusal analysis. It will be identical for the inlays, the teeth with cavity and attachments. At this stage it is a question of completing the CAO study and the tooling method.

For 1987, there projects for aid for diagnostics in ODF

and parradontology, also the tooling of brackets and splints - the first open door to prosthesis ....

The marketing log. will certainly be part of the first versions. It is important to note that the power of the cmputer means devised permits us to hope for an opening toward a powerfull , fast and an easy to mannupulate program.

The log. will be evolutive and shall be disponible as it is today with individual micro-computers. It will be possible to get a specific log. from a specific school, taking for granted that the latter would have effecientently collaborated to the development corresponding to the line of work from our laboratory. It will be identical for the training which, under the control a strictly dental team, will assure the theorical and practical training of the CFAO in prosthesis . This is surely a good method of marrying industrial means and the training of an odontologist by odontologists.

We announced, toward the end of 1983, it would take 2years to produce a prototype system; we have kept our word. Today, we have attained an clinical phase. It will permit us to modify and make more and more compatible, a system today in a prototype state. It is in this manner that a dental team of more than 50 dental-surgeons and docters, for which I am responsible, work around elements to contribute their experiences for the development of the system.

The objective is left to the company that is respomsible for licences to commercialize the first equipments in series during the second quarter of 1986. Parallel to this project

we are undertaking a very important work on the new materials some of which would be presented during the first quarter of 1986.

Training cycles on the new methology will begin from April 1986 in specially studied structures for the prosthesists and dental surgeons. Left to be explained is the cost and the condition of making profit from such a material. This will be the object of a future article in the Tonus column.

Dr. Francois DURET.....

Towards a computerized prosthesis

by
Dr. François Duret

Translated from the "Computer Science" Section of
TD [Tonus Dentaire] 73 - 15 November 1985, pp. 55-57

At present, the fixed dental prostheses are constructed by a succession of steps closely connected to one another. If any one step is missed out, the reconstruction undertaken by the practitioner may be unsuccessful. During this therapeutic procedure, which constitutes the transfer of information from one body to another, support for the studied relief (impressions, models, etc.) and for the shape of the future prosthesis (wax, liners, etc.) constitutes the basic rule of a technique that is still unique despite having been known for more than three centuries. Although great progress has been made in the quality of these procedures and especially in the fidelity of information transfer, it cannot be denied that little fundamental evolution has been achieved in this part of our work. But there's every chance that things will change in the coming months ...

Computer-assisted design and manufacture (CADM) of dental prostheses actually indicates a new line of work, and it is not unreasonable to predict that it will develop broadly in the near future in our dentists' and prosthetists' offices, as has been the case in other technical sectors. The inventive aspect of the concept obligates us to speak more of revolution in the method rather than evolution in performing the procedure.

This seems an appropriate time to describe the equipment developed in Hennson's laboratories and to be presented for the first time at ADF 1985, the annual meeting of the French Dental Association. Although we announced at the Garancière conferences in 1983 that we would need two years to develop a prototype and three years to deliver the first instruments (Antenne 2), we were unaware of the technical difficulties we were to encounter. Today, however, now that this first stage has earned its due, it doesn't seem

ClearCorrect Exhibit 1002, Page 1381 of 3373

entirely absurd to us to predict that the first instruments will appear in the third or fourth quarter of 1986.

COMPOSITION OF THE SYSTEM

The system consists overall of an optical probe, of a signal-processing software module, of a combination of microprocessor and CAD software, of a numerical control module and of a micromilling machine.

The **optical probe** (Figure No. 1) measures the teeth along three axes in space, or in other words in three dimensions. Because of the highly innovative aspect of the method used, we are forced to be extremely circumspect in describing the technology employed. Closely related to Moiré optics such as described by the ancients (CdP No. 50), it offers the advantage of complying with a particularly strict set of specifications: above all, the absolute error in determination of a point in the space of the tooth being mapped is better than 20 μm.

Connected to the probe and highly dependent on it is the **image-processing system** – QOS No. 39 – which must digitally record the data transmitted by the CCD (charge-coupled device) and sort the information to avoid overloading the computer. The CCD consists of a matrix of microsensors and is remarkable for its scanning fidelity and speed (3 to 6 MHz). Among other properties it is capable of producing an image on a plane surface at rates of several times per seconds. It will generate faithful and precise information about the environment sensed by the probe. The resulting values, processed by a hard-wired or wireless processor, can be digested by the software that controls construction of the prosthesis. The function of the image-processing processor is therefore simply to digitize, simplify and then transmit the support zones for calculation of the future prosthesis.

The primary function of the **prosthesis design software** (Photo No. 2), which runs on a lightweight, powerful and fast **32-bit microprocessor**, is to generate the future prosthesis corresponding to the identity of the patient being treated. In doing so it does not recreate the same element n times, but instead generates an interior and exterior shape corresponding to the important features of the mouth to be reconstituted. This is true computer-assisted design performed by dentists for dentists, using a standard CAD kernel (in this case Euclid of Matra Datavision). The design of denture impression surfaces is

ClearCorrect Exhibit 1002, Page 1382 of 3373

not a specific and calculated outgrowth, but is the result of three considerations involving fluid flow dynamics, space minimization and disinsertion risk. The polished surfaces, shape and volume designed by the software is based on what will be identified as privileged zones, or in other words contact zones, vestibular and lingual curves and bite space. What happens is therefore original and ideal design of a theoretical tooth, to be retained or modified by the dentist.

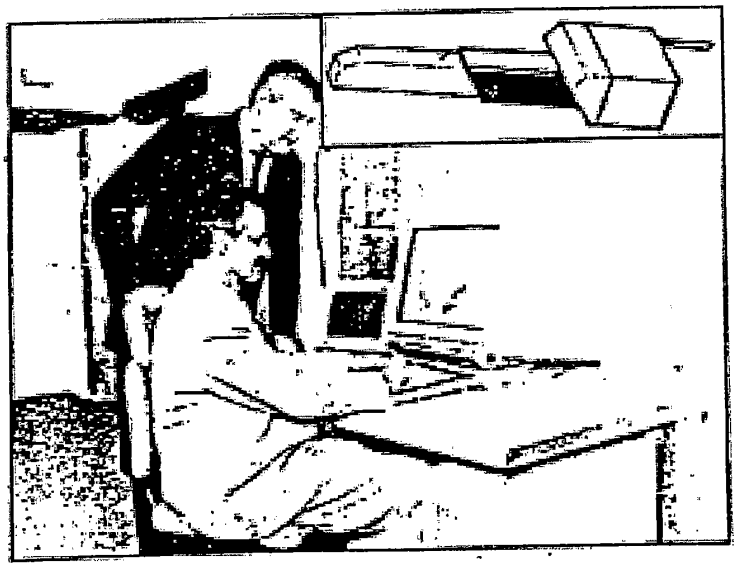


Figure 1 – The optical probe.

Photo 2 – Design software and 32-bit microprocessor.

This design stage is followed by **computer numerical control** (CNC) of the machine tool. This specific software, which is a blend of hard-wired and written instructions, must generate not a shape but instead a tool trajectory. The trajectory is related on the one hand to the definition required for a dental prosthesis and on the other hand to the geometric characteristics of the cutting tool. Developed specifically for our application, it ensures that the machine tool is controlled during machining of the internal and external parts of the future prosthesis via displacement in three axes.

The **numerical controlled machine tool** merely executes the instructions transmitted by the CNC software. It has several tools and several shape supports, thus meeting the requirements of good automatic machining performed by smooth or linear stepping

ClearCorrect Exhibit 1002, Page 1383 of 3373

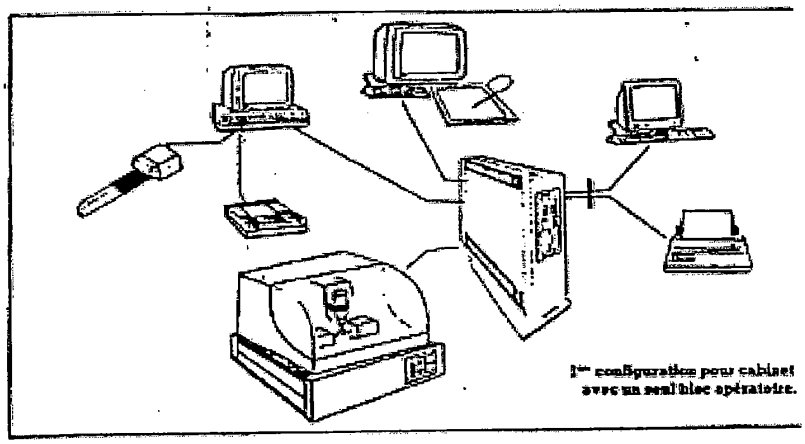
motors. The final reproduction may need semiautomatic finishing to permit immediate filling (preforms of predetermined colors) or touchup for more demanding practitioners.

The **materials** used in this technology are novel, with mechanical and biological characteristics approaching those of the tooth that they will replace. The fact that they are prepared industrially and not subjected to any structural modification before being implanted in the mouth explains the importance of this evolution and the quality of conformity with the physical parameters of the buccal environment.

SYSTEM CONFIGURATION

From this brief outline, it will be obvious that the basic components fit together in a modular fashion eminently suitable for dentists' offices regardless of their configuration.

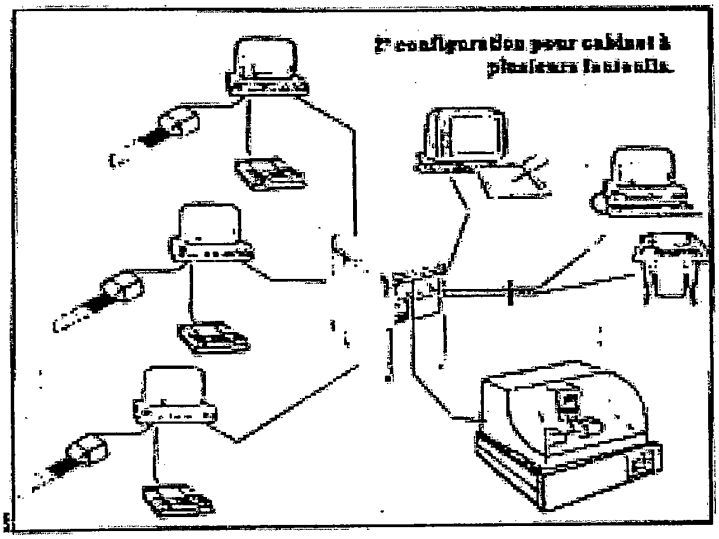
In dentists' offices having only a single operating room (1st configuration), it is possible to use a complete system or merely a probe and a transmission system (modem). All of these transmission systems are compatible with information quality, such as secrecy (encoding of access to the data), and they are amenable to specific software modifications. Finally, they offer the practitioner the possibility of tracking the evolution of the programs in time.



1st configuration: for office with a single operating room.

ClearCorrect Exhibit 1002, Page 1384 of 3373

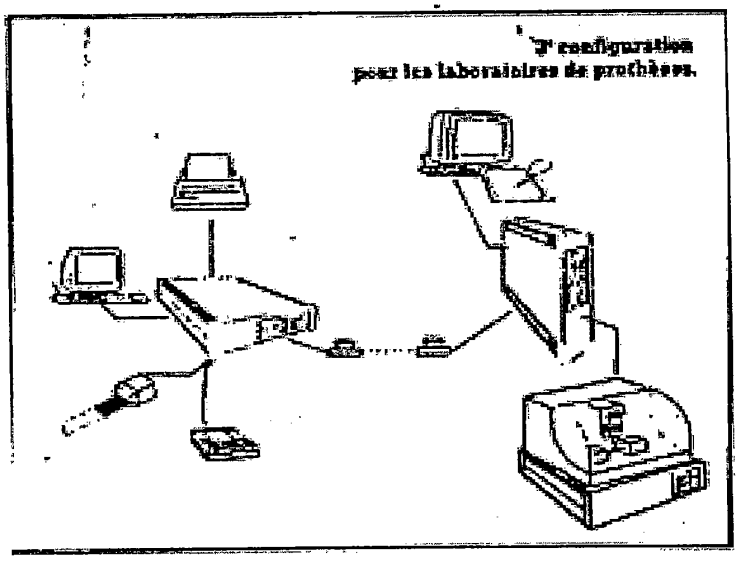
In a **multi-chair office** (2nd configuration), the sharing of certain data is perfectly compatible with the modular structure of the system. Thus the microprocessor, the CAD software and the micromilling machine and its numerical control can be connected to several optical probes, as is the compressor for the units [sic: something missing]. This structure in no way prevents the use of a modem for transmission to fully equipped prosthesis laboratories. All the advantages of the first configuration are included here in their entirety.



2nd configuration: for office with several dentist's chairs.

In **prosthesis laboratories** (3rd configuration), either the information will be processed by the CAD software of the laboratory and machining will take place in the laboratory, or the numerical control information will be retransmitted to a machine tool located in the office of the requesting dentist, depending on whether the dental surgeon is equipped with a data-acquisition system. Today, some prosthetists include CAD in their basic training, thus making them prepared to respond to this new demand.

ClearCorrect Exhibit 1002, Page 1385 of 3373



3rd configuration: for prosthesis laboratories.

METHOD OF USE

We can schematically describe the procedure of constructing a cosmetic or practical crown by several stages. These stages depend essentially on the configuration mode adopted.

In the **first configuration** (fully equipped office), we perform the following operations:

– Taking an impression: the practitioner, after having made his cut in his accustomed manner, will have to clean and dry the zone to be scanned. The use of standard classical gingival retraction methods is desirable to allow scanning in the sulcus. The use of a specific product deposited on the gum or even on the tooth may improve encoding quality. At this stage, the practitioner picks up the probe, which is a kind of endoscopic microcamera, and takes a series of snapshots under the control of a standard video monitor next to his unit. By means of a pedal, the image can be frozen for closer inspection, or the view can be validated or rejected. It is possible to repeat the scan of certain particularly inaccessible zones. One-hand operation takes less than 3 minutes to complete scanning of the cut tooth, of its neighbors and of the antagonist surface.

– A relatively short time (between 2 and 4 minutes) is necessary for image processing and correlation of the different views. Meanwhile the patient can rinse and the practitioner can clean and store the probe. This is the only action to be performed in the mouth of a patient for whom a single element or element of small extent is to be prepared.

– The next part of the procedure is achieved by means of the CAD software, and it can take place in the dentist's office or in his prosthesis laboratory. It needs a minimum of learning, which will be imparted by specific and mandatory training upon acquisition of the system. This type of training is standard in computer science. It is always well received and leads to fruitful exchanges of information. The teeth plotted by the probe are displayed on the CAD screen and can be oriented at any selected angle. The cut is then verified and either accepted or rejected. In the latter case, the impression must be taken once again after the stump has been touched up. If the work has been accepted, the software will smooth out any undercuts and will expand the stump to leave space for the filling cement (denture impression surfaces of the crown).

To construct polished surfaces, a model will be proposed to the practitioner. He will then be able to accept or modify the shape by using a certain interactive function number. For example, by means of a zoom effect, he will be able to modify the shape of an edge and to approximate the contact zones. It is also possible to modify a sulcus, the cervical border, the position of the centers or the tip of the cuspids. In any case, the language will be simple and will use terms that are specific to dental practice. For example, the concept of "act on a deformation vector" would be expressed as "mesialize the vestibulo-lingual cuspid" of the lower molar. It will be possible to study the occlusal movements on the basis of several theories, and the specific occlusal relief can be modified according to which theory is chosen. We see that the action permitted by the CAD software is related entirely to design of the wax template and to modeling of the occlusal surface.

Machining and filling constitute the final phase of the operation. Whereas modeling on the CAD screen can last between 2 and 10 minutes, the duration of the machining phase depends on the complexity of the element, the hardness of the material and the desired finish condition. This working phase must be initiated with the utmost care, because it represents the final stage and above all the point at which the quantified data are given physical form. For these reasons it must be executed with the proper care and, even though it is entirely automated (including tool changing and part touchup), it must be checked regularly to ensure its successful completion. After a preform has been chosen in a standard color matching the mouth (2B, 4A, etc.), the part to be machined is mounted

ClearCorrect Exhibit 1002, Page 1387 of 3373

on the table and fixed automatically, after which the machining cycle is started by depressing a single button (start-stop). At present, the cycle lasts between 15 and 20 mm per element for an excellent finish, but it can be shortened by machining the denture impression surfaces while the CAD software is designing the polished surfaces and by fine-tuning the cutting machine.

Polishing, detailing and lacquering or glazing (depending on material) are desirable. It is possible to check the exactness of the part by rescanning it with the optical probe and comparing the result with that used as working basis for numerical control.

Thus about 20 to 25 minutes has been needed to construct a cosmetic crown, including taking of an impression, all accomplished in a single session. During machining, it is possible to perform an oral maintenance procedure, so that the patient is not confined too long to the chair without therapeutic reason. In the **modem configuration,** the only work needed in the dentist's office is to take and check the impression as well as to perform part of the machining treatment (between 5 and 7 minutes). The rest of the work can be accomplished rapidly in the prosthesis laboratory, during the day if necessary.

FUTURE DEVELOPMENTS

The present explanation relates to single elements or elements of small extent. Within six to nine months it is anticipated that bridges of large extent and direct occlusal analysis will be developed, as will inlays, dowel crowns and retainers. For this purpose it will merely be necessary to amplify the CAD study and the machining method.

For 1987, the goals are diagnostic aids in dento-facial orthopedics and paradontology as well as the machining of brackets and splints, opening the first door to removable prostheses, etc.

Management software will most certainly be part of the first versions. It must be said that the power of the computer equipment used allows us to hope that we will chance upon a powerful, fast and user-friendly program.

The software programs will be forward-compatible and will be just as available as is now the case for individual microcomputer science. It will be possible to buy one software program or another from one school or another to the extent that such school has

ClearCorrect Exhibit 1002, Page 1388 of 3373

effectively collaborated in the development corresponding to the working directions of our laboratory. The same conditions will apply to training which, under the control of a strictly dental team, will ensure theoretical and practical learning about CADM in prosthetics. Is this not an elegant method of marrying industrial resources to the training of odontologists by odontologists?

In late 1983 we announced that we would need two years to deliver a prototype system, and we have kept our promise. Today we are now embarking on the clinical experimentation phase. In this way we will be able to modify a system that today is in the prototype stage, and to make it increasingly compatible. Thus a dental team of more than 50 dental surgeons and physicians under my responsibility is working on all aspects of the elements in order to contribute their experience to the development of the system.

For the license development company, the objective remains to bring the first series-produced instruments to market during the second half of 1986. In parallel, we are undertaking very important studies on new materials, some of which will be introduced during the first half of 1986.

Training courses in the new methodology will begin in April 1986, in structures specially designed for prosthetists and dental surgeons.

All that remains is to explain the costs and the conditions for amortization of such equipment. This will be the subject of a future article in the columns of Tonus.

ClearCorrect Exhibit 1002, Page 1389 of 3373

The Microcomputer in the Orthodontic Office

JAMES K. ECONOMIDES, DDS

The microcomputer has the ability to perform the same dramatic changes for our profession as it has for business and industry in the past decade. The reason that orthodontists are interested in the computer is simple. They see the computer as the answer to providing more control of the office and more time to practice orthodontics. The time factor is what the computer is all about. If the computer system cannot produce a significant time saving, there is no advantage in having it. However, there is no doubt that a computer can perform certain functions far more rapidly than a human. One pushes a button and the answer appears effortlessly. But, it is well to keep in mind that one cannot receive data that is worthwhile, unless it is entered properly on a daily basis.

Administrative efficiency is the key to productivity. In general, the problems are managerial in nature, rather than technical. Managers who expect the computer to correct sloppy office control systems will certainly be unhappy with the computer as a management tool. Offices that have developed a computer system and are doing well with it were superbly managed prior to the involvement of the computer. The more organized the office, the easier the computer fits into the system.

Prototype

In the Spring of 1977, the Albuquerque Study Group set a goal of developing an orthodontic system on a microcomputer. The group developed a prototype that was implemented in several off ices across the country. The plan was and is to keep the user group small until the programs can be made to perform as many repetitive tasks as possible, as quickly as possible. Many of the best suggestions have come from staff members, who put up with many early problems very patiently.

We evaluated the pros and cons of using the microcomputer as a storage device. We decided that all possible transactions would be entered in the computer instead of using the present system of recording manually on paper. Our criterion was that the computer had to be equal to or better than the previous system or we would not computerize that function. For example, our research staff of programmers could not provide a system that was as good as the week-at-a-glance appointment book, so that was not included.

We found that an orthodontic patient requires about 220 variables, all changing at the same time during the course of treatment. No wonder record keeping can be such a demanding area of practice administration. An average patient's record at dismissal contains

ClearCorrect Exhibit 1002, Page 1390 of 3373

about 3000 characters (bytes) of information. While a single entry in handwritten or electronic form has equal manpower demands, when it comes to retrieval, the handwritten system becomes a very expensive and slow process. In this use, the computer begins to show its ability as a cost effective device for the orthodontist.

In the beginning, it was an adventuresome step to leave a tried and tested paper system for an electronic system in which there was no paper, except when a printout was requested. Also, in the beginning, there was a loss of time, because a dual system is run side-by-side until the computer is up to speed. Depending on the number of patient records to be entered, two to four weeks is a reasonable time to bring the system up to working condition. In the early stages, the time for the two systems was equal; but now the computer system provides many hours of time saved per month.

The Software

The software, or computer program, is the custom-made part of the computer system. The software is the instruction sheet, which tells the user and the computer what is to be done with each bit of data that is handled. A thorough knowledge of the orthodontic profession is very important in developing the software program.

Unfortunately, the process of software development is like an endless puzzle. When one door is opened, then one can see ten new ways to change direction and improve the program. Developing software is a fulltime job and usually very slow to debug. However, some offices require such unique systems, that custom software is the only answer for them. Custom software is packed with problems and many times more costly than stock software packages. Software with a track record is a sounder choice, because it generally has fail-safe and backup systems to protect the data. Companies that develop software usually do it on specific hardware, and the internal instruction system varies enough so that their software will only run well on their hardware. To use other hardware may require expensive conversion by a programmer and sometimes, conversions can be as difficult as writing an entirely new program. So, system compatibility of hardware and software is an important consideration when evaluating an in-house system.

Here is a list of components in our master program:

1. Treatment section.

2. Personal data section.

3. Diagnostic treatment plan.

4. Graph of treatment progress.

ClearCorrect Exhibit 1002, Page 1391 of 3373

5. Day sheet.

6. Automated billing system (with age dating).

7. "Did not keep appointment" search.

8. "Remove bands" search.

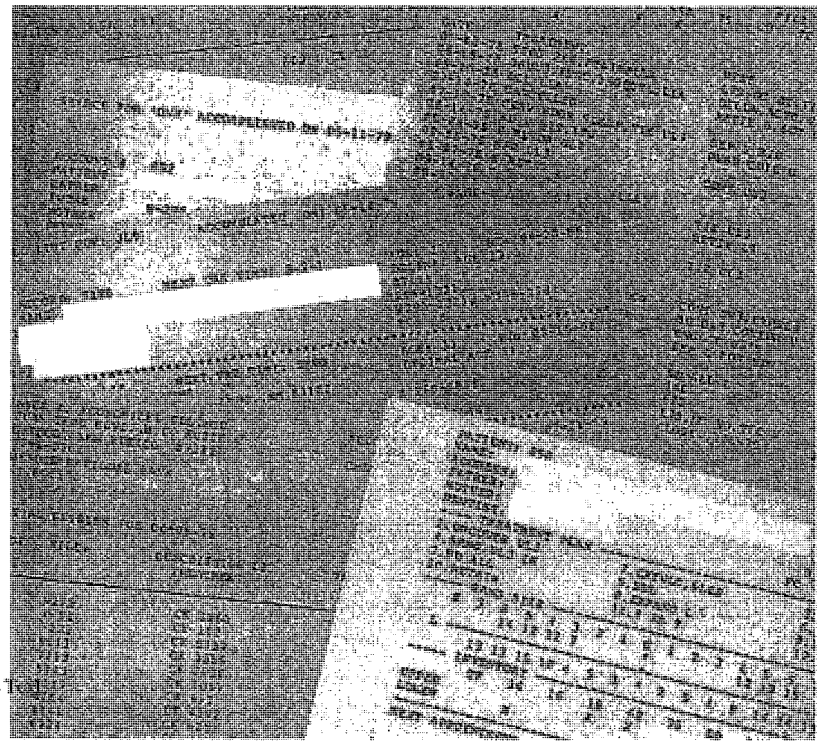
9. Recall appointment system

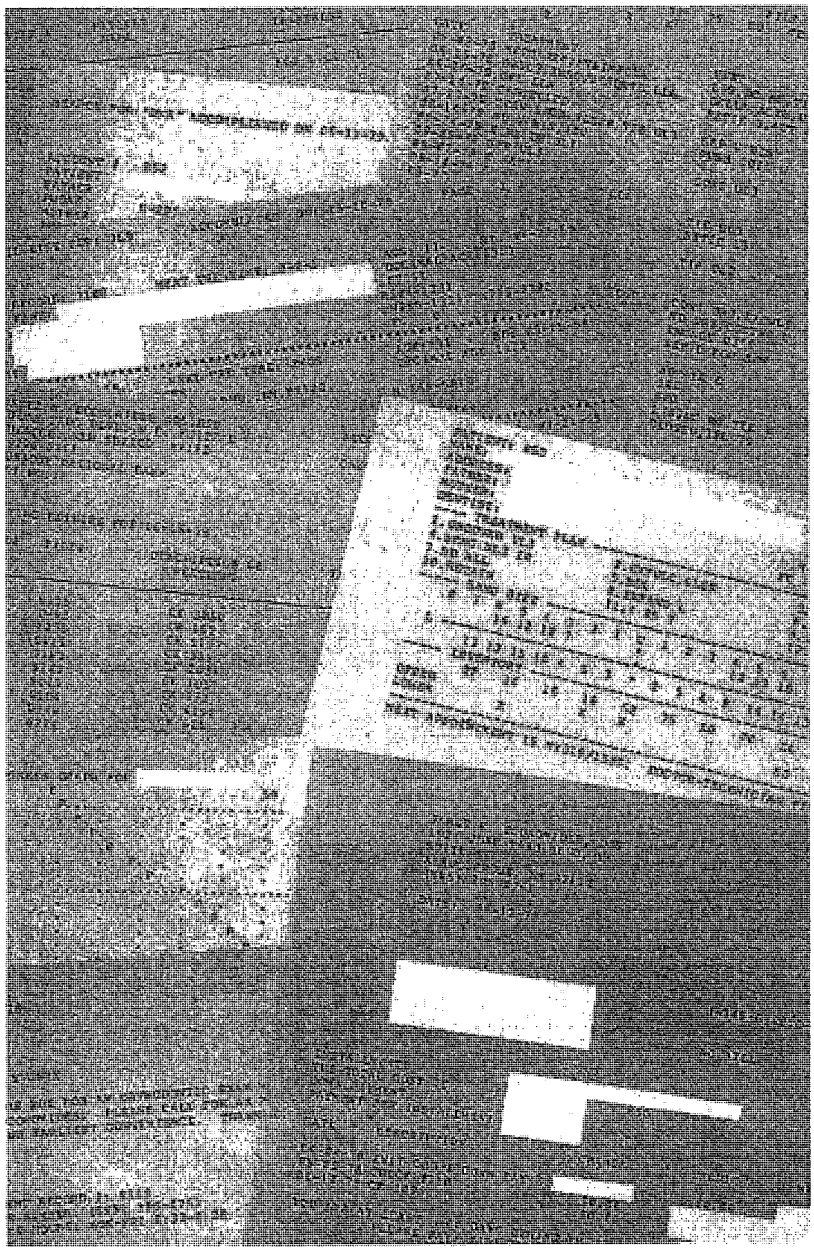
10. Accounting system.

a. Monthly summaries.

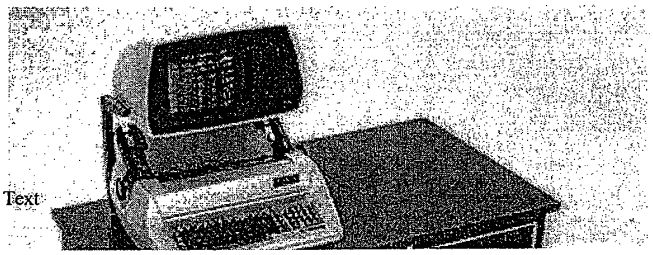
b. Deposit slips for bank deposits.

It took 24 months to develop these programs, involving in excess of 5 man-years of labor. Our experience has led us to use a system of conversational programming, because orthodontic offices do not have experienced computer operators. This self-explanatory type of programming has proven a wise choice, as complete beginners can operate the system after a short explanation. There is understandable fear on the part of a neophyte that comes from not understanding the hardware and the software. In each office one person must be responsible for the function of the system. The best result is obtained when the doctor takes the time to learn the fundamentals. However, other staff members can function very well in this area.

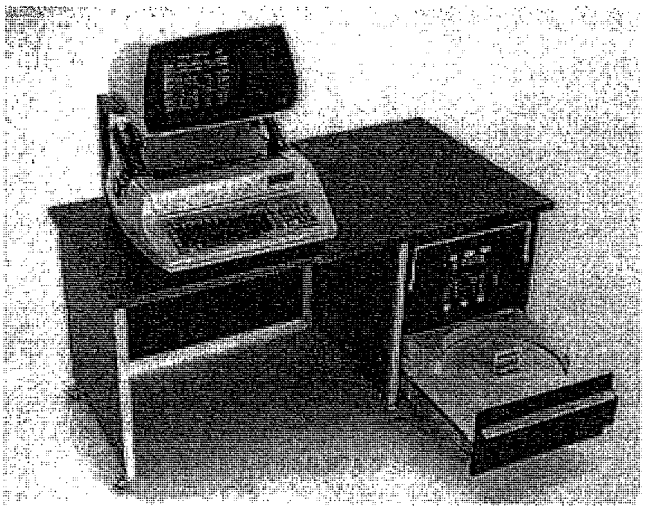




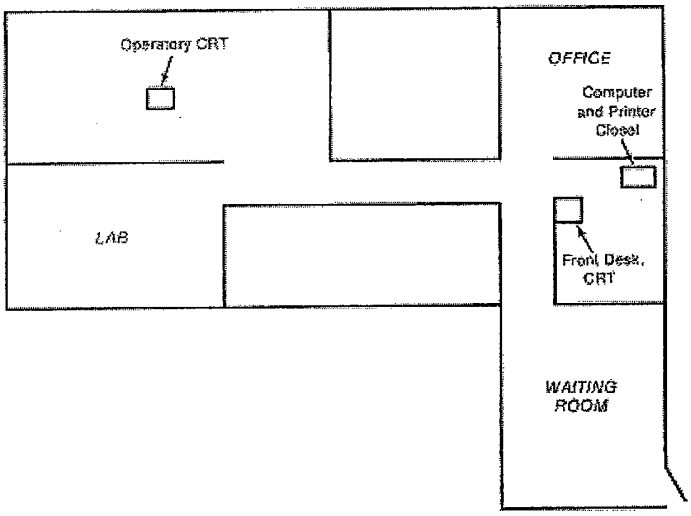
The Hardware



ClearCorrect Exhibit 1002, Page 1393 of 3373



Typical microcomputer system. (Photo courtesy of Data Terminals and Communications, Campbell, CA 95008.)



Sample computer layout.

Volume of data handled is an important consideration when purchasing an in-house computer system. The cost can vary greatly, mostly on the basis of storage capacity and storage mechanics.

It should be noted that changes in systems can be very expensive, unless the lease contract has an upgrade clause in it.

ClearCorrect Exhibit 1002, Page 1394 of 3373

One of our early fears was maintenance of the electromechanical devices that are moving millions of times per day. The designers claim that the machine, in normal working order, makes one error in one million searches of floppy disk drives, and one error in a billion for hard disks. When these devices begin to increase these errors, realignment will be required. Repairs to the system should consist of an exchange of modules, so that the system can always be up and working, as the off ice is wholly dependent upon the system and cannot operate without it. Many systems have self-diagnostic components, which can tell the operator where the problem area is. A system that will satisfy the needs of remote office sites seems to be a factor for consideration.

Relatively small space is required for the microcomputer and the normal temperature and humidity ranges of offices are adequate for it. The noise from the cooling fans is considerable. A small compartment near the front desk or bookkeeping area can be helpful in noise abatement. It is most convenient for the computer to be monitored by a front off ice person. This person is generally given the responsibility for scheduling the activities of the machine.

Here is an example of a microcomputer system with a price of $20,000. The following approximate costs would apply for a $100,000 practice with 50% overhead (sole proprietorship). The tax credit is spread evenly over a 5-year period, as are the tax savings from the depreciation and interest where applicable.

Initial cost	$20,000
Tax credit	– 1,340
Depreciation tax savings (3600/yr x.3)	– 5,400
	$13,260
Cost/hour (1540 hrs) after taxes	$1.72/hr
Cost/hour (purchase with borrowed money @ 12%)	$2.33/hr
Cost/hour (typical lease 18%; no pass through of tax credits; higher deduction)	$2.57/hr
Maintenance contract (industry average)	$0.63/hr*

*Nationally, maintenance contracts are .75-1.0% of wholesale cost of hardware.

If a decision is made to commit to an in-house computer system, look for a test system and an organization that is service-oriented. The computer increases expenses early; but its purpose is mainly to perform tasks, not to reduce costs. Bargain basement models for hobbyists and do-it-yourselfers are not commercial grade equipment and will not meet the expectations of the orthodontist user.

Current System

Our computer-aided management system has evolved over many long hours of labor. The current system writes all our records electronically on a CRT (cathode ray tube) and stores them on a computer disk. We can retrieve a patient's treatment record on the CRT faster than

ClearCorrect Exhibit 1002, Page 1395 of 3373

any office file clerk can search through a file cabinet looking for it. Additional benefits of the computer include the ability to produce a daily patient progress graph, forge a link to the accounting ledger, and maintain patient information and current appliance status. However, its single most important contribution has been the reduction of stress as we perform our daily tasks. One of its capacities is to act as a memory, to bring the user up to date instantly, removing the need to keep every little detail about a case in his head.

Before the use of the computer, the stress level increased as each billing day came around. We would all lend a hand. Today, we are able to carry out our daily activities and go through a billing period without putting in extra hours. An interesting sidelight of this approach to billing is the third person authority that the computer provides. An unbelievable increase in collections came immediately with the first month's billing. Our collection rate has picked up continuously because of our ability to keep patient accounts current and bring delinquents up to date. There are complaints about statements from time to time, but research resolves 99% of them in favor of the computer.

The system provides two protections. One is from in-house misappropriation of funds and the other from the loss of records through catastrophic events. The compaction of data into small plastic disks that can be copied and moved to a safe location off the office site provides security. It is also a tool to provide better information to make sound decisions in times of declining orthodontic economics.

Conclusion

In conclusion, I would like to offer a suggestion for the formation of a library consisting of software that will be produced by the orthodontic community, for the orthodontic community. The small number of potential users means that software production will be slow in coming and very expensive to produce. If these programs were to be filed in a software library, they can become public domain and interested parties will not have to pay the high cost of licensing fees every time they begin to use a system.

We are continually attempting to improve our programs and make them more sophisticated. Only the tip of the iceberg has been exposed. Many promising developments will be forthcoming as more users contribute to the accumulation of knowledge.

ClearCorrect Exhibit 1002, Page 1396 of 3373

Am. J. Ortho. 36:5
May 1950

SOME OBSERVATIONS ON THE HISTORY AND USES OF THE KESLING POSITIONER

WILLIAM A. ELSASSER, A.B., B.S., D.D.S., SAN FRANCISCO, CALIF.

THE history of the Kesling positioner has been adequately documented by its creator, Dr. Kesling, so this paper will dwell only briefly on the subject. However, the use of the positioner is rather intimately related to a group of mechanical and biological phenomena which should be thoroughly understood by all those who make use of the appliance. The bulk of this presentation, therefore, will be concerned primarily with these phenomena and their relationship to positioner therapy.

The history of the positioner begins with the desire of Dr. H. D. Kesling to produce an appliance which would influence all of the teeth to flow into the desired positions without the use of bands or wires. At the same time, he wanted something which would produce proper arch form according to type.

Thus he set to work, at first with the idea of producing something which would bring about complete treatment. After much effort, an appliance was produced which would complete all of the artistic aspects of the case such as minor rotations, space closing, and bite opening. Of course, in order for this appliance to accomplish its purpose, basic treatment has first to be accomplished. In other words, the jaws must be in proper relationship, the cusp and inclined plane relationship of the teeth correct, and gross rotations corrected.

The introduction of the positioner was truly a milestone along the road to the perfection of orthodontic techniques. It made possible refinement of cases which could formerly be refined only by long months of tedious arch wire adjustments. The main advantage of the appliance lies in its simplicity of design. Dr. Kesling has adequately covered its fabrication, so only an outline will be given here. It consists merely of a rubber mold of the teeth in correct occlusion. This correct occlusion is achieved by setting up the teeth much as prosthetic teeth are set up. The teeth from which the setup is made are obtained from the patient's casts. The teeth are sawed from the casts and then set up in correct occlusion. An impression is then made, and it is poured in stone. From these stone models, a rubber mold is made. This is the positioner. If it has been properly constructed, it duplicates normal occlusion.

It was Kesling's original intention that the positioner could be used for the complete retention period. On the West Coast it was used as a retainer for some time after its introduction, but within the last few years many men have felt that the positioner will not allow for the proper stabilization of the teeth in their alveolar processes. The reason for this is quite apparent. Since the majority of positioners are constructed of rubber or some other elastic material, it is an active appliance each time it is slipped over a tooth which does not con-

From the University of California.
Read before the Rocky Mountain Society of Orthodontists, Denver, Colo., Nov. 14, 1949.

form to its (th
it is placed in
positioner will
become common
order to put th
for the remain
to stabilize in t

In speakin
retention. As i
relapse has alw
from both the bi

It is axion
complete harm
forces on the d
necessary. Thi
only strive for
of cases. Rete
part of orthodo

It has bee
device by which
As stated befor
and stable equi
necessary.

The term "
pediatricians, o
is meant by the
rium" in ortho
not only on ind
of any one toot
to bear upon it
teeth and the p
to bear upon th
of the balance

To clarify
Of course, we k
number of dire
produced by th

Now let us
will affect thes
force couple be
we must move t

In addition
we must consid
arch, and the s
an arch. The
is that in the la

ALN013110

ClearCorrect Exhibit 1002, Page 1397 of 3373

form to its (the positioner's) pattern. Since it expends active forces each time it is placed in the mouth, it has been assumed by a great many users that the positioner will not permit the final settling down of a case. It has therefore become common practice to use a positioner for a period of six to eight weeks in order to put the refining touches on a case, and then to shift to regular retainers for the remainder of the retention period. In this way the teeth are allowed to stabilize in their alveolar processes after final correction by the positioner.

In speaking of positioners, it is inevitable that we touch on the subject of retention. As long as orthodontic patients have been treated, retention without relapse has always been the goal. This subject has been investigated extensively from both the biological and the physical viewpoints.

It is axiomatic that if an orthodontic case is completed with the teeth in complete harmony with the facial pattern and with a perfect equilibrium of forces on the denture, and on the individual teeth, no retention would ever be necessary. This, however, is perfection, and since we are but human, we can only strive for perfection even though we achieve it in only a small number of cases. Retention, therefore, is still, and will continue to be, an important part of orthodontic therapy.

It has been stated in various ways that retention in orthodontics is that device by which the teeth are prevented from returning to their former positions. As stated before, if the correction of the malocclusion has established also a new and stable equilibrium of forces upon the teeth, retention would not be at all necessary.

The term "equilibrium" has been used by chemists, physicists, psychiatrists, pediatricians, orthodontists, and others, so it becomes necessary to clarify what is meant by the termn with respect to orthodontics. The use of the term "equilibrium" in orthodontics usually refers to the balance of forces brought to bear not only on individual teeth, but also upon the dentures as a whole. The position of any one tooth in the denture is due to the resultant of all of the forces brought to bear upon it. It follows that since the dental arch is made up of a series of teeth and the positions of each individual tooth are the result of forces brought to bear upon them, then the shape and position of the dental arch are the result of the balance or equilibrium of mechanical forces brought to bear upon it.

To clarify the situation, let us take the position of one tooth as an example. Of course, we know that there are forces brought to bear upon it from an infinite number of directions, but we will consider three of the main forces. These are produced by the lips or the cheeks, the tongue, and physiologic mesial drift.

Now let us pause to see how tooth movement, through orthodontic therapy, will affect these forces. If we move a tooth lingually, then we unbalance the force couple between the tongue and the lips. If we are to prevent relapse, we must move the tooth in yet another direction to achieve equilibrium.

In addition to these local muscular forces brought to bear upon each tooth, we must consider the relationship between the forces brought to bear upon the arch, and the shape of the arch itself. The term "dental arch" literally means an arch. The only real difference between it and an arch used in a building is that in the latter there is no internal force or force which is brought to bear

ALN013111

ClearCorrect Exhibit 1002, Page 1398 of 3373

from within the concavity of the arch. In the dental arch, however, the force of the tongue on the anterior teeth corresponds to a force from within the concavity of the arch.

In the building arch, all of the force is directed from the exterior of the convex surface. As everyone knows, the keystone locks the series of stones composing the arch into a solid unit which opposes these external forces. Unfortunately, in the dental arch, these external forces are not only balanced by the forces within the concavity of the arch or the forces of the tongue, but these lingual forces may exceed the external forces, thus spreading apart the units of the arch.

From this analysis of forces brought to bear upon the dental arches, it is apparent that the very integrity of the arch itself depends upon its position in space with reference to the forces brought to bear upon it. That is to say, there must be a balance between the external forces (lips and cheeks) and the internal forces (tongue). The shape of the arch will conform to the directional resultant of these forces.

If, for instance, an arch is made too wide during treatment then the external medially directed forces will exceed those from the tongue, and the result will be lingual collapse.

Excess lingual movement of lower anterior teeth will have twofold results in the type of relapse. In the first place, the anteriorly directed lingual force will exceed the posteriorly directed labial force. This will result in anterior movement with consequent spacing in the anterior teeth. In addition, if, as is frequently the case, the cuspids are expanded in order to make sufficient space to move the anterior teeth lingually, relapse may be due to labial force in the expanded cuspid region, resulting in collapse of the whole anterior segment.

Again, if we move teeth too far distally in order to make space available to align the lower anterior teeth, subsequent physiologic mesial drift on the buccal segments will result in collapse of the anterior segment.

It must always be borne in mind that an untreated malocclusion represents equilibrium. If a case is to be treated properly, the original equilibrium must be so altered that when the teeth are moved to their new positions, a new equilibrium results. If this were done in all cases, we would need no retention devices. However, the number of cases in which this perfectly balanced new equilibrium is achieved is extremely small.

For the moment, we must assume that a stable equilibrium of forces brought to bear upon a tooth or teeth cannot be achieved practically through orthodontic therapy. Perhaps the main reason for this lies in the fact that we have no practical way of measuring the balance of forces brought to bear upon the teeth and the dental arches. Physically, perfect equilibrium then is, on the basis of chance alone, extremely rare in the completed orthodontic case. If this is the situation, and if the teeth will relapse toward their original positions after treatment, if equilibrium is not established, why do we attempt retention at all? Why do we not take a chance on relapse right at the time of appliance removal?

The theory has been advanced many times that putting retainers on a patient immediately after appliance removal gives the bone a chance to harden

around the teeth.
from relapsing t
surrounds them.

The validity
There are cases w
even though the
are many more c
to the fact that t
is not in equilibr
ance cannot be d
event a new equili

All this does
importance in or
through bone, th
after the applian
in order to suppo

Most retaine
cally placed in or
positions. This t
rium of denture
retainer should b
teeth against the

There are in
two things in co
place for as long
structed the reta
if a new and sta
ment.

After viewi
apparent that th
equilibrium was
been used many
sary in order to
see some of the m

In an atten
attained through
making two sets
set of these mod
most orthodontic
study of the trea
by means of a th
contact points.
are set up for arti

In making t
of these is equili
required in this

ALN013112

ClearCorrect Exhibit 1002, Page 1399 of 3373

around the teeth. This, according to many orthodontists, will prevent the teeth from relapsing to their former positions, due to the rigidity of the bone which surrounds them.

The validity of this theory is, of course, open to a great deal of discussion. There are cases which appear to resist relapse when the retainers are removed, even though the forces upon the teeth are not in equilibrium. However, there are many more cases which relapse badly when the retainers are removed, due to the fact that the newly acquired set of forces brought to bear upon the teeth is not in equilibrium. For all practical purposes, then, the idea of bone resistance cannot be depended upon to retain the teeth in their new positions in the event a new equilibrium of forces has not been established.

All this does not mean, however, that adequate retention is not of prime importance in orthodontic therapy. It is true that, since the teeth have moved through bone, they will be loose in their new alveolar processes immediately after the appliance is removed. It is, therefore, good practice to place retainers in order to support the tissues while recovery is taking place.

Most retainers are so constructed that clasps and labial wires are strategically placed in order to resist the tendency of the teeth to return to their former positions. This type of construction is, of course, not necessary if a new equilibrium of denture forces has not been established. In a well-treated case the retainer should be constructed primarily as a splint designed to immobilize the teeth against the forces of occlusion.

There are innumerable types and designs of retainers, but all of them have two things in common. The first is that most retainers will hold the teeth in place for as long as they are worn. The second is that, no matter how well constructed the retainer, the case will surely relapse when the retainer is removed, if a new and stable equilibrium of forces has not been established during treatment.

After viewing retention from the standpoint of equilibrium, it becomes apparent that the retainer establishes stability only so long as it is worn, unless equilibrium was established during treatment. The term "equilibrium" has been used many times in the last several paragraphs. This repetition was necessary in order to establish the importance of the subject. We can now begin to see some of the motivation which brought into being the positioner.

In an attempt to visualize beforehand the equilibrium which could be attained through treatment, Dr. Kesling and others advocated the practice of making two sets of models at the beginning of treatment of each patient. One set of these models is used as a part of the patient's record, as is the case in most orthodontic practices. The second set of models is used for a mechanical study of the treatment plan. In this case the teeth are removed from the models by means of a thin band saw similar to the type sometimes used to relieve tight contact points. These teeth are then set up in much the same way that teeth are set up for artificial dentures.

In making this setup, one should strive for several ideals, but the main one of these is equilibrium. It is an easy task to state that a stable equilibrium is required in this setup, but how does one achieve it? In other words, since I

ALN013113

ClearCorrect Exhibit 1002, Page 1400 of 3373

cannot, obviously, measure it quantitatively, how will I know when I have achieved it in the setup? Unfortunately, there is no pat formula for this, but several points can be borne in mind while making the setup.

The first consideration is one which was first brought forth by Nance in which he stated that lower teeth cannot be moved distally without subsequent relapse, unless it can be established that these teeth, in the etiology of the malocclusion, have drifted mesially. If the latter is the case, the lower buccal teeth can be moved distally in the amount of the established mesial drift.

Another point which must be considered is expansion. It has been asserted many times that expansion of the dentures stimulates the growth of basal bone, thus resulting in a newly stabilized position of the teeth. Through vital staining and cephalometric techniques, it has been shown that this assertion is not true. In making the test setup then, expansion in anything but extremely moderate amounts should not be introduced, because, as a means of orthodontic therapy, it is generally unsatisfactory.

A third point, and a very important one to consider, is that the series of alveolar sockets in the line of occlusion can be thought of as a trough. Any teeth that are out of the general line of the trough can be safely moved into it, since the line of occlusion or the trough represents stable equilibrium. The question immediately arises, "If we are to move teeth into the trough, and we cannot move a great amount distally, and we are not allowed a great deal of expansion, how are we ever going to obtain sufficient space to move these teeth into the trough?"

I do not wish to place salt on old wounds, but since I was asked to speak of the positioner, and since the whole theory of the positioner is based on stable equilibrium, I must state that if there is not sufficient space to place all the teeth in the trough, then extraction must be considered.

In setting these teeth up for analysis, it will be noticed, in many cases, that in order to make the upper and the lower casts articulate, not only must the teeth be set up in proper relationship to the bony bases, but also the bases of the casts must be altered from their original anteroposterior relationship. We are all aware that in the correction of most Class II cases, the relationship of maxillary and mandibular dentures is changed, either by mandibular repositioning or by tooth movement.

If this repositioning is purely mechanical, ordinary retainers will not retain the case. On the other hand, mechanically jumped bites can be held with the positioner for as long as the positioner is worn. This, however, is merely putting off the ultimate relapse.

If the Class II malocclusion has been corrected by impeding growth in the upper jaw, and allowing growth to take place in the lower jaw, as has been implied by Kloehn, then the positioner is an excellent retention device. It will be found that in cases of this type, the teeth can be settled into occlusion in the new jaw relationship beautifully by means of this appliance.

From the foregoing, it can be seen that from setting up the teeth for analysis, it is an easy step to mold the setup in rubber. Since this setup represents what we wish for in any particular case, it is only rational to follow this

HIS

procedure. This rubb
of the case after basic

Thus far in this
been presented. It w
discussing some of the

Perhaps the main
is its tendency to clo
wholly accurate to el
that the patient is we
contribute to bite clos

It must be borne
positioner will be refl
are not properly corr
corrected in the finish
in the positioner set
on the positioner.

It is common pr
master models in an
of the articulator. J
Most men make this
amount was decided
way space. The ratio
freeway space is that
the upper and lower
sion while the positio
sion will hold the posi

This reasoning is
patient relaxes, his je
freeway space. Any
the mandible hangs, i

This is an excell
tioner, but it would
lower buccal teeth w
patient. The reason
pressure to bear upo
of the posterior teeth

This would be th
way space, since par
In most cases I have
the posterior buccal
opened beyond the fi
tension, and depressi
doubt this point. I rec

Another very im
tioner is the patient
then it is obvious t

ALN013114

ClearCorrect Exhibit 1002, Page 1401 of 3373

procedure. This rubber appliance can then be used to achieve the final finish of the case after basic treatment has been completed.

Thus far in this presentation, the advantages of using the positioner have been presented. It would be neither fair nor scientific to end this paper without discussing some of the disadvantages of the appliance.

Perhaps the main weakness of the positioner, according to many of its users, is its tendency to close the bite after only a few weeks of use. It would not be wholly accurate to claim that bite closure in these cases is due only to the fact that the patient is wearing a positioner. However, there are many factors which contribute to bite closure, and faulty positioner construction is one of these.

It must be borne in mind that any errors made in the construction of the positioner will be reflected in the finished occlusion of the patient. If rotations are not properly corrected in setting up the positioner, they will not be properly corrected in the finished occlusion. Elevation and depression of individual teeth in the positioner setup will be seen in the occlusion just as they were set up on the positioner.

It is common practice in the fabrication of the appliance to mount the master models in an articulator and then proceed to open the bite on the pin of the articulator. After this point is reached, the appliance is "waxed up." Most men make this opening about two to two and one-half millimeters. This amount was decided upon because it is thought to approximate the average freeway space. The rationale behind this opening of the bite in the amount of the freeway space is that having a layer of rubber between the occlusal surfaces of the upper and lower teeth will keep the muscles of mastication in a state of tension while the positioner is in place in the mouth. It is supposed that this tension will hold the positioner in place while the patient is sleeping.

This reasoning is not without logic. It is common knowledge that when a patient relaxes, his jaw drops open to physiologic rest position, which gives the freeway space. Any opening beyond this position puts the muscles, on which the mandible hangs, in a state of tension.

This is an excellent reason for the bite opening when fabricating the positioner, but it would seem to me that a layer of rubber between the upper and lower buccal teeth would invite bite closure in the finished occlusion of the patient. The reason for this, of course, is that each time the patient brings pressure to bear upon this layer of rubber, there would be a depressing action of the posterior teeth which would ultimately result in a close-bite.

This would be the case even if the layer of rubber did not exceed the freeway space, since part of the positioner therapy is to bite into the positioner. In most cases I have seen, however, the thickness of this layer of rubber between the posterior buccal segments exceeds the freeway space. When the jaws are opened beyond the freeway space, the muscles of mastication are always under tension, and depression of the posterior teeth will be the result. For those who doubt this point, I recommend a review of the excellent work of John Thompson.

Another very important point to consider before deciding to use the positioner is the patient cooperation. If the positioner is not worn as prescribed, then it is obvious that the desired results are not going to be obtained.

ALN013115

ClearCorrect Exhibit 1002, Page 1402 of 3373

A third objection to positioner therapy, according to some operators, is that the appliance does not close spaces or achieve proper interdigitation of the teeth in many cases. This objection again is a valid one.

Having covered three of the main defects of the positioner, I think it is in order to point out that two of these can be controlled by the operator and that the third, poor results with poor patient cooperation, is just as much a problem in the use of any other orthodontic appliance.

Dealing first with the close-bite problem, it was decided in one of the study clubs in California that after the positioner setup was made, it was good practice to depress the six upper and lower anterior teeth on the setup until a 1 to 2 mm. open-bite was the result in the final waxup of the case. From this point on, the fabrication of the positioner was carried out exactly as before. Due to the anterior open-bite in the setup, when the positioner is completed, the layer of rubber between the incisal edges of the upper and the lower anterior teeth is at least 2 mm. thicker than that between the upper and lower posterior teeth. With this arrangement, wearing of the positioner forces the anterior teeth to strike rubber before the posterior teeth do so. Obviously this will have a depressing action on the anterior teeth rather than on the posterior teeth, thus acting to prevent bite closure.

Concerning the objection that the positioner will not close spaces or achieve proper interdigitation in some cases, I can only say that it is my belief that in many of these cases, basic appliance therapy has not been carried out as it should have been, and too much has been expected of the positioner.

With these remarks, I rest my case for the use of the positioner. It is an excellent appliance for the purpose for which it was originally intended, and if used properly will produce wholly satisfactory results.

MEDICAL CENTER.

IMPROVED D

1·

AFTER first pr
the improved
ing its conception.
own practice. Pri
for an attachment
for use with the tw

Until recently,
alloy band techniq
terior teeth, which
protruded into the
It was felt any im·
for use with the al
the twin wire appl
sal use. It also se·
ponent parts assen
ing operation coul
the sliding sleeve a·

The open tub·
for the stationary
anterior band mai
inch outside diame
ponent. I have u·
and found it to b·
terior sections of a
0.010 inch by 0.02·
from 0.012 inch to
means of employi
dentures after ali;
0.010 inch twin wi·

After having
an attachment, a
fit would add refi
ing the summer o
for further impr
ment facilities of
graduate enginee
assistance, the im

The improved
section. The cha

ALN013116

ClearCorrect Exhibit 1002, Page 1403 of 3373

A

SHUSAKU YAMAMOTO

Appln: 2000-584831
Your Ref.: AT-00006JP

(Translation)

Japanese Laid-Open Publication No. 63-11148

Laid-Open Publication Date: January 18, 1988
Japanese Patent Application No. 61-154879
Filing Date: July 1, 1986
Inventor: T. OZUKURI
Applicant: T. OZUKURI

Specification

1. Title of the Invention
Dental orthodontic device

2. Claim
A dental orthodontic device of a shape memory plastic material exhibiting a shape memory effect at around 37°C, the dental orthodontic device having recessed portions corresponding to teeth, the recessed portions being formed in accordance with a teeth form and gums, wherein the recessed portions corresponding to the teeth consist of a normal dentition.

3. Detailed Description of the Invention
(Field of the Invention)
The present invention mainly relates to a dental orthodontic device used for correcting a dentition of the permanent teeth when having replaced temporary teeth in infancy and for arranging a dentition of adults.

ClearCorrect Exhibit 1002, Page 1404 of 3373

(Prior Art)

Since temporary teeth are not replaced with permanent teeth at the same time, the permanent teeth inevitably tend not to be arranged straight.

Conventionally, dentists connected teeth using a very thin wire to forcibly correct the dentition. With the method using the wire, the wire needed to be wound around each tooth and to be connected to all the teeth. In addition, the wire needed to be re-tightened every several months, i.e., each time the dentition was corrected.

(Problems to be Solved by the Invention)

With the above-described dental orthodontic method, it was very troublesome to wind a wire around each tooth and connect the wire to the adjacent teeth sequentially. The wire needed to be re-tightened every several months by a dentist, which imposed the trouble of seeing the doctor.

The wire, once attached, could not be detached for one or two years until the dentition was corrected, which was embarrassing and was not well received by young women.

(Means for Solving the Problems)

The present invention provides a dental orthodontic device which is easy to attach and detach and reduces the necessity of seeing the doctor, and thus solves the above-mentioned problems. This is realized by means of a dental orthodontic device formed of a shape memory plastic material exhibiting a shape memory effect at around 37°C. The dental orthodontic device has recessed portions corresponding to teeth which are formed in accordance with a teeth form and gums of the user and rearranged into a normal dentition, or

ClearCorrect Exhibit 1002, Page 1405 of 3373

in accordance with a teeth form and gums of a human having a normal dentition.

(Function)

When the above-mentioned dental orthodontic device is formed based on the teeth form of the user, the dental orthodontic device matches the teeth form of the user, and is freely deformed when worn. Therefore, the dental orthodontic device can very easily be attached to the teeth. Since the dental orthodontic device is deformed into a corrected dentition as its temperature approaches the body temperature after being attached, the dentition correction can be performed with no discomfort.

A dental orthodontic device which is formed based on the teeth form of a human having a normal dentition, other than the user, is easy to produce and can be mass-produced.

(Examples)

Hereinafter, an example of a dental orthodontic device according to the present invention will be described with respect to Figures 1 through 3.

Reference numeral 1 represents a main body of a horseshoe-shaped dental orthodontic device formed of a shape memory plastic material (for example, polynorbornene). The main body 1 exhibits a shape memory effect at around 37°C, which is a human intrabuccal temperature, and exhibits substantially the same level of flexibility as that of plastics and synthetic rubbers and is freely deformable at around room temperature. The main body 1 is structured of an upper insertion portion 11 which is inserted between a surface of teeth/gum of the upper jaw and the inner surface of the upper lip, a lower insertion portion 12 which is

ClearCorrect Exhibit 1002, Page 1406 of 3373

inserted between a surface of teeth/gum of the lower jaw and the inner surface of the lower lip, an occlusion portion 13 which is occluded by the upper and lower teeth, and a rear portion 14 which is located on the back of the upper and lower teeth. On an upper surface and a lower surface of the occlusion portion 13, recessed portions 13a which are shaped based on the teeth of the user and then corrected are formed.

When the user puts the main body 1 of the dental orthodontic device into his/her mouth and bites the occlusion portion 13 by the upper and lower teeth, the upper and lower insertion portions 11 and 12 are inserted between the teeth and the upper lip/lower lip, and the rear portion 14 adheres to the back of the upper and lower teeth. Since the main body 1 is flexible in the mouth, each tooth fits into the recessed portion 13a of the occlusion portion 13. The recessed portion 13a corresponds to the respective tooth in the current dentition.

When time passes with the main body 1 being bitten and with the temperature of the main body 1 approaching 37°C, the main body 1 recovers to a corrected dentition by the shape memory effect. Since each recessed portion 13a of the occlusion portion 13 has the same shape as that of the corresponding tooth, each tooth which is fit into the corresponding recessed portion 13a does not easily come off from the recessed portion 13a, and is moved into the corrected dentition. By repeating this process, the dentition is gradually corrected.

Next, a method for producing the main body 1 of the horseshoe-shaped dental orthodontic device will be described.

ClearCorrect Exhibit 1002, Page 1407 of 3373

First, two teeth forms of the patient (user) are made of wax (including the upper and lower teeth and gums). One of the teeth forms is used to produce a teeth form model of plaster. From the other teeth form made of wax, the teeth are removed. From the teeth form model produced of plaster, the teeth including the roots are excised. The roots of plaster are buried in the gums of the teeth form produced of wax, from which the teeth have been removed, such that a normal dentition is formed. Thus, another teeth form model is produced.

For a teeth form produced based on a human having a normal dentition, the above-mentioned means for arranging the teeth produced of plaster is not necessary.

The teeth form including the gums of wax and the teeth of plaster is set in an occlusion device. A gap of 3 mm is made between the upper and lower front teeth, and a gap of 2 mm is made between the upper and lower molar teeth. Such gaps provide a physiologic rest position. In this state, the upper and lower teeth and the upper and lower gums are entirely covered with a bite. Next, when the bite is cured to some extent, the teeth form is opened, together with the occlusion device. Thus, recessed portions made by the teeth and the gums of a normal dentition are formed in an upper surface and a lower surface of the bite. In addition, the teeth form formed of the bite is horseshoe-shaped and has the shape of a mouth piece.

Then, a plaster releasing agent is applied to the entirety of the mouth piece. The mouth piece is put into a mold and the mold is filled with plaster. The mold is formed such that the plaster, when cured, can be separated into a lip side portion (front portion) with respect to the

ClearCorrect Exhibit 1002, Page 1408 of 3373

mouth piece and a tongue side portion (back portion) with respect to the mouth piece. When the plaster in the mold is cured, the cured plaster form is separated into two, and the mouth piece is removed. When the separated plaster forms are assembled, a teeth form having the shape of the mouth piece, namely, including a normal dentition and normal gums, remains, and a space remains therearound.

Next, the space is filled with powder or small pieces of a shape memory synthetic resin such as, for example, granular or squamiformed polynorbornene, and then heated. Further, the plaster forms once separated are put into a heater while being assembled and then heated at 150°C for several tens of minutes. After the heating, the plaster forms are separated and the molded resin is removed. Thus, the dental orthodontic device shown in Figures 1 through 3 is obtained. The removed dental orthodontic device memorizes a normal dentition which has the shape of the plaster form, and is freely deformable at less than 37°C and becomes a normal dentition at around 37°C. Accordingly, the dental orthodontics described above can be performed.

The dental orthodontic device removed from the plaster form is polished in order to remove burr and the like.

(Effect of the Invention)

As described above, the present invention is modeled on the teeth and gums of the user and is like a mouth piece formed of a shape memory plastic material and having a normal dentition. When using this for correction of the dentition, the dental orthodontic device can be attached to the teeth easily and the user feels comfortable since the dental orthodontic device is initially soft. When the temperature of the device becomes about 37°C by his/her own

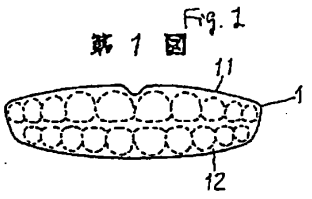
ClearCorrect Exhibit 1002, Page 1409 of 3373

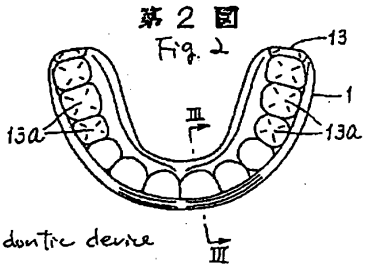
intrabuccal temperature, the dental orthodontic device is deformed to have a normal dentition and thus can correct the dentition of the user. Since the dental orthodontic device can be freely attached and detached, the correction can be performed at only the time periods that the user wants to do the correction. Therefore, the conventional problem which is caused by the requirement that the user should constantly wear a device is solved. Since the same device can be used until the dentition becomes normal, it is not necessary to see the doctor every several months.

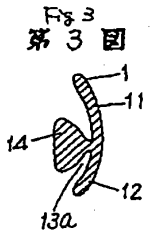
4. Brief Description of the Drawings

Figure 1 is a front view illustrating an example of a dental orthodontic device according to the present invention; Figure 2 is a plan view thereof; and Figure 3 is a cross-sectional view along line III-III thereof.

1 ... Main body of a dental orthodontic device, 13 ... recessed portions corresponding to teeth







1 -- Main body of a dental orthodontic device
13 -- Recessed portions corresponding to teeth

ClearCorrect Exhibit 1002, Page 1410 of 3373

INDEX NUMBER

American Journal of ORTHODONTICS and DENTOFACIAL ORTHOPEDICS

Volume 92 • DECEMBER 1987 • Number 6

ORIGINAL ARTICLES

Magnetic versus mechanical expansion *Vardimon, Graber, Voss, and Verrusio*

Associations between occlusion and signs and symptoms of TMJ dysfunction *Riolo, Brandt, and TenHave*

Computerized analysis of shape and stability of mandibular arch form *Felton, Sinclair, Jones, and Alexander*

High-speed screen/film combinations in cephalometric radiography *Kimura, Langland, and Biggerstaff*

Skeletal age assessment with first, second, and third fingers *Leite, O'Reilly, and Close*

Three-dimensional finite element stress analysis *Tanne, Sakuda, and Burstone*

CLINICIANS' CORNER

Method to correct angle ANB for geometric effects *Hussels and Nanda*

CASE REPORT *Deguchi and Amari*

AMERICAN BOARD OF ORTHODONTICS

IM MEMORIAM

REVIEWS AND ABSTRACTS

NEWS AND COMMENT

DIRECTORY: AAO OFFICERS AND ORGANIZATIONS

Complete contents begin on page 5A

Official publication of the
American Association of Orthodontists, its constituent societies, and the American Board of Orthodontics

Published by
The C. V. Mosby Company

ISSN 0889-5406

ClearCorrect Exhibit 1002, Page 1411 of 3373

A computerized analysis of the shape and stability of mandibular arch form

J. Mark Felton, D.D.S., M.S.D.,* Peter M. Sinclair, D.D.S., M.S.D., Daniel L. Jones, Ph.D.,*** and Richard G. Alexander, D.D.S., M.S.D.******
Dallas, Texas

To determine whether a particular ideal orthodontic arch form could be identified, the mandibular dental casts of 30 untreated normal cases, 30 Class I nonextraction cases, and 30 Class II nonextraction cases were examined. Following computerized digitizing and the use of a mathematic function called polynomial of the fourth degree, arch forms were generated for each sample and then compared to 17 commercially produced arch forms. Results showed that no particular arch form predominated in any of the three samples. A shape representing a combination of the "Par" and "Vari-Simplex" arch forms approximated to only 50% of the cases in the three samples. The remaining 50% of the cases displayed a wide variety of arch forms. Cases that had changes in arch form during nonextraction treatment frequently were not stable; almost 70% showed significant long-term posttreatment changes. Customizing arch forms appears to be necessary in many cases to obtain optimum long-term stability because of the great individual variability in arch form found in this study. (AM J ORTHOD DENTOFAC ORTHOP 1987;92:478-83.)

The achievement of a stable, functional, and esthetic arch form has long been one of the prime objectives of orthodontics. A key aspect in the achievement of this goal is the identification of a suitable arch form to use in the treatment of each case.[1,2] Many clinicians tend to adopt one particular arch form for the treatment of all malocclusions. The arch form chosen is often the one that creates, in the orthodontist's opinion, the optimum esthetic and functional occlusion.[3-7] Despite numerous investigations, there is currently little agreement as to the best size and shape for an ideal orthodontic arch form. It has long been suggested that considerable variability occurs in the arch forms of different types of malocclusions, which, if proved true, may preclude the effective use of a single ideal arch form for all cases.[8-13]

For more than 100 years, researchers have been trying to define the "ideal" arch form, frequently using the concept that the dental arch is symmetric in nature and can be represented by an algebraic or geometric formula. Shapes investigated have included the ellipse,[7,14,15] parabola,[16,17] and catenary curve[18] as well as mathematic formulas such as the cubic spline,[19,20] conic section,[21] and polynomial function.[22,23] Each of these shapes has received both praise and criticism, and several form the basis from which commercially produced arch forms have been derived.[3,4,7,24-27]

Recently, the idea of individualizing arch forms from the original mandibular arch has become more popular.[9,13,28] With the continuing development of computer-assisted analysis, this approach of custom designing arch forms may provide the optimum solution for accurately describing the ideal orthodontic arch form for each case.[19,22,23] With these developments in mind, the purpose of this study was fourfold:

1. To determine whether a sample of untreated normal cases displayed a particular arch form
2. To determine whether samples of Class I and Class II cases displayed similar arch form characteristics
3. To determine if treatment-induced changes in arch form were stable on a postretention evaluation
4. To determine whether any of 17 commercially produced arch forms were suitable for use in the majority of clinical cases

MATERIALS AND METHODS

The following samples were used in this study:

1. The mandibular dental casts of 30 skeletal and

Based on a thesis by J. Mark Felton submitted to the Department of Orthodontics, Baylor College of Dentistry, Baylor University, in partial fulfillment of the requirements for the degree of master of science in dentistry.
This research was supported in part by Baylor College of Dentistry Research funds.

*Orthodontist in private practice, Oklahoma City, Okla.
**Associate Professor, Department of Orthodontics, Baylor College of Dentistry.
***Dental student, Baylor College of Dentistry.
****Clinical Professor, Department of Orthodontics, Baylor College of Dentistry.

ClearCorrect Exhibit 1002, Page 1412 of 3373