Table I. Sample characteristics

	Pretreatment $\bar{x}$ *(yr-mo)*	*Posttreatment* $\bar{x}$ *(yr-mo)*	*Retention removal* $\bar{x}$ *(yr-mo)*	*Postretention* $\bar{x}$ *(yr-mo)*
Class I	12-7	14-7	18-10	28-1
Class II	12-7	14-6	18-6	25-2

Mean postretention period: Class I, 9 years 3 months; Class II, 6 years 8 months.

dental Class I nonextraction orthodontically treated cases, randomly selected on the basis of the availability of records (23 female patients, 7 male patients).

2. The mandibular dental casts of 30 skeletal and dental Class II nonextraction orthodontically treated cases (18 female patients, 12 male patients), randomly selected on the basis of the availability of records (ANB > 4, Class II molars)
3. Mandibular dental casts of 30 untreated normal cases (19 female subjects, 11 male subjects) from the sample of 120 cases of Dr. Lawrence Andrews of San Diego, Calif., which was used to derive the "six keys to occlusion" and the "straight wire appliance."[29]

Pretreatment and posttreatment mandibular dental casts were examined for each of the treated cases, which were from the practice of one of the authors (R.G.A.) (Table I). Postretention casts were available for 15 of the Class I and 15 of the Class II cases (that is, patients who responded to a recall request). None of the cases had undergone any palatal expansion, orthognathic surgery, or fixed prosthodontic therapy. Patients with missing teeth or obvious tooth size discrepancies were not included in the study. All the treated cases in this sample underwent therapy in the 1960s and early 1970s with fully banded, nonstraight wire, 0.018-inch slot systems. The arch form used was individualized for each case, based on the original mandibular arch and the clinician's concept of an optimum arch form.

On each of the mandibular casts for all three samples, a lead pencil was used to clearly mark the midpoint of the incisal surface of the incisors, the cusp tips of the canines, the buccal cusp tips of the first and second premolars, and the mesiobuccal cusp tip of the first molars (Fig. 1). A point midway between the central incisors was also marked to serve as a point of origin and as a midline reference. The occlusal surfaces of the casts were then photocopied with a millimeter scale placed adjacent to the teeth and any magnification caused by the photocoping process was then automatically corrected using a known reference on the millimeter scale. The cusp tips were used rather than the most buccal points on the teeth's labial surfaces because labial surface points frequently could not be accurately marked on the model and then reproduced during the photocopying process. The photocopied images were placed on the recording surface of a digitizer and 13 points were digitized and recorded from each cast. Remeasurement of 10 casts showed no statistically significant measurement error.

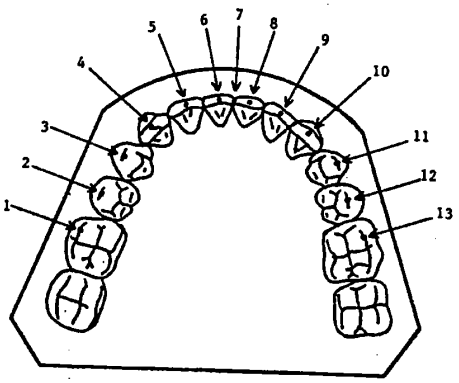


Fig. 1. Points digitized on the dental casts.

A sample of 17 commercially produced arch forms (ten basic shapes with a total of 17 sizes) was photocopied in a similar fashion (Table II, Fig. 2). Based on data for the normal mesiodistal size of mandibular teeth, pencil marks representing the positions of the cusp tips of the mandibular teeth were made on the photocopied images of the arch forms.[30] Each of these arch forms was then digitized in turn and, using a mathematic function known as a polynomial of the fourth degree, a mathematic equation was computed that would describe the exact shape and characteristics of each of the arch forms.

Changes in arch form during treatment and postretention were calculated using the polynomial function to provide smooth symmetric shapes for evaluation. Comparisons were made of the arch forms of each of the three samples and then of the three samples and the 17 commercial arch forms to determine the best fits. Similar comparisons were made with the arch forms broken down into anterior (incisor) and posterior segments. Differences between the canine and molar widths of the casts of each of the three samples and of the arch forms were also calculated.

Statistical analysis involved the use of the Pearson product–moment correlation coefficient to determine

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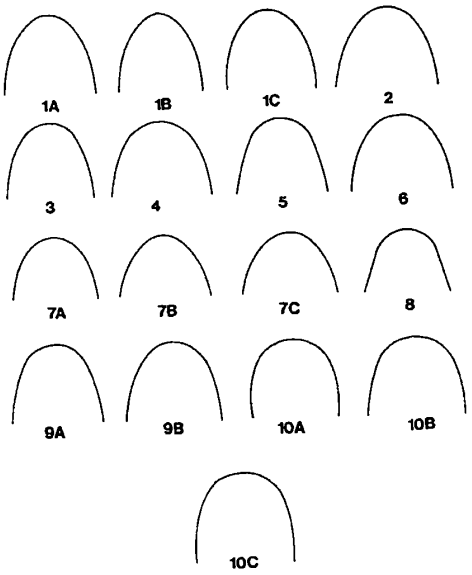


Fig. 2. The 17 commercial arch forms used.

Table II. Commercial arch forms used

Arch wire shapes	*Arch wire sizes*	*Arch wire name*
AW1	AW1a	Brader arch form, size 58*
	AW1b	Brader arch form, size 54*
	AW1c	Brader arch form, size 50*
AW2	AW2	Pentamorphic, tapered†
AW3	AW3	Pentamorphic, narrow tapered†
AW4	AW4	Pentamorphic, normal†
AW5	AW5	Pentamorphic, narrow ovoid†
AW6	AW6	Pentamorphic, ovoid†
AW7	AW7a	Par arch form, blue size‡
	AW7b	Par arch form, white size‡
	AW7c	Par arch form, black size‡
AW8	AW8	Bonwill-Hawley arch form§
AW9	AW9a	Vari-Simplex, small size‡
	AW9b	Vari-Simplex, large size‡
AW10	AW10A	Tru-Arch form, small size‖
	AW10b	Tru-Arch form, medium size‖
	AW10c	Tru-Arch form, large size‖

*American Orthodontics, Sheboygan, Wis.
†Rocky Mountain/Orthodontics, Denver, Colo.
‡Ormco, Glendora, Calif.
§Hawley (1905).
‖"A" Company, Inc., San Diego, Calif.

the strength of the correlation between each of the arch forms and the dental casts. Chi-square analysis, Student's t tests, and standard scores were used to determine the significance of the best fit scores and the comparisons of casts and arch forms.

RESULTS

1. Untreated normal sample. This sample showed no predominance of any particular arch form and none of the commercially available arch forms was found to show a statistically superior closeness of fit (Table III). The most commonly seen arch form was closest to the shape of the Vari-Simplex* (27% of cases), closely followed by the Tru-Arch† (20% of cases), and the Par arch* form (17% of cases). Combining the data for the very similar Par and Vari-Simplex arch forms showed that this general shape, which represented 44% of the untreated normal sample, was statistically ($P < 0.05$) more common than the remaining arch forms.

2. Class I cases. This sample showed no predominance of any particular arch form before treatment and none of the commercially available arch forms was found to show a statistically superior closeness of fit (Table IV). A combination of the Par and Vari-Simplex arch forms, which represented the arch forms of over 50% of the pretreatment cases (16 of 30), was statistically ($P < 0.05$) more common than the remaining arch forms.

Posttreatment, no single arch form predominated statistically despite the clinician's preference for an arch form similar to the Par and Vari-Simplex shapes, which resulted in 18 of the 30 cases (60% of the sample) having a different arch form posttreatment from that which they displayed pretreatment. At the postretention evaluation in 67% of the 15 cases followed to this stage, changes made in arch form during treatment were not maintained; most cases tended to return toward their original arch form. No particular arch form predominated at the postretention evaluation.

3. Class II cases. This sample showed no predominance of any particular arch form before treatment and none of the commercially available arch forms was found to show a statistically superior closeness of fit (Table V). As in the Class I sample, a combination of the Par and Vari-Simplex arch forms, representing 18 of the 30 cases (60%), was statistically ($P < 0.05$) more common than the remaining arch forms. Posttreatment, no single arch form predominated and 16 of the 30 cases showed arch forms similar to those of the Par and Vari-Simplex shapes. During treatment 21 of the 30 cases (70% of the sample) had their arch forms

*Ormco, Glendora, Calif.
†"A" Company, Inc., San Diego, Calif.

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Table III. Untreated normal group—Number of cases showing best fits to commercial arch forms

	No. of cases (total = 30)
Brader	2
Pentamorphic, tapered	0
Pentamorphic, narrow tapered	1
Pentamorphic, normal	4
Pentamorphic, narrow ovoid	0
Pentamorphic, ovoid	0
Par arch form	5
Bonwill-Hawley	4
Vari-Simplex	8
Tru-Arch	6

changed and at the postretention evaluation it was found that in 60% of the 15 cases followed to this stage, the changes made in arch form during treatment were not maintained. No particular arch form predominated at the postretention period.

4. Comparison of arch widths between samples. Before treatment the intercanine widths of the Class I and Class II groups were statistically similar, but the Class I group was 1.2 mm ($P < 0.05$) smaller than the untreated normal sample (Table VI). After treatment (T2) all three groups had very similar intercanine widths after the dimensions of the Class I and Class II groups had been increased by 0.8 and 0.7 mm, respectively, during treatment. Postretention (T3), only the Class I group was statistically smaller ($P < 0.001$) than the normal group, having had a 1.2 mm decrease from T2 to T3.

Before treatment the intermolar widths of both the Class I and Class II samples were smaller ($P < 0.05$) than those of the normal group (Table VI). After treatment (T2) all three intermolar widths were very similar; the Class II group remained stable to T3 and the Class I group showed a small (0.4 mm) reduction in intermolar width, causing it to be smaller ($P < 0.01$) than the normal group at T3.

DISCUSSION

Since the time of Edward Angle, orthodontists have tried to determine the ideal arch form or "true line of occlusion."[1] Many different solutions to this problem have been proposed, but few have stood the test of time. The results of this study tend to support previous findings suggesting that there is no single, universal, ideal arch form applicable to all cases.[8,10,12] Biologic variability appears to be so great that even in a sample of untreated normal cases, no predominant arch form could be identified. The best that could be achieved was a general shape, represented by a combination of the Par and Vari-Simplex arch forms, which still approximated to only 44% of the sample.

Table IV. Class I cases—Number of cases showing best fits to commercial arch forms

	Pretreatment No. of cases (total = 30)	*Posttreatment No. of cases (total = 30)*	*Postretention No. of cases (total = 15)*
Brader	6	2	0
Pentamorphic, tapered	0	0	0
Pentamorphic, narrow tapered	4	6	2
Pentamorphic, normal	0	2	2
Pentamorphic, narrow ovoid	0	0	0
Pentamorphic, ovoid	0	0	0
Par arch form	8	7	3
Bonwill-Hawley	3	2	0
Vari-Simplex	8	11	8
Tru-Arch	1	0	0

Table V. Class II cases—Number of cases showing best fits to commercial arch forms

	Pretreatment No. of cases (total = 30)	*Posttreatment No. of cases (total = 30)*	*Postretention No. of cases (total = 15)*
Brader	2	1	2
Pentamorphic, tapered	1	0	1
Pentamorphic, narrow tapered	4	4	3
Pentamorphic, normal	1	2	0
Pentamorphic, narrow ovoid	0	0	1
Pentamorphic, ovoid	1	1	0
Par arch form	9	8	0
Bonwill-Hawley	1	2	0
Vari-Simplex	9	8	8
Tru-Arch	2	4	0

Looking at the question of whether specific malocclusions have characteristic arch forms, this study found no specific arch form that would characterize either Class I or Class II malocclusions.[12,20] There was little difference between the arch forms of the two groups; both showed just over half their cases approximating to the same combination of the Par and Vari-Simplex arch forms that was identified as having the best fit for the untreated cases. Even with this lack of uniformity, it was found that of the cases whose arch

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Table VI. Mandibular arch widths

Sample	*Intercanine width (mm)*			*Intermolar width (mm)*		
	T1	*T2*	*T3*	*T1*	*T2*	*T3*
Normal	26.3	26.3	26.3	45.0	45.0	45.0
Class I	25.1	25.9	24.7	43.2	44.1	43.7
Class II	25.6	26.3	25.4	43.3	44.5	44.5

forms were changed during treatment, close to 70% had returned to their original shapes by the long-term postretention evaluation. These findings are similar to several other studies that have suggested that changes in mandibular arch form, such as might be caused by expansion of canines, are not stable and that clinicians should try to maintain the original arch form to increase their chances for long-term stability.[31-35]

The data from this study suggested that there was a tendency for the patients in the Class I and Class II malocclusion groups to have smaller arch widths than the untreated normal group. Increasing the intercanine width to approximately the dimensions of the normal group during nonextraction treatment was found to be unstable, while increases in the intermolar widths, particularly in the Class II sample, showed considerable long-term stability as has been suggested previously.[36,37] The use of a single arch form for all cases might thus lead to a consistent tendency to increase arch dimensions that the clinician may find to be unstable in a considerable percentage of cases.

CONCLUSIONS

1. The cases in the untreated normal sample did not show any particular ideal arch form.

2. The Class I and Class II samples' pretreatment arch forms were similar overall, but no one characteristic arch form predominated in either group.

3. A combination of the arch forms represented by the commercially produced "Par" and "Vari-Simplex" shapes showed the closest fit, approximating about 50% of the cases in all three samples. The remainder of the cases showed a wide variety of arch forms.

4. Changes in arch form with treatment frequently were not stable; almost 70% of cases showed significant long-term posttreatment changes.

5. No one arch form can be expected to fit every dental arch. Some customizing will be needed in many cases to obtain the optimum stable orthodontic result.

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REFERENCES

1. Angle EH. Treatment of malocclusion of the teeth. 7th ed. Philadelphia: SS White & Co., 1907.
2. Black GV. Descriptive anatomy of the human teeth. 3rd ed. Philadelphia: Wilmington Dental Mfg. Co., 1894.
3. Bonwill WGA. Geometrical and mechanical laws of articulation. Trans Ocont Soc Pa 1885;119:33.
4. Hawley CA. Determination of the normal arch and it application to orthodontia. Dent Cosmos 1905;47:541-52.
5. McConnail MA, Scher EA. The ideal arch form of the human dental arcade with some prosthetic application. Dent Record 1949;69:285-302.
6. Scott JH. The shape of the dental arches. J Dent Res 1957;36:996-1003.
7. Brader AC. Dental arch form related to intraoral forces: PR = C. Am J Orthod 1972;61:541-61.
8. Hellman M. Dimensions vs. form in teeth and their bearing on the morphology of the dental arch. Int J Orthod 1919;5:615-51.
9. Stanton FL. Arch predetermination and a method of relating the predetermined arch to the malocclusion to show the minimum tooth movement. Int J Orthod 1922;8:757-78.
10. Izard G. New method for the determination of the normal arch by the function of the face. Int J Orthod 1927;13:582-95.
11. Williams PN. Determining the shape of the normal arch. Dent Cosmos 1917;59:695-708.
12. White LW. Individual ideal arches. J Clin Orthod 1978;12:779-87.
13. Robnett JH. Segment concept in arch pattern design. Am J Orthod 1980;77:355-67.
14. Sicher H. Oral anatomy. 2nd ed. St. Louis: The CV Mosby Company, 1974.
15. Currier JH. Human dental arch form. Am J Orthod 1969;56:164-79.
16. Wheeler RC. A textbook of dental anatomy and physiology. 2nd ed. Philadelphia: WB Saunders Co., 1950:196-215, 352-406.
17. Burstone CJ. Uses of the computer in orthodontic practice. J Clin Orthod 1979;13:442-53, 539-51.
18. Musich DR, Ackerman JL. The cantenometer, a reliable device for estimating dental arch perimeter. Am J Orthod 1973;63:366-75.
19. BeGole EA. Application of the cubic spline function in the description of dental arch form. J Dent Res 1980;59:1549-56.
20. Diggs DB. The quantification of arch form [M.S.D. thesis]. Seattle: University of Washington, 1982.

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21. Sampson PD. Dental arch shape: a statistical analysis using conic sections. AM J ORTHOD 1981;79:535-48.
22. Lu KH. Analysis of dental arch symmetry [Abstract]. J Dent Res 1964;43:780.
23. Sanin C, Savara BS, Thomas DR, Clarkson OD. Arc length of the dental arch estimated by multiple regression. J Dent Res 1970;49:885.
24. McKelvain GD. An arch form designed for use with a specific straight wire orthodontic appliance [MSD thesis]. Dallas: Baylor College of Dentistry, 1982.
25. Engel GA. Preformed arch wires: reliability of fit. AM J ORTHOD 1979;76:497-504.
26. Ricketts RM. Research in factors of appliance design and arch form. Pacific Palisades, California: Foundation for Orthodontic Research, 1979.
27. Roth RH. Straight wire mechanics syllabus. Burlingame, California: Foundation for Advanced Continuing Education, 1978.
28. Andrews LF. The six keys to occlusion. AM J ORTHOD 1972;62:296-309.
29. Andrews LF. The straight wire appliance. Br J Orthod 1979; 6:125-43.
30. Moorrees CFA. The dentition of the growing child. Cambridge, Massachusetts: Harvard Press, 1959.
31. Gardner SD. Posttreatment and postretention changes following orthodontic therapy. Angle Orthod 1976;46:151-61.
32. Reidel RA. Retention. In: Graber TM, Swain B, eds. Current orthodontic concepts and techniques, vol 1, 2nd ed. St. Louis: The CV Mosby Company, 1985:1095-1137.
33. Strang RHW. The fallacy of denture expansion as a treatment procedure. Angle Orthod 1949;19:12-7.
34. Walter DC. Changes in the form and dimension of dental arches resulting from orthodontic treatment. Angle Orthod 1953;23: 3-18.
35. McCauley DR. The cuspid and its function in retention. Am J Orthod 1944;30:196-205.
36. Coombs CL, Deming DC. An evaluation of dental arch form during and following orthodontic treatment as determined by spline curves. Eugene, Oregon: University of Oregon, 1979.
37. Shapiro PA. Mandibular arch form and dimension. AM J ORTHOD 1974;66:58-70.

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Accuracy of Cephalometric Prediction in Orthognathic Surgery

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The reliability of predicting the results of orthodontic surgical treatment was analysed. The sample consisted of 30 patients treated with one of the following six types of surgery: mandibular anterior alveolar surgery; maxillary anterior alveolar surgery; mandibular setback surgery; mandibular advancement surgery; Le Fort I surgery; and a combination of Le Fort I and mandibular setback surgery. Comparisons of tracings of the initial cephalometric radiographs, the prediction tracing and the six-month follow-up film showed great variation in the results both within and between the surgical subgroups. Generally, it was easier to predict the treatment results of alveolar segmental osteotomies, especially in the mandible, than of operations in which the whole mandible was repositioned. The results from Le Fort I surgery with or without a concomitant mandibular setback showed the greatest difference between the predicted and the actual outcome. The postoperative vertical dimension appeared to be particularly hard to predict. Explanations for these discrepancies are offered and possibilities for improvements suggested. It is concluded that prediction tracings are still of value despite the poor accuracy in some cases.

During the last few decades, there has been tremendous expansion of orthognathic surgery as a method of treating dentofacial deformities. Increasingly sophisticated methods have been designed to enhance the surgical outcome. At the same time the need to predict the end results has grown, and retrospective studies of treated patients have provided the clinician with guidelines for estimating the effect of the hard tissue surgery on the soft tissues.[1–3] The prediction, usually based on the patient's dental casts and cephalograms, has a three-fold purpose: 1) to assist the surgeon and orthodontist in the evaluation of the eventual treatment effects on stability and facial esthetics; 2) to give the patient a reasonable preview of the result; and 3) to provide a medium for dialogue between the patient and the treatment team during the preoperative planning stage.

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Several methods of prediction have been suggested. McNeill et al.[4] used sectioning and repositioning of the patient's casts in combination with cephalometric prediction of the postsurgical dental and soft tissue relationships. Lines and Stoffelshäuser[1] used a similar approach, while the method of Henderson[5] differed slightly. The latter author combined the patient's cephalometric tracing with a transparent profile photograph, and the effect of different osteotomies on the profile was assessed by sectioning the transparency along the proposed osteotomy lines. In the prediction methods of Worms et al.[6] and Fish and Epker,[7] normative data on the soft tissue profile and incisor position in relation to the jaw bases were important guidelines in the planning procedure.

Recently, computer-aided methods for the planning of craniofacial and orthognathic surgery have been published.[8–13] The computer methods have been based on cephalometric radiographs, computerized tomographic (CT) data, or a combination of the two to provide a graphic prediction of the surgical result. Lately, some computerized systems using cephalograms or photographs have even become commercially available (Quick Ceph, Q

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matic Processing, Loma Linda, CA; ACCU-CEPH, Analog Digital Services, Albuquerque, NM; Dentofacial Planner, Dentofacial Software Inc., Toronto, Canada; and McGhan Pre-view, McGhan Medical Corp., Santa Barbara, CA). In reaction against the enthusiastic development of this new, expensive computer technology, some surgeons have questioned its real value compared with conventional methods of surgical planning.[14]

The reliability of the prediction tracing has almost never been considered. Therefore, the present investigation was undertaken as a preliminary attempt to study the accuracy of our prediction method, which is very similar to the one described by McNeill et al.[4]

Materials and Methods

Thirty of the most recent patients treated with various types of orthognathic surgery at the Maxillofacial Unit, Faculty of Odontology, Göteborg, Sweden were selected for study. A criterion for the selection was that the patient had been treated with one of the following six types of surgery: mandibular anterior alveolar surgery; maxillary anterior alveolar surgery; mandibular setback surgery; mandibular advancement surgery; Le Fort I surgery; or a combination of Le Fort I and mandibular setback surgery. Furthermore, prediction tracings made from cephalometric radiographs during the planning of treatment had to be available. Follow-up cephalograms taken at least six months postoperatively (range, 6–20 months; mean, 7.6 months) were also required. All recordings were made in the intercuspal position and with attention paid to the patient's lips, which should be in repose. In cases of reduced vertical dimension with a resultant overclosure, the cephalogram used for prediction was taken with the patient biting on a wax index to correct the facial height deficiency. Three oral surgeons and three orthodontists were involved, but each treatment and planning were supervised by the senior oral surgeon and orthodontist.

The prediction technique used relied on both dental casts and lateral cephalograms. The tentative position of the teeth and the intermaxillary relationships were estimated from the casts. The predicted postorthodontic position of the incisors in relation to their jaw bases was transferred from the casts to the tracing of the preoperative cephalogram. A partial tracing of the teeth and base of the jaw(s) to be moved was then constructed in a different colour. This tracing was taped to the full tracing in a position where the occlusion corresponded with postoperative dental cast prediction. The soft tissue outline was finally constructed taking into consideration the published ratios relating dental and skeletal movements to changes in the covering facial soft tissue profile.[1,13]

Results

Generally, the accuracy of prediction of the postoperative outcome showed great variation, both between and within the surgical subgroups. The results are therefore reported as tracings for each individual case (Figs. 1–3) instead of giving mean values of selected quantitative variables. The most easily predicted results were those following mandibular alveolar surgery, but those obtained after maxillary alveolar surgery were also predictable (Fig. 1). In the maxillary subgroup the major difference between the prediction tracing and follow-up cephalograms was in the angulation of the anterior segment. The incisors tended to become more retroclined at surgery than was intended. This difference in dental and skeletal position was reflected by a similar difference between the predicted and actual position of the covering soft tissue.

In general, the patients in whom surgical setback or advancement of the whole mandible was performed (Fig. 2) showed postoperative results that deviated more from the prediction tracings than those in the segmental subgroups. The new position of the mandibular jaw base, both in the horizontal and vertical plane, appeared more difficult to predict than the occlusion. The exact position of the lips and soft tissue chin seemed difficult to anticipate, especially in the mandibular setback subgroup.

Finally, the results of Le Fort I surgery with or without a concomitant mandibular setback surgery (Fig. 3) showed the greatest difference between prediction and actual outcome. Although the variation was great, however, in both subgroups there was a patient whose result was predicted almost perfectly (patient KW (female) treated with Le Fort I only and patient PN (male) in the subgroup with combined surgery). The postoperative vertical dimension appeared particularly hard to predict when surgery included movement of the whole maxilla.

Discussion

The prediction of orthodontic treatment results, both in children and adults, has been done for more than 25 years.[15,17] Especially when facial growth has been included in the prediction, its reliability has been under discussion.[18–20] The literature does not indicate, however, that there has been a similar

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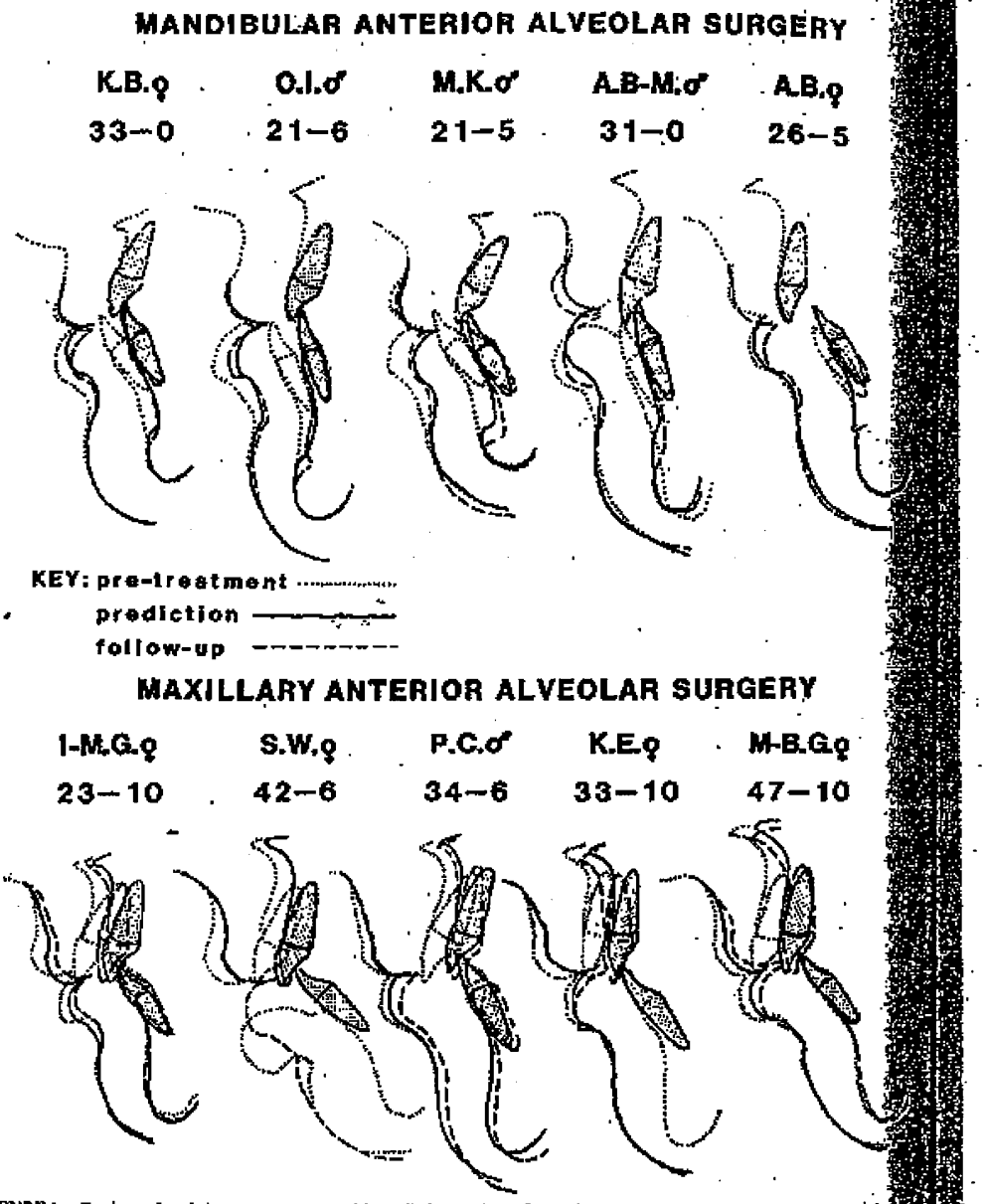
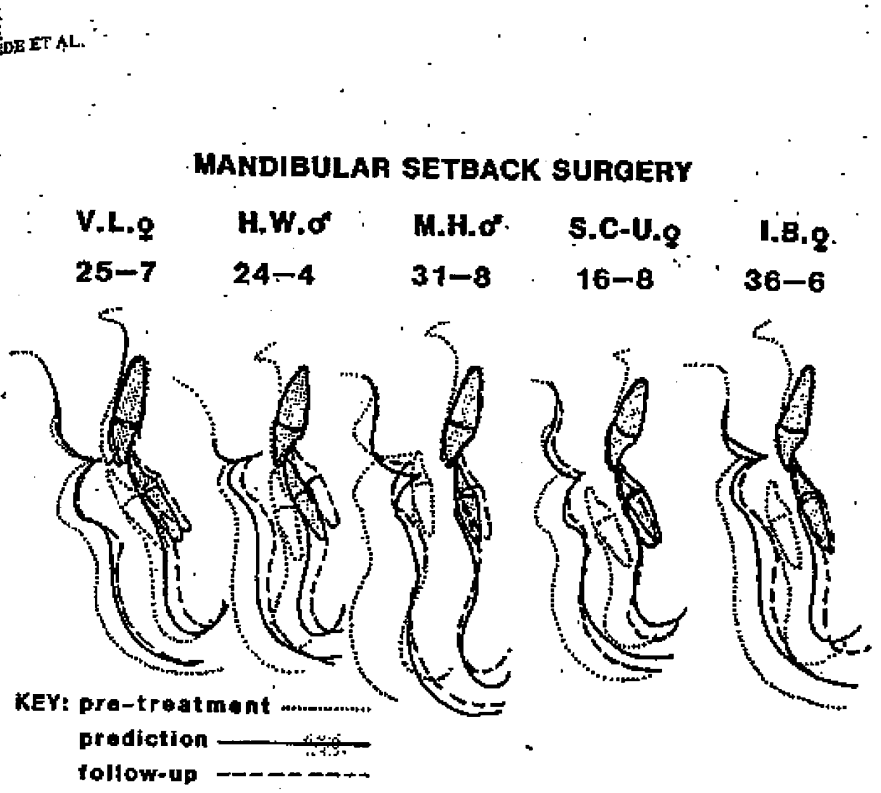


FIGURE 1. Tracings of cephalograms compared with prediction tracings of 10 patients belonging to two treatment categories. Age at surgery are indicated (years-months). The concordance between predicted and actual outcome was better after mandibular surgery than after similar treatment in the maxilla.

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...URE 2. Tracings of 10 patients treated with two types of mandibular surgery. Ages at surgery are indicated (years-months). ...ough there were some variations, the position of the mandibular base appeared more difficult to predict than the occlusion.

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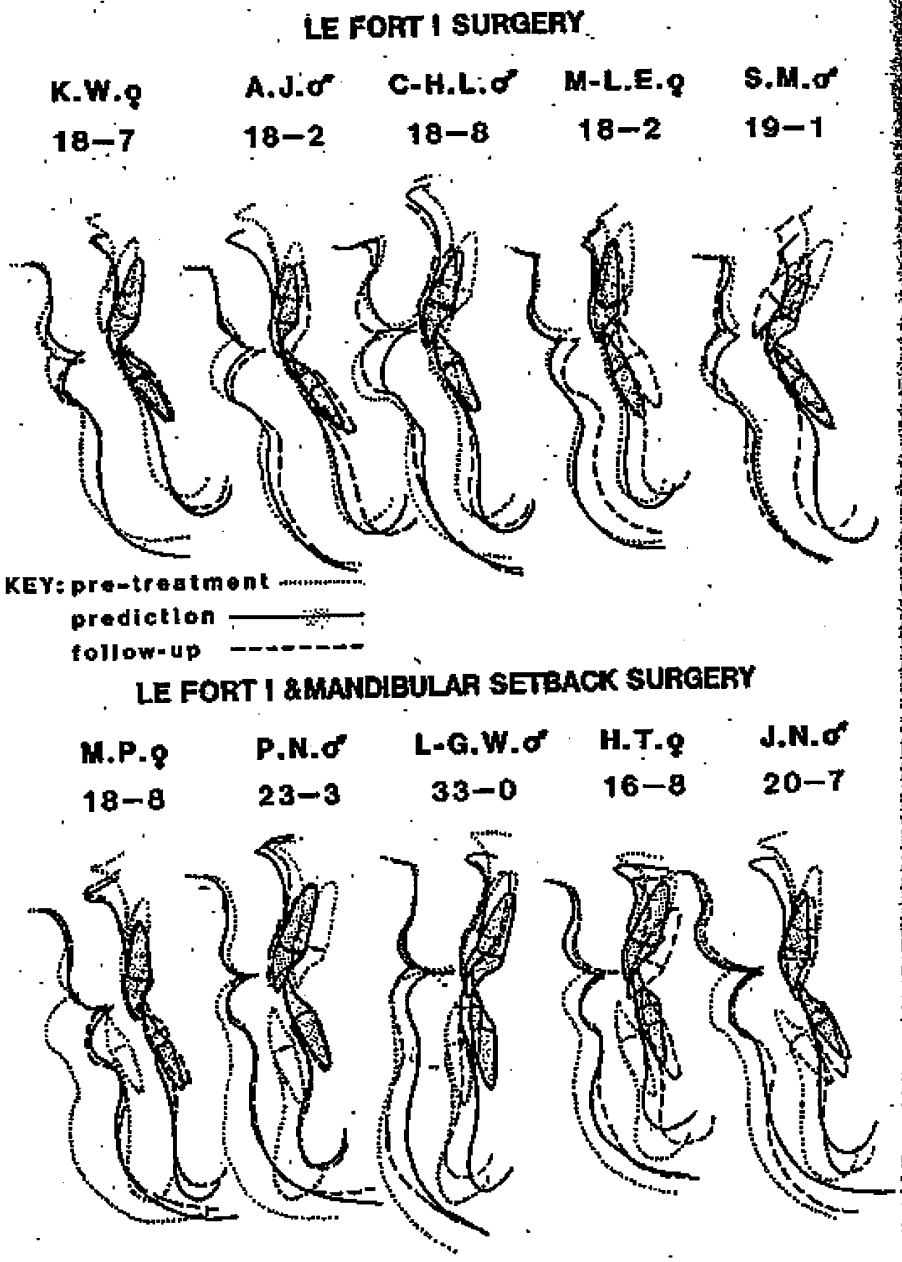


FIGURE 3. Tracings of 10 patients treated with Le Fort I surgery only, or with Le Fort I plus mandibular setback. Ages at surgery indicated (years-months). Great variation was found, but generally the results of these types of surgery appeared difficult to anticipate. The vertical dimension, in particular, was difficult to predict.

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...ite ab...ut the accuracy of predicting the results ...orthognathic surgery. Only isolated cases have ...n reported comparing the predicted result with ...actual outcome of treatment. Statements such ...reasonable resemblance to the plan"[5] and ...ose to prediction"[21] are based on subjective ...luations. With few exceptions, comparisons ...ve not been made by measuring or by superim...sing prediction and follow-up tracings of the ...phalograms.[3,9,22]

There might be several reasons for the rather ...or concordance between the predicted and the ...tual result found in many cases in the present ...dy. Although the criteria for assignment of pa...nts to this study were rigid, slight deviations ...ch as minor lip strain or imperfect occlusion of ...mandible at follow-up, could not be completely ...oided. However, a more valid explanation for the ...corded differences might be that the prediction ...s made prior to *all* treatment. This meant that ...t only the surgical result had to be predicted but ...o the effect of the presurgical orthodontic treat...ent. There were some cases (e.g., female VL in ...mandibular setback subgroup and case male US ...ated with mandibular advancement) where the ...thodontic proclination of the incisors was greater ...an predicted, and this influenced the new position ...the jaw base achieved at surgery. To improve the ...racy of the prediction, a new evaluation should ...ve been made immediately before surgery.[6]

The type of surgery was another important factor ...ffecting the quality of prediction of the surgical ...rthodontic treatment, as also noted by Profitt and ...ker.[15] Separation of our patients into small sub...roups, therefore, seemed appropriate. Anterior ...gmental surgery, especially in the mandible, was ...asier to perform according to a predetermined ...an, and the desired result was therefore easier to ...chieve than, for instance, in cases where Le Fort I ...rgery had to be used. In this operation the ver...al dimension has proved particularly difficult to ...ontrol.[23,24] No doubt, "the accuracy and useful...ss of prediction is clearly dependent on the clini...an's ability to follow the plan accurately."[9]

A further reason for some of the discrepancies ...between the plan and the follow-up results was the ...ccurrence of a varying and sometimes unpredict...le relapse. For example, in mandibular setback ...ses where the surgical movement also included ...losure of an anterior open bite, the mandible ...nded to relapse vertically to a greater extent than ...as predicted. Similarly, some of the present cases ...splayed a varying relapse after correction of short ...terior facial height by Le Fort I surgery. In unfor...ate cases all the factors just discussed might co...incide, which would explains the difficulties in ob...taining accurate predictions.

The value of prediction tracings must be stressed despite the rather poor accuracy in some cases. There are several advantages. To be able to make a prediction, the orthodontist and surgeon are forced to plan treatment in detail and even perform mock orthodontic and surgical treatment to test the feasibility of the therapy. In addition, the visual impression of the predicted end result makes it easier for the patient to decide about treatment. As the treatment team gains further experience and more follow-up investigations are performed, the accuracy of the prediction of the final outcome of orthognathic surgery should improve.

References

1. Lines PA, Steinhäuser EW: Diagnosis and treatment planning in surgical orthodontic therapy. Am J Orthod 66:378, 1974
2. Dann JJ, Fonseca RJ, Bell WH: Soft tissue changes associated with total maxillary advancement: a preliminary study. J Oral Surg 34:19, 1976
3. Engel GA, Quas RE, Chaconas SJ: Soft-tissue change as a result of maxillary surgery. A preliminary study. Am J Orthod 75:291, 1979
4. McNeill RW, Proffit WR, White RP: Cephalometric prediction for orthodontic surgery. Angle Orthod 42:154, 1972
5. Henderson D: The assessment and management of bony deformities of the middle and lower face. Br J Plast Surg 27:287, 1974
6. Worms FW, Isaacson RJ, Spiedel TM: Surgical orthodontic treatment planning: Profile analysis and mandibular surgery. Angle Orthod 46:1, 1976
7. Fish LC, Epker BN: Surgical-orthodontic cephalometric prediction tracing. J Clin Orthod 14:36, 1980
8. Bhatia SN, Sowray JH: A computer-aided design for orthognathic surgery. Br J Oral Maxillofac Surg 22:237, 1984
9. Harradine NWT, Birnie DJ: Computerized prediction of the results of orthognathic surgery. J Maxillofac Surg 13:245, 1985
10. Marsh JL, Vannier MW, Stevens WG, et al: Computerized imaging for soft tissue and osseous reconstruction in the head and neck. Clin Plast Surg 12:279, 1985
11. Cutting C, Bookstein FL, Grayson B, et al: Three-dimensional computer-assisted design of craniofacial surgical procedures: optimization and interaction with cephalometric and CT-based models. Plast Reconstr Surg 77:877, 1986
12. Ueda K, Kobayashi M, Nakajima T, et al. Three-dimensional prediction of mandibular movement in the treatment of prognathism. J Oral Maxillofac Surg 44:21, 1986
13. Walters H, Walters DH: Computerised planning of maxillofacial osteotomies: the program and its clinical application. Br J Oral Maxillofac Surg 24:178, 1986
14. Tessier P, Henrary D: Three dimensional imaging in medicine. A critique by surgeons. Scand J Plast Reconstr Surg 20:3, 1986
15. Proffit WB, Epker BN: Treatment planning for dentofacial deformities, *in* Bell WH, Proffit WR, White RP (eds): Surgical Correction of Dentofacial Anomalies. Philadelphia, WB Saunders, 1980, p 187
16. Steiner CC: Cephalometrics in clinical practice. Angle Orthod 29:8, 1959

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17. Ricketts RM: Cephalometric synthesis. Am J Orthod 46:647, 1960
18. Ricketts RM, Bench RW, Hilgers JJ, et al: An overview of computerized cephalometrics. Am J Orthod 61:1, 1972
19. Greenberg LZ, Johnston LE: Computerized prediction: The accuracy of a contemporary long-range forecast. Am J Orthod 67:243, 1975
20. Houston WJB: The current status of facial growth prediction: a review. Br J Orthod 6:11, 1979
21. Phillips JG: Photo-cephalometric analysis in treatment planning for surgical correction of facial disharmonies. J Ma... Oral Maxillofac Surg 6:174, 1978
22. Buchman J, Wirth PJ: Comparison of two methods of pre... prediction in surgical treatment of mandibular pro... nathism. J Oral Maxillofac Surg 41:17, 1983
23. Van Sickels JE, Larsen AJ, Triplett RG: Predictability ... maxillary surgery: a comparison of internal and exter... reference marks. Oral Surg 61:542, 1986
24. Riddell A, Adell R, Kahnberg K-E, et al: The vertical dim... sion in Le Fort I surgery (in preparation)

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Automated finite element modeling of a human mandible with dental implants

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Abstract

This paper presents an automated procedure to generate a three-dimensional finite element model of an individual patient's mandible with dental implants inserted. The reconstruction of the geometry as well as the modeling of the material properties for the different types of bone in the jaw is based on CT data.

For this purpose various methods of image processing, geometric modeling and finite element analysis are combined and extended. Special emphasis is given to the automated assignment of the material properties based on the density values of the CT data, a technique that replaces the geometric modeling of the inner structures of the bone and makes it possible to run the generation process of the model in an automated way.

Finally we focus on a comparison of a mandible with different material modeling strategies that shows the quality of the finite element models.

1 Introduction

Stress transmitted to the bone around osseointegrated implants can cause reabsorption of the bone and other biomechanical remodeling processes, that can end in the loss of the implants. Structural analysis using the finite element method is becoming very common in computer aided surgery planning (CAS), but building a finite element model of individual patients' bones and implants is a costly process.

Our intention was to develop an automated procedure for the reconstruction of the individual patients' bone geometry on the basis of computer tomography (CT) data and a tool for the surgeons to place implants into the bone interactively. These geometry models are then converted to finite element models using adaptive tetrahedral meshing.

Besides the exact geometric modeling, the material properties given to the bone have a major impact on the analysis results. For technical parts and materials, for instance in mechanical engineering, the material properties and the geometry are well defined. In biomechanical structures like the human mandible however, the type of bone as well as the density are changing strongly throughout the geometry, thus averaging and assignment of only one or two material properties can lead to inaccurate results.

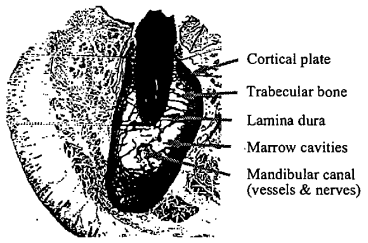


Figure 1: Buccolingual section of the mandible

Figure 1 shows the two main bone types of the mandible, the hard cortical plate that forms the shell of the jaw, and the trabecular (spongy, cancellous) bone inside. The thickness of the corticalis and the consistency of the spongiosa vary strongly throughout the mandible. The trabecular bone is composed of plate-like bone partitions with bone marrow spaces of various sizes and shapes and contains the mandibular canal for the inferior alveolar vessels and nerves and other cavities [Woelf79]. An exact border between the cortical and cancellous bone cannot be determined.

For these reasons we define a range of seven bone material properties from very soft cancellous bone to hard cortical bone. These are then assigned to to the elements of the mandible finite element mesh depending on the density values in the patient's CT data. The analysis results are then compared to finite element models with only one material defined for the entire bone.

The advantages of this automated geometry and material modeling system are better implantation planning tools, enhanced positioning, design and longevity of the implants, minimization of the stresses induced into the bone and thus prevention of damage or loss of the implants.

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2 Previous work

Several authors published finite element studies of human bones with osseointegrated implants or prostheses systems, for example dental implants in the mandible or femoral implants. They are mostly concentrating on the implant design, the bone-implant interface and the stresses induced into the bone. The following descriptions focus on mandible models with endosseous dental implants.

Some of the studies are confined to a small area or volume of bone around the implants. They use either two-dimensional scenarios of implants placed into a rectangular area of bone assuming symmetry [Siege93] or three-dimensional implant models placed into a rectangular volume of bone. Material definitions are then made for two bone materials, a layer of cortical bone covering the inner trabecular bone.

The analysis focuses on the minimization of the stresses and strains in the implant-bone interface that result to different loads by testing different implant materials and shapes. These studies are confined to a small volume of bone around the implant and two material properties. They do not investigate the impacts of the implant on the entire bone structure and they assume an exact border between the two materials.

Other analysis studies use complete three-dimensional models of bones, for instance a human mandible. The geometry of these models was either idealized and created with a CAD system [Borus96, Kregz93], reconstructed from CT scans [Hart92] or from a real mandible specimen that was cut into slices [Meije93]. Two of these three-dimensional models [Hart92, Meije93] model the border of the cortical plate and assign different material properties for cortical and cancellous bone, the others use average bone materials for the whole jaw model.

None of the authors published an automated procedure to reconstruct the individual bone geometry of a patient's mandible and they assigned a maximum number of two different material definitions for cortical and trabecular bone, assuming a distinguished border of the cortical plate.

3 Data acquisition

The geometry and material data are acquired from CT-slices of the patient. The maximum available spatial resolution within a slice is about 0.5 mm and about 1 mm between two slices. In order to minimize the radiation for the patient, in most real data-sets the distance between two layers is greater. Typical resolutions of the 2D-Slices are 256×256, 512×512 or 1024×1024. Each pixel possesses an information depth of either 12 Bit (4096 grey values) or 16 Bit (65536 grey values). The data are given in the DICOM format and can be read into the Tübinger Med-Station, an interface for medical diagnosis and therapy on all different kinds of digital medical image data [Grune95]. The Med-Station offers different kinds of 2D and 3D filter operations for viewing and for the segmentation of the data-set.

4 Segmentation

The segmentation of the mandible from the CT data-set is done using the automatic digital image segmentation tool implemented in the Med-Station [Grune95]. This tool uses a threshold technique to detect edges automatically. It works fine for the outer shape of the mandible, because its density in the grey values differs significantly from the surrounding tissue.

If the CT-data contain major artifacts, e.g if some of teeth have fillings, or if the mandible is in contact with other bones in the region of the temporo-mandibular joint, the contours of the mandible cannot be detected properly and user interaction is necessary. Our tool then gives the possibility to select and modify the contours or to insert additional contours using a method that is based on the intelligent scissors proposed by Mortensen and Barrett [Morte95]. When the gestured mouse position comes in proximity to an edge of the mandible, a live-wire boundary snaps to, and wraps around the object of interest.

As a result of the 2D-segmentation we get a stack of bitmaps that are used as input data for the reconstruction of the mandible shape.

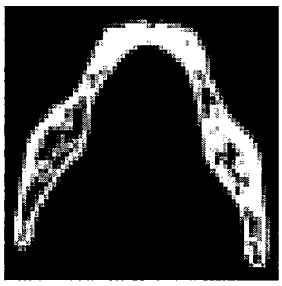


Figure 2: CT slice of a mandible

As you ca see in Figure 2, it is not possible to reliably detect any border between the cortical plate and the cancellous inner region of the mandible without massive interaction of a medically skilled user. In our tests, various users chose different border contours for the cortical plate, and these often resulted in bad geometries after the reconstruction over several slices. The main disadvantage however was the time-consuming interactive editing of the inner contours.
On the other hand, the trabecular regions of the mandible contain areas of higher and lower densities and the mandibular canal, that cannot be modeled in the required level of detail.

For these reasons we decided to just segment the outer shape of the mandible and to solve the problem

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of the different types and regions inside the jaw by assigning different material properties to the tetrahedral finite elements depending on the density grey values in the CT data-set. An exact geometric modeling of the cortical and cancellous zones inside the jaw bone can thus be omitted.

5 Reconstruction

The reconstruction of the mandible geometry from the bitmap stack is done by a marching cubes algorithm [Liebi96]. The result is a closed triangle mesh that represents the shape of the jaw bone.

Because these surface triangle meshes contain several thousand small triangles, a mesh simplification is done to reduce the number of triangles. We use a multi-resolution model for the reduction, in order to be able to re-insert the small triangles at the locations where the implants are inserted into the mandible.

5.1 The marching cubes algorithm

The output triangle mesh of the mandible must define a closed 2-manifold in order to represent a volume and allow for 3D-meshing. This implies that no vertex of the triangle mesh is complex and each edge of the triangle mesh belongs to exactly two triangles. In its original version the Marching Cubes algorithm only produces a set of triangles without neighborhood information and it does not take care of this special topological requirements. The output triangle set contains complex vertices as well as edges that share more than two triangles. Such cases occur if one or more intersection points between the edges of a cube and the object are equal to a vertex p_{ijk} of the cube. This is the case if the grey-values $f(p_{ijk}) = c$, where c is the threshold value. In this cases triangles as they are stored in the look-up tables of the marching cubes algorithm degenerate to edges or vertices. This is shown in Figure 3.

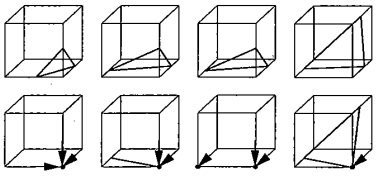


Figure 3: Degeneration of triangles at cube corners.

5.1.1 Anti-grid-snapping

The idea of the anti-grid-snapping avoids the generation of non-manifold triangle meshes in the marching cubes algorithm. It is based on the following observation: *If none of the gray-values $f(p_{ijk})$ of the vertices considered by the marching cubes algorithm is equal to the threshold value c the marching cubes algorithm generates a 2-manifold triangle mesh.* Therefore, if we detect a vertex p_{ijk} with $f(p_{ijk}) = c$ the threshold value c is a little bit changed but the classification of the vertex remains the same. In such a way all intersection vertices belong to the inner of the edges of the cubes and the output of the algorithm is always a 2-manifold mesh. For the changes of the threshold values in practice we use the values k_{anti} and $1 - k_{anti}$ instead of 0 and 1 performing the linear interpolation to define the intersection vertex between the actual surface and an edge of a cube.

5.1.2 Generating the connectivity

In the following steps aside from the geometry of the mesh, also its connectivity is of interest. The connectivity of a triangle mesh comprehends all adjacency relationships of the mesh. To establish the connectivity of the resulting mesh we note that all inner edges of the volume data-set belong to four cubes and it is enough to compute the intersection vertex between the surface and an edge only once. If the volume data-set is processed in sequential order this can easily be done: in each marching step of the algorithm only three of the twelve edges have to be considered. The other nine edges belong to an already processed cube:

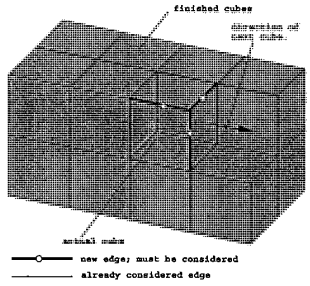


Figure 4: In each marching step only on three edges intersection points must be computed.

If a new intersection vertex is found on an edge it is stored in a vertex array and its position pos_{index} in the vertex array is stored in a pair $((i,j,k), pos_{index})$, where (i,j,k) is the identifier of the edge. To avoid the allocation of unnecessary storage only those pairs are stored for which an intersection is found. For fast relocation of a pair a binary search tree is used.

5.1.3 Inner mandible structures

Depending on the inner bone densities and the chosen threshold value, the marching cubes algorithm also reconstructs the shape of the inner cancellous structures of the jaw.

Because these inner meshes are very fine and complicated and introduce problems to the automated geometry modeling process, we decided to use the ver-

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tices of these inner meshes as additional mesh seeds for the finite element tet-mesher. Because these Steiner vertices represent locations of a high grey value gradient in the CT data-set, the resulting finite element tetrahedron boundaries are most adapted to the geometrical structures inside the mandible and thus optimized for later material properties assignment.

5.2 Mesh simplification

One of the major drawbacks of the original marching cubes algorithm is that due to the given subdivision of space it produces much more triangles than necessary to approximate the boundary surface of the object. Therefore, several enhancements of the original algorithm like adaptive marching cubes [Bloom88] and data reduction by grid snapping [Moore92] where suggested in the literature. Although good reduction rates can be achieved by an adaptive marching cubes algorithm, its implementation is very difficult and therefore error prone [Kloos94].

Therefore, we decided to use only grid-snapping. In this technique intersection vertices on the edges of the cubes with a distance smaller than d_{snap} to a corner vertex of the cube are replaced by the corner vertex itself. The value of d_{snap} is chosen between 0 and 0.5 times the edge length of the cube. In order to avoid the generation of non-manifold triangle meshes the snapping is not performed if multiple edges would be generated. We found, that using grid-snapping depending on the value of d_{snap} reduction rates up to 40% are possible, but the resulting triangle meshes are still very large:

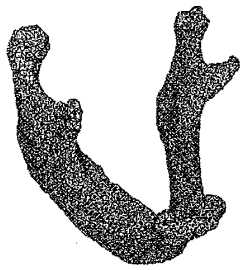


Figure 5: Reconstructed mandible with about 80000 triangles.

Boundary conform 3D-meshing of this surface would result in a FE-mesh that does not allow fast FE-computations. Therefore, the output triangle mesh of the marching cube is converted into a multiresolution model. This model maintains the surface mesh at different levels of detail, where the levels of detail may be different in distinct areas of the object. In such a way the mesh can be refined interactively in the areas of interest, e.g. around the implant, see Figure 6.

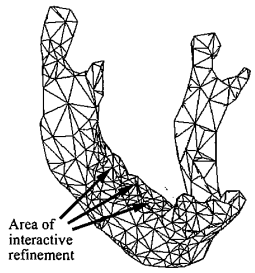


Figure 6: The triangle mesh of the mandible after reduction and selective refinement in the molar area contains only about 900 triangles.

5.3 The simplification algorithm

The simplification algorithm successively simplifies the original triangle mesh Σ_M by removing vertices from the current triangulation. All triangles adjacent to the removed vertex are removed from the current triangulation and the resulting holes are retriangulated. To chose the next vertex for removal, we use the Haussdorff distance between each vertex and the retriangulated area in case of its removal, compared to other authors who use energy criteria [Hoppe93]. This is done until no further vertices can be removed from the simplified triangulation without exceeding a predefined distance between the original triangulation and the simplified one. This is described in detail in [Klein96].

A major problem not considered by the simplification algorithms described in the literature so far is that during the simplification process it may happen that the simplified mesh self intersects. Self intersections occur relatively often while simplifying areas where the mandible is very thin.

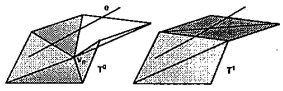


Figure 7: Left: triangle mesh before the removal of vertex v_n. Right: After the removal of v_n, edge e intersects the newly generated triangles.

To avoid such self intersections we included an efficient intersection test into our simplification algorithm. This test is based on the following observation, see Figure 7: *Let T^0 be the set of triangles adjacent to vertex v_n and T^1 the triangles forming the retriangulation of the remaining hole after the removal of vertex v_n. Then a self intersection occurs if and only if an edge e intersects a triangle $\Delta \in T^1$.* To perform these test a regular grid structure is used. Each grid cell contains all edges of the current triangulation intersecting the cell. To keep this data structure consistent in each simplification step the inner edges of the removed tri-

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angles are deleted from and the new edges are inserted into the grid structure. To insert into and delete edges from the regular grid a modified 3D-DDA-algorithm is used.

Using this grid structure only the edges contained in bounding box of each new triangle with respect to the grid have to be considered for the intersection test.

5.4 The multiresolution model

From the simplification algorithm a multiresolution model can be generated:

- A sequence of the inverse vertex removal operations performed during the simplification algorithm and the coarsest level of detail generated by the simplification algorithm are stored. Then, starting with the coarsest level of detail the original model can be generated by applying the stored operations in reverse order. If in addition not only refinement operations but also coarsening operations should be supported also the vertex remove operations themselves must be stored.
- In addition to the sequence of the vertex remove operations and their inverse operations dependencies are necessary. These dependencies store the information needed to determine for each vertex remove operation or its inverse which triangles must be present in the current triangle mesh before the operation can be performed.

We use an interactive multiresolution viewer to extract triangle meshes of different levels of detail and to do the refinements at the locations of the implants. The multiresolution model is described in more detail in [Klein97].

6 Implant modeling

The implant modeling package consists of two essential parts, the interactive placement of the implants into the bone and the intersection calculations between the bones and implants.

6.1 The interactive positioning tool

The positioning tool is used to select and interactively place implants into the bone. It has several buttons to move and rotate the implant and four viewports: one isometric viewport that can be manipulated by the user and three viewports for top and side views of the implant position. Several other zoom and viewport options are available and easy to use.

6.2 The intersection algorithm

The geometry of the bone and the positioned implants are directly exported to an intersection calculation routine which performs the Boolean operations. This program determines the surface mesh that represents the

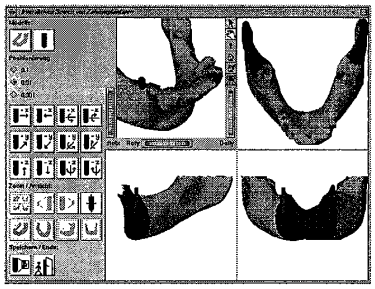


Figure 8: Interactive positioning of an dental implant into the mandible bone

bone with the holes where the implants fits into. Additionally, the implant is modified so that its edges and its faces are identical to the edges and faces of the hole in the bone. This is necessary for the generation of consistent finite element models.

We use the following algorithm for the efficient realization of Boolean operations between two closed triangular surface meshes:

- Determine all triangles of the bone geometry that have an intersection with the implant and calculate the resulting intersections. To accelerate these calculations we use a plane sweep algorithm for the bounding boxes of the triangles. But also a regular grid structure may perform well for this purpose.
- Insert all intersection points and edges into the two intersected triangle meshes. The main operation in this step is to insert vertices and edges into the triangles and to compute a regular retriangulation of the triangles.

After this computations the result of different Boolean operations can be computed easily by establishing new neighborhoods between every four triangles incident to an intersection edge.

6.3 Improvement of the intersected meshes

After the Boolean operation the resulting triangle meshes contain very small triangles and triangles with bad aspect ratios, see Figure 9. For FE-computation such triangles must be eliminated. For this purpose the following steps are performed:

- Remove vertices that are close to the intersection polygon generated during the Boolean operation. In such a way triangles which are to small are avoided.
- Optimize the resulting mesh by inserting Steiner vertices.

To optimize the resulting mesh we use a modification of the refinement algorithm proposed by Chew [Chew93]. This algorithm enhances the idea of the Delaunay triangulation to 2D-surfaces embedded in 3D.

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The usage of this algorithm ensures that none of the angles of the triangles in the resulting Steiner triangulation is smaller than 30°:

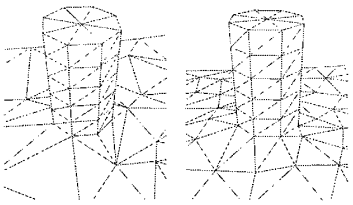


Figure 9: Left: After intersection, the resulting mesh contains small triangles and triangles with bad aspect ratio. Right: After inserting Steiner vertices.

7 Finite element analysis

A series of finite element computations have been performed with a mandible model containing two molar implants to verify the quality of the models obtained by our automated modeling process and to simulate the stresses induced to the bone under typical chewing conditions. Special emphasis is given to a comparison of the results of our automated material properties assignment to a mandible model having only one material property defined.

Three steps are required to build a finite element model based on the surface triangle meshes of the mandible and the implants: 3D-meshing with tetrahedral finite elements, material properties modeling and definition of the load cases. These steps are performed using the commercial finite element preprocessing system PATRAN, numerical solving is done by ABAQUS, and results postprocessing and visualization is again performed in PATRAN.

7.1 Finite element meshing

After conversion from our own geometry representation format to the PATRAN neutral file format, the surface mesh data of the mandible and the implants are imported to the preprocessor. The volumes of the mandible and implants are then meshed with second order tetrahedrons (Tet10), which have ten nodes (four corner and additional six edge nodes) and produce more accurate analysis results than first order tetras.

Because we use smaller triangles in the mandible surface model and additional inner Steiner points close to the location of the implants, the PATRAN tetmesher produces a finer finite element mesh automatically in these areas that are of most interest to the structural analysis and a coarser mesh in the other regions of the mandible. The model shown in Figure 11 has 4741 elements.

7.2 Material properties

For the bone material properties we defined a range of seven material definitions from hard cortical properties (bone1) to medium cancellous bone properties (bone5) and soft trabecular bone properties (bone7) for the areas that contain many marrow spaces, the mandibular canal or other cavities. All seven bone materials were assumed to be homogeneous, isotropic and linearly elastic. Although cortical bone is an orthotropic material, this simplification was made for the calculations. Cortical (bone1) and cancellous bone's (bone5) material properties as well as the titanium material properties for the implants are taken from the Biomaterials Properties Database at the University of Michigan [O'Bri96]:

Material properties	Elastic Modulus (GPa)	Density (g/mm^3)	Poisson Ratio
bone1 (cort.)	14.7	0.0013	0.3
bone2	10.0	0.0013	0.3
bone3	5.0	0.0013	0.3
bone4	2.0	0.0013	0.3
bone5 (canc.)	0.5	0.0013	0.3
bone6	0.25	0.0013	0.3
bone7	0.1	0.0013	0.3
titanium	117.0	0.0045	0.33

Table 1: Material properties of bone and titanium

To assign one of these seven material properties to each tetrahedron of the model, we wrote a PATRAN extension that exports the geometry of the tetrahedrons, searches and averages all grey values from the CT data-set contained in the tetrahedron, and assigns the corresponding material property.
Due to the inner Steiner points (see section 5.1.3) the grey values of most of the tetrahedrons are almost homogenious. In this case an average grey value can be computed and the corresponding material assigned. In the other case where the grey values vary strongly throughout the tetrahedron, it must be subdivided further until the homogenious case is achieved. This is again done be inserting additional mesh seeds for the remeshing.
For the two mandible models with only one material property we use for the comparison, we assigned cancellous (bone5) and cortical bone properties (bone1) throughout the jaw.

7.3 Load case

The following set of boundary conditions and loads has been defined for our model:

- Two mastication forces of 80N onto the implants,
- 10 muscle forces of 30N each induced at the angle and lower ramus of the mandible where the masseter muscle inserts,

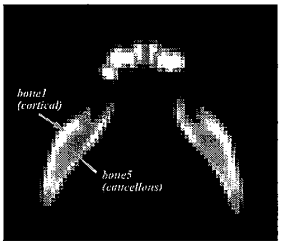


Figure 10: Material properties assignment depending on the density grey values in the CT data-set

- fixed elements in the temporo-mandibular joint.

Figure 11 shows our mandible model with 4741 Tet10 elements and the load case described above:

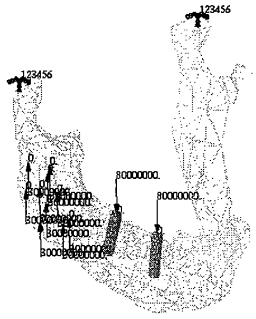


Figure 11: Mandible finite element model with mastication and muscle forces

7.4 Finite element analysis results

The results of the finite element structural analyses for the three models show that the joints and the areas around the implants have the highest resulting stresses induced by the loading.

The implant close to the ramus where the masseter muscle inserts induced high stresses into the surrounding bone. For the model with only cancellous material defined, the highest value of the minor principal stress that can cause reabsorption of the bone was at about -70MPa, a very high value compared to the ultimative compressive strength of bones.

The model with cortical bone material defined for the whole mandible showed significantly lower stresses around the implants. The highest value of the minor principal stress reached about -48MPa.

The model that had the range of seven bone material properties assigned to the tetrahedrons automatically reaches its extreme minor principal stress at about -52MPa, which is between the values of the models having cancellous and cortical material properties assigned throughout. This value is closer to the all-

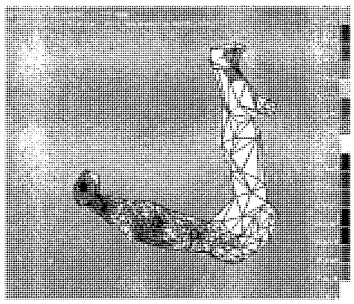


Figure 12: von-Mises average stress induced into the mandible

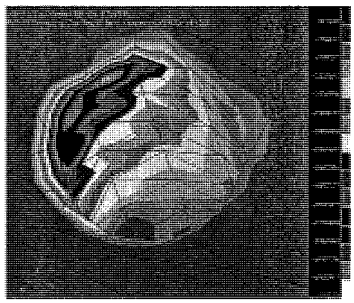


Figure 13: Minor principal stress induced around the implant (cancellous bone material properties)

cortical model, because the location where the implants were inserted contained mostly cortical bone. The differences in the resulting stresses induced into the bone get greater, if the implant is primarily located in the softer regions inside the mandible, for instance if the patient's cortical plate is not closed at the location where the implants are inserted. This occurs, if the implants are inserted too early after the loss of teeth, or if the jaw already atrophied.

8 Conclusions

The finite elements analysis results show that the chosen methods for the segmentation, the reconstruction of the bone shape and the material properties assignment can be automated for minimum user interaction and result in high quality finite element models. The advanced modeling of the material properties can reduce the amount of geometric modeling to the reconstruction of the bone's shape, using the inner Steiner points delivered by the marching cubes algorithm for optimization of the finite element mesh generation.

References

[Bloom88] J. Bloomenthal. Polygonization of implicit surfaces. *Computer Aided Geometric Design*, 5:341–355,

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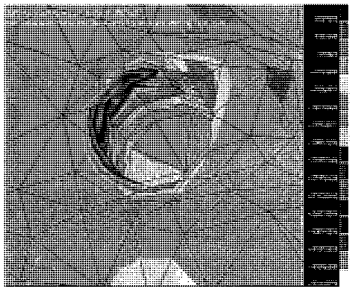


Figure 14: Minor principal stress induced in the area around the implant (automatically assigned range of seven bone material properties)

1988.

[Borus96] Boruszewski, Tortamano, Neto, and Saito. Stress distributions in mandibles around osseo-integrated implants, according to the occlusion pattern, using MSC/NASTRAN three-dimensional modeling. Universidade de São Paulo, Brasil, 1996.

[Chew93] L. P. Chew. Guaranteed-quality mesh generation for curved surfaces. In *Proceedings of the Ninth Annual ACM Symposium on Computational Geometry*, pages 274–280. ACM, ACM Press, 1993.

[Grune95] T. Grunert, J. Fechter, G. Stuhldreier, H.-H. Ehricke, M. Skalej, R. Kolb, and P.E. Huppert. A PACS Workstation with integrated CASE tool and 3D-Endosonography application. In *Computer Assisted Radiology CAR 95*, pages 293–298, 21.-25. June, Berlin, Germany 1995.

[Hart92] R. T. Hart, V. V. Hennebel, N. Thongpreda, W. C. Van Buskirk, and R. C. Anderson. Modeling the biomechanics of the mandible: A three-dimensional finite element study. *Journal of Biomechanics*, 25(3):261–286, 1992.

[Hoppe93] H. Hoppe, T. DeRose, T. Duchamp, J. McDonald, and W. Stuetzle. Mesh Optimization. *Computer Graphics (SIGGRAPH '93 Proceedings)*, vol. 27, pages 19-26, August 1993.

[Klein97] R. Klein and J. Krämer. Multiresolution representations for surface meshes. In *Proceedings of the SCCG (Spring Conference on Computer Graphics), Budmerice, Slovakia*, 1997.

[Klein96] R. Klein, G. Liebich, and W. Straßer. Mesh reduction with error control. In R. Yagel, editor, *Visualization 96*, pages 311–318. ACM, 1996.

[Kloos94] Uwe Kloos. *Graphisch-Interaktive Simulation unter Berücksichtigung medizinischer Fragestellungen*. PhD thesis, Fakultät für Informatik, Universität Tübingen, July 1994.

[Kregz93] M. Kregzde. A method of selecting the best implant prosthesis design option using three-dimensional finite element analysis. *Int. J. of oral and maxillofacial implants*, 8(6):662–673, 1993.

[Liebi96] G. Liebich. *Erzeugung von Oberflächen- und Finite-Elemente-Modellen aus Tomographiedaten*. Master thesis, Fakultät für Informatik, Universität Tübingen, December 1996.

[Loren87] W. E. Lorensen and H. E. Cline. Marching cubes: A high resolution 3D surface construction algorithm. In Maureen C. Stone, editor, *Computer Graphics (SIGGRAPH '87 Proceedings)*, vol. 21, pages 163–169, July 1987.

[Meije93] Meijer, Starmans, Steen, and Bosman. A three-dimensional finite element analysis of bone around dental implants in an edentulous human mandible. *Archs oral Biol.*, 38(6), 1993.

[Moore92] Doug Moore and Joe Warren. Compact isocontours from sampled data. In Paul Heckbert, editor, *Graphics Gems III*, pages 23–28. Acad. Press, Boston, 1992.

[Morte95] Eric N. Mortensen and William A. Barrett. Intelligent scissors for image composition. In Robert Cook, editor, *SIGGRAPH 95 Conference Proceedings*, Annual Conference Series, pages 191–198. ACM SIGGRAPH, 1995.

[O'Bri96] William J. O'Brien. Biomaterials properties database. *http://www.lib.umich.edu/-libhome/Dentistry.lib/Dental_tables/toc.html*, University of Michigan, Quintessence Publishing, 1996.

[Siege93] Siegele and Soltesz. Finite-Elemente- Berechnungen zur Beanspruchung des Kieferknochens um Zahnimplantate. *Zeitschrift für zahnärztliche Implantologie*, 1993.

[Woelf79] Woelfel, Julian B., *Permar's Outline for Dental Anatomy*, Lea and Febiger, Philadelphia 1979.

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3-D element generation for multi-connected complex dental andmandibular structure

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Abstract
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Index Terms
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Controlled Indexing
biomechanics computational geometry dentistry finite element analysis medical image processing mesh generation

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3D FEM biomechanical behavior dental prosthetics dentistry geometrical complexities image slices mandibular structure medical image processing multi-connected complex dental structure occlusive functional analysis tetrahedron three-dimensional finite element generation method
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3-D Element Generation for Multi-Connected Complex Dental and Mandibular Structure

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Abstract

This paper presents a novel three-dimensional finite element generation method for assessing the biomechanical behavior of multi-connected complex teeth and mandible structure. Tetrahedron was chosen as the basic element type for its adaptability to structures with different geometrical complexities. The element generation was implemented by combining two tetragons in adjacent image slices. By examining all combinations of tetragons and their degradations, a software system was developed for interactive element generation, which results in a series of tetrahedrons based on the principle that each combination should lead to elements with exact and close connection. Extensive validation was performed to ensure the accuracy of the algorithm. The method was applied to an occlusive functional analysis of dental prosthetics, generating 4762 nodes and 18534 tetrahedral elements with 9 different materials.

1. Introduction

Finite Element Method (FEM) is a widely used technique in engineering, which has become a routine tool for evaluating the mechanical behavior of engineering structures. With the development of medical imaging techniques such as CT, MRI and PET, FEM was introduced in biomedical engineering for analyzing mechanical behavior of human structures since mid 1970[1-4]. However, due to the complexity of human anatomical structures, this numerical method was often carried out in two-dimensional planar cases. Recently, there have been reports of 3-D FEM analysis of human bone structures [5-9], but substantial simplification was applied in order to conform to the requirements of the existing FEM software. For instance, in the femora and joint biomechanical analysis, the bone was considered as a single-connected structure, which combined the marrow with outer bone as a whole solid structure. Even when multi-connection was taken into account in some studies [10-14], the associated topology was usually simple.

Since FEM is a numerical modeling method, the validity of its results is mainly dependent upon three types of modeling factors. The first factor is the similarity of the finite element model to the real shape of the object to be analyzed. Excessive simplifications of a 3D-shape to a 2D-element model will result in considerable errors in the computed data. The second factor is the effectiveness of modeling the boundary conditions. This is especially critical in contact problems, in which the stress and strain in contacting surfaces are important. The third factor is related to the modeling of the material properties of the structures. Improper material parameters will lead to erroneous results.

Among the above three factors that determine the validity of FEM results, the boundary condition and material parameters can be interactively modified should the initial values be sub-optimum. By assigning a new set of boundary conditions and material parameters and then re-executing the FEM software, one can readily get a new set of numerical results. The shape modeling, however, is of particular difficulty when auto-mesh-generation is not possible. This is usually the case with complicated, multi-connected structures with different materials. In this case, the element generation becomes the main obstacle for carrying out FEM numerical analysis.

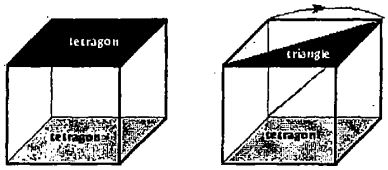
This paper presents a new method for generating 3D finite elements for complicated, multi-connected biomedical structures with different material characteristics. All element divisions of normal and degraded combination of tetragons are examined. Extensive element check is performed during element generation for deriving correct 3D tetrahedron elements without overlapping and spacing.

2. Method of Element Generation

Hitherto, substantial work has been carried out for mesh generation with common geometrical complexity [1,2,15-

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(a) (b)

Figure 1. Tetrahedron generation. (a) An upper and a lower tetragon form a normal tetrahedron. (b) An upper triangle and a lower tetragon form a distorted tetrahedron.

18]. Our aim is to develop a method for generating 3D finite elements for more complex cases corresponding to real 3D anatomical structures. We have chosen tetrahedron as the basic element type rather than hexahedron or other types. This is mainly because of the restrictions imposed by FEM software. For instance, two tetragons in adjacent layers can usually be combined to form a normal hexahedron, as shown in Fig.1a. However, once a tetragon is degraded into a triangle, its combination with a tetragon will produce a distorted hexahedron that is strongly prohibited by the FEM software due to the concern of singularity of the resultant stiffness matrix. In practice, this restriction can be satisfied in cases with relatively simple topology. However, when the topology becomes more complicated, the combination of nodes in adjacent slices tends to be arbitrary. Combinations of (3+4)-nodes (triangle plus tetragon, see Fig.1b) and (2+4)-nodes (line plus tetragon) can be usually encountered. As tetrahedron is the simplest element type, it can accommodate all 3D shapes of different complexity without degradation.

Our method was implemented in the form of tetragon plus tetragon combination. Two tetragons in adjacent slices are designated to form 6 (or 5) tetrahedrons. The division depends on the triangular distribution in each slice that forms the tetragon. Figure 2 demonstrates an example case, in which triangles 123 and 143 in the lower slice are combined with triangles 567 and 587 in the upper slice. All together, there are 7 possible divisions, each producing 6 tetrahedral elements and 8 outer surface triangles. Other three normal combinations of tetragons were also investigated, which produced 16 divisions. Therefore, normal tetragon plus tetragon combination will produce 23 divisions, each results in 5 or 6 tetrahedrons and 8 outer surface triangles.

In addition to the above considerations, it is also important to consider the degradation of normal tetragon combinations. Figure 3 illustrates the element generation when the combination shown in figure 2 is degraded due to the fact that nodes 7 and 8 become identical. There are other

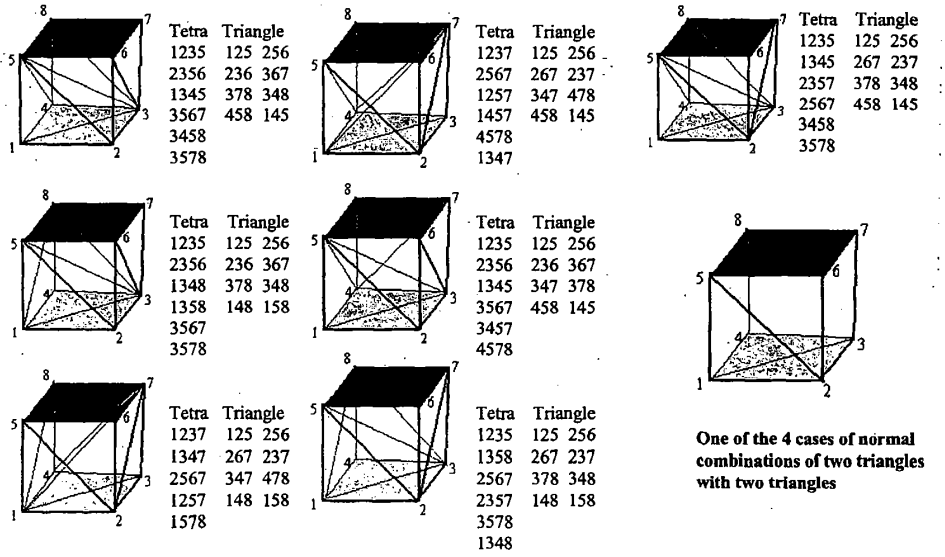


Figure 2. Sample generation of tetrahedrons from the combination of tetragon 1234 with tetragon 5678, which results in 7 divisions. Tetra: tetrahedron

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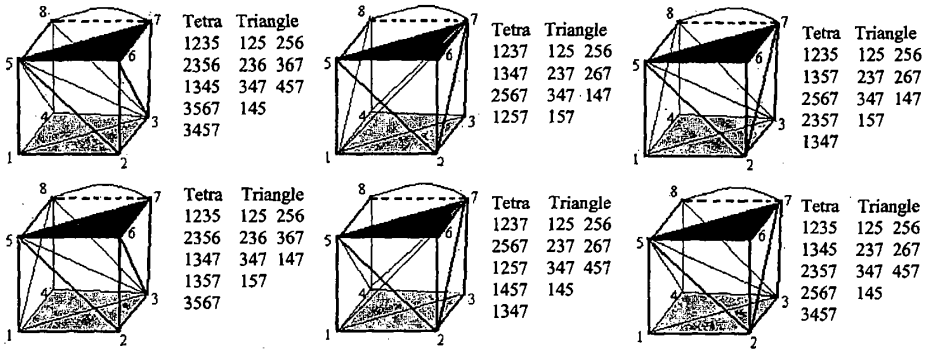


Figure 3. Sample generation of tetrahedrons from the combination of tetragon 1234 with triangle 567, which results in 6 divisions. It is a degradation of Fig.2, since node 7 and 8 become identical.

degradations that can be encountered, and their divisions are stored in a database for practical element generation in our system.

It should be noted that, prior to 3D-element generation, all contours, both inner and outer, of every object in each CT/MRI image slice need to be delineated. We have implemented an automatic contour tracking system for this purpose. Subsequently, element nodes were designated interactively in each slice both along the derived boundaries and within the interior areas. After that, triangulation was performed to form 2D planar element, *i.e.* triangles, in each slice. During this process, the material property was set by assigning each triangle with a predefined material index. Different material index corresponds to different material parameter, which will be used in subsequent FEM computation. During 3D-element formation that combines upper planar triangles with lower planar triangles, the material property of each element was inherited from the planar triangular material index. When the material indices of the upper and lower planar triangles are different, the generated tetrahedron will bear a material index of that of either triangle, or determined manually.

During the element generation process, we usually designate two tetragons in upper and lower slice, respectively. This enables the manual manipulation to be performed efficiently. Each tetragon normally consists of two triangles. When the topology does not allow the normal combination of tetragons, we have to choose degraded combinations to generate tetrahedron elements. These degraded combinations include: (1) a triangle plus a tetragon, (2) a line (two nodes) plus a tetragon, (3) a node plus a tetragon, (4) a triangle plus a triangle, (5) a line plus a triangle, and (6) a node plus a triangle.

The element generation was implemented progressively. All the generated elements must be correct, *i.e.* the outer surface triangles of a given non-terminating element should be shared by only one adjacent element. Otherwise, special considerations must be taken into account. To do so, we attempted all possible tetragon and/or triangle combinations. The outer surface triangles corresponding to each combination were recorded and compared with all the proceeding outer surface triangles accumulated during the process. Those combinations that result in surface conflict were discarded. Among the remaining possible combinations, the one with the maximum surface contact was chosen, if there were more than one candidate. In this way, we can guarantee that the element generation process will produce proper tetrahedrons without any surface conflict.

Finally, we also have to consider the element spacing problem, *i.e.* there might be spacing between the generated tetrahedrons. They are introduced by the conservative nature of the selection process described above. This results in the lack of a necessary tetrahedron linking between two lines (see Fig.4) in the upper and lower slices respectively. This

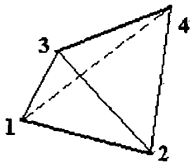
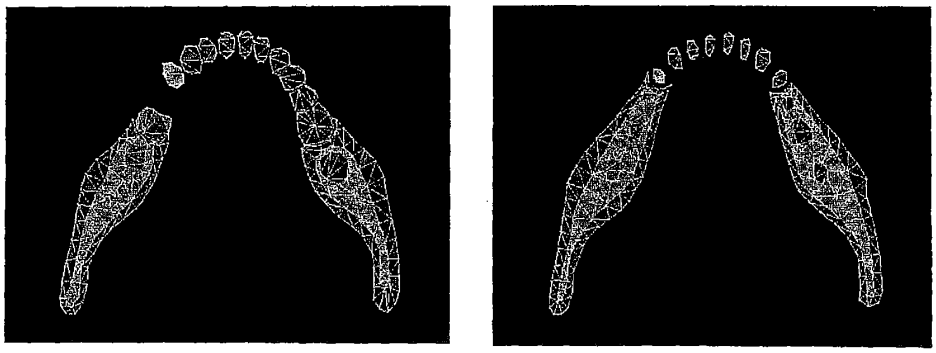


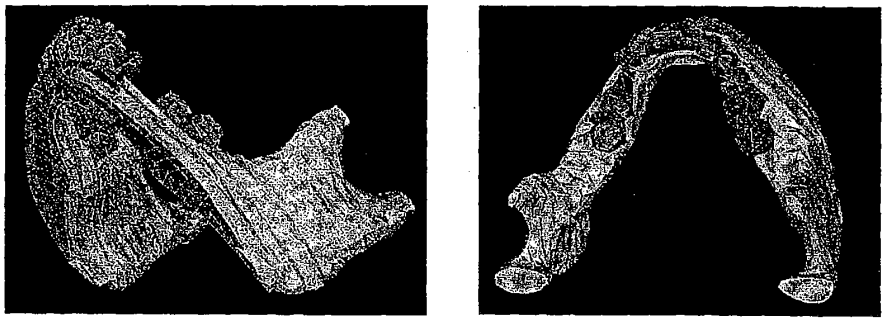
Figure 4. A tetrahedron formed by line 12 and line 34 in lower and upper slice respectively.

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(a) (b)

Figure 5. Sample planar mesh generation for two adjacent slices of a teeth and mandible structure. Colors represent different material characteristics.



(a) (b)

Figure 6. 3D views of the whole structure which is composed of tetrahedral elements. Colors represent different material characteristics

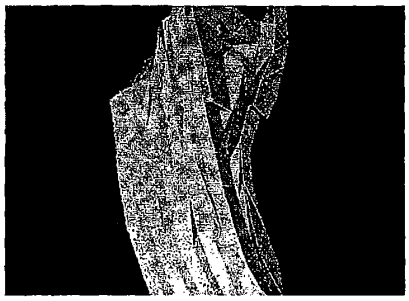


Figure 7. Local 3D view of the marrow structure.

situation can be resolved by examining all the outer surface triangles. Inner tetragon and/or triangle combinations will produce tetrahedrons with outer surface triangles that are shared once by other tetrahedrons. Once an inner trans-slice triangle is not shared by other tetrahedron, a supplement tetrahedron linking these two lines must be added. This last procedure will ensure that the whole 3D elements are generated correctly without any overlapping and inner spacing between all the elements.

3. Results

We have used the above method to generate a 3D finite element model for a complex teeth and mandible structure. The source CT image consists of 42 slices, with a slice thickness of 2 mm, and in-plane resolution of $1 \times 1 mm^2$. Figure 3 shows two adjacent planar triangulations, indicating the complicated topology around the right and left molars.

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Different colors represent 9 different materials involved, *i.e.* 5 tooth materials, 1 mandible bone, 1 marrow, 1 pericementum, and 1 gingiva.

The entire structure consists of 4762 nodes. With interactive element generation, 18534 tetrahedrons with different material characteristics were produced. Figure 5 shows two 3D views of the generated elements, representing the 3D shape of the structure.

The generated elements were then fed into ANSYS v5.0 (ANSYS Inc, Canonsburg, Pennsylvania, USA) finite element analysis software to simulate different restoration operations. There were minimum (8) warnings, no error, produced by the software, indicating that the angles of some elements are outside the optimal range of 45-135 degrees. However, the computed results agreed well with clinical observations. The simulation provided new insights into the tooth restoration strategy.

4. Discussion and Conclusion

Finite element method is an effective tool for modeling biomechanical behavior of anatomical structures. The validity of the results is determined by the correctness of shape modeling, boundary conditions and material properties. As both computer hardware and software are now powerful enough to tackle larger and complicated numerical analysis, the shape modeling becomes the main obstacle in implementing biomechanical simulation with FEM. We presented here a novel method for 3D-element generation in complicated multi-connection human structures. Situations related to both normal and degraded combinations of tetragons have been investigated. Strict element checks ensure the generated tetrahedrons are consistent without overlapping and spacing between elements. The proposed system for 3D finite element generation was applied to a teeth and mandible structure with multi-materials and complex topology. The accuracy of the FEM results proved the viability of the technique.

5. Acknowledgment

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6. References

[1] Prendergast PJ. Finite element models in tissue mechanics and orthopaedic implant design, *Clin Biomech* 1997; 12: 343-366.

[2] Zhnag M, Mak A, Roberts VC, Finite element modelling of a residual lower-limb in a prosthetic socket: a survey of the development in the first decade, *Med Eng Phys* 1998; 20:360-373

[3] Yoganandan N, Kumaresan SC, et al, Finite element modeling of the C4-C6 cervical spine unit, *Med Eng Phys* 1996; 18:569-574

[4] Schuller-Götzburg P, Krenkel C, 2D-finite element analyses and histomorphology of lag screws with and without a biconcave washer. *J Biomech* 1999; 32:511-520

[5] Martinez JB, Oloyede VO, Broom ND, Biomechanics of load-bearing of the intervertebral disc: an experimental and finite element mode. *Med Eng Phys* 1997; 19:145-156

[6] Cheng CK, Chen HH, et al, A three-dimensional mathematical model for predicting spinal joint force distribution during manual liftings. *Clinic Biomech* 1998; 13:S59-S64

[7] Bandak FA, Tannous RE, Toridis T, On the development of an osseo-ligamentous finite element model of human ankle joint, Int *J Solids & Struct* 2001; 38:1681-1697

[8] Bartos M, Kestranek Z, et al, On the 2D and 3D finite element simulation in orthopaedy using MRI, *Math & Comput in Simulation* 1999; 50:115-121

[9] Jacobs CR, Davis BR, et al, The impact of boundary conditions and mesh size on the accuracy of cancellous bone tissue modulus determination using large-scale finite-element modeling, *J Biomech* 1999; 32:1159-1164

[10] Viceconti M, Bellingeri L, et al, A comparative study on different methods of automatic mesh generation of human femurs. *Med Eng & Phys* 1998; 20:1-10

[11] Niebur GL, Feldstein MJ, et al, High-resolution finite element models with tissue strength asymmetry accurately predict failure of trabecular bone, *J Biomech* 2000; 33:1575-1583

[12] Spears IR, Pfleiderer M, et al, The effect of interfacial parameters on cup-bone relative micromotions: A finite element investigation *J Biomech* 2001; 34-113-120

[13] Scifert CF, Brown TD, Lipman JD, Finite element analysis of a novel design approach to resisting total hip dislocation *Clinic Biomech* 1999; 14:697-703

[14] Pietrabissa R, Contro R, Experimental and computational approach for the evaluation of the biomechanical effects of dental bridge misfit. *J Biomech* 2000; 33:1489-1495

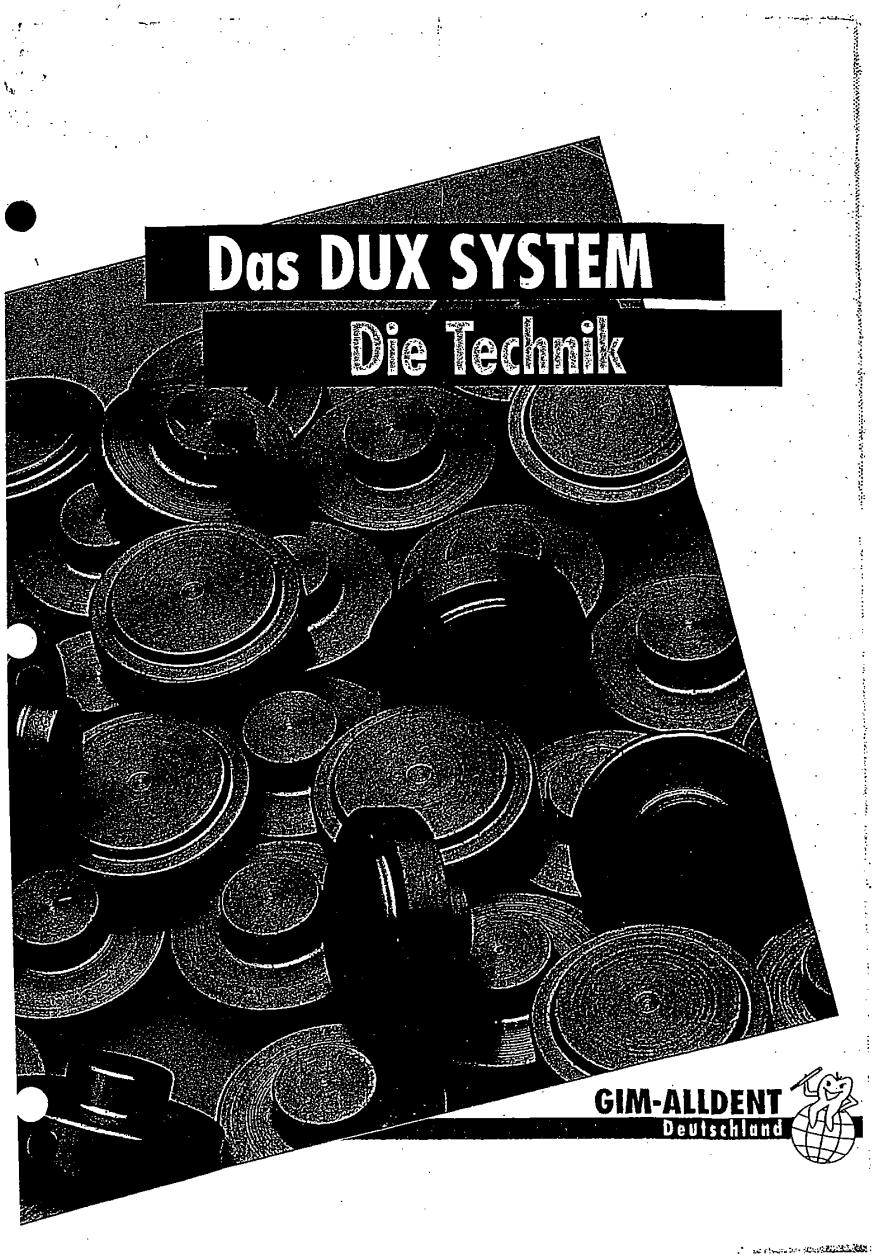
[15] Krejci R, Bartos M, et al, 2D and 3D finite element pre- and post-processing in orthopaedy. *Int J Med Inform* 1997; 45:83-89

[16] Todd BA, Wang H, A visual basic program to pre-process MRI data for finite element modeling, *Comput Biol Med* 1996; 26:489-495

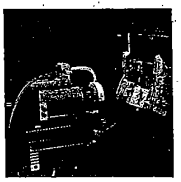
[17] Wu JZ, Herzog H, Epstein M, Evaluation of the finite element software ABAQUS for biomechanical modelling of biphasic tissues. *J Biomech* 1997; 31:165-169

[18] Couteau B, Payan Y, Lavallee S, The mesh-matching algorithm: an automatic 3D mesh generator for finite element structures. *J Biomech* 2000; 33:1005-1009

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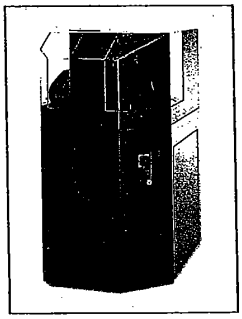
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Die horizontale Präzisionsfräsmaschine arbeitet in 3 Achsen. Die speziell für das Labor entwickelte computergesteuerte Fräsmaschine bearbeitet Titan oder andere fräsbare Dentallegierungen. Für die Zukunft kann die Anwendung auch auf fräsbare Keramik erweitert werden.
Die Maschine besitzt eine Präzisionshalterung für den Rohling, die eine zweiseitige Bearbeitung ermöglicht. Die Spindel ist präzisionsgelagert und bewegt sich spielfrei. Das Maschinengehäuse besteht aus Stahlblech mit einer Plexiglashaube. Im Unterbau befindet sich die elektronische Steuereinheit mit der gesamten Hardware.
Die Steuerung erfolgt durch die in Punkt 2.) beschriebene DV-Anlage.

Technische Daten:

Anschlußwerte:	220 V, 1 Phase, 25 Hz, 25 A
Spindelantrieb:	Achsensynchronmotor 220 V, 3 Phasen, 0,75 kW, gesteuert durch Frequenzumformer, Antrieb zur Spindel über Zahnriemen. Spindel mit Ericsson Schnellwechsler. Aufrüstung zur Zweispindelanlage möglich. Aufnahme eines automatischen Schnellwechslers möglich.
Antrieb der Arbeitsachsen:	Gleichstrommotoren 60 V max. 6A (30 A max.), gesteuert durch Impulsmodulationsverstärker. Übertragung erfolgt mittels Zahnriemen.
Werkzeug:	Ericsson Schnellwechselsystem für Konus ISO 30 mit ER 16 Zange.
Kühlmittelpumpe:	Achsensynchronmotor (AC/DC) 2700 U/min, 220 VAC; 0,1 kW; 50 Hz.
Pumpenleistung:	16 l/min
Steuerung:	PC mit Interface (Hard- und Software)
Arbeitsbereich:	X-Y-Z = 70mm x 40mm x 20mm
Gehäuseabmessungen:	730mm x 1010mm x 1500mm (außen)
Gewicht:	445 kg (ohne Kühlmittel)



Electronic Acknowledgement Receipt	
EFS ID:	38190398
Application Number:	16723706
International Application Number:	
Confirmation Number:	1026
Title of Invention:	AUTOMATED TREATMENT STAGING FOR TEETH
First Named Inventor/Applicant Name:	Ian Kitching
Customer Number:	107046
Filer:	Charles C. Hagadorn III/John Macalagay
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Application Type:	Utility under 35 USC 111(a)

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File Listing:

Document Number	Document Description	File Name	File Size(Bytes)/ Message Digest	Multi Part /.zip	Pages (if appl.)
1	Non Patent Literature	Z-AADR-SUMMARY-OF-1980.PDF	116242 74142fb5e9dedcfd8e32fd96b1922e7563eb79f4	no	1

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		Total Files Size (in bytes):	49595579		

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<u>New Applications Under 35 U.S.C. 111</u>
If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.
<u>National Stage of an International Application under 35 U.S.C. 371</u>
If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.
<u>New International Application Filed with the USPTO as a Receiving Office</u>
If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.

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JCO Interviews Dr. James A. McNamara, Jr., on the Frankel Appliance, Part 2: Clinical Management

EUGENE L. GOTTLIEB, DDS
DR. JAMES A. MCNAMARA, JR.

DR. GOTTLIEB Jim, let's begin at the beginning in your approach to the clinical management of the Frankel appliance and the Frankel patient.

DR. MCNAMARA Before the patient comes in, I always want to know who referred him to the office--whether it was a general dentist with whom I have a good working relationship and who is familiar with Frankel therapy, or whether it was another Frankel patient. In other words, I want to know whether they are coming to my office expecting a traditional approach to treatment, or whether they are acquainted with functional jaw orthopedics.

DR. GOTTLIEB Why do you especially want to know that?

DR. MCNAMARA It is a question of how much time I will have to spend explaining what functional appliances are all about. If someone is coming in expecting headgear and fixed appliances and I plan to use a Frankel, time is spent describing how muscle, bone, and teeth are treated simultaneously, rather than just teeth.

At the time of the initial phone call to my office, the prospective patient is told that two headfilms--lateral and PA--will be taken at the initial examination.

DR. GOTTLIEB Why do you do that?

DR. MCNAMARA The films are taken for two reasons: diagnosis of the malocclusion, and to look for any possible underlying airway problems, which might not be obvious during a clinical examination. It is also an excellent visual aid when I discuss the patient's problem.

DR. GOTTLIEB Do you just eyeball the films or trace them? And what are you specifically looking for?

DR. MCNAMARA At the initial examination, I make a brief analysis of the films--visually or by tracing. In the lateral headfilm, I look for the presence of hypertrophied adenoids and enlarged tonsils, for missing and unerupted teeth, or any-thing else unusual. In the PA film, I am primarily concerned with enlarged turbinates and deviation of the septum.

I also take a health history on a form that is given to the patient when they arrive at the office. This is the usual family history, general medical, and dental and orthodontic information. I also ask specific questions regarding their respiratory history--whether they snore when they are sleeping, what they are allergic to, whether they breathe through their mouth, if they have frequent colds, if they have frequent sore throats or tonsillitis, or if they have any chewing or swallowing difficulty. I also ask for their complete ear, nose, and throat and allergy history, including whether or not tonsils and adenoids have been removed.

DR. GOTTLIEB Do you routinely refer patients who have a significant problem in this area to a

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specialist?

DR. MCNAMARA Yes, I would say 10-15% of my patients are referred at some time to an ENT specialist for an evaluation.

DR. GOTTLIEB Prior to treatment?

DR. MCNAMARA Usually, but it also can be during or after treatment.

DR. GOTTLIEB What did you do to establish a relationship with an ENT physician or physicians? You didn't just send a patient over?

DR. MCNAMARA When I became interested in the relationship of upper airway obstruction to craniofacial growth, I called my daughter's pediatrician and asked him to recommend an ENT specialist who would be intellectually alert, open to new ideas, and able to evaluate research data. I also asked him to locate a pediatric allergist with the same qualifications. The four of us met for lunch. I showed them some cases and explained what I was looking for, and they were interested. So I arranged for an evening meeting in my practice, and I invited eleven patients whom I suspected of having various respiratory problems to come in with their parents. We each took turns examining the patients and the records, and I explained what I thought was wrong. They were amazed at the quality of the radiographs, and what they could see on them. ENT physicians do not routinely use lateral and PA headfilms to diagnose enlarged adenoids and tonsils.

DR. GOTTLIEB Has this group diagnosis approach continued on a routine basis?

DR. MCNAMARA My main interaction has been with ENT physicians. I have had some interaction with pediatric allergists, but not too much with pediatricians. I usually refer a patient with a respiratory problem directly to the ENT physician, and send a copy of my referring letter to the pediatrician. I might add that I have made it a point to address almost every group in my area associated with these kinds of problems, including the ENT department, the allergy section of internal medicine, the dental assistants, the oral surgery and plastic surgery departments, and the pediatric association. These people are at least aware of what I am doing.

DR. GOTTLIEB As a practical matter, do you find referrals coming back in your direction from these specialists?

DR. MCNAMARA Not in any abundance. Occasionally, I will get a referral from one of the three ENT physicians to whom I refer patients. I also have had a few referrals from the allergist and several pediatricians. However, as we all learn from one another, I expect this interaction to increase.

DR. GOTTLIEB Let's continue with the first visit. I interrupted you at history taking.

DR. MCNAMARA The next thing I do is observe the patient from a distance, either in the waiting room or in the operatory chair, just to see if they are active or quiet. Not every patient is a Frankel candidate, not only from a physiological standpoint, but also from a psychological standpoint.

DR. GOTTLIEB Do you screen out the hyperactive patient?

DR. MCNAMARA Not necessarily, but presentation must be tailored to the needs of the patient. With some I can be gentle and relaxed, and with others I must be quite forceful. So, I like to observe

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the patient from a distance to evaluate which approach is more suitable. Then I start with a discussion of the "chief complaint"--to find out why the patient is there, whether or not they are concerned about facial esthetics, whether the visit was recommended by a dentist, a family member, or a friend. I usually do a thorough clinical examination, based on my cephalometric diagnostic criteria (McNamara, '82a), with the headfilms right on the viewbox next to the patient.

DR. GOTTLIEB What are you specifically looking for in the clinical examination?

DR. MCNAMARA I always measure the relationship between the upper lip and the tip of the incisor clinically, because this is difficult to evaluate from a radiograph. I also measure the amount of gingiva showing when the patient smiles broadly. I like to see the upper lip at about the gingival border, although some people have a short upper lip and some have a long upper lip, so there is some variation. It is also extremely important in a clinical examination to evaluate facial muscle balance. Of particular interest to me is a hyperactive mentalis muscle, which is usually an indicator of a hypoactive orbicularis oris muscle, since one of the goals of Frankel treatment is to eliminate the hypoactivity of the orbicularis oris and the hyperactivity of the mentalis through lip seal exercises in conjunction with appliance wear.

DR. GOTTLIEB I think that Frankel believes that is one of the main differences between his appliance and others.

DR. MCNAMARA Absolutely. Incidentally, Mike Dierkes, Bob Scholz, Ray Howe, and I recently visited the orthodontic department of the University of Bonn in West Germany, where we examined patients treated with activators, bionators, and other similar appliances. One of our principal findings was that the functional appliances in use in their clinic were very effective in the anteroposterior correction of skeletal discrepancies, but had a much less favorable effect on facial muscle balance. We saw many patients, in whom activator-type appliances were used, in which there was still mentalis hyperactivity present at the end of treatment. I must add that mentalis hyperactivity sometimes persists after Frankel treatment, if the lip pads are not placed low enough in the vestibule, or if there is an uncorrected airway obstruction, or if lip seal exercises are not routinely performed by the patient.

DR. GOTTLIEB Do you also look at other facial muscle activity?

DR. MCNAMARA It is important to evaluate the general tonus of the masticatory and facial musculature as a whole. Patients with a very hyperactive muscle activity will usually have a retrusive maxillary and mandibular dentition, and often a retrusive maxilla as well. In such a case, the FR-2 does not increase muscle activity, but rather decreases it. It is extremely important to explain the presence of abnormal muscle function to the patient and parents, using a mirror and audiovisual materials. Occasionally, one or both parents may have a similar problem. Most of the time when I point this out to the parents, they will tell me that they do not like this in themselves, and would like to correct it in their child. Occasionally, I will even prescribe lip exercises for the parents, if they are interested in doing them.

I then have the patient bring the lower jaw forward to an anterior position. In a likely Class II Frankel candidate, the lower jaw should be able to be brought forward and produce an improvement in facial form, provided that the incisors do not interfere.

Also, at the first appointment, I usually show the patient a videotape, put out by Unitek, which is a short overview of what to expect. This really helps in giving the patient and parents the feeling of

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what I am trying to accomplish.

Hopefully, by the end of the initial examination, the patient and parents understand the basic philosophy of Frankel therapy, which is treating not only the teeth, but also the skeletal structures and the muscular system at the same time. I talk about the goal of treatment, namely facial balance a normal relationship between the cranial base, the maxilla, and the mandible in the vertical, transverse, and anteroposterior dimensions. I emphasize that this treatment removes inhibiting factors and maximizes skeletal growth. This is in contrast to traditional orthodontic therapy, which exerts a force to produce a result. I show how the FR-2 will help retrain the mentalis muscle, which will allow for the possible repositioning of the lower incisors; how it will retrain the lateral pterygoid muscle to fire in a different way, which ultimately leads to alterations in mandibular growth; and how the buccal musculature can be retrained, thereby increasing arch width.

The last thing that is done at the initial examination is to prescribe a series of lip exercises in which a tongue blade or toothpick is held between the lips with the teeth together for at least 30 minutes per day. At the same time, the patient is instructed to consciously try to relax the mentalis muscle.

DR. GOTTLIEB And, once again, what do you want to accomplish with the lip exercises?

DR. MCNAMARA The purpose of the lip exercises is to encourage nasal breathing, strengthen the orbicularis oris muscle, and decrease mentalis activity.

DR. GOTTLIEB Is this usually accomplished, and if so, in how much time?

DR. MCNAMARA Improvement in mentalis muscle function should be noticed in two to four months. Remember that, as soon as possible, the FR-2 is inserted and the exercises are done with the Frankel in place. So, with the appliance in place, the mentalis is being inhibited by the lower labial pads.

I also recommend another exercise that can be done when the patient is reading or watching television. The patient is instructed to use his index finger to hold down the mentalis muscle while closing his lips together. It is quite a strain to do it. Frankel recommends that the patient use some kind of reminder to keep his lips together, such as self-stick notepads with a picture of lips drawn on them or the word "LIPS" written on them. These can be placed in various positions around the house--on the TV, mirror, refrigerator, and bedstand. Several companies that produce patient motivational materials have produced stickers that are useful in reminding the patients to keep his or her lips together.

DR. GOTTLIEB It sounds as if that first appointment takes a long time.

DR. MCNAMARA The first appointment usually takes about 30 minutes.

DR. GOTTLIEB Do you conduct the whole meeting?

DR. MCNAMARA Yes, I do. However, I am sure that in some offices auxiliary personnel might be very helpful.

DR. GOTTLIEB The next appointment is the records appointment?

DR. MCNAMARA Yes. Usually, in my office, the lateral and PA headfilms have already been

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taken. At the records appointment, a panoramic radiograph, intraoral and extraoral photographs, and impressions for dental casts are taken. It is also a good idea to make an 8mm movie or a videotape record on selected patients. It is difficult for most people to appreciate the changes that occur with

Frankel therapy from a static photograph. A videotape before treatment, and at six months, at one year, and at two years after the beginning of treatment is one of the best ways for the clinician to make his or her own patient motivational material.

DR. GOTTLIEB With that lengthy initial visit, how long is the consultation visit which follows the records appointment?

DR. MCNAMARA If both parents have been at the initial examination, the consultation can be rather short. It is usually longer if one of the parents was not present for the initial examination. I encourage both parents to be at the consultation and, if possible, all of the siblings. All of the family members must be very supportive, and help the patient to remember to keep the appliance in with a minimum of teasing. Getting the family on the orthodontist's side is important in receiving the proper amount of cooperation.

At the consultation visit, it should be made clear that the Frankel is not the only appliance that will be used. Usually, there are three phases--an initial fixed appliance phase, primarily for the rotation of molars, and for the vertical and anteroposterior positioning of upper and lower incisors; the second phase is the Frankel phase; and the third phase is a final phase of fixed appliance therapy, usually lasting 6 to 9 months.

DR. GOTTLIEB Do you charge a separate fee for each phase of treatment?

DR. MCNAMARA I avoid charging a separate fee for Frankel therapy. I believe it is important to incorporate a functional appliance as one part of the total therapy. That is my style. I know other orthodontists who do charge a separate fee for each phase.

DR. GOTTLIEB Let's run through what you would consider to be a typical three-phase treatment.

DR. MCNAMARA In the first phase, the fixed appliances are usually limited to the incisors and molars, with bands on the molars and bands on the incisors. With the exception of the vertical position of the upper incisors, which is determined at the time of clinical examination, incisor positions are determined cephalometrically. The facial surface of the upper incisors should be 4 to 5mm ahead of a vertical line dropped from Point A. The upper incisor tip should be 2 to 3mmbelow the upper lip line at rest.

Anteroposteriorly, the lower incisors should be 1 to 3mm in front of the A-Po line. (The use of the A-Po line in mandibular retrusion cases is discussed in detail in McNamara, '82a.) The vertical position of the lower incisors is related to the existing anterior facial height. If there is an excessive curve of Spee and the anterior facial height is either normal or excessive, intrusion mechanics with a utility arch is usually used. If there is an excessive curve of Spee and a short anterior facial height, no attempt is made to intrude the lower incisors in the first phase. Molar extrusion usually occurs during the Frankel phase in short face individuals.

The molars are usually rotated posteriorly, if necessary, with a transpalatal arch. When the incisors and molars are oriented properly the archwires and appliances are removed and the impressions for the FR-2 are taken.

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DR. GOTTLIEB How are the teeth held in place while the Frankel is being made?

DR. MCNAMARA I now use a technique suggest by Ray Howe. At the time the impressions are taken for the Frankel models, an additional set of impressions is taken and upper and lower invisible retainers are made.

DR. GOTTLIEB What is an invisible retainer?

DR. MCNAMARA This is a type of retainer developed by Bob Ponitz ('71). Thin sheets of clear acrylic are heated and then sucked over the work models. The acrylic is then trimmed at the level of the gingiva. The retainers are worn full-time until the Frankel appliance is delivered, as well as during the break-in period when the Frankel is not in the mouth.

We should talk some about the impressions for the Frankel, because it is extremely important to anatomically reproduce the soft tissue with no lateral distortion. A traditional orthodontic tray with a wide bead of wax is not adequate for the Frankel impression in most instances, because it does not allow for an accurate reproduction of the soft tissue.

DR. GOTTLIEB What trays do you use?

DR. MCNAMARA The two types of trays that I have found to work are individually molded (custom) trays and thermal sensitive trays. I currently use thermal sensitive trays (Great Lakes Orthodontic Products, Buffalo, New York), which are made out of non-heat-conducting plastic. The trays are dropped in a water bath at about 175 degrees, placed on the study model for a rough trim, placed back in the water bath, and then placed in the patient's mouth and molded to fit the patient'sarch. Compound can be used to extend the trays in the lower labial region and in the areas of the tuberosity. It is only necessary to use about one-half of the usual amount of alginate in these trays, because they fit so closely, and it is not necessary to use adhesive. If the trays are dried with an air syringe, the alginate will usually stick to the tray.

DR. GOTTLIEB What should a good Frankel impression look like?

DR. MCNAMARA The ideal Frankel impression has maximum extension vertically, but minimumextension laterally and anteroposteriorly (Fig. 9). There should not be thick rolls of alginate in the vestibule, because this will distort the extensions of the vestibular shields when the appliance is made.

The next step after impressions are taken is to take the bite registration. The bite registration for a Class II patient is taken with the mandible protruded no more than 4 to 6mm . As I said before, in a severe Class II case it is not advisable to bring the patient to an end-to-end incisal relationship, because it will usually be too difficult for the patient to bring his or her jaw forward that far into the appliance. After 4 to 6 months of full-time appliance wear, the appliance is advanced again.

DR. GOTTLIEB How do you take the bite registration?

DR. MCNAMARA I place three thicknesses of Hygienic yellow horseshoe wax, which have been heated in water until they become semi-soft, behind the upper incisors. I do not cover the upper incisors, because they are a necessary guide in aligning the skeletal midlines.

DR. GOTTLIEB Do you guide the jaw closure with your hand?

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DR. MCNAMARA I usually give the patient a mirror, and have him or her practice opening and closing in the desired jaw position.

DR. GOTTLIEB What is the desired jaw position?

DR. MCNAMARA If the dental midline and skeletal midline coincide, I have the patient line up the dental midlines. If they do not coincide, it is important to align the skeletal midlines, not the dental midlines. It is important, in making the bite registration, to allow at least 3mm of clearance in the bicuspid or deciduous molar area to allow the crossover wire to traverse interocclusally. When the patient does not have a steep curve of Spee, Jon Sammann suggests placing a tongue blade in the posterior region, in order to judge how much anterior opening will result. When it is correct, the clinician removes the tongue blade, and duplicates this relationship in the bite registration.

DR. GOTTLIEB How do you take the bite registration for a Class III?

DR. MCNAMARA In taking the bite registration for a Class III, the jaw is not brought forward. Rather, the bite registration is taken in the most comfortable retruded mandibular position (Fig. 10). It is very important to minimize bite opening, and to allow only enough bite opening to permit correction of an anterior crossbite, if one is present. If a crossbite is not present, as in a dental Class I but a skeletal Class III case, the bite should be taken in the existing positive overbite relationship with minimal vertical opening.

The next step is preparation of the work models (Fig. 11). The models used in the construction of the FR-2 are trimmed like study models and not like models for retainers, because there must be enough base to provide an adequate area for carving. After the bases have been trimmed with the construction bite in place, the models are thoroughly cleaned and debubbled, and excess flash is removed.

DR. GOTTLIEB What carving do you do on the models?

DR. MCNAMARA Usually, even with the best tray, the depth of the labial sulcus is not adequately reproduced. So, I use a knife or a rotary instrument to increase the depth of the labial sulcus to 12 to 14mm below the gingival border of the incisors. With the introduction of compound on the impression trays, the amount of carving in these areas has been greatly reduced.

DR. GOTTLIEB Do you always make sure that the pads are 12-14mm below the gingival border,regardless of patient size?

DR. MCNAMARA No. Of course it depends on the anatomy of the patient. Frankel recommends that the carving of the work models should be done with the patient present. I often use a gauge made up of a pair of lip pads available from most of the commercial laboratories (Fig. 12). The pads are placed in the labial sulcus in the patient's mouth at the proper depth and the distance from the top of the incisors to the depth of the sulcus is measured in millimeters. The labial sulcus on the model is trimmed to match this measurement, after which the mandibular cast is smoothed down to the level of the mandibular sulcus in the posterior region.

On the maxillary cast, the sulcus depth should be 10-12mm above the gingival margin of the posterior teeth. It is very important that the area posterior to the muscle attachment over the first bicuspid or first deciduous molar be outlined, since most impression trays do not give an adequate representation of this region. It is also important to define the border of the maxillary vestibular

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region anterior to the muscle attachment. This usually involves a scalloping out in the area above the cuspid. I should emphasize that the clinician, not the laboratory technician, should do the preparation of the work model.

DR. GOTTLIEB Are there any special instructions to the laboratory?

DR. MCNAMARA Most of the laboratory prescription forms ask for the same information. The clinician must indicate the type of appliance, and usually request a standard wax relief for the vestibular shields. Any special instructions calling for special relief, omitting lingual springs, or pointing out an asymmetry in the appliance should be written very clearly.

DR. GOTTLIEB How long does it take to have the appliance made?

DR. MCNAMARA The current delivery time in the United States is 2 to 4 weeks. Of course, the shortest delivery time is most desirable.

DR. GOTTLIEB Do you check the appliance yourself when it is delivered?

DR. MCNAMARA Yes. First, it is a good idea to check that there has been no mix-up, and that the appliance is the one intended for the patient. Then I check the general contour of the appliance. I place the appliance on the work models, and set the models flat on their backs on the lab bench. If the backs are still in their proper orientation, you can be assured that there has been little, if any, distortion in fabrication. If the backs of the models are not flush with one another, I am suspicious that it has been necessary to open the bite to allow the crossover wire to pass through the posterior region, or that some other distortion has occurred in the laboratory. If the Frankel appliance doesn'tfit the work models, then chances are it won't fit the patient.

DR. GOTTLIEB For those that don't fit, do you prescribe a complete remake, or do you try to adjust it to fit?

DR. MCNAMARA The laboratories are now very proficient in making the appliance, and there are very few times when the appliance absolutely won't fit. Appliance distortion is usually the fault of the orthodontist, rather than the laboratory, and is due to improper impression taking, model preparation, or bite registration. Most appliances fabricated by an experienced laboratory will ultimately fit the patient. The amount of appliance adjustment necessary at the time of delivery is most directly related to the previous experience that the clinician has had with the Frankel appliance. Probably half of the appliances that I deliver require no adjustment whatever. Most of the others require minor recontouring of the lower labial pads, the vestibular shields, or the lingual shield. Occasionally, however, more than a few minutes are needed to achieve correct appliance fit. As a general rule, the better the impressions and model carving, the less chair time necessary to fit the appliance properly.

DR. GOTTLIEB How do you present the appliance to the patient?

DR. MCNAMARA I give the appliance to the patient and instruct him to put it in his mouth. Usually, this is accomplished quite easily by having the patient hold one hand on the appliance and one hand on the cheek at the corner of the mouth, and rotate the appliance in on one side. Then the other side can be seated. If the teeth on the model have been notched in the laboratory,-per instructions, the patient will not be able to seat into the appliance all the way, because the teeth in the mouth have not yet been notched.

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DR. GOTTLIEB Do you try on the appliance before notching?

DR. MCNAMARA I usually do, because I do not want to notch the teeth if the appliance is incorrect. Occasionally, there has been an error in the bite registration, and the appliance simply does not fit. If the appliance is satisfactory, I notch the teeth with a diamond cylinder bur. I notch the distal aspect of the deciduous cuspid, the mesial aspect of the first deciduous molar, and the distal aspect of the second deciduous molar. The first permanent molar, of course, is not notched. Permanent teeth are not notched, but the work models of a patient with partial or complete permanent dentition are notched.

DR. GOTTLIEB Is this because you separate the permanent teeth, rather than notch them in the mouth?

DR. MCNAMARA Right. After the notching (or separation), it is best to place two index fingers under the inferior aspect of the vestibular shields and push the appliance vertically upward to check whether the wires are seated into the notches on the maxillary teeth.

DR. GOTTLIEB What else do you do?

DR. MCNAMARA At this time, I check to see that there is not an overextension of the vestibular shields in the posterior and canine regions. The same procedure is carried out in fitting the appliance to the mandible, except, of course, that there is no notching of mandibular teeth. The practitioner should use his thumbs to push down on the appliance, while pushing up on the jaw with his fingers, making sure that the appliance will seat firmly without causing pain to the patient. There may occasionally be some soreness on the distal aspect of the lower lingual shield, or on the inferior or anterior aspect of the lower labial pads. If so, the position of the shield or pad is adjusted. The top of the lower labial pad should be at least 5mm below the gingival margin. As a rule of thumb, the amount of gingiva showing above the pads is equal to the height of the pads vertically. Check to make sure that the contour of the lower labial pads is teardropped in cross-section, rather than rectangular. If necessary, a cone-shaped carbide bur can be used to smooth the pads from the inside so that the contour approximates a teardrop shape. This will prevent unnecessary gingival stripping, which might otherwise occur as the patient opens and closes his or her jaw. If this contouring causes the pads to be too far away from the alveolus, it is important to move the pads inward for a better fit (Fig. 13). This is done by drilling out the ends of the support wires of the labial pads with a fissure bur. The pads can then be slid backward (or forward) with the support wire. If this movement of the pads results in less than 5mm of space between the vestibular shield and the lower labial pad, the anterior part of the vestibular shield should be ground away to allow room for the insertion of the lateral frenum. If this is not done, there will be sore spots in that area.

DR. GOTTLIEB This adjustment of the pads is not the same as that for advancement of the Frankel .

DR. MCNAMARA No. This is for the comfort of the patient and proper fit of the appliance on insertion. The advancement of the appliance is done at a later stage by making cuts through the vestibular shields.

DR. GOTTLIEB The appliance must seem like quite a mouthful.

DR. MCNAMARA The first time a patient puts the appliance in his mouth, the cheeks are often somewhat full, but the patient's face shouldn't look too distorted, and there should not be any lumps

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or swellings in unexpected areas. The face should be palpated on the outside to make sure there are no sharp edges of the appliance sticking into the cheeks. There should be a gradual blending of the appliance with the hard structures of face.

DR. GOTTLIEB What are your home instructions to the patient?

DR. MCNAMARA The instructions to the patient are that the appliance is to be worn on a full-time basis, with the exception of eating, toothbrushing, playing contact sport, playing musical instruments, and during language lessons. While it is important to stress ultimate full-time wear, there is a break-in period. The patient is instructed to wear the appliance for a few hours a day at first, increasing wear an hour or two each day over a two-week period. At the end of two weeks, most patients are wearing the appliance full-time, except at night. The invisible retainers are worn when the Frankel is not in place during the break-in period, but should be discarded as soon as full-time wear is achieved. Only after a patient is wearing the appliance full-time during the day is he or she allowed to sleep with it at night.

DR. GOTTLIEB Why?

DR. MCNAMARA One of the functions of the Frankel appliance is to promote the establishment of a neuromuscular reflex response to bring the jaw forward, and it takes several weeks to do so. I also want to make sure that the patient does not develop sore spots during the night, which would cause the appliance to be ejected during sleep. It takes a certain amount of time to get used to it.

DR. GOTTLIEB Doesn't the appliance interfere with proper speech at first?

DR. MCNAMARA Yes. To maximize cooperation, the patient must learn to speak properly while wearing the appliance. So, I have the patient read out loud to his parents or another member of the family with the appliance in place for 30 minutes per day for at least two weeks or until satisfactory speech patterns are reestablished.

DR. GOTTLIEB How often do you see the patient after the insertion of the appliance?

DR. MCNAMARA I often see the patient for a comfort adjustment or two at the request of the patient. The first scheduled check of the appliance occurs two weeks after delivery, and it is checked at five-week intervals after that.

DR. GOTTLIEB What happens at the check-up visits?

DR. MCNAMARA Usually one member of my staff will see the patient first to look for any problems, talk with the patient, ask him or her about hours of wear, and get some idea of the level of cooperation. We look for a buildup of plaque or calculus on the appliance as an indication that the patient is wearing it. We check for areas of hyperemia, and to see where the patient bites most comfortably. After a while, clinical judgment comes into play. After you have seen many Frankel patients, it is fairly easy to pick out where the problems are.

DR. GOTTLIEB Do you have the patients keep a chart?

DR. MCNAMARA It is a good idea to have the patients keep an appliance wear record, and to check it at each visit. Appliance wear should total 20 hours per day. Most patients will have very little difficulty achieving that, if they are properly motivated.

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DR. GOTTLIEB How do you handle sore spots?

DR. MCNAMARA To locate them precisely, pressure indicator paste can be used, just as it would be used for adjusting a denture. The most common places of irritation are in the lower labial region, where indicator paste is probably not even needed. Less easily identified are sore spots in the maxillary tuberosity region and on the lower lingual shields.

DR. GOTTLIEB Do you use any medication for sore spots?

DR. MCNAMARA I usually don't. Occasionally, I may use benzocaine or Orabase.

DR. GOTTLIEB Is appliance breakage a problem?

DR. MCNAMARA Breakage is usually limited to cracks in the vestibular shields. They are readily repaired by using an adhesive and backing it up with cold cure acrylic. The wires break occasionally, and these can be repaired with electric or flame soldering or a tube repair soldering a piece of tubing across the break. The earlier Frankel appliances were very prone to wire breakage, and the Frankel appliance justifiably gained the reputation as a very fragile appliance. During the last few years, the sizes of the wires have been increased, particularly since no part of the appliance is now used for tooth movement. Wire breakage no longer is a routine problem.

DR. GOTTLIEB What adhesive do you use in repairing the acrylic?

DR. MCNAMARA I use a cyanoacrylate type adhesive. The bond usually does not hold indefinitely, so it is a good idea to do further repair with acrylic within a short time after the bond repair. Occasionally an appliance gets stepped on or chewed up by a dog and has to be completely remade.

DR. GOTTLIEB Is there a charge for remaking the appliance?

DR. MCNAMARA Definitely. A significant amount of time and effort is required. Not only is the fabrication charge involved, but also the time and expense of impression taking, model preparation, and appliance adjustment.

DR. GOTTLIEB What signs of change do you look for after the appliance has been in place for a while?

DR. MCNAMARA After the patient has been wearing the appliance for several months, they should have some difficulty positioning their lower teeth and jaw posteriorly. They can do it, but it is uncomfortable. I call this phenomenon the "pterygoid response", because presumably the lateral pterygoid muscles are helping keep the mandible forward, as they did in our monkey experiments.

DR. GOTTLIEB In so short a time, it must be a dual bite.

DR. MCNAMARA It is a dual bite, but one without the usual pejoratives that accompany that term. There is a functional change occurring--a shortening of the lateral pterygoid, as shown by Petrovic and associates ('75), or some other musculature change. Occasionally, a patient will tell you he can't bite on his posterior teeth. The only place he can occlude is on the anterior teeth. This is particularly true in a patient who has a short pretreatment anterior facial height. About three months after the first occurrence of the lateral open bite, the bite is usually closed. If the patient doesn't experience difficulty in positioning the jaw backward, the clinician should be suspicious that the patient is not

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wearing the appliance.

DR. GOTTLIEB On the cooperation score, I recall from one European report that a full fifty percent of removable appliance patients did not complete their course of treatment. Do you have a batting average for your practice?

DR. MCNAMARA I would say that the batting average is probably 80-90% success for most orthodontists I know who have mastered the technique. In my practice, the Frankel patients are made to feel very special. If a patient begins to flounder, I immediately ask the patient if he or she would like to stop treatment. The answer is usually "no", and I tell the patient that I will give him or her two weeks to keep a record of how much time the appliance is worn, after which we will discuss whether treatment should continue. The vast majority of patients get back on track and do quite well. Occasionally, a patient is discontinued and put on recall for other orthodontic approaches at a later date. If a patient obviously will not wear the appliance, it is foolish to continue.

One alternative for the noncooperative patient is the use of the Herbst appliance (Pancherz, '79, '81). The Herbst appliance is a type of fixed functional appliance that is cemented to both arches. The maxillary and mandibular splints are connected by piston-like attachments, which force the mandible in a forward position. The Herbst appliance seems to produce rapid mandibular growth, but it has the disadvantage of also producing rapid dentoalveolar change as well. Of course, no significant retraining of the perioral musculature is possible, as occurs with the Frankel appliance. However, for the noncooperative patient, the Herbst appliance seems to be a good alternative. Thus far, patient acceptance has been excellent.

DR. GOTTLIEB How long does the usual FR-2 treatment last?

DR. MCNAMARA The entire period of treatment, including pre- and post-Frankel fixed appliance phases, is approximately three years. The Frankel phase lasts about two years.

DR. GOTTLIEB Do you use Class II mechanics on Class II patients in the post-Frankel phase?

DR. MCNAMARA Almost always. I usually band the first molars and bond upper and lower five to five, and immediately put on Class II elastics. Our research has shown that it is possible to get similar skeletal results with Class II elastics in given patients as it is with functional appliances (McNamara, '80), so I almost always back up the Frankel cases with Class II elastics in the final fixed appliance stage.

At the end of the fixed appliance phase, I use a positioner to attain final tooth alignment. I am now experimenting with building a protrusion component into the positioner, as opposed to fabricating it on the hinge axis. The positioner is constructed with the lower arch slightly protruded. The preliminary results of using this type of positioner look very promising.

DR. GOTTLIEB Is the positioner your retention appliance in Frankel cases? Not the Frankel itself?

DR. MCNAMARA In my practice, patients wear a positioner for six weeks or so, and then go through a series of invisible retainers, which are used to sequentially reposition specific teeth in the arch. When the teeth are exactly where they should be, I use either a Ricketts retainer or a Frankel as a retention device, particularly if I am not entirely satisfied with the muscle retraining achieved in the Frankel phase. The Frankel will not retain exact tooth positions, so it is sometimes necessary to use a Frankel at night and retainers during the day. It is also possible to have a patient wear invisible

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retainers on a full-time basis and wear the Frankel over them at night.

DR. GOTTLIEB How do you use the invisible retainers during the retention phase?

DR. MCNAMARA A set of impressions is taken and usually no more than one tooth in a quadrant--usually a cuspid or bicuspid--is repositioned, as needed. Then, as I mentioned earlier, a piece of clear acrylic is heated and sucked onto the dental cast with a vacuum-forming device. So, it is really a mini-positioner which has a thin occlusal coverage. After about 6 weeks another set of impressions is taken, and additional teeth may be moved, until all the teeth are detailed the way I want them to be. Invisible retainers are very inexpensive, and work well as transitional retainers.

DR. GOTTLIEB You did not mean to imply before that you can do the same thing with a fixed appliance that you can do with a functional appliance, did you?

DR. MCNAMARA The answer obviously is "no", because the effect of the multibanded appliance is limited primarily to the dentoalveolar area. While there are some possibilities of modifying maxillary growth through orthopedic headgear, or perhaps limiting mandibular growth to a certain extent with a chin cup, there is no way to influence muscle function or bone growth with an edgewise appliance or most other fixed appliances, with the possible exception of Class II elastics or a Herbst appliance.

DR. GOTTLIEB How would you sum up the goal of functional jaw orthopedics?

DR. MCNAMARA The goal of functional jaw orthopedics is to change the dental and skeletal positions to a more normal relationship, and to change the level of muscle activity to a level which is harmonious with the normalized skeletal relationships; to go from a state of homeostasis with an abnormal configuration to a state of homeostasis with a more normal configuration. The problemwith many types of conventional orthodontic treatment is that the emphasis has been placed primarily on the teeth and secondarily on bone, with almost no emphasis placed on muscle. From a biological point of view, using only fixed appliances often alters a system, the components of which are in balance with each other, and imbalances it, even though one component (in this case the teeth) may be more normal (more straight). The final result can be relapse or rebound toward the pretreatment state of balance.

DR. GOTTLIEB Do all functional appliances have the same goals?

DR. MCNAMARA The stated goal of all functional appliances would be to change function, but specifically what they accomplish really depends on the design of the appliance.

DR. GOTTLIEB That is an important point. Please explain it.

DR. MCNAMARA Well, there are four major effects that have been cited in the literature as being responsible for the correction of a Class II malocclusion to a Class I normal occlusion . The first can be termed the headgear effect, which is essentially a restriction of maxillary growth. This can be achieved by a headgear; a Harvold Woodside activator, or by any other type of appliance that applies a restrictive force on the upper jaw. So far, my experience has been that the headgear effect is limited in the FR-2, so this effect is not a major contributor to the Class II correction with the Frankel. I might add that I consider the lack of restriction of maxillary growth to be an advantage, since the majority of Class II cases do not have a protrusive maxilla (McNamara, '81b). In fact, many maxillae are already retruded.

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The second type of effect can be termed the Harvold-Woodside activator effect. Both Harvold and Woodside have advocated the differential eruption of teeth as a primary modus operandi of Class II correction. One function of a Harvold-Woodside activator is to prevent the eruption of the upper posterior segment, which normally erupts in a downward and forward direction, while simultaneously allowing the eruption of the lower molars and bicuspids. The effect of the differential eruption is to change the posterior vertical occlusal relationships. An FR-2 has some of the Harvold-Woodside activator effect, in that it does seem to inhibit the downward and forward movement of the upper buccal segment through the action of the occlusal rests and interproximal wires. However, I have seen many Frankel cases in which the achieved correction cannot be explained by considering differential eruption of teeth alone.

The third type of effect can be termed the classical activator (or bionator) effect. Many of the European appliances, particularly those with acrylic coverage of the lower teeth, often cause a forward movement of the lower teeth. Since the FR-2 has no component which contacts the lower teeth, this appliance cannot directly cause the movement of lower teeth, except in those cases in which the lower incisors have been held posteriorly by a hyperactive perioral musculature.

The fourth effect is the stimulation of mandibular growth, a phenomenon which has been shown to be predictable experimentally. It is my experience that with the proper wearing of a properly made and managed appliance, this type of result will occur during Frankel therapy (Fig. 4), as with other types of functional appliances which produce an alteration in the postural position of the mandible.

DR. GOTTLIEB What happens to the position of the condyle in the fossa with the use of the FR-2? Does it pull the condyle out of the fossa initially? And does the condyle grow back into the fossa?

DR. MCNAMARA Basically, that is correct. It is obvious from laminagraphs before and after placement of an FR-2 that the condyles are displaced downward and forward along the articular eminence. All the evidence, both experimental and clinical, seems to indicate that there is a secondary compensation in the mandibular condyle and that, over a period of time--which may take six months or a year--there is a gradual remodeling of the head of the condyle back into the fossa. So, initially a functional change, not an anatomical change, is produced; but, given enough time and the proper environment, the mandibular condyle will grow backward and reestablish its normal anatomical relationships.

DR. GOTTLIEB So, there is absolutely no question in your mind that the FR-2, and some of the other functional appliances, can actually increase the length of the mandible, and that this occurs by growth of the condyle?

DR. MCNAMARA Yes. This occurs at the condyle and also along the posterior border of the ramus.

DR. GOTTLIEB In most instances you prefer the FR-2 to other functional appliances?

DR. MCNAMARA Yes. For example, if a Harvold-Woodside activator, a bionator, and an FR-2 are compared, one sees three very different approaches to the treatment of function. In my estimation, the Harvold-Woodside activator perhaps does affect mandibular growth rate and direction, but it does so in a very different way than does a Frankel. The patient can't wear the activator all of the time. It is usually worn at night or when the patient is at home. The muscles are not directly retrained to cause the patient to function in a more forward position. In fact, the reverse may occur as the stretch reflex is used to impart a retrusive force to the maxilla. The bionator and the Frankel are similar in that they do position the jaw forward, and are worn 24 hours a day.

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I think that one of the advantages of the Frankel over the bionator is that the first action of the Frankel is on muscle. As a biologist, it makes sense to me that if you are going to change the form-function relationship, you must change the activity of the lateral pterygoid, which presumably both appliances can do, but using a Frankel you also act directly on the perioral musculature. Establishing muscle balance, I think, has been shown to be a significant contributor to the stability of the dentition and of the corrected anteroposterior jaw relationships. The Frankel also has the additional advantage of producing a moderate amount of passive expansion. If you treat a patient with a moderate arch length discrepancy or a narrow maxilla, both of these problems can be addressed with the FR-2, without using an active force on the teeth. Other functional appliances can also produce expansion, but the action of the appliance is more biomechanical in nature, in that the expansion is produced either actively by expansion screws or through guiding channels on the appliance. With these kinds of appliances, there is no retraining of the adjacent soft tissue, as occurs with the vestibular shields of the Frankel appliance.

DR. GOTTLIEB You said that the Frankel does not have any tooth-moving effect in a labial direction?

DR. MCNAMARA Well, we make every effort to avoid it in the maxilla. In those cases with a normal position of lower incisor relative to mandible, we do not usually see any tooth movement at all. In some cases, in which the lower incisors have been trapped lingually by hyperactive perioral muscle function, the lower incisors will come forward during treatment.

DR. GOTTLIEB Due to tongue function?

DR. MCNAMARA I think so; that combined with the inhibition of the hyperactivity of the perioral musculature.

DR. GOTTLIEB Do you use an FR-2 for a dental open bite, as well as for a skeletal open bite?

DR. MCNAMARA Some of the dental open bites can be corrected with lip seal exercises alone, but the skeletal open bites are candidates for either an FR-2 or an FR-4, depending on whether there is an anteroposterior discrepancy as well as a vertical excess. In some long anterior facial height cases, I also use a vertical-pull chin cup (Pearson, '78), either alone or in combination with a Frankel, to assist in keeping the mouth closed and the appliance in place.

DR. GOTTLIEB What are your criteria for case selection for FR-2 appliances? Which cases are the good candidates and which are the poor ones?

DR. MCNAMARA The best possible Frankel patients are those who have an anteroposterior mandibular deficiency, or a vertical mandibular deficiency, or both. The patients who are least likely to have a successful Frankel treatment are Class II patients with an excessive vertical dimension, or those with an excessive amount of maxillary prognathism. Fortunately, the incidence of maxillary prognathism is low; but, unfortunately, the number of steep mandibular plane angle cases is high (McNamara, '82b).

DR. GOTTLIEB Do you just not treat these with a Frankel?

DR. MCNAMARA If I use a Frankel on a high angle Class II, I make sure that the patient does all the lip seal exercises, and that the airway is clear. If the airway is not clear and the patient cannot get a proper lip seal, closure of the mandibular plane angle probably will not occur, even though a

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change in molar relationship takes place. The Frankel appliance can produce additional growth in deficiency cases, but unfortunately can only camouflage, not eliminate, previously existing excesses in facial dimensions, such as excessive anterior facial height which is present at the beginning of treatment.

DR. GOTTLIEB Would you care to comment on what diagnostic analysis methods other than your own would or would not produce the correct diagnosis for a Frankel case?DR MCNAMARA Using a simple ANB difference as a measure of maxillary versus mandibular position is inadequate, because this measure is not sensitive to changes in vertical dimension. I am biased toward the method I use (McNamara, '82a), because it is simple and straightforward, but I am sure that there are other methods that might give much the Fame information. However, if the clinician is concentrating on the position of the lower incisor relative to the mandibular plane and hasn't ever thought about the fact that the mandibular plane angle can be reduced or that the mandible itself can be changed in size and position, the clinician would be making treatment decisions that would be appropriate in a nongrowing patient, but inappropriate in a growing patient. I think that Ricketts' analysis (Ricketts '60, '81) could be used--and part of my analysis is based on his ideas.

DR. GOTTLIEB Is an orthodontist going to be in trouble in Frankel treatment, if he uses someanalysis other than yours or Ricketts'?

DR. MCNAMARA Not as long as he or she understands the information obtained from the analysis. For example, an SNA angle of 77 degrees may indicate that there is something wrong with the cranial base, but more likely indicates a retrusive maxilla; if the SNA angle is 86 degrees, chances are that the patient has a prognathic maxilla, but it must be checked clinically by evaluating, for example, the nasolabial angle. No analysis is sacred, and regardless of the analysis used, it must confirm clinical judgment.

DR. GOTTLIEB Well, there are analyses and analyses. You may recall the original work of Krogman and Sassouni, in which they analyzed the same case with all the methods that then existed, and the diagnosis varied greatly according to the analysis used. So, it must make a difference, if one is serious about diagnosis, which analysis is used.

DR. MCNAMARA The clinician must not use an analysis that is only sensitive to the maxillomandibular relationship, such as is the case with the ANB angle. The analysis must also be sensitive to the position of the maxilla and mandible relative to the cranial base, not only anteroposteriorly but vertically as well. Many of the traditional cephalometric analyses are not appropriate in the diagnosis of the prospective Frankel patient.

DR. GOTTLIEB How early do you start treating patients with a Frankel?

DR. MCNAMARA With a severe skeletal problem, it is probably better to get in as soon as the problem is identified. I have had two 4.5-year-olds who have been excellent patients. However, the routine Class II patient is most easily treated in the late mixed dentition stage, preferably about a year before the eruption of the bicuspids. The patients are in a period of fairly rapid growth at this time, and are usually very cooperative.

DR. GOTTLIEB Differences between males and females in growth timing would also be a consideration .

DR. MCNAMARA Yes. After age 14, most girls are not growing very much, but males continue to

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grow until age 18 or 19. But chronological age is not as important as skeletal age, and the clinician must be aware of the maturation level of the individual patient. For example, I have successfully treated a 16-year-old female, in part with a Frankel appliance. Her skeletal age was closer to 12-13 years at the beginning of the treatment, so I was able to take advantage of the potential for further skeletal growth.

DR. GOTTLIEB Do you treat adult patients with an FR-2?

DR. MCNAMARA I have had limited experience with adults, and I have not been encouraged at all by the results. I treated an adult male who was 20 years old, who wore the appliance faithfully for two years, and showed 3mm of mandibular growth (McNamara, '82b). That was more than would be normally expected, but he needed 10 or 12mm of mandibular growth in order to avoid surgery. It is my current thinking that there is probably fairly limited ability to adapt in the adult temporomandibular joint. Our recent experimental studies in adult rhesus monkeys, who wore protrusive appliances, indicate that there is variable adaptive potential in the mandibular condyles of adults (McNamara et al., '82). In some individuals, it may be possible to obtain a few millimeters of increased mandibular length through wearing a functional appliance. However, I do not think that it is possible to correct a severe skeletal discrepancy in an adult routinely with functional appliance therapy alone.

DR. GOTTLIEB Do functional appliances cause temporomandibular joint problems?

DR. MCNAMARA Not in my experience. We have not had any cases of temporomandibular joint dysfunction associated with a Frankel. Jos Dibbetts in the Netherlands, in a thesis on temporomandibular problems in adolescents, found that functional appliances tended to relieve temporomandibular joint problems, so it might be just the other way around.

DR. GOTTLIEB Does the use of FR-2s permit you to extract less?

DR. MCNAMARA I have probably extracted teeth in less than 10% of the cases in which an FR-2 was used, but I do not use a Frankel in Class I crowded cases. Overall in my practice, I probably extract in 30-35% of the adolescent and adult cases that I treat. While the Frankel does not eliminate extractions, I would say that the amount of extraction has been significantly reduced in my mixed dentition population.

DR. GOTTLIEB Jim, do you have any concluding remarks?

DR. MCNAMARA Just a few. It should be clear from what I have said that the Frankel appliance, or any other functional appliance for that matter, is not a panacea. For example, the Frankel appliance is not the answer to severely crowded cases. It cannot produce controlled movement of individual teeth as can fixed appliances. In addition, I have seen through my own experience that treatment with the Frankel appliance is not automatically successful, unless the clinician has a thorough understanding of the management of the appliance. In my estimation, Frankel therapy is just as demanding as any other orthodontic technique. Hopefully the American orthodontist will combine his or her existing knowledge of fixed appliances with the treatment possibilities offered by the Frankel appliance, so that a clinical result will be achieved that is better than if either method were used alone.

DR. GOTTLIEB Jim, thank you very much for giving us your perspective on the biological basis and clinical use of the Frankel appliance.

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ACKNOWLEDGEMENTS -- The preparation of this manuscript was made possible, in part, by USPHS grant DE 03610. Illustrations are by William L. Bruden. □

FIGURES

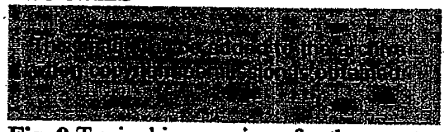


Fig. 9 Typical impressions for the construction of a Frankel appliance. In maxillary impression (left), note the reproduction of the areas of muscle attachment (see arrows). In mandibular impression (right), note the thin roll of alginate at the margins of the impression, particularly in the area of the labial vestibule. The lingual anatomy has also been reliably reproduced (Impressions taken by Dr. Raymond P. Howe.)



Fig. 10 Construction bite registration. Three thicknesses of yellow wax (A) are compressed laterally after the proper bite registration has been achieved (B).

Fig. 10 Construction bite registration. Three thicknesses of yellow wax (A) are compressed laterally after the proper bite registration has been achieved (B).

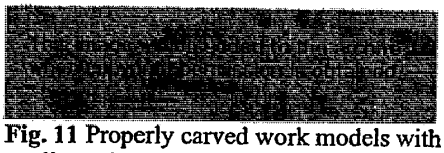


Fig. 11 Properly carved work models with red wax construction bite in place. Pencil outlines of the appliance have been added. (Courtesy of S.A. Huge.)



Fig. 12 Gauge used to measure correct depth of labial sulcus.

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Fig. 13 Comfort adjustments are made by freeing the ends of the lower labial support wires from the vestibular shields (hole marked at A), and sliding the wires forward or backward as necessary for the comfort of the patient.

Fig. 13 Comfort adjustments are made by freeing the ends of the lower labial support wires from the vestibular shields (hole marked at A), and sliding the wires forward or backward as necessary for the comfort of the patient.

REFERENCES

1 Brieden, C: Maxillary skeletal changes with the use of the Frankel appliance studied by the implant method. Master of Science thesis, Department of Orthodontics, University of Detroit, 1981.

2 Delaire, J.: The potential role of facial muscles in monitoring maxillary growth and morphogenesis. In: Muscle Adaptation in the Craniofacial Region, D.S. Carlson and J.A. McNamara, Jr. (Eds.), Monograph 8, Craniofacial Growth Series, Center for Human Growth and Development, The University of Michigan, Ann Arbor, 1978.

3 Frankel, R.: The treatment of Class II, division I malocclusion with functional corrections. Am. J. Orthodont. 55: 265-275, 1969.

4 Frankel, R.: Guidance of eruption without extraction. Trans. Europ. Orthodont. Soc. 47:303-315, 1971.

5 Frankel, R.: Decrowding during eruption under the screening influence of vestibular shields. Am. J. Orthodont. 65: 372-406, 1974.

6 Frankel, R.: Lip seal training in the treatment of skeletal open bite. Europ. J. Orthodont. 2:219-228, 1980.

7 Frankel, R. and C. Frankel: A functional approach to the treatment of skeletal open bite. Am. J. Orthodont. In press, 1982.

8 Graber, T.M. and B. Neumann: Removable Orthodontic Appliances. W.B. Saunders, Co., Philadelphia, 1977.

9 McDougall, P.D., J.A. McNamara, Jr. and J.M. Dierkes: Arch width development in Class II patients treated with the Frankel appliance. Am. J. Orthodont. In press, 1982.

10 McNamara, J.A., Jr.: Neuromuscular and Skeletal Adaptations to Altered Orofacial Function. Monograph 1, Craniofacial Growth Series, Center for Human Growth and Development, The University of Michigan, Ann Arbor, 1972.

11 McNamara, J.A., Jr.: Neuromuscular and skeletal adaptations to altered function in the orofacial

ClearCorrect Exhibit 1002, Page 1469 of 3373

region. Am. J. Orthodont. 64:578-606, 1973.

12 McNamara, J.A., Jr.: Functional adaptability of the temporomandibular joint. Dent. Clin. N. Am. 19:457-471, 1975.

13 McNamara, J.A., Jr.: Functional determinants of craniofacial size and shape. Europ. J. Orthodont. 2:131-159, 1980.

14 McNamara, J.A., Jr.: Development of occlusion and facial balance in Orthodontics: State of the Art (H. Barrier, ed.), University of Pennsylvania Press, 1981a.

15 McNamara, J.A., Jr.: Components of Class II malocclusion in children 8-10 years of age. Angle Orthodont. 51:177-202, 1981b.

16 McNamara, J.A., Jr.: A method of cephalometric analysis. Am. J. Orthodont. submitted for publication, 1982a.

17 McNamara, J.A., Jr.: Craniofacial adaptations in an adult patient following functional regulator therapy. Am. J. Orthodont. submitted for publication, 1982b.

18 McNamara, J.A., Jr. and D.S. Carlson: Quantitative analysis of temporomandibular joint adaptations to protrusive function. Am. J. Orthodont. 76:593-611, 1979.

19 McNamara, J.A., Jr., R.J. Hinton, and D.L. Hoffman: Historical analysis of temporomandibular joint adaptation to protrusive function in young adult rhesus monkeys (Macaca mulatta). Am. J. Orthod. Submitted for publication, 1982.

20 McNamara, J.A., Jr. and S.A. Huge: The Frankel appliance (FR-2): Model preparation and appliance construction. Am. J. Orthodont. 80:478-495, 1981.

21 Pancherz, H.: Treatment of Class II malocclusions by jumping the bite with the Herbst appliance. A cephalometric investigation. Am. J. Orthodont. 76:423-442, 1979.

22 Pancherz, H.: The effect of continuous bite jumping on the dentofacial complex: A follow-up study after Herbst appliance treatment of Class II malocclusions. Europ. J. Orthodont. 3:49-60, 1981.

23 Pearson, L.E.: Vertical control in treatment of patients having backward-rotational growth tendencies. Angle Orthodont. 48:132-140, 1978.

24 Petrovic, A.: Recherches sur les mecanismes histophysioiogique de la croissance osseuse craniofacial. Ann. Biol. 9:303-311, 1970.

25 Petrovic, A.: Mechanisms and regulation of mandibular condylar growth. Acta. Morphol. Neerl.-Scand. 10:25-34, 1972.

26 Petrovic, A., C. Oudet, and N. Gasson: Effets des appareils de propulsion et de retropulsion mandibulaire sur le nombre des sarcomeres en serie de muscle pterygoidien externe et sur la croissance du cartilage condylien du jeune rat. Orthod. Franc. 44:191-212, 1973.

27 Petrovic, A., J. Stutzmann, and C. Oudet: Contro process in the postnatal growth of the condylar cartilage. In: Determinants of Mandibular Form and Growth, J.A. McNamara, Jr. (Ed.), Monograph

ClearCorrect Exhibit 1002, Page 1470 of 3373

4, Craniofacial Growth Series, Center for Human Growth and Development, The University of Michigan, Ann Arbor, 1975.

28 Petrovic, A., J.J. Stutzmann, and N. Gasson: The final length of the mandible: Is it genetically determined? In: Craniofacial Biology, D.S. Carlson (Ed.), Monograph 10, Craniofacial Growth Series, Center for Human Growth and Development, The University of Michigan, Ann Arbor, 1981.

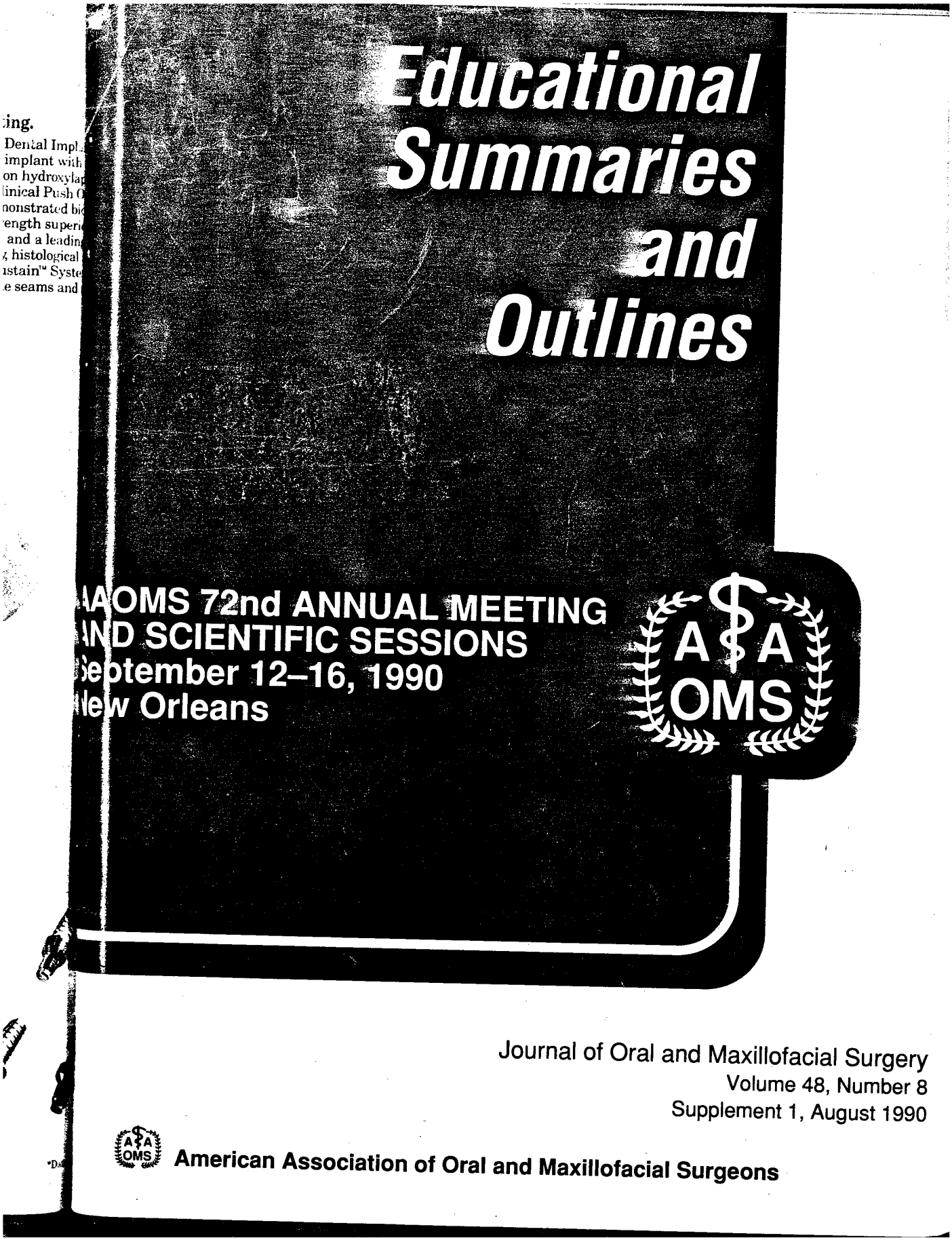
29 Ponitz, R.J.: Invisible retainers. Am. J. Orthodont. 59:266-272, 1971.

30 Proffit, W.R.: Equilibrium theory revisited: factors influencing position of the teeth, Angle Orthod. 48:175-186, 1978.

31 Ricketts, R.M.: A foundation for cephalometric communication. Am. J. Orthodont. 41:330-357, 1960.

32 Ricketts, R.M.: Perspectives in the clinical application of cephalometrics. Angle Orthodont. 51:115-150, 1981.

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Journal of Oral and Maxillofacial Surgery
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American Association of Oral and Maxillofacial Surgeons

SYMPOSIUM: COMPUTERIZED FACIAL IMAGING IN ORAL AND MAXILLOFACIAL SURGERY

Presented on Thursday, September 13, 9:00 a.m.-12:00 noon
Moderator: Bejan Iranpour, DDS, MS, Rochester, NY

New Advances in Personal Computer Applications for Cephalometric Analysis, Growth Prediction, Surgical Treatment Planning and Imaging Processing

Melvyn S. Wishan, DDS, MDS, Beverly Hills, CA

A decade has seen a revolution in the way in which we diagnose, treatment plan, and counsel our patients. Advancing technology in Computer Graphics has led the way in Facial Imaging. The Video Treatment Objective (VTO) has now become commonplace in many offices and institutions throughout the nation. Through continuing efforts in software enhancements, our tasks as practitioners are made easier and less time consuming, while at the same time we are able to look into the future with more assurance than ever before. These computer modalities increase our own awareness and at the same time enrich our patient doctor rapport. We are once again "personalizing" our approach to patient treatment. As databases evolve and programming efforts continue, editing of the images becomes more automated. Growth Forecasting is more reliable and Video "Aging" becomes more of a reality.

The orthodontist and oral and maxillofacial surgeon may not only be able to predict that a 10 year old will need orthognathic surgery at age 17, but will also be able to graphically show the patient and family why, i.e. the expected dentofacial deformity is readily apparent in the "aged" Computer Image.

Current advances in realtime treatment planning, analysis, and forecasting will be shown in this presentation. Challenges for the immediate future will be demonstrated.

Imaging—Basic Soft Tissue

Bruce S. Kuhn, DDS, MD, Omaha, NE

The time is past due where hard and soft tissues are separated in the treatment of many facial deformities. Oral and maxillofacial surgeons have been a leader in osseous surgery of the face for the past thirty years. Oral and maxillofacial surgeons are in a unique position having a unique opportunity to treat the total face. Changes of the aging face as well as developmental deformities require both hard and soft tissue evaluation as well as treatment. Computer imaging will not only help us to better diagnose and treatment plan patients but also allow these patients to visualize possible changes proposed and allow them to objectively judge their own facial aesthetics.

Computer facial imaging has become a major tool in many progressive orthognathic and facial plastic surgery practices academically and privately over the past three years. Until recent advances in computer facial imaging, soft tissue surgical predictions were difficult, cumbersome and time consuming. Acetate, cut and paste photographs and hand drawings were crude visual representations at best. Computer technology now allows visual diagnosis, treatment planning and treatment objectives for surgeons and patients with life like images. The ability to educate patients, referring doctors and surgeons by the use of these computers is unparalleled.

Evaluation of the facial components in two dimensions are excellent at this time. We are now seeing technology for skeletal and soft tissue evaluation in three dimensions.

An overview will be presented to include the goals of computer imaging, components of an imaging system generating quality images, skeletal and soft tissue evaluation as well as clinical presentation of predictions and surgical results.

References

Sarver, D.M., Johnston, M.W., Matukas, V.J.: Video imaging for planning and counseling in orthognathic surgery. JOMS 45:939-945, 1988

Cutting, C., Bookstein, F.L., Grayson, B., et al: Three dimensional computer assisted design of cranial facial surgical procedures: Optimization and interaction with cephalometric and CT based models. Plast Reconstr Surg 77:877-885, 1986

Laney, T.L., Kuhn, B.S.: Computer imaging in orthognathic and facial cosmetic surgery. Clin Oral Maxillofac Surg, September 1990

New Methods for Three Dimensional Analysis of Craniofacial Deformity

Barry H. Grayson, DDS, New York, NY

The purpose of this presentation is to demonstrate the application of three-dimensional cephalometric analysis in the evaluation and treatment plan of patients with craniofacial asymmetry. While this technique provides a true three-dimensional computer generated image of cephalometric landmarks, it allows the clinician to rotate the image for viewing from various angles and to perform mock surgery. The mock surgical data regarding change in location of dental landmarks (molars and incisors) are used for the construction of the intermedi-

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Symposium: Computerized Facial Imaging in Oral and Maxillofacial Surgery (cont'd)

ate and final splints. This method is demonstrated to overcome the intrinsic problem encountered when one uses a symmetrical articulator to stimulate the path of closure in an asymmetrical patient for intermediate splint construction.

The three-dimensional data set is derived by correlating points found on conventional postanterior and lateral cephalometric films. Such pairs of two-dimensional locations are converted to a single three-dimensional location using a computer and a digitizer pad. The computer computation is based upon a variant of the Ray Intersection Method commonly used in stereophotogrammetry. Normative data based upon 403 cephalogram pairs, were taken from Michigan normative sample. The three-dimensional landmark sets for patients are compared to the normative set in such a way that a quantitative surgical plan results. Review of a clinical series of patients with hemifacial microsomia suggest that in addition to lengthening of the ramus, leveling of the occlusal plane and positioning the symphysis on the midsaggital plane, there is a need for rotation of the body and ramus around the vertical axis. Clinical cases will be shown to demonstrate this point.

The method of three-dimensional cephalogram cephalometrics has made a major change in the way we view surgical correction for the patient with craniofacial asymmetry.

References

Grayson, B.H., Bookstein, F.L., Cutting, C.B., et al: The three-dimensional cephalogram: Theory, technique, and clinical application. Am J Ortho Dentofac Orthop 94:327-377, 1988

Grayson, B.H.: Cephalometric analysis for the surgeon. Clin Plast Surg 16, October 1989

Cutting, C.B., Bookstein, F.L., Grayson, B.H., et al: Three-dimensional computer assisted design of craniofacial surgical procedures: Optimization and interaction with cephalometric and CT based models. Plast Reconstr Surg, June 1986

SYMPOSIUM: ORTHOGNATHIC SURGERY IN THE GROWING PATIENT

Presented on Thursday, September 13, 12:30-2:30 p.m.
Moderator: John Paul Stella, DDS, Ft. Worth, TX

Biological Patterns in Craniofacial Morphogenesis

Alphonse R. Burdi, PhD, Ann Arbor, MI

Our understanding of the natural history, morphogenesis, and delineation of craniofacial malformations has increased dramatically during the last ten years. This information explosion has caused both clinicians and basic scientists to revisit the classically-held views, and often dogma, on how the normal human facial regions develop. The specific focus of this presentation will be on both the current and emerging concepts, paradigms and fundamental information dealing with the biology of normal and abnormal craniofacial morphogenesis in humans. The presentation will first highlight the classically-held picture of early craniofacial morphogenesis. A critical look will also be given to the concept of developmental critical periods as such a concept relates to interregional morphogenic timing and the origins of isolated and syndromic craniofacial birth defects. Building upon this information base, the presentation will then highlight the important concepts of developmental fields and patterns of morphogenesis at the cell, tissue and structural levels. Certainly a number of craniofacial regions could easily serve as excellent examples to bring this morphogenic information together into a cohesive picture, or paradigms, of normal and abnormal craniofacial morphogenesis. Examples specifically selected for this conference include the "coronal ring" paradigm in the craniofacial synostoses, the optic field paradigm in hypertelorism, the paradigm of morphogenetic patterning in the temporomandibular compartment, and the morphogenic template paradigm related to such interesting clinical entities as mandibulofacial dysostosis and the Apert syndrome.

References

Spyropoulos, M., Burdi, A.R.: Morphogenic fields in craniofacial biology, in Craniofacial Morphogenesis and Dysmorphogenesis. Monograph 21, Center for Human Growth and Development, University of Michigan, 1988

Burdi, A.R., Lawton, R., Grosslight, J.: Prenatal pattern emergence in early human facial development. Cleft Palate J 25:8-15, 1988

Burdi, A.R., Kusnetz, A., Venes, J., et al: The natural history and pathogenesis of the cranial ring articulations: Implications in understanding the pathogenesis of the Crouzon craniostenotic defects. Cleft Palate J 23:28-39, 1986

Orthognathic Surgery Related to Clefts

Timothy A. Turvey, DDS, Chapel Hill, NC

Facial clefting disorders are unique from other malformations in that tissues are missing, hypoplastic or fail to fuse. Consequently, either the clefting disorder itself or the scarring which results from early surgery adversely affect growth of all cellular layers. Extensive soft and hard tissue surgical construction often is necessary to improve these conditions and the timing and sequencing are critical.

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Computer Treatment Estimates in Orthodontics and Orthognathic Surgery

MICHAEL B. GUESS, DDS, MS, WOLFGANG V. SOLZER

Orthodontists spend a good deal of their time evaluating radiographs, photographs, and models. Their detailed findings about the malocclusion can be overwhelming to a patient who is primarily interested in esthetics. An orthodontist armed even with the most meticulous tracing and VTO will rarely find a patient who can thoroughly understand final treatment goals from a two-dimensional cephalometric tracing and plaster models.

Today's interactive computer graphics offer new opportunities to predict treatment results, demonstrate them to the patient, and compare them to actual results.[1] Commercial applications of this technology include flight simulators, computer-aided design/computeraided manufacturing (CAD/CAM), and computer-aided design drafting (CADD). Interactive graphics enable an architect to show a completed building with landscaping to a client before beginning construction. Different color pictures can be combined and altered to produce a single advertisement. A product design can be evaluated before expensive development and manufacturing.

Until recently, only large companies could afford a computer graphics system. Now, smaller and more powerful machines are bringing interactive graphics to an affordable level for such applications as medical and dental research. New advances will soon allow a computer treatment estimate (CTE) to be made for each patient in an individual orthodontic practice.

Patient Study

Nine orthodontic patients were selected for a study comparing CTEs to actual treatment results. Pretreatment photographs chosen for computer prediction included four intraoral frontal (three open bite and one closed bite) and four extraoral profile (two surgical and two nonsurgical).

The x-rays and tracings, treatment plan, diagnosis, progress notes, and pretreatment photographs for each patient were used to prepare a written prescription and acetate tracing estimate (Figs. 1, 2). The graphic artist used only the pretreatment photographs, prescriptions, and estimates, except in the closed bite case. In that pretreatment photograph the mandibular teeth were not sufficiently visible, so the artist was allowed to use the post-treatment photograph to trace the mandibular arch.

Each pretreatment photograph was wiped with film cleaner and placed on the drum of a

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Hell 341 laser scanner. This machine converts original material (35mm film, transparencies, or illustrations) into digital information, which can be transferred to four-color film negatives or positives for printing or sent to a graphic arts workstation for manipulation.[2,3] For this study, the workstation was a Scitex 350 Response System.

The artist called up the original photograph and manipulated it until it matched the acetate tracing (Fig. 3). The completed estimate was converted to film. A color proof (Cromalin) was made of each pretreatment photograph and CTE (Fig. 4). Post-treatment photographs were then scanned and converted to proofs (Fig. 5).

The CTEs turned out much like the actual treatment results (Figs. 6, 7).

Computer estimates were also done for a patient evaluation of ceramic bracket placement (Fig. 8), a mandibular bicuspid extraction case (Fig. 9), and an extraoral frontal photo graph (Fig. 10). Post-treatment comparisons were not available for these photographs, but they do show other capabilities of the CTE.

Discussion

The artist could have spent more time manipulating the images to produce even closer estimates, but this would be undesirable because of increased labor and computer costs. A more accurate but time-consuming method would be to scan the outline of the acetate estimate with a mouse and store it digitally, rather than simply using it as a guide.

There is also the possibility that the predicted results could not be achieved due to limitations of the orthodontist, the appliance, or the patient's physiological or psychological makeup. The actual treatment in these cases was superior in detail to the CTEs, so the computer would not have created unrealistic patient expectations.

The CTE can be adversely affected by errors in the original records, VTO, orthodontic or surgical treatment, and graphic technique, and by factors such as reproducibility of soft tissue measurements, growth, and relapse. A frontal intraoral CTE can be thrown off by incorrect estimation of torque, tip, overjet, or overbite, or by a poor perspective in the pretreatment photograph.

Although the VTO[4,5] is a good reference for determining treatment objectives, no prediction can be completely accurate in a surgical case. Surgical complications, anatomical structure, physiology, weight change, and patient health can affect the outcome. Additional variables such as head position are complicated by the interlabial position, by head posture, and by angulation of the camera and patient.

Equipment

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The Scitex system is relatively large, complex, and expensive, and takes many weeks to master. However, the demand for computer graphics has led to the development of less sophisticated, personal-computer-based systems.

One example is the Targa color video board, which can produce more than 16 million colors. Training for this icon-driven system takes only about eight hours. A PC-based system including the Targa board plus accounting, database, records, and desktop publishing functions would cost about $30,000.

Another benefit of such a system is that all records can be stored on floppy disk, magnetic tape, videocassette, or compact disc, which would permit patient records to be stored off the premises in a fraction of the space they now occupy. Duplicating records to digital information is legally acceptable in 30 states,[6] and several companies now offer an archival service. In addition, telecommunication would allow orthodontists miles apart to examine and discuss the same case.

PC-based systems have two major drawbacks. First, although the image may appear sharp on the computer screen, a good film copy is hard to produce due to limitations in the output camera, film grain size, and number of scan lines. Second, these graphics systems produce what is considered a low-resolution image of 1000 × 1000 lines. Continuous-tone images start at 4000 × 4000 lines; the Scitex is an 8000-line system.

Conclusion

The continued development of computer graphics has exciting prospects. Individualized bracket prescriptions could be accomplished through telecommunication to a manufacturer, which would use CAD/CAM to produce optimal torque, tip, and base designs based on the physiology and desired tooth movements for each patient.[7-9] The future orthodontist might enter a treatment plan with appliance preference, and the computer would provide a photographic estimate including archwire sequence, plus the amount of time needed for each phase and the estimated results with or without patient cooperation. The orthodontist would also be able to plan treatment based on various possible outcomes in soft tissue appearance.

The CTE will not standardize orthodontics. Average treatment time will not decrease, and the orthodontist will have to spend just as much time in diagnosis and treatment planning. A computer will never be a substitute for good diagnostic records and procedures, but it will become an increasingly useful tool in dentistry.

ACKNOWLEDGMENTS: We would like to express our sincere gratitude to Drs. Gerald Kess, Richard McLaughlin, and Marvin Zuravsky for the patient records that made this study possible. The critical review of the manuscript by Dr. Zeev Davidovitch was appreciated. Finally, we are indebted to the staff of Riverside Graphics and Felicitas S. Guess for their

creative contributions.

MICHAEL B. GUESS

 Dr. Guess is a resident in the Department of Orthodontics, Ohio State University, 305 W. 12th Ave., Columbus, OH 43210.

WOLFGANG V. SOLZER

 Mr. Solzer is a graphic artist in Reno, NV.

Hell 341 laser scanner

Hell Co., Kiel, West Germany.

Scitex 350 Response System

Scitex America Corp., Bedford, MA.

board

AT&T Information Systems, Morristown, NJ.

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FIGURES

Fig. 1

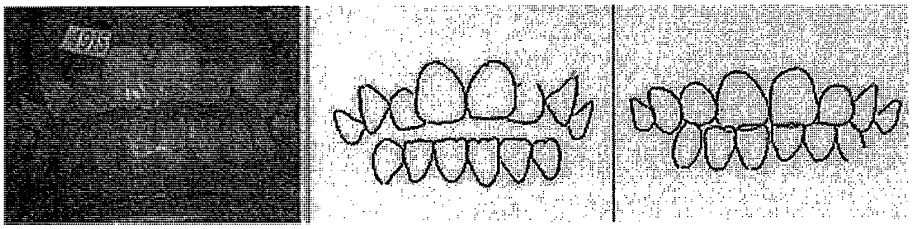


Fig. 1 Pretreatment photograph and acetate tracing of anterior open bite case; acetate tracing of desired result.

Fig. 2

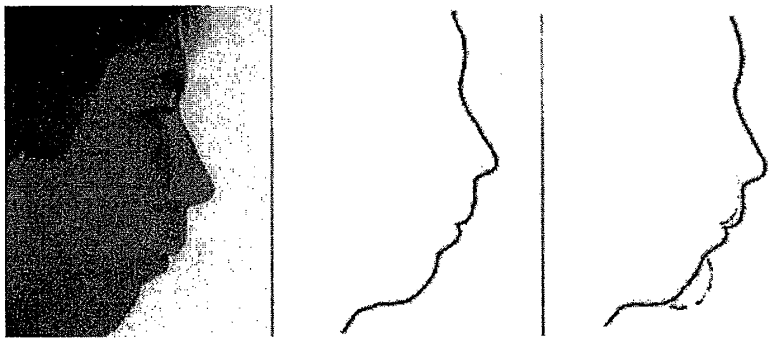


Fig. 2 Pretreatment photograph and acetate tracing of retrognathic patient with steep mandibular plane; acetate tracing of desired profile change.

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Fig. 3

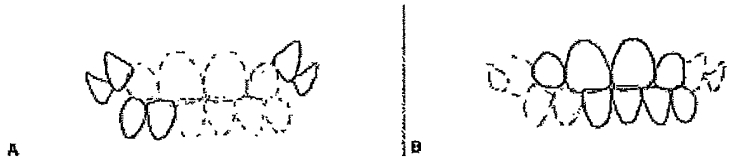


Fig. 3 A. Graphic artist first rotates upper and lower Incisors Into desired positions. **B**. Remaining teeth are repositioned according to prescription.

Fig. 4



Fig. 4 Computer treatment estimates of patients in Figs. 2, 3.

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Fig. 5

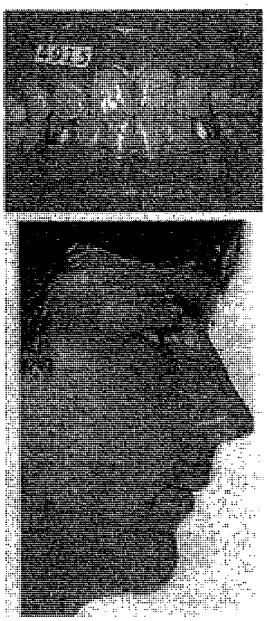


Fig. 5 Actual post-treatment photographs of patients in Figs. 2, 3.

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Fig. 6

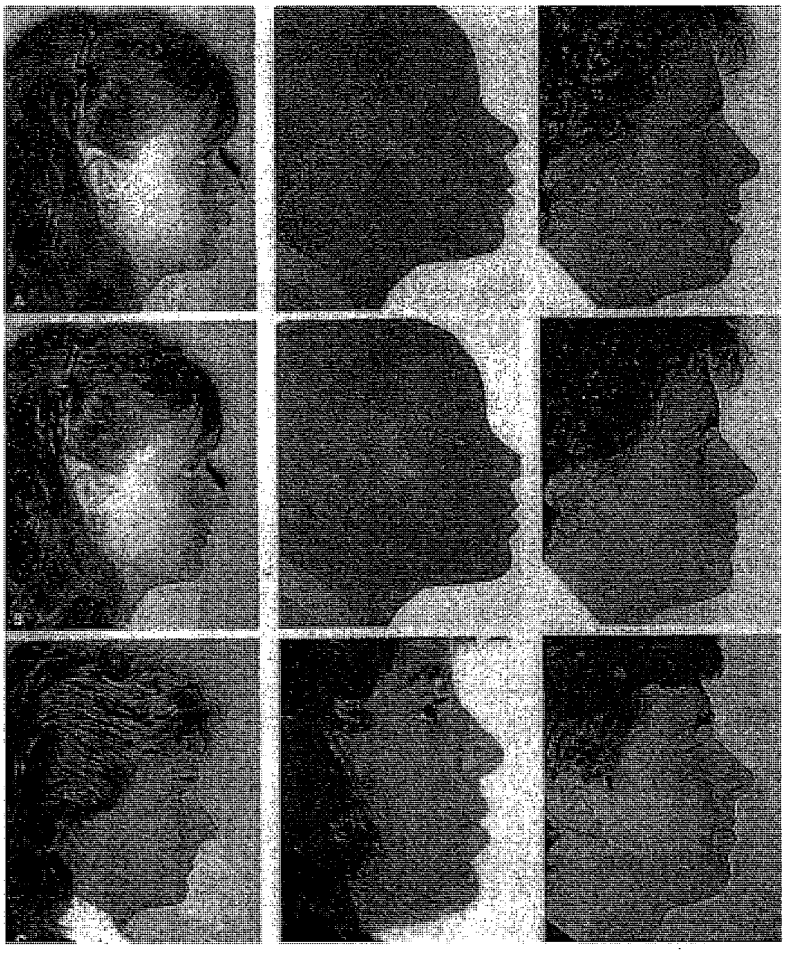


Fig. 6 A. Pretreatment photographs. **B**. Computer treatment estimates. **C**. Post-treatment photographs.

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Fig. 7

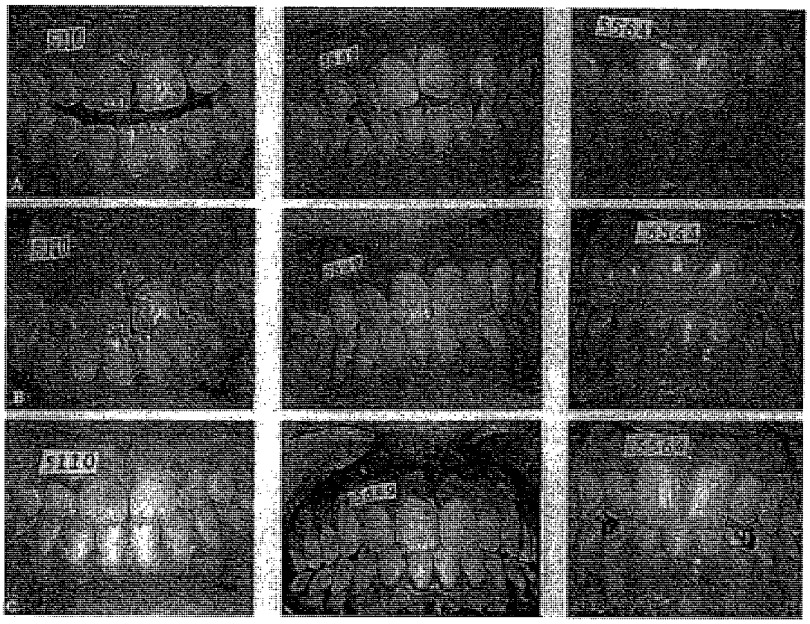


Fig. 7 A. Pretreatment photographs. **B.** Computer treatment estimates. **C.** Post-treatment photographs.

Fig. 8

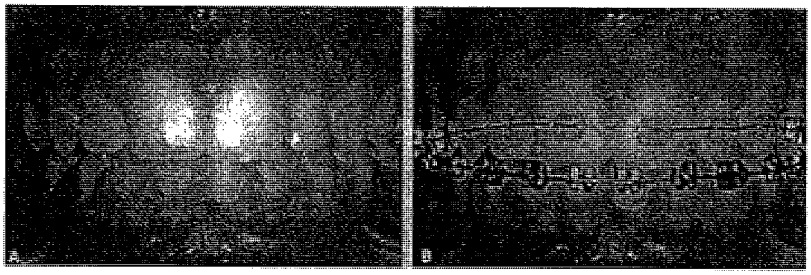


Fig. 8 A. Pretreatment photograph. **B.** Ceramic brackets added by computer for patient evaluation; note extra mandibular right first bicuspid bracket.

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Fig. 9



Fig. 9 A. Actual progress photograph. **B.** Computer estimate of bicuspid extractions.

Fig. 10



Fig. 10 A. Pretreatment photograph of patient with deep mentolabial fold and maxillary incisor procumbency. **B.** Computer treatment estimate.

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References

1. Lewell, J.: *Computer Graphics,* Orbis Publishing Ltd., London, 1985.

2. Guess, M.B. and Solzer, W.V.: Computer-generated treatment estimate, J. Clin. Orthod. 21:382-383, 1987.

3. Guess, M.B. and Solzer, W.V.: Computer-generated diagnostic correction of anterior diastema, J. Prosth. Dent. 59:629-432, 1988.

4. Ricketts, R.M. et al.: *Bioprogressive Therapy,* Rocky Mountain Orthodontics, Denver, 1980, pp. 3549.

5. Holdaway, R.A.: A soft-tissue cephalometric analysis and its use in orthodontic treatment planning, Am. J. Orthod. 84:1-28, 1983, 85:279-293, 1984.

6. AAO Bulletin, January 1988, p. 6.

7. Cutting, C. et al.: Three-dimensional computer-assisted design of craniofacial surgical procedures: Optimization and interaction with cephalometric and CT-based models, Plast. Reconstr. Surg. 77:877-885, 1986.

8. Marsh, J.L. et al.: Computerized imaging for soft tissue and osseous reconstruction in the head and neck, Clin. Plast. Surg. 12:279, 1985.

9. Toth, B.A.; Ellis, D.S.; and Stewart, W.B.: Computer designed prosthesis for orbitocranial reconstruction, Plast. Reconstr. Surg. 81:315-324, 1988.

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2092 Digital Subtraction without Cephalostats and Stents. S. DUNN* (New Jersey Dental School, Newark, New Jersey and Rutgers University, Piscataway, New Jersey).

Previous studies have shown that digital subtraction radiography is an effective diagnostic tool for the early detection of periodontal disease. The difficulty with existing systems is that they require extraoral mechanical control of the imaging geometry for exact registration of the radiographs. The purpose of this study is to show that extraoral mechanical control is not necessary and that registered images for subtraction can be obtained using a different model of the imaging geometry. The new method is based on a model of projective invariants. The mathematics describe how properties of objects remain the same even under different imaging geometries. The position of any point is expressed using coordinates that are independent of the image coordinates, angulation or translation errors. A standardized series of 87 radiographs from the bicuspid-molar region of a dry mandible were taken with known translations of 0, 2, 4, 8 and 16mm in both horizontal and vertical directions and rotations about both axes of 0, 2, 4, 8, 16 and 32°. The focus to film distance was 30cm and the object to film distance was as short as possible, the exposure was at 60KVp and 12mA. The films were digitized to a resolution of 480 by 512 with 8 bits per pixel. A synthesized view is created by computing the invariant coordinates of each point in the film with angulation error and computing its position in an image with the desired orientation. The synthesis is repeated for each of the 86 films and then subtracted from the original digitized radiograph. A multiway ANOVA ($p<0.01$) shows that the difference is independent of position in the film, translation error or angulation error. Thus, digital subtraction can be done by synthesizing images without cephalostats and stents.

2093 Texture Measurements as Predictors of Correctness of Subtraction Evaluations. K. ALLEN*, E. HAUSMANN, M. PIEDMONTE, L. EMRICH (University at Buffalo, School of Dental Medicine, Buffalo, NY, USA).

Two logistic regression models were were developed to assess the relationship of texture measurements made on subtraction images of serial radiographs to the correctness of evalutions of crestal bone change made on the radiographs. 20 trained observers evaluated 64 subtraction images from radiographs made on skulls where the parameters of lesion size, angle discrepancy of x-ray beam orientation of the two serial radiographs, and the amount of soft-tissue equivalent material present were experimentally controlled. For each subtraction 30 texture measurements were made in the trabecular region. A stepwise regression procedure was used to determine which were the best predictors of the correctness of evaluations made by the observers. The models were validated on a set of independent observations. Model 1 predicted 98% of correct evaluations and 11% of incorrect evaluations correctly; Model 2 predicted 93% of correct evaluations and 21% of incorrect evaluations. The amount of soft tissue equivalent material present was then introduced as an additional factor into the models. Then Model 1 predicted 74% of correct evaluations and 58% of incorrect evaluations correctly; Model 2 predicted 88% of correct evaluations and 24% of incorrect evaluations. The presence of different amounts of soft tissue affect the predictive ability of texture measurments. NIH Grant DE08544.

2094 Computer-based Image Analysis of Artificial Root Surface Caries. T. J. HEAVEN*, F. F. FEAGIN[1], A. R. FIRESTONE (U. of Alabama, [1]School of Dentistry, Physiology & Biophysics, Birmingham, AL).

A limitation of radiographic films of teeth for the diagnosis of approximal caries is the variability introduced during clinical interpretation of the radiograph. Extracted human premolar roots (n=9) were painted with epoxy except for a 2 mm^2 window and exposed to an *in vitro* caries system for 13 days. Clinical radiographs were taken using intraoral ultraspeed film. 5 of the roots were subsequently exposed to a remineralizing system for 8 days and radiographed once during and again after this period. A thin section (200 μm) was then cut from each lesion and microradiographed. An image analysis system was used to automatically locate the lesion and measure maximum lesion penetration, mean lesion penetration, area, and mean lesion mineral density relative to sound dentin on the the clinical films and the microradiographs. The mean lesion mineral density was statistically different ($p<0.05$, ANOVA) in the remineralized group as compared to demineralized-only group, as measured on the microradiographs. Correlation between parameters from the microradiographs and clinical films was strongest for mean penetration ($r=0.88$). The mean coefficient of variation for each parameter as measured from the two types of film was <10%. This system can provide objective quantitative measurements from clinical films and microradiographs. Supported in part by NIDR Grant 06951 and NIH BRSG SO7 RR05300.

2095 Evaluation of Site-Specific Differences in Trabecular Bone Using Fractal Geometry. R. L. WEBBER*, J. B. HAZELRIG, J. R. PATEL, H. R. VAN DEN BERG, and J. E. LEMONS. (Bowman Gray School of Medicine, Winston-Salem N. C. and the University. of Alabama at Birmingham, Birmingham, Alabama, U. S. A.)

Previous work by Ruttimann and colleagues showed that the fractal dimension obtained from analysis of existing uncontrolled dental radiographs of pre- and post-menopausal women discriminated between these groups. This controlled *in vitro* study is an extension of that work intended to determine the sensitivity of the method to variations in projection geometry, to anatomical location, and to the degree of mineralization of the trabecular bone.

10 osseous jaw segments from two mandibles were radiographed at three constrained angles spanning a range of ten degrees before and after demineralization of the trabecular bone by osseous infusion with 10% formic acid. Mineral loss was computed by chemical analysis of the filtrate. Fractal dimension was computed from digitized images of the radiographs using the method described by Ruttimann.

Analysis of the data (three factor, factorial ANOVA) shows that fractal dimension discriminates between anatomical location of the trabecular bone ($p<0.01$) and the degree of induced demineralization ($p<0.05$), irrespective of the angles used to produce the radiographs.

2096 Digital Quantification of the Trabecular Pattern and the Effects of Magnification. P.F. VAN DER STELT* and W.G.M. GERAETS (Academic Center for Dentistry Amsterdam, Amsterdam, the Netherlands).

Previous studies have shown a correlation between several parameters describing the structure of the trabecular bone pattern and diseases related to changes in bone metabolism, e.g., osteoporosis. These parameters can be obtained by means of digital image processing of bone radiographs. So far a rigid standardization (gradient, magnification, projection, etc.) has been used when digitizing the area of interest. This study aims at the effect of magnification on the reliability of the parameters used. A high correlation of a parameter with magnification means that magnification must be standardized in order to obtain reproducible results. Twelve radiographs were randomly selected from a pool of 1058 human wrist radiographs. A 20x20 mm section of the trabecular area depicted on these radiographs was digitized as 512x512x8 bit images (1 pixel = 0.04 mm). Subsequently this area was magnified in 10 steps, each time with a factor of two. Eleven parameters were determined for each radiograph and each magnification. These parameters included the 'length of the trabecular pattern', the number of 'nodes' and 'endpoints', the 'fractal dimension', the 'area of bone', and others. All parameters showed a significant correlation with magnification (Pearson's r = between 0.922 and 0.983, $p<0.05$) except for the 'fractal dimension' ($r = .833$) and the 'area of bone' ($r = -0.555$). The 'fractal dimension' was constant up to a magnification of 16. This means that magnification is an important factor which has to be kept constant in order to obtain a standardized quantitative description of the trabecular pattern. The findings support the fractal geometry of the trabecular pattern found in previous studies. This study was supported by the Dutch National Informatics Facility, Grant NF-62-296.

2097 Alveolar Bone Quality Classification. C.F. HILDEBOLT*, M.W. VANNIER, M. J. GRAVIER (Washington Univ., St. Louis), D.J. ZERBOLIO Jr. (Univ. Missouri, St. Louis), and M.K. SHROUT (Medical College of Georgia, Augusta).

A new method for objective classification of alveolar bone quality based on bitewing radiography was tested in dry skulls. The consensus of two experts was used to rate the bone quality of the right and left sides of 75 dry mandibles (150 quadrants). Ten (10) randomly selected quadrants with poor bone quality and 10 with good bone quality were radiographed. The radiographs were digitized, and cumulative relative gray scale frequency (CRGSF) histograms of alveolar bone distal to the first molars were used to develop a classifier that correctly rated 18 of the 20 quadrants. A test set of ten (10) additional randomly selected quadrants (5 = good and 5 = poor quality), not used in training the classifier development, were correctly rated by the classifier (accuracy = 90%). We found that alveolar bone quality determinations based on radiodensitometry agrees with subjective visual bone quality assessments in dry skulls. This study was supported in part by NIDR project DE08173.

2098 Artificial Intelligence in Oral and Maxillofacial Radiology. M.J. Bloom*, T. Liang, J. Peters, S. Shemlon, PJ Desjardins, & S. Dunn, UMD-New Jersey Dental School, Newark, NJ

The purpose of this study was to determine the feasibility of using standard morphological criteria to count the number of teeth in a digitized panoramic radiograph using a rule-based expert system. Five panoramic radiographs of skulls with intact dentition (32 teeth) were made using a General Electric Panelipse Machine. The panoramic films were then digitized using TIPS software/Hewlett-Packard Vectra computer. Each film was then segmented and used to create a database describing the morphologic features found in each radiograph. The rule-based expert system, written in "PROLOG", was created using Wheeler's Dental Anatomy text to describe the expected morphology of individual teeth. The expert system then compared the observed morphologic features in the digitized radiograph to the rules defined by the dental anatomy text. The rules include definitions of general shape, width, adjacency and occlusal opposition. The rule-based system correctly identified all of the teeth present in 4 of the radiographs. [Two teeth were missed in the 5th radiograph.] The results suggest that it is feasible to automatically interpret dental radiographs using standard morphologic features of the dentition. Supported by UMDNJ Foundation and Warner-Lambert Bioengineering Fellowship.

2099 Automated Identification of Landmarks in Cephalometric Radiographs. B. PASS* and P.H. GREGSON (Univ. of Texas HSC at San Antonio, Texas, and the Technical University of Nova Scotia, Canada).

Cephalometric (lateral skull) radiographs contain anatomical landmarks that are used to calculate characteristic dimensions. These dimensions are used to diagnose craniofacial malformations and aid in treatment planning. At present the landmarks are located manually while viewing the radiograph on a light table. This process is subject to variation between observers and also between repeated assessments by the same observer. A prototype computer program has been developed that can automatically locate these landmarks. The algorithm accomplishes this using image processing and feature recognition techniques. Constructing a resolution pyramid enables the algorithm to work on smaller, lower resolution images in order to substantially reduce the number of computations. Prefiltering, using a median filter, and edge enhancement, using gradient operators, are performed on the images. The algorithm is then supplied with anatomical knowledge in order to search for features containing the landmarks. At present the program locates 17 bony and 10 soft-tissue landmarks. A preliminary test of the algorithm compared its performance with 2 experts in locating 9 landmarks on 5 cephalograms. The interobserver and computer-observer discrepancies, taken as geometrical distances between marked points, were the same to a significance level of 0.05 using a two-tailed paired t-test. By implementing computer image processing techniques it may be possible to significantly improve the reliability and accuracy of cephalometric analysis.

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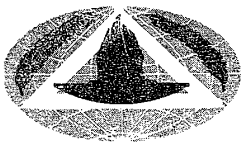
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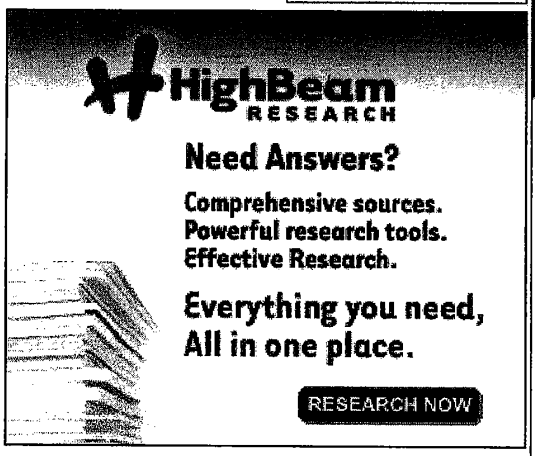
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Tooling & Production

November 01, 1996

Dental implants are fixtures for artificial teeth that are implanted directly into the jaw bone. As a permanent replacement for missing teeth, they are growing in popularity over the traditional denture treatment, but the current state of the art in implant technology can use some improvement. Current implants can come loose, and by exerting excessive levels of stress on the jaw, they can ultimately cause the bone to weaken.

ANSYS Inc's (Houston, PA) finite element analysis (FEA) software is being used by Crystal Medical Technology, Birmingham, AL, to simulate stresses on the jaw caused by dental implants. Crystal was founded by Clint Folsom with the goal of improving dental implant technology. "He setup Crystal to improve on dental implants which incorporate two or three threaded connectors depending on the design," says Greg Bailey, engineering manager at Crystal, who has worked with Mr Folsom for 8 years. "We've gone from 7[inches]-dia pipe threads to 2mm





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Integrated Orthodontic Management System for Virtual Three-Dimensional Computer Graphic Simulation and Optical Video Image Database for Diagnosis and Treatment Planning

Kiyohito Hikage (Research Student, Department of Orthodontics, School of Dentistry, Niigata University (Director Prof. Kooji Hanada); Hikage Orthodontic Clinic

Received February 26, 1987

Keywords: Virtual three-dimensional computer graphic simulation, Visual Treatment Objective (VTO), computer analysis of patients with malocclusion, computer diagnosis, orthodontic clinical simulation system

Abstract: The purpose of the research is to automate the diagnosis and the establishment of a treatment course in clinical orthodontics by the use of cephalograms and the simulation analysis of dental arches and, at the same time, to realize an integrated computerized clinical orthodontic support system that uses optical still-image disk drives to manage raw image data allowing, for example, a quick retrieval of photographs.

To achieve the said purpose, the following system was developed and its feasibility was studied for practical use.

1) Using cephalograms and life-sized photographs of upper and lower dental arches as point data, approximately 200 persons and their individual case IDs were stored in a 1 MB disk to determine the measurement points that will provide an efficient data storage and a realistic reproduction.
2) For each case, 7 cephalograms were used, each with 96 points. 68 data points were stored as upper and lower dental arch data for three courses. During analysis, realistic teeth and occlusion arch form images based on cephalogram trace lines and tooth crown patterns were reproduced. In synchrony with this, virtual three-dimensional setup models were constructed. Numerical analysis and graphic simulation on a monitor and output from a plotter were automated at the same time and used with the cases.
3) In forecasting natural growth and changes in treatment with the growth, VTO was automatically constructed using realistic forecasted images to quantify the diagnosis of hard tissue and soft tissue.
4) In pattern matching of cephalograms, the degree of improvement in discrepancy and aesthetics and the need for improvement were automatically calculated visually for the forecasted and actual growth and change in treatment for hard tissue and soft tissue by total area superimposition (TS) and 6-area superimposition (6S).
5) In the simulation of dental movement, individual ideal arches were created using virtual three-dimensional models that worked in synchrony with computerized VTO of dental movement, discrepancy and tooth extraction and non-extraction.
6) Profilograms, polygons, 11 factors and 32 factors were output and displayed to supplement the visual display.

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7) Raw image data representing intraoral, craniofacial and X-ray photographs were recorded on an optical disk and stored in an image relational database that was linked with a simulation system to create an integrated system.

Preface

Remarkable improvements have been made in recent years in the field of clinical orthodontics in terms of techniques, knowledge and concepts. Quantitative analysis in the field of orthodontics began with the development of cephalometric roentgenography by Broadbent and Hofrath in 1931. Various attempts have been made and various methods have been devised and used for the evaluation, research and diagnosis of cranio-maxillo-facial growth.

In particular, Savara[31], Walker[32] and others have blazed the trail for the use of computers with cephalograms[24, 26]. Rickets, Gusino[28 - 30] and others have also developed a computerized system called bioprogressive therapy system[7, 8] for diagnosis and treatment planning[25, 27]. In Japan, computers have been tried, for example, with polygon tables and profilograms and for model analysis and automatic extraction of measurement points.[4 - 8, 10, 13 - 19]

Personal computers have entered the age of 16-bit [architecture], and 8086 microchip processors being used by many Japanese domestic manufacturers have provided a performance high enough to withstand practical use in various fields. A 16-bit personal computer, a digitizer, a high-resolution color CRT monitor, a 24-dot Kanji printer and a high-speed color multi-pen XY plotter were used to configure a system to achieve the following objectives.[1-5, 9, 11, 12, 15, 20-23]

1) To automatically output profilograms and polygon tables for different analytic methods.

2) To automatically create cephalogram trace lines, and display and output growth/treatment forecasts based on Visualized Treatment Objective (VTO).

3) To identify changes in teeth, chin jaw, cranium and lips to enable a visual analysis of the discrepancy or malocclusion or the aesthetics of hard tissue and soft tissue.

4) To create a virtual three-dimensional setup model based on cephalograms and dental arches and simulate the growth changes of the mandibula, teeth and lips and changes in treatment.

5) To link[12, 20] the image databases that use optical still image disk drives as a relational database[9] and to simultaneously provide a real-time display on a monitor of the aforesaid analysis and the raw data (cephalograms, panorama X-ray photos, facial and intraoral photos) immediately when necessary.

When the above-described system was studied for its use in the diagnosis and the establishment of treatment policies for orthodontic patients, its efficacy for clinical use was also established as described further in this paper.

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System Configuration and Analytic Method

1. Hardware Configuration

The simulation system that was researched and developed used cephalograms and life-sized photographs of oral cavity models as raw data. Point data expressed as XY coordinate values read by a digitizer are saved in a data disk. When a new case is registered in a data disk, a case ID (identification) is assigned. When data representing a treatment course is added, the case number is entered. Based on the case number, the date of birth, date of first dental examination and other information are read from the data disk. The date of data collection and the [patient's] age that is automatically calculated are automatically saved as well. When an analysis is performed, trace line drawings based on cephalogram data, and teeth and occlusion arch form images based on dental arch data are realistically displayed on a CRT.

The cephalogram trace line drawings, and teeth and occlusion arch form images are synchronized to create a virtual three-dimensional setup model by computer graphic simulation. Raw image data based on X-ray photographs and dento-facial photographs are read by a 3-tube video camera and recorded on an optical still-image disk that is linked with a relational database to create an image database that comprise an integrated system.

The hardware configuration of the system is shown below (Figures 1 through 5).

1) Computer

16-bit personal computer

MULTI 16 III or II (manufactured by Mitsubishi Electric)

IF-800 model 50 (manufactured by Oki Electric Industrial)

2) Digitizer

Gradimate [transliteration] U4-30 (manufactured by Oscon Denshi Sha [transliteration])

3) High-speed color XY plotter

FP 5301 (manufactured by Graphtec)

4) 24-pin Kanji printer

5) Disk drives

8-inch floppy disk drive: 1 megabyte x 2

5-inch floppy disk drive: 1 megabyte x 2

8-inch hard disk drive: 10 megabytes x 2

6) Optical still-image disk file system

TQ-2300F (manufactured by Matsushita Electric)

7) Three-tube color video camera

WY-5000 (manufactured by Matsushita Electric)

8) Polaroid camera with 1x magnification

Orthoscan camera (manufactured by Unitech)

9) High-resolution color CRT monitor

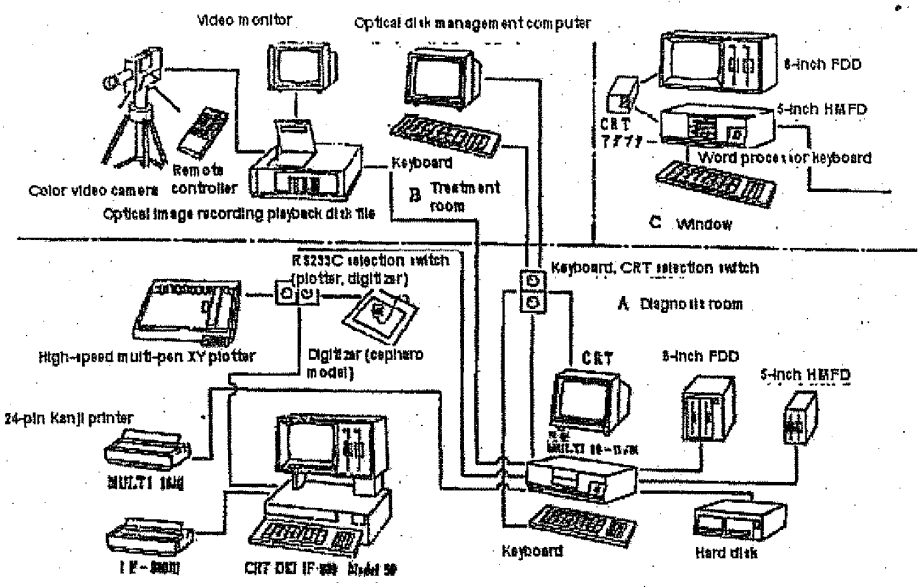


Figure 1 Integrated Orthodontic Clinical Support Hybrid System

A: Virtual three-dimensional cephalo model setup simulator analysis computer system

B: Semiconductor laser read/write retrieval filing optical disk system

C: Patient management system using a relational database



Figure 2 Virtual three-dimensional cephalo model setup simulator analysis computer system (Figure 1, A)

A: CRT 640 x 475 dots, 8 colors; AA: CRT 640 x 400 dots, 8 colors; B, BB: Computer; C: 8-inch FDD, 1 MB x 2; D: 5-inch HM FD, 1 MB x 2; E: 24-pin Kanji printer; F: High-speed multi-pen XY plotter; G: Digitizer; H: Hard disk, 10 MB x 2; I: Keyboard

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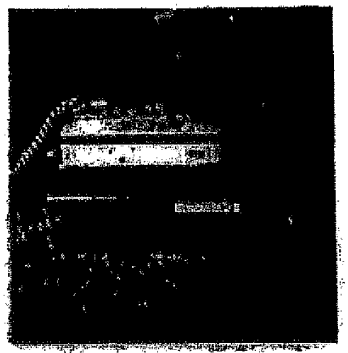


Figure 3 Polaroid camera for entering teeth and dental arch data

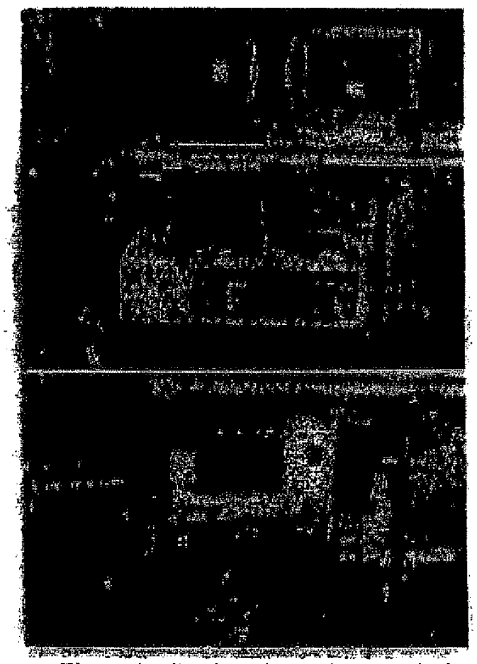


Figure 4 Semiconductor laser optical reading/writing retrieval filing optical disk system (Figure 1, B)
A: Main unit; B: 3-tube color video camera

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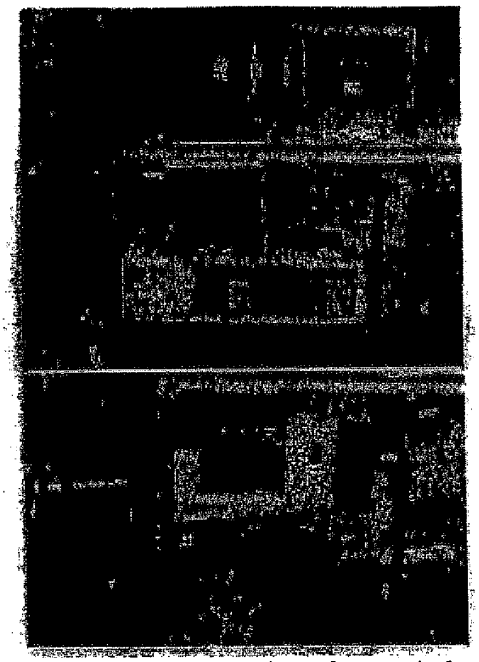


Figure 4 Semiconductor laser optical reading/writing retrieval filing optical disk system (Figure 1, B)
A: Main unit; B: 3-tube color video camera

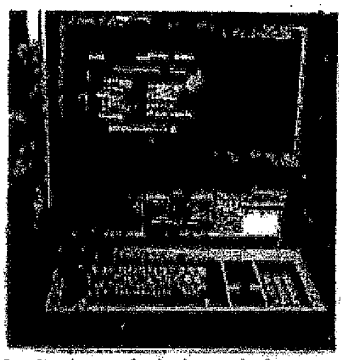


Figure 5 Patient admission window management system using a relational database (Figure 1, C)

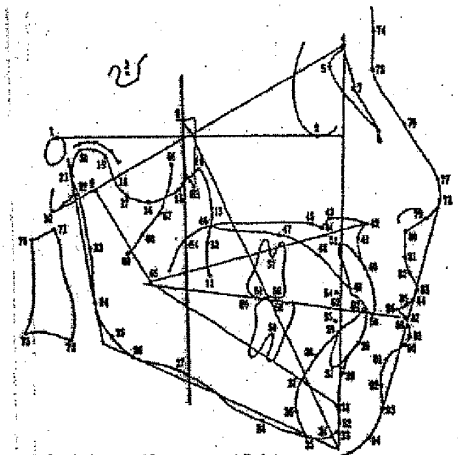


Figure 6 Cephalogram Measurement Points

1 P	2 OR	3 S	4 NA	5 N2	6 N3	7 N4	8 PT		
9 DC	10 BA	11 Md1	12 Md2	13 Md4	14 Cp	15 Md6	16 Gn		
17 Md7	18 Md9	19 Md10	20 MD11	21 Md12	22 AR	23 Md14	24 Md15		
25 CC	26 Md17	27 Md18	28 Md19	29 Sy1	30 B	31 PM	32 PO		
33 Pog	34 GN	35 ME	36 Sy8	37 Sy9	38 Sy10	39 Sy11	40 Mx1		
41 A	42 ANS	43 Mx4	45 Mx5	46 PNS	47 Mx8	48 Mx9	49 Mx10		
50 UIcd	51 UIm	52 LIcd	53 LIm	54 UC	55 LC	56 UMBcd	57 UM6rt		
58 LMBcd	59 LM6rt	60 UMdist	61 LMdist	62 TI	63 PTM	64 SP	65 XI		
66 Ad1	67 Ad2	68 Ad3	69 Ad4	70 Ax1	71 Ax2	72 Ax3	73 Ax4		
74 SF1	75 SF2	76 SF3	77 SF4	78 EN	79 SF6	80 SF7	81 AS		
82 SF9	83 UL	84 SF11	85 SF12	86 EM	87 SF14	88 SF15	89 LL		
90 SF17	91 BS	92 SF19	93 DT	94 POS	95 GNS	96 MBS			

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2. Measurement Points

Ninety-six (96) measurement points were selected to obtain cephalogram data. These points were decided based on their need for reproducing cephalogram trace line drawings, performing numerical analysis of angles, lengths and the like and for preparing different polygon tables. The selection of 96 points was also meant to improve data storage efficiency (Figure 6). As for the dental arch data, to enable the reproduction of the teeth and occlusion arch form images based on dental crown patterns and to perform numerical analysis and the preparation of polygon tables, a total of 68 points (a maximum of 76 points if the third molar has erupted) were selected (Figure 7) broken down as 2 mesio-distal contact points for each tooth, 56 points for the left and right sides of the maxilla and the mandibula if the second molar has erupted, 4 points as reference points for the reference line with the maxilla and mandibula occluded and 8 points for basal arch width and basal arch length for the maxilla and the mandibula. Figures 8 and 9 show the lengths and angles of the items used for analyses in the cephalograms with the subject system.

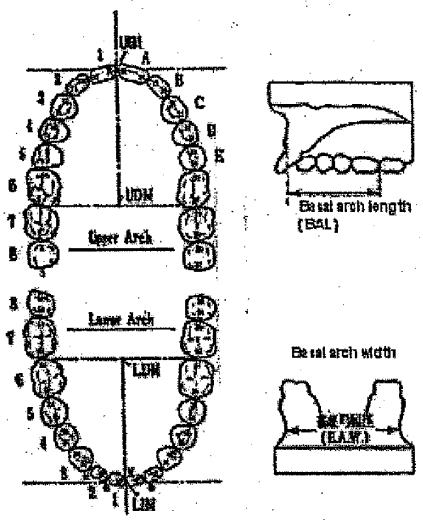


Figure 7 Measurement Points for Dental Arch Model

3. Virtual Three-dimensional Setup Model

Seven (7) cephalograms were stored for each case. For each cephalogram, 96 points were read from the data disk to recreate the cephalogram trace line drawing. Porion, orbitale, sella turcica and upper and lower central incisors and the first molars were stored in advance as pattern data with 18 points in the program disk. The data was read out during analysis, and automatic drawing and output were done in synchrony for each point.

Three courses of dental arch data were stored in the data disk for each case, namely, before, during and after treatment. For each course, 68 points were read out during analysis to create a teeth and occlusion arch form images. As for dental crown patterns, 13 points representing the standard morphology for each tooth were stored in advance in the program disk for 32 teeth. They were synchronized at the mesiodistal contact points when displaying for analysis, and teeth and occlusion arch form images were created adjusted to

match the magnification in length. To synchronize the cephalogram trace line drawings and the teeth and occlusion arch form images, corrections were made to match the incisal edge of the central incisor and the first molars. A virtual three-dimensional setup model was created in synchrony, thus allowing a visual analysis and numerical analysis to be performed at the same time.

Figure 10 shows an actual simulation using a virtual three-dimensional setup model of growth and change in treatment of maxillary prognathism.

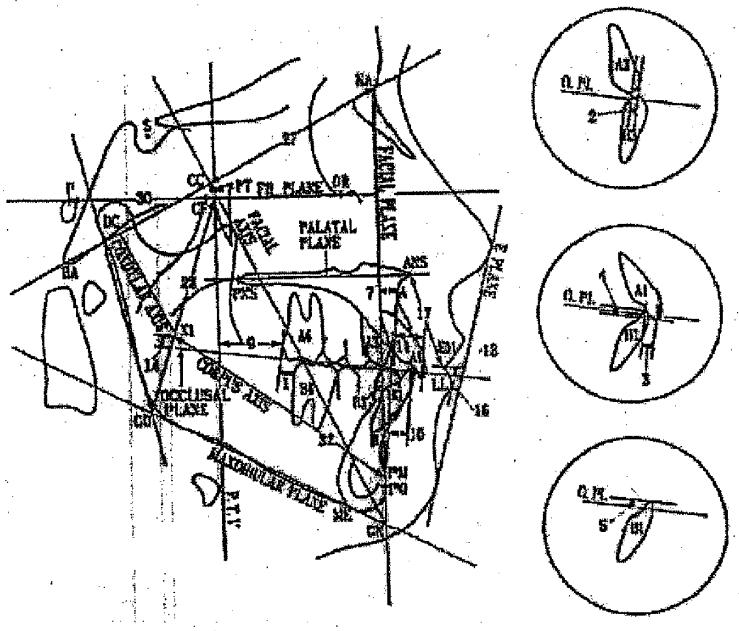


Figure 8 Analyzed Items (Lengths)

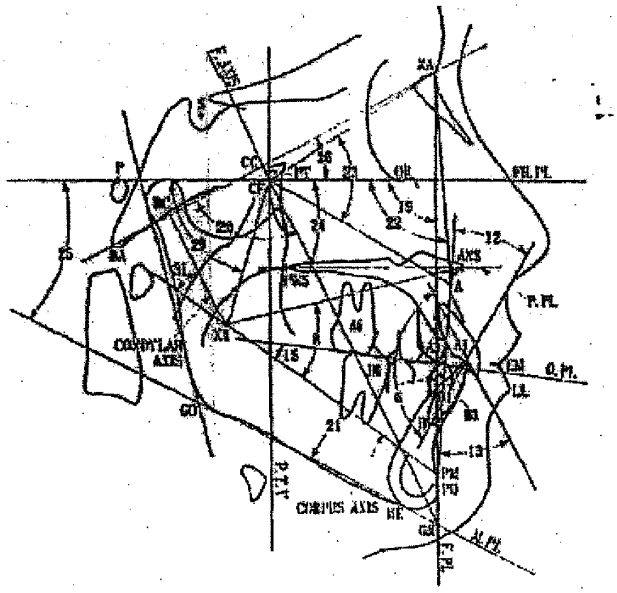


Figure 9 Analyzed Items (Angles)

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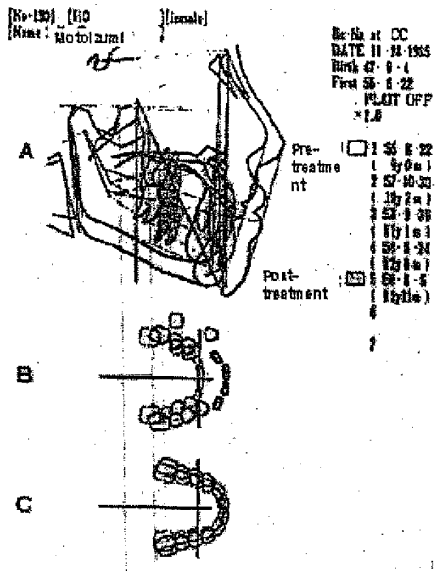


Figure 10 Virtual Three-Dimensional Setup Model

A: Computer graphics-generated cephalogram trace line drawings by superimposition of pre- and post-treatment

B: Dental arch model pre-treatment

C: Dental arch model post-treatment

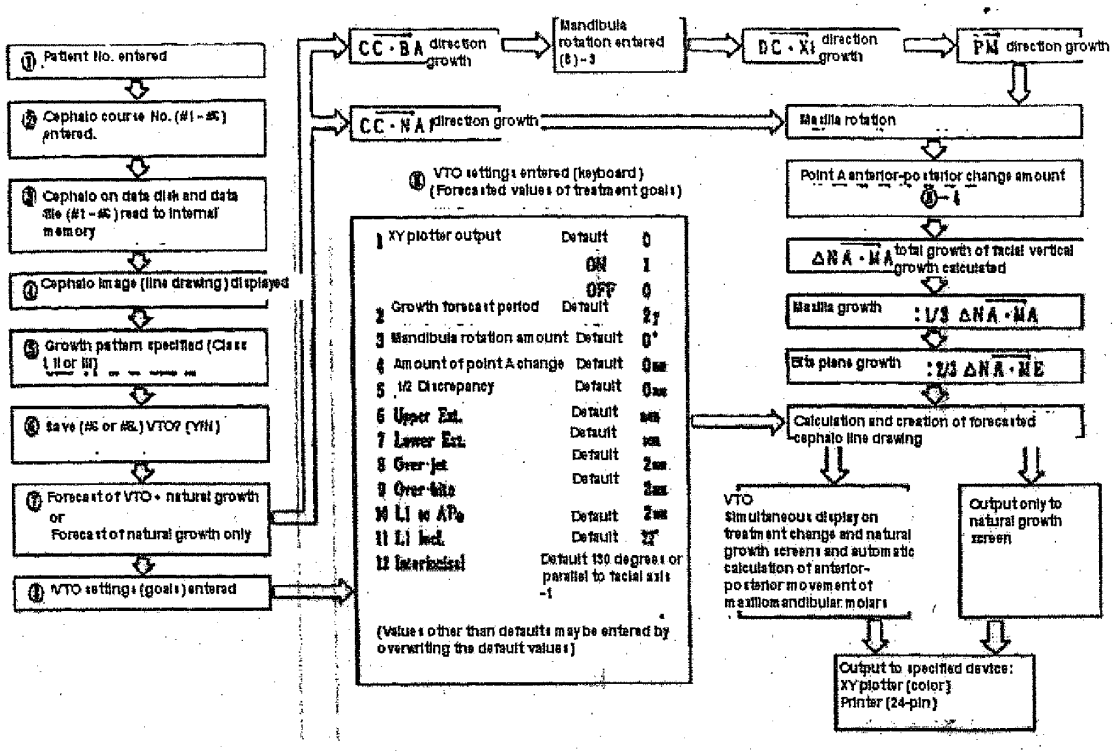


Figure 11 Flowchart and Algorithm for VTO Creatio0n Program Based on Computer Graphic Simulation to Forecast Growth and Change in Treatment

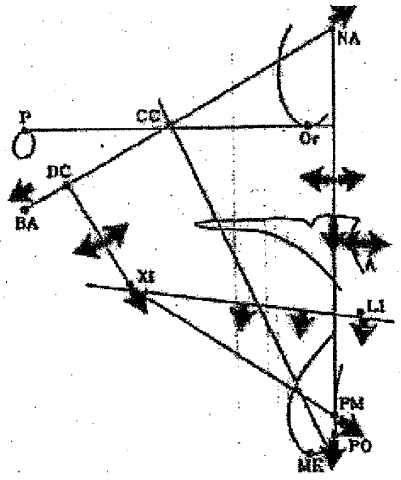


Figure 12 Summary Growth Algorithm of Growth Vectors of Different Areas in C-VTO

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4. Use of Computer VTO to Forecast Growth and Treatment Change

The VTO method developed by Ricketts was modified to create a computerized VTO ("C-VTO") that used computer graphics. Cephalogram trace line drawings were automatically created from 96 data points to forecast growth and change in treatment. Figure 11 shows the program flowchart and the algorithm. To better approximate the growth change for specific individuals, the following definition was used:

> Individual growth amount = growth amount of visual norm x IL (individual length)/VNL (visual norm length)

Visual norm is the average visual value from cephalogram trace line drawings from 96 points for each age. Visual norm length is the length of specific areas based on the visual norm. Specific areas refer to CC-NA, CC-BA, CC-Xi, Xi-PM, NA-ME, NA-ANS, NA-TI and CC-GN.

C-VTO allows the forecasting of natural growth (defined as growth under nontreatment), and growth and change in treatment. Twelve (12) items can be set interactively reflecting the practitioner's experience. The growth of different areas and the amount and the need of treatment can be studied and forecasted. The process by which aesthetics and discrepancy can be resolved for hard tissues and soft tissues was identified.

A default value is set for each item required for achieving the ideal goal. The practitioner enters values for each item considering the amount of improvement possible with treatment based on his experience. When values are set for all items, a VTO is automatically created, and CC-NA-BA drawing is superimposed on the cephalogram trace line drawing before change and displayed. For evaluation purposes, a menu allows the selection and display of a partial superimposition display of 6 areas (6S). The superimposition of 6 areas (6-area superimposition) is represented as 6S, and the specific areas referred to by 6S are: 1S, NA-BA at CC; 2S, NA-CC at NA; 3S, E-line at a point of intersection E-line and occlusal plane; 4S, mandibular plane at Go' (Go' is the intersection between point 21-24 line and mandibular plane); 5S, mandibular plane at Pog; and 6S, palatal plane at ANS.

The 12 items used for creating VTO and their default values and preferred values are as follows.

1) The default value for "outputting to an XY plotter" is 0. "1" is entered to produce an output.

2) The default value for "growth forecast period" is 2 years (y). The units used for the input is years, and the value should preferably be 3 years or less. The value of 0 is used for adults.

3) The default value for the "amount of rotation of the mandibula is 0°. Rotation in the clockwise direction is indicated by a minus (-) sign. The default value for the facial axis is assumed to be constant, but a desired value may be entered to rotate and change the direction of growth of the mandibula.

4) The default value for "amount of change of point A" is 0 mm. A desired value is entered if point A is to be controlled by orthopedic changes.

5) The default value for "1/2 discrepancy" is 0 mm. The value that is entered is one-half of the shortage of eruption space prior to change, i.e., one-half of the total sum of the amount of overlap due to crowding.

6) The default value for "Upper Ext" is no dental extraction. If dental extraction is performed, 4 is entered for the first premolar, and 5 is entered for the second premolar.

7) The default value for "Lower Ext" is the same as that for the upper jaw.

8) The default value for "Overjet" is 2 mm.

9) The default value for "Overbite" is 2 mm.

10) The default value for "L1 to APo" is 2 mm. The distance from the occlusal plane to the incisor edge of the mandibular central incisor is 1 mm and the distance to the APo line is 2 mm. The distance to the APo line can be changed by entering a value for the length.

11) The default value for "L1 inclination" is 22°. The desired angle between the mandibular central incisor and the APo line is entered.

12) The default value for "Interincisal" is 130°. The desired angle is entered, and "-1" is entered to set maxillary central incisor to be parallel to the facial axis.

After these inputs are made, the change with treatment of the maxillary and mandibular central incisors and the amount of mesiodistal movement (1: A1, 6: A6, 1: B1, 6: B6) of the maxillary and mandibular first molars are automatically calculated and forecasted. The amount of additional torque on the bracket of the maxillary central incisor is automatically calculated and displayed at the same time.

The VTO is automatically created in the afore-described manner. The sequence of the algorithm is described next with reference to a flowchart (Figure 11).

① VTO is selected in the main menu, and the case to be forecasted is selected. When the case number is entered, ID data such as the case name, date of birth and the age at the time of the first dental examination, the date on which the stored cephalogram was taken and the age at that time, and the course number are displayed. ② The course number of the cephalogram to be forecasted is entered. ③ Point data of the desired cephalogram is read into an internal memory from the data disk. ④ The cephalogram trace line drawing is created on the screen. ⑤ The growth change pattern is specified. ⑥ Whether to store the results or not is entered. ⑦ Whether to forecast only the change with natural growth or the change due to a combination of natural growth and treatment is entered. ⑧ If the change due to treatment and growth is to be forecasted, the values for the aforesaid 12 items are entered, and a VTO output is obtained. To save the results, the VTO is stored in #6 (course number 6), and natural growth is stored in #7 (course number 7). These information can be retrieved and studied or analyzed at any time in the future just like any other course cephalogram data.

Figure 12 shows the growth vectors used with the C-VTO. Figure 13 shows the method by which the amount of additional torque on the bracket of the maxillary central incisor jaw required for achieving the treatment goal is automatically calculated.

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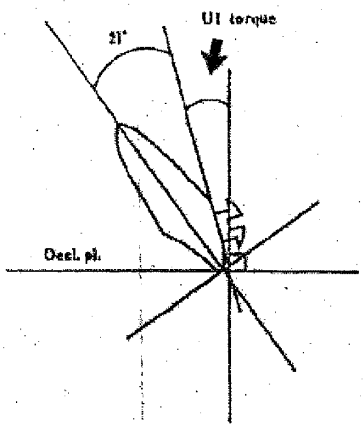


Figure 13 Automatic Calculation of Bracket Torque of Maxillary Central Incisor

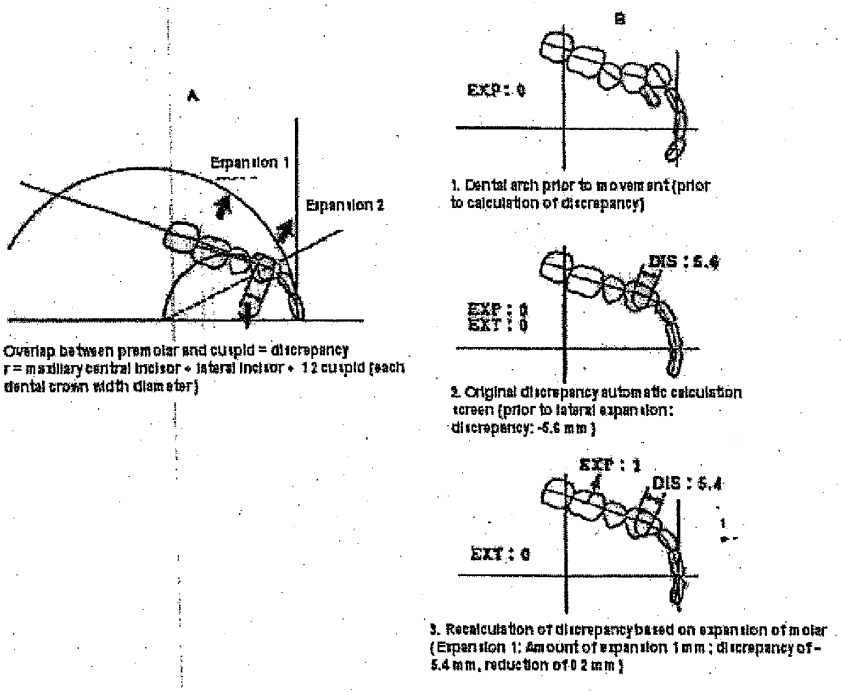


Figure 14 Automatic Calculation of Discrepancy During Dental Movement Analysis by Computer Graphic Simulation

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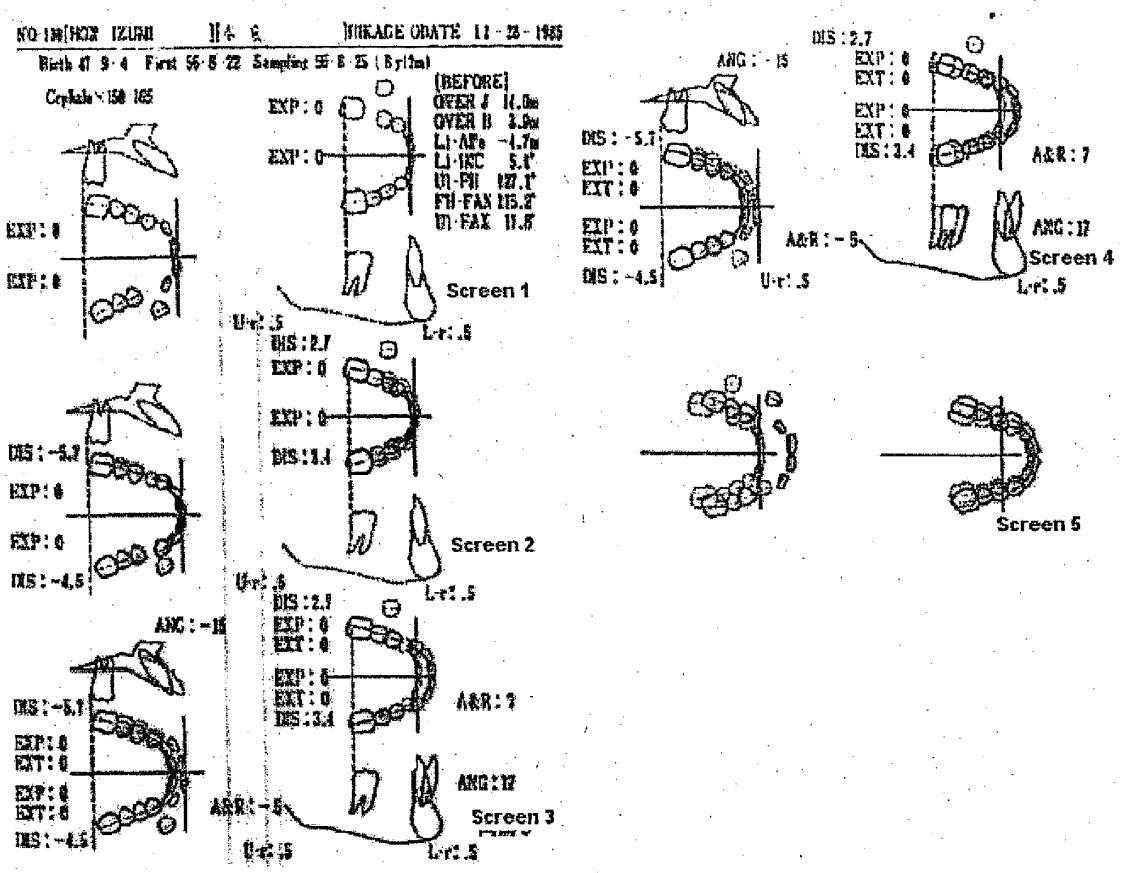


Figure 15 Computer Graphics Simulation of Teeth Movement for Case 1

Top left: Screen 1: Dental arch data image synchronized with magnification factor for cephalogram data before treatment

Center left: Screen 2: Automatically calculated simulation of discrepancy under expansion 0 condition specified interactively

Bottom left: Screen 3: Simulation of advancement of mandibular front teeth and retraction of maxillomandibular front teeth under condition of first molars being fixed

Top right: Screen 4: Simulation of space closing by advancement of first molar after movement of maxillomandibular front teeth

Bottom right: Screen 5: Simulation of dental arch in occlusional state before and after treatment

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Table 1 Mean and Standard Deviation for Sizes (mm) of Major Areas for Ages between 7 and 15

Hard tissue		Age 7	Age 8	Age 9	Age 10	Age 11	Age 12	Age 15
CC-NA	Mean	52.39	53.53	54.12	54.51	55.75	56.29	58.03
	Std. Dev.	2.32	2.73	2.44	2.65	2.73	2.56	2.83
CC-BA	Mean	42.50	43.47	44.15	44.94	45.98	47.01	50.11
	Std. Dev.	1.77	1.89	1.86	1.88	1.54	2.05	2.70
CC-CD	Mean	26.05	27.08	27.75	28.94	29.54	30.41	32.99
	Std. Dev.	2.24	1.78	1.95	1.82	2.04	2.22	2.09
CD-XI	Mean	27.56	28.60	29.47	30.33	31.02	32.07	34.93
	Std. Dev.	1.74	1.81	1.97	2.11	2.21	2.37	2.70
XI-PM	Mean	56.54	58.13	59.49	60.68	62.19	64.09	68.19
	Std. Dev.	2.64	2.72	2.64	2.55	2.43	2.94	3.30
NA-ANS	Mean	47.81	49.48	51.02	52.34	53.80	55.33	58.23
	Std. Dev.	2.10	2.38	2.43	2.49	2.26	2.56	2.77
NA-TI	Mean	70.38	72.10	73.69	75.87	77.20	79.45	83.44
	Std. Dev.	2.28	2.31	2.39	2.47	2.47	2.73	3.12
NA-ME	Mean	105.63	108.06	110.91	113.55	115.96	118.63	125.58
	Std. Dev.	3.17	2.92	3.25	3.56	3.15	3.88	5.25

5. Setup Model for Analysis of Tooth Movement

The system is capable of performing such things as automatically calculating the discrepancy and synchronizing the movement with the C-VTO based on cephalogram trace line drawings, the lateral movement for tooth extraction or non-extraction, molar and cuspid, advancement-retraction of the front tooth and the molar, the anterior-posterior positional relationship between the tooth axis of mandibular tooth and APo and the vertical positional relationship of their bite planes and the distance between soft tissues and the E-line. These items can be studied at the same time and displayed in different colors before and after the changes. Images of different parts can be displayed as static or dynamic images and superimposed on each other, allowing a dynamic analysis of visual images. To enable a simulation of the movement of the dental arch, three stages of course data are stored in a data disk for each case. During analysis, tooth crown pattern data is read from a program disk. At the mesiodistal contact positions for each case, course and dental arch point data that were accessed from the data disk, the individual tooth crown patterns are synchronized with individual tooth, and the position of each tooth is reproduced to match the magnification factor of the diameter in the width direction of the tooth crown for the specific case data, thus providing teeth and occlusion arch form images with a realistic morphology.

Figures 14A and B show the method used for the automatic graphic simulation of the discrepancy used by the subject system. The drawing method is a variation of the Bonwill-Hawley method. The front teeth are drawn as an arc that passes through the contact point. The radius r is a predetermined value that is the sum of the width diameter of the central incisor and the lateral incisor plus one-half of the width diameter of the cuspid. The values can be changed interactively during program execution to account for the movement

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of the cuspid in the lateral direction and in the mesiodistal directions (Figure 14A). With this method, the arch form in the lateral direction is accepted as a straight line that connects the mid-points of the mesiodistal contact points of the cuspid and the first molar. Figure 14-B1 shows the dental arch prior to movement. In Figure 14-B2, the central incisor, the lateral incisor and the cuspid are positioned in that order starting from the mid-point of an arc with a radius r. In the lateral direction, the first molar is first rotated so that the contact point aligns itself along a straight line. This is followed by the positioning of the second premolar and then the first premolar. When doing this, the amount of overlap between the cuspid and the first premolar, i.e., the distance between the mesiodistal contact point of the cuspid and the mesiodistal contact point of the first premolar, becomes the original discrepancy (Figures 14-A and B2). Total discrepancy is defined as the sum of the left and right original discrepancies. Figure 14-B3 shows a simulation of reducing the discrepancy by lateral expansion. This can be performed on the cuspid and the first molar and is performed when there is a need to reduce discrepancy of a tooth non-extraction and, in particular, when there is a need to expand the scope of applicability to tooth non-extraction in class II cases. Expansion of the cuspid occurs when the value of r is increased, and a mesiodistal movement/lingual movement occurs when the value of r is reduced. When the first molar is laterally expanded by 1 mm, there is a reduction in total discrepancy by 0.2 mm from -5.6 mm to -5.4 mm as shown in Figures 14-B2 and 3.

Figure 15 shows the procedure for a simulation analysis of tooth movement. ① When the case number is entered, the name, the date of birth and age are displayed. The course number to be displayed is entered. ② The teeth and occlusion arch form images and cephalograms of the upper and lower jaws and the central incisor and the first molar are displayed. ③ The original discrepancy and total discrepancy are calculated. ④ In a simulation whereby discrepancy is reduced by lateral expansion and its amount automatically calculated, whether or not discrepancy can be eliminated by expansion by tooth non-extraction is first studied. If this is not possible, tooth extraction or the mesiodistal movement of the molar or some other solution is studied. Ordinarily, lateral expansion is performed on a constricted dental arch, but if the second molar has already erupted, that is also added as a reference, and the amount of lateral expansion between the first molars is determined so that there is the least discrepancy between the maxilla and the mandibula. ⑤ The anterior-posterior position of the front teeth is determined in the following way. C-VTO is performed, and a value such as one-half discrepancy or some other value is entered to determine the distance between the APo of the incisal edge of the mandibular central incisor and the bite plane. The amount of advancement or retraction and the movement in the vertical direction and the change in the tooth axis are calculated. When an input is made to the simulator using those values as references, the overlap between the premolar and the cuspid after a lateral expansion of the molar and the determination of the anterior-posterior position of the front tooth are displayed. Then, a decision is made on tooth extraction or not, taking into account such factors as the presence of wisdom teeth in the mandibula. ⑥ In the case of a tooth extraction, that location is entered, and a display is again made with the first molar fixed. If there is a tooth extraction space between the premolar and the cuspid, the procedure proceeds to the next step. However, if there is an overlap, the mandibular front teeth is positioned at a slightly more anterior position, or a distal movement of the first molar is set without

advancement [of the mandibular front tooth] or both movements are set. If there are no further changes, the first molar that had been fixed is made to undergo a mesial movement to check the state after closure of the space. This state represents the individual ideal arch that is reached with the subject simulator. The teeth and occlusion arch form images with the maxilla and the mandibula in the occlusal state prior to analysis ⑦ and the expected teeth and occlusion arch form images with the maxilla and mandibula in the occlusal state after the treatment are displayed. This completes the simulation.

6. Six-Area Superimposition Method (6S) and Total Area Superimposition Method (TS)

With the subject system, the 5-area superimposition (5S)[29] reported by Ricketts was modified so that the following six areas were extracted and automatically superimposed and displayed (6-area superimposition (6S)): NA-BA at CC (1S), NA-CC at NA (2S), E-line at a point of intersection E-line and occlusal plane (3S), mandibular plane at Go^5 (Go^5 is the intersection between point 21-24 line and mandibular plane) (4S), mandibular plane at Pog (5S), and ANS-PNS at ANS (6S). Furthermore, total area superimposition (TS) at the different areas was realized. For each case, a comparison can be made between: pre-treatment and visual norm; before, during and after treatment; C-VTO and nontreatment before treatment; and all of the aforesaid. This allows the visual evaluation of abnormalities such as overall change or internal change with respect to specific points and reference planes.

The use of the six-area superimposition method covering 1S through 6S allows the quantification of the following evaluation.

1S: The amount necessary for controlling and forecasting the growth and change based on treatment of the chin of the mandibula and the maxillary first molar. 2S: The amount necessary for controlling and forecasting the growth of the mandibula and the direction for treatment modification. 3S: The amount necessary for controlling and forecasting the growth and change based on treatment of the soft tissue and hard tissue. 4S: The amount necessary for controlling and forecasting the growth and change based on treatment of the mandibular body and mandibular condyle. 5S: The amount necessary for controlling and forecasting the growth and change based on treatment of the entire mandibula, mandibular condyle, mandibular front teeth and first molar. 6S: The amount necessary for controlling and forecasting the growth and change based on treatment of the maxillary front teeth and the maxillary first molar.

7. Automatic Display of Profilogram and Polygon Tables

Sakamoto's profilograms, the polygon tables reported by Iizuka and Ishikawa and Ricketts' analytic method can all be displayed. Furthermore, the combination of the measured items is modified to prepare unique polygon tables that are comprehensive and allows the superimposition in color of all courses. A unique analysis is also possible.

Profilograms are the most simple, clear and indispensable analytic method for the diagnosis of mandibular prognathism which is especially prevalent in Japan. Profilograms are used for the evaluation of the amount of maxillomandibular orthopedic changes required.

Ricketts' analytic method evaluates the facial types of Dolico, Mesio and Bracky and is used along with the superimposition method for the diagnosis of maxillary prognathism. Five (5) factors, 11 factors, internal structure and 32 factors were output to the CRT monitor and from the printer.

The aforementioned analyses were used in conjunction with C-VTO, pattern matching using the superimposition of the actual course, teeth and occlusional arch form images and supplemented the numerical analysis based on visual evaluation, thus clarifying the diagnosis, evaluation of courses and forecasting of growth and changes in treatment.

8. Image Database Using Optical Still-Image Disk Files

Cephalograms, panoramic X-ray images, and facial and intraoral photographs were stored on 20 cm spiral disks to allow their immediate retrieval whenever necessary and their examination by computer simulation. Results could be recorded and virtual three-dimensional setup models could be more effectively used. A communication capability was added to an E-file based automatic database creation program so that optical disks could be directly controlled, thus meeting various retrieval demands (Figures 1, 4, 5).

9. System Integration and Relational Database

Database languages (condor s20, dBASE II and III, RBASE 4000 and 5000, and others) for personal computers were used to create a database for the data management for clinical orthodontics. Management of cases, results representing angles and lengths of different cases calculated by simulation, treatment equipment, treatment patterns or case IDs are stored. Based on that, various data processing can be performed and data can be efficiently used. Even though there are limits imposed by the recording media, as many as roughly 1 billion results can be stored. The statistical processing of the visual norms was performed using Japanese language E-files. A system can be created with a database language and be made usable in only several minutes if the number of items is few. Also, since changes can be made midstream, data items can be added or deleted as trial runs are made so that a well-thought ideal database can be created over time.

The use of a database language allows searches to be performed using different search conditions (such as searching for similar cases) or to group the results. Data files can be managed by batch processing or by directly entering commands, thus simplifying the creation of programs. Because data can be shared, data can be used in many ways. If necessary, data can be used with a high density (Figures 1, 2, 4, 5).

Table 2 Mean and Standard Deviation (mm) for Annual Growth for Ages 7 to 12

Hard tissue		Age 7 to 8	Age 8 to 9	Age 9 to 10	Age 10 to 11	Age 11 to 12
CC-NA	Mean	1.14	0.59	0.39	1.24	0.54
	Std. Dev.	1.42	0.92	1.18	1.31	1.08
CC-BA	Mean	0.97	0.68	0.79	1.04	1.04
	Std. Dev.	1.19	0.85	1.27	1.57	1.13
CC-CD	Mean	1.03	0.67	1.19	0.60	0.87
	Std. Dev.	0.82	0.43	0.81	0.83	0.57
CD-XI	Mean	1.04	0.87	0.86	0.68	1.05
	Std. Dev.	0.75	0.40	0.48	0.44	0.55
XI-PM	Mean	1.59	1.36	1.19	1.51	1.89
	Std. Dev.	0.88	0.69	0.56	0.63	1.00
NA-ANS	Mean	1.67	1.54	1.32	1.46	1.53
	Std. Dev.	0.80	0.75	0.64	0.75	0.73
NA-TI	Mean	1.72	1.59	2.18	1.33	2.25
	Std. Dev.	1.08	0.93	0.99	1.24	1.39
NA-ME	Mean	2.44	2.85	2.64	2.41	2.66
	Std. Dev.	1.30	0.99	0.95	1.22	1.46

Table 3 Mean and Standard Deviation for Annual Growth for Periods of More than 2 Years for Different Age Groups

Hard Tissue		Age 12-15	Age 9-12	Age 8-12	Age 7-12	Age 7-15
		3	3	4	5	8
CC-NA	Mean	0.58	0.72	0.69	0.78	0.71
	Std. Dev.	0.40	0.33	0.27	0.23	0.21
CC-BA	Mean	1.03	0.95	0.89	0.90	0.95
	Std. Dev.	0.47	0.29	0.29	0.23	0.20
CC-CD	Mean	0.86	0.89	0.83	0.87	0.87
	Std. Dev.	0.55	0.23	0.21	0.19	0.20
CD-XI	Mean	0.95	0.87	0.87	0.90	0.92
	Std. Dev.	0.34	0.33	0.31	0.36	0.28
XI-PM	Mean	1.37	1.53	1.49	1.51	1.46
	Std. Dev.	0.73	0.35	0.28	0.27	0.32
NA-ANS	Mean	0.97	1.44	1.46	1.50	1.30
	Std. Dev.	0.45	0.35	0.29	0.32	0.22
NA-TI	Mean	1.33	1.92	1.84	1.81	1.63
	Std. Dev.	0.68	0.61	0.43	0.31	0.24
NA-ME	Mean	2.32	2.57	2.64	2.60	2.49
	Std. Dev.	1.05	0.67	0.64	0.53	0.48

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Table 4 Mean and Standard Deviation (mm) of Thickness of Soft Tissues at Ages 10, 12 and 15

Soft tissue thickness		Age 10	Age 12	Age 15
A-AS	Mean	12.50	13.73	14.77
	Std. Dev.	1.71	1.34	1.72
U1-UL	Mean	13.77	13.51	13.81
	Std. Dev.	1.59	1.70	1.33
LI-LL	Mean	13.70	14.59	15.14
	Std. Dev.	1.35	1.52	1.56
B-BS	Mean	13.57	13.74	14.21
	Std. Dev.	1.99	2.52	1.99
GN-GN'	Mean	7.60	7.90	9.35
	Std. Dev.	1.58	1.77	2.25
PO-PO'	Mean	12.24	12.83	13.39
	Std. Dev.	1.58	1.74	2.41

10. Statistical Analysis of Visual Norms and Annual Growth for the Realization of C-VTO Using Longitudinal Data (Table 1-4)

Thirty-two (32) children (16 boys and 16 girls) having an ideal occlusion were selected from the longitudinal data on 180 children living in Kawanishi-cho, Nakauonumagun, Niigata Prefecture kept by the Department of Orthodontics, School of Dentistry, Niigata University. Their cephalograms were statistically processed.

As for hard tissues, the average values and standard deviations were calculated for age 7 through age 12 and age 15 for eight items (CC-NA, CC-BA, CC-CD, CD-Xi, Xi-PM, NA-ANS, NA-TI and NA-ME) and accepted as visual norms (Table 1). As for the amount of annual growth, the average amount of annual growth and the standard deviation were calculated for each year between ages 7 and 12 and for the three years between 12 and 15 (one-third of the growth amount occurring over those three years) (Table 2), and also for the following five age ranges: age 7 through 12; age 8 through 12; age 9 through 12; age 7 through 15; and age 12 through 15 (Table 3).

As for soft tissues, the average value and standard deviation were calculated for five items (A-AS (thickness of the lip at point A), U1-UL (thickness from the incisor edge of the maxillary central incisor to point 83 on the lip), LI-LL (thickness from the incisor edge of the mandibular central incisor to point 89 on the lip), B-BS (thickness of the lip at point B), GN-GN' (thickness of the soft tissue at area GN) and Po-Po' (thickness of the soft tissue at area Po)) for ages 9, 12 and 15 (Table 4).

Clinical Application and Results

The clinical applicability of the subject system was evaluated for the typical cases encountered in clinical orthodontics: maxillary prognathism, mandibular prognathism and crowding.

Case 1: Maxillary prognathism, age 9 at the time of first dental examination, girl (Figures 15 through

19). Overbite 3.9 mm, overjet 14.0 mm. She exhibited a typical extreme deep bite and overjet with recessed lower lip. The 5 factors were: facial axis 85.5° (nearly mean), facial depth 88.1° (within 1 SD), mandibular plane 21.1°, lower face height 42.3° and mandibular arc 33.2° (-2 SD for MP and LFH and more than +2 SD for MA). This was a class II case with a Brachy facial pattern (euryprosopic facial pattern). Figure 15 shows the procedure for the simulation of the movement of the teeth. Screen 1 shows the maxillomandibular bones and the upper and lower dental arches before treatment. Screen 2 shows the automatically calculated simulation of the discrepancy with the central incisor and the first molar fixed in the anterior-posterior direction. The discrepancy on the left side of the mandibula was -2.7 mm, and -3.4 mm on the right side. The discrepancy on the left side of the maxilla was +4.5 mm, and +5.7 mm on the right side. Taking into account the C-VTO and the automatically calculated values of -4.7 mm for L1-APo and L1 inclination of 5.1°, retraction of the maxillary front teeth was set to -5 mm, inclination to -15°, advancement of the mandibular front teeth to 7 mm and forward inclination to 17°. L1-APo was changed by 7 mm to be 2.3 mm, and the L1 inclination was changed by 17 ° to 21.7°. Screen 4 shows the results of the simulation of the advancement of the maxillary and mandibular first molars. The left side of screen 5 shows the occlusional state of the upper and lower dental arches, and the right side shows the simulated occlusion arch form image provided by the system.

In reality, even though the treatment was started without a dental extraction, bite raising was extremely difficult. Figure 17A shows the pretreatment state. Bioprogressive therapy that lasted 1 year and 2 months resulted in the overjet to be reduced by 7 mm, a fair degree of improvement. However, since a more effective mandibular growth was necessary, the multi-bracket device was removed when the state shown in Figure 17B was reached. A policy was established to convert the biting force to promote growth of the mandibula in the forward direction. When a tooth positioner that would convert the biting force to a force that would promote a forward growth of the mandibula was used, a favorable growth of the mandibula was achieved as expected (Figure 17C). Figures 17A through C show the actual line drawings displayed on the C-VTO screen for the time of initial dental examination (course 1), during treatment (course 2) and post-treatment (course 4). Figure 17D shows a superimposition of the images before, during and after treatment, i.e., the superimposition of Figures 17A, B and C at NA-BA at CC. Figure 17E shows the 6-area superimposition (6S) image. Figure 17F shows the superimposition at the occlusal plane at TI and compares the C-VTO against the actual change in the soft and hard tissues. To explain further, this shows the superimposition of Figure 17C (age 12) and the C-VTO forecast (two years after age 10) based on Figure 17B (age 10). There is a good match between the actual and the forecast, and discrepancy is absent between the E-line and the upper and lower lips. Figure 18 shows the total area superimposition. Figure 19 which is an output from the XY plotter of the 6S superimposition clearly shows the internal changes that occurred at the different areas. The total area superimpositions in Figures 17D and 18 show the improvement in the overbite and overjet between the maxillary and mandibular front teeth and the general improvement provided by mandibular growth.

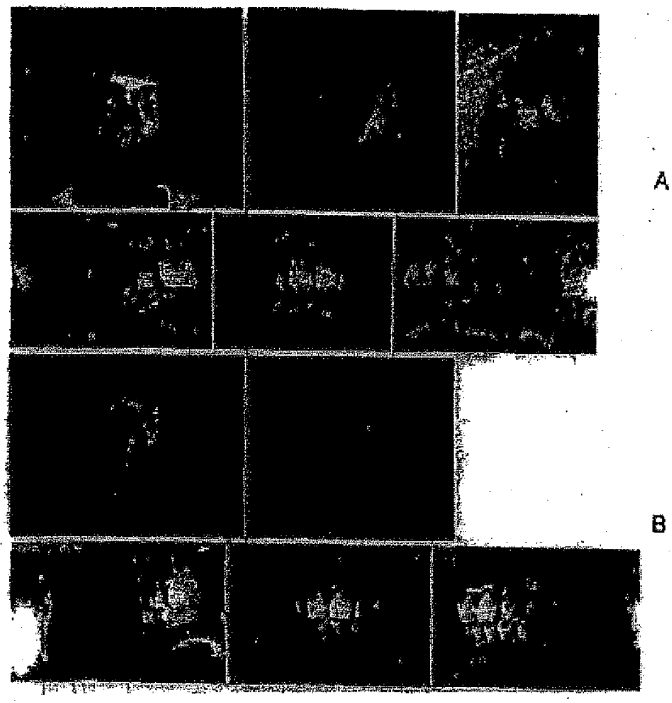


Figure 16 Facial and Intra-oral Photographs for Case 1
(A: Before Treatment; B: After Treatment)

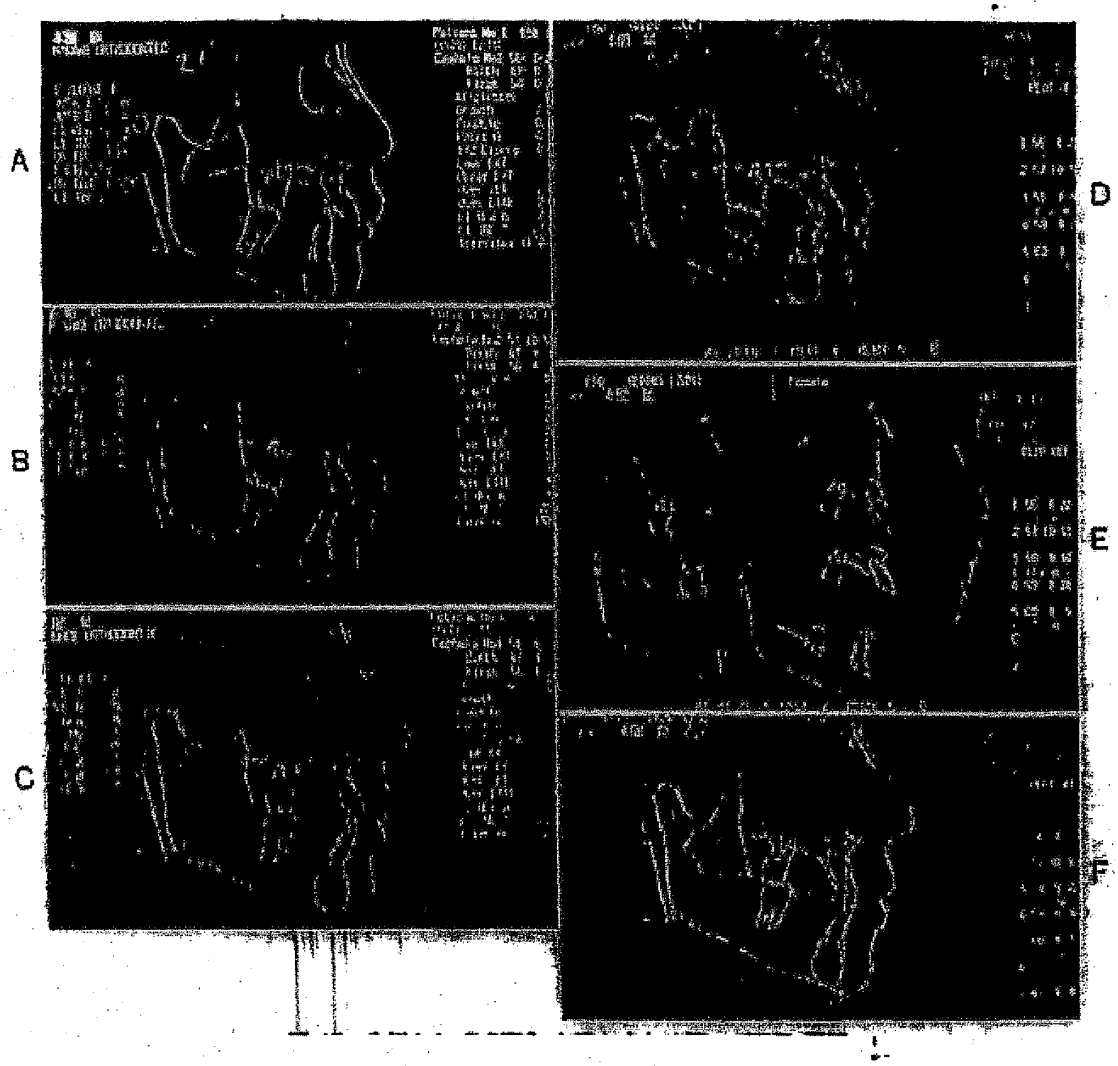


Figure 17 CRT Images of C-VTO and Superimposed Images for Case 1

A: Pre-treatment (9y0m); B: During treatment (10y2m); C: Post-treatment (12y0m); D: Total area superimposition before, during and after treatment (NA-BA at CC); E: Six-area superimposition (6S) before, during and after treatment; F: Superimposition of C-VTO and post-treatment (occlusal plane at TI)

Case 2: Structural mandibular prognathism in a girl 8 years of age when first examined. Her profilogram indicated a mandibula that was severely displaced upwardly and forwardly (Figure 20A). If left unattended, the biting force will aggravate the amount and direction of maxillomandibular growth, causing her maxilla to grow downwardly and her mandibula to grow upwardly and forwardly eventually necessitating a surgical operation to shorten the mandibula. This was believed to be a fairly severe case at the limit. The treatment that was tried consisted of using a chin cap as the base and combining it with an acrylic resin

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monoblock ("ARMB") to improve the growth direction and consequentially the overbite. To elaborate, the diagnosis of the case was an excessive overgrowth of the mandibula that was accompanied by a forward displacement and a deep overbite and that the use of a chin cap alone will change the direction of maxillary growth in the downward and rearward direction, further aggravating her condition. The treatment device had to exert a forward traction. Treatment was started with a simple regular chin cap and ARMB. The wearing of the ARMB was made to have a similar effect as the improvement achieved with an improved overbite. To explain further, with a normal overbite, the biting force and the traction force of the chin cap are believed to combine to promote a forwardly growth of the maxilla and a rearward rotation and retraction of the mandibula while suppressing the forward mandibular growth. By providing the ARMB with the same effect in this case with a reversed overbite, the biting force and the traction force of the chin cap that work as an aggravating force on the maxilla and the mandibula were converted to work as forces that improve the positions of the maxilla and the mandibula. In other words, the ARMB was devised and used to serve as an inclined plane type sliding plate and a force direction converter that converted the vertical components of the biting force and traction force to remedial horizontal components.[3)] This resulted in a rearward rotation of the mandibula by approximately 2° and a retraction of the chin, improving the position of the mandibula and the direction and amount of maxillomandibular growth as expected and consequently improving the overbite. As a result the SNP angle was improved by 3° from 84.3° measured at the time of first examination to 81.3°. Figure 20B shows an example of the forecast using C-VTO (blue) based on the data (yellow) obtained during the first examination. The major settings of the 12 items were growth 2y, condyle 2°, lower-Ext 4, upper-Ext 4, L1-APo 3.7 mm, L1-inc 20° and interincisal being parallel to the facial axis. Figure 21 shows the output of the XY plotter showing the superimposition of the images from the initial examination (red), during treatment (green, after improvement of the overbite) and C-VTO (blue) prepared based on data during treatment (green) with interincisal set to 130° and L1-APo and L1-inc being constant. Figure 22 shows a 6-area superimposition (6S) of the nontreatment (green) C-VTO automatically forecasted using pre-treatment (red) data and post-overbite improvement (blue). Figure 23A shows the condition prior to treatment, and Figure 23B shows the condition after improvement of the overbite. In Figure 20B, the C-VTO was calculated with a setting for a clockwise rotation of 2°. This assumed that the rearward rotation of the mandibula was necessary. The actual result matched with an increase of 2° in the mandibular plane. Figure 23C shows the result of the C-VTO using settings of 3.7 mm overjet (over-correction), 2 mm overbite and -1 for interincisal (-1 is the parameter that specifies U1 to be parallel to the facial axis) with the mandibular front teeth set at the position post-improvement of the overbite (B). As Figure 23C shows, since the U1-torque changed from 25.5° to 6.3°, a reversed torque of 19.2° is required on U1 to make the U1 parallel to the facial axis after improvement of the overbite. The figure shows that a torque of 6.3° is required at the bracket. In this way, C-VTO is capable of not only making forecasts at the time of initial examination about growth and change in treatment but can also perform simulations about the required amounts for achieving the treatment goals midstream into a treatment process. The amount of additional bracket torque to use was studied in this case.

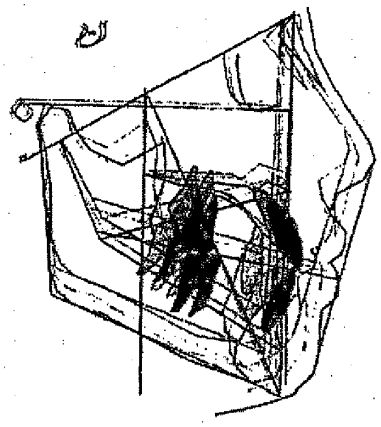


Figure 18 Superimposed Line Image Output at NA-BA at CC for Case 1
(Before, During and After Treatment (Red, Green and Brown)

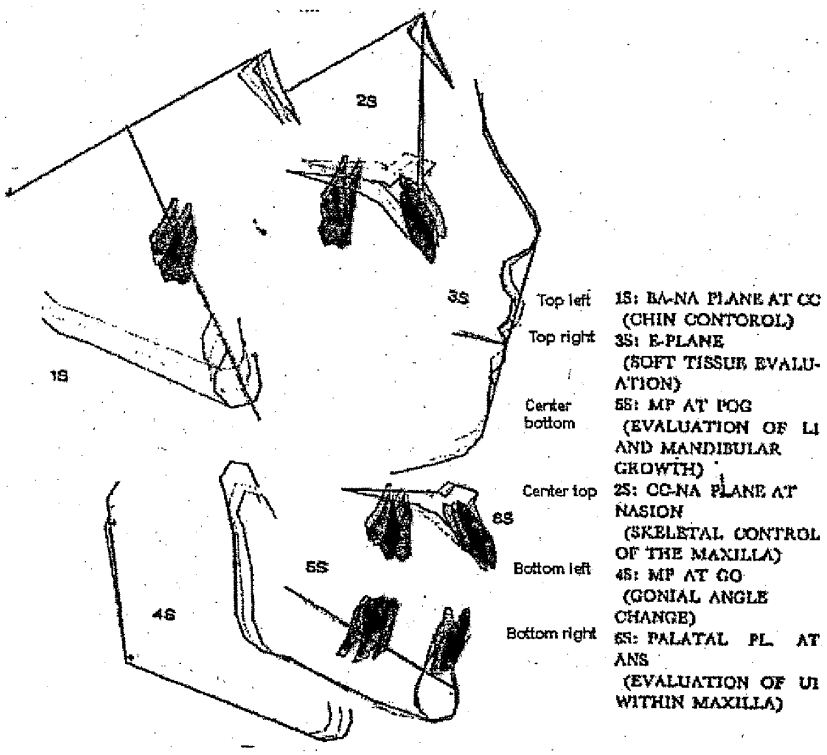


Figure 19 Six-Area Superimposed Image Output from XY Plotter

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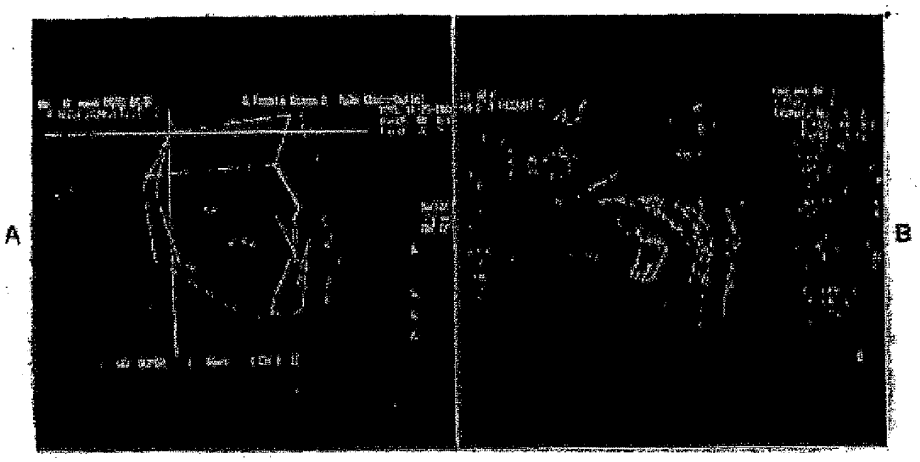


Figure 20 Profilogram (A) from First Examination and C-VTO (B) Created from First Examination for Case 2

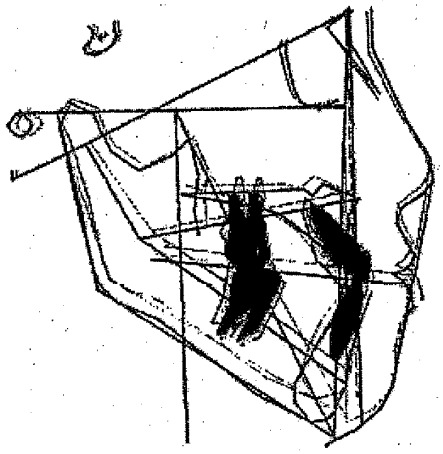


Figure 21 Case 2: Superimposition Showing Initial Examination (Red), After Overbite Improvement (Green) and C-VTO (Blue) for NA-BA at PT where C-VTO (Blue) Was Created Using During Treatment Image (Green) With Interincisal at 130° Without Changing the L1 Position

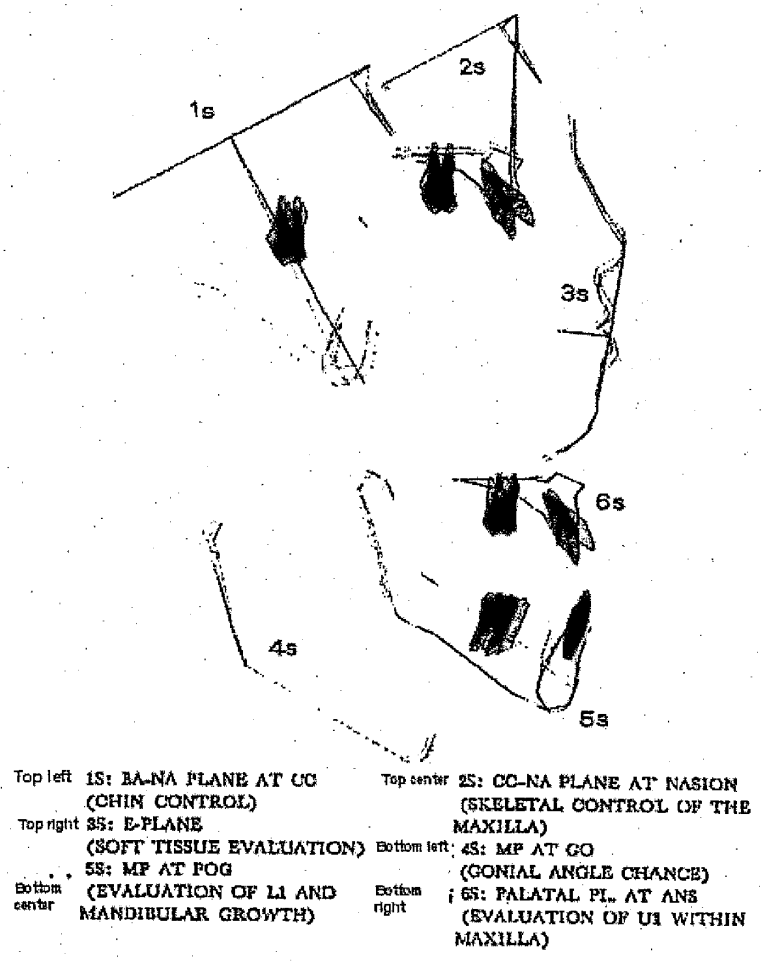


Figure 22, Six-Area Superimposed Image Output from XY Plotter

Case 3: Crowding complicated by cross-bite of the front teeth in a female 20 years of age at the time of initial examination. Maxillary discrepancy of -14.6 mm and mandibular discrepancy of -7.5 mm.

Figure 24A shows the C-VTO. The 1/2 discrepancy was set to -3.5 mm with an extraction of the mandibular first premolar and extraction of the maxillary second premolar. The other settings were default values. Figure 24B shows the dental arch prior to movement. Figure 24C shows the screen with the discrepancy automatically calculated. The results showed -5.3 mm for the left side and -2.2 mm for the right side for the mandibula and -9.0 mm for the left side and -5.6 mm for the right side for the maxilla. Figure 24D shows a simulation of a dental extraction and the automatically calculated amount of reduction of the discrepancy by the lateral expansion of the maxillary first molar. The automatic calculation of the numerical

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value of discrepancy after expansion and the simulation of the dental extraction were performed at the same time. In other words, shown is the state with the extraction space following the alleviation of crowding by lateral expansion and the fixation of the first molar by extraction. The results showed a reduction of discrepancy by 0.2 mm on the left side and 0.3 mm on the right side by a lateral expansion of 1 mm for the mandibula, and a reduction by 0.5 mm on the left side and 0.2 mm on the right side by a lateral expansion of 1 mm for the maxilla. However, after considering the extraction space and other conditions, a decision was made on a dental extraction. The result was used to forecast the C-VTO shown in Figure 24A. Figure 24E shows the simulation of the dental arch before and after a mesiodistal movement without the condition used in Figure 24D of fixing the first molar. The results show a closure of the extraction space, retraction of the mandibular front teeth by 2 mm, linguoclination of 3°, advancement of the maxillary front teeth of 1 mm and a labioclination of 6°. Figure 24F shows a simulation of two images, one showing the occlusion state of the maxillomandibular dental arches before movement and occlusion state for the teeth and occlusion arch form after movement that achieved individual ideal arches.

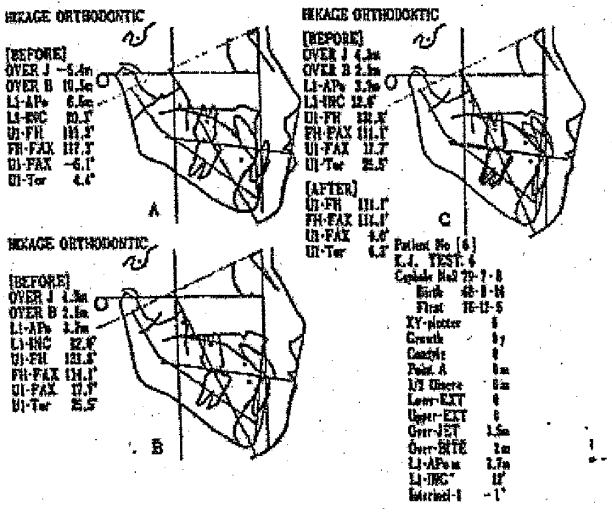


Figure 23 Automatic Calculation of Required Reverse Torque (Additional Bracket Torque) on Front Teeth Based on C-VTO Created Using Improved Overbite for Case 2

A: Before treatment (8y3m); B: During treatment after overbite improvement (10y10m); C: C-VTO created using during treatment image (B) under the condition that position of L1 with respect to APo-line is unchanging (U1 torque = 6.3°)

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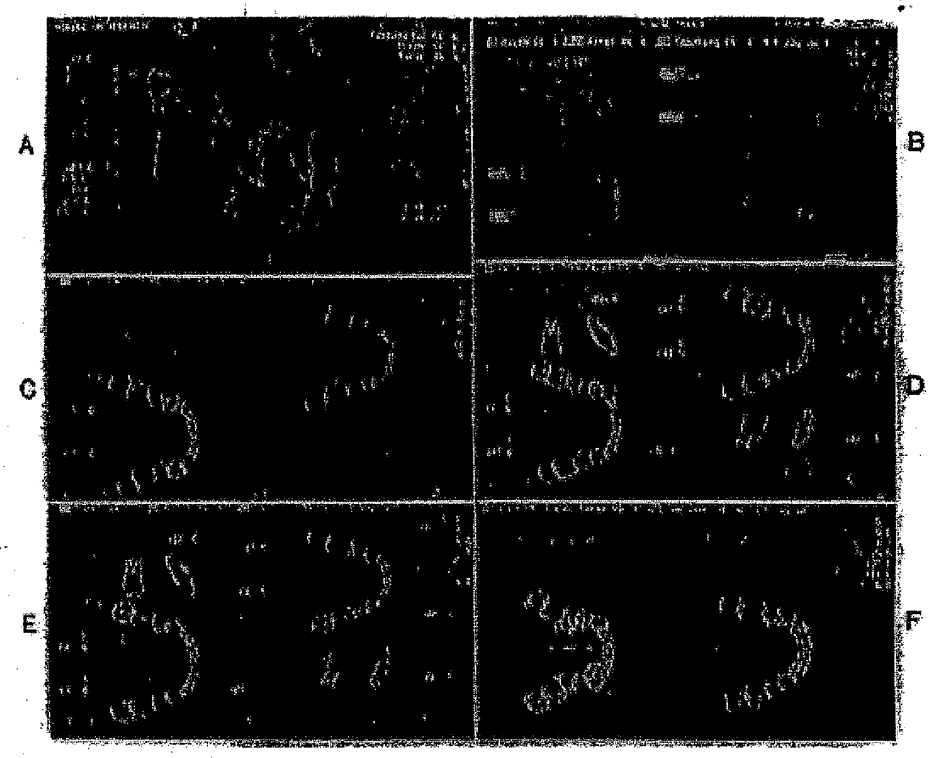


Figure 24 Creation of Virtual Three-Dimensional Setup Model by Linking of C-VTO and Teeth/Dental Arch Movement Simulation and Dynamic Analysis Screen Showing Process Leading to Individual Ideal Arch Form

(A) C-VTO; (B) Before movement; (C) Automatic calculation of discrepancy; (D) Reduction of discrepancy by lateral expansion and dental extraction; (E) Closure of extraction space by mesiodistal movement of first molar; (F) Simultaneous display of occlusal state before movement and after achievement of individual ideal arch

Discussion

The straight wire appliance added three-dimensional shapes and structures to bracket slots, significantly reducing the workload imposed on practitioners for the processing of arch wires. Furthermore, with the advent of lateral expansion, forward and rearward traction devices for the maxilla and other good devices and parts such as functional appliances, improvements by orthopedic change and orthodontic change can be more efficiently performed given some level of ingenuity and skill. It is not an exaggeration to state that clinical orthodontics has progressed to a highly sophisticated level. However, any equipment requires an accurate diagnosis and the establishment of a proper treatment policy for its full capabilities to be used. The analysis of dental movement, C-VTO and the automation of superimposition made possible by the subject

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system should provide a strong assistance in the diagnosis prior to start of treatment, the establishment of a treatment plan and the evaluation of growth and treatment effects. Examples of the use of computers in orthodontics include attempts at pattern analysis based on statistical processing [14, 19], use of databases[10] and automatic extraction of cephalogram trace line drawings.[16, 17]

With the subject system, the use of a personal computer has been expanded beyond the traditional automatic analysis based on profilograms and polygon tables. The system has been developed to be easy to use and provide a better diagnosis, analysis and treatment environment. The system has been used for three years and improved. Cephalograms and dental arch data are entered and stored as point data. During analysis, cephalogram trace line drawings and virtual three-dimensional setup models of teeth and occlusion arch form images are automatically created. Creation of C-VTOs, superimposition with C-VTOs, superimposition with actual treatment courses and graphic simulation of dental movement analysis can be performed to simulate the process leading to individual ideal arches.

In the example of the maxillary prognathism shown in Figure 17D, total area superimposition at CC-NA and CC clearly shows the growth and improvement of the mandibula while the 6S shows the change at different areas. In the improvement of a reversed overbite such as the case shown in Figure 20A where the chin is displaced forwardly and upwardly, the maxillomandibular improvement in the anterior-posterior direction by a rearward and downward rotation of the mandibula was automatically calculated as C-VTO to study the treatment limits.[3] With respect to changes in the gonial angle, the traditional measurement method using AR does not provide a full understanding of the change. As Figure 22 shows, however, the subject system allows the reduction of the gonial angle to be visually confirmed by the evaluation of 4S in a 6S superimposition. In Figure 22, red identifies the state before treatment, blue the actual condition after improvement of the overbite and green the forecasted natural growth without treatment. Since the automatic calculation and display of the torque on the maxillary front teeth is performed by C-VTO processing, matching brackets can be selected. The degree of maxillary or mandibular prognathism was traditionally represented by the ANB angle, but that is inadequate in many cases. The 6S evaluation and other methods appear to provide a more complete representation. The evaluation of soft tissue at the E-line is greatly affected by settings used for the mandibular front teeth in a C-VTO and the decision on dental extraction or not. Since the condition of the soft tissue is automatically calculated based on decisions on the position of the mandibular front teeth that are made while considering the improvement in discrepancy, aesthetics can also be considered and studied at the same time. As for the movement analysis of teeth, dental extraction can be analyzed in terms of lateral expansion and other methods so that the non-extraction option is fully considered and dental extraction is selected only when truly necessary. The position of the maxillomandibular front teeth and complicated changes in soft tissue and hard tissue can be derived based on the setting used for the position of the mandibular front teeth. The change in soft tissue corresponding to changes in hard tissue can be automatically displayed and simulated. Figure 17F shows the output image of the actual change in soft tissue and the results

created by C-VTO superimposed on each other. There is a good match between the upper lip and the lower lip. The improvement in the anterior-posterior position of the chin by a rearward rotation in the case of a mandibular prognathism was forecasted and quantified by the C-VTO which was developed. However, the retraction that is achieved with treatment, changes that slightly reduce the gonion or improvements provided by surgical shortening of the mandibula cannot be automatically calculated without improvements being made to the program. The realization of this capability with a C-VTO remains to be an issue for the future.

Orthodontic treatment is a repetition of diagnosis and the execution of the improvement plan. The ability to dynamically evaluate craniofacial, dental arch and soft tissue morphologies and to diagnose and evaluate growth and treatment changes will provide a tremendous contribution to treatment and research. The purpose of this research was to automate the complicated procedure by developing and putting a system to practical use. The system allows the following to be performed in daily clinical practice with less effort.

1) The creation of cephalogram trace line drawings and computer graphic setup simulation models based on teeth and dental arch occlusion form images for the evaluation of morphologies and growth and the change in treatment. These images can be dynamically linked in synchrony at a reference position on an occlusion plane to create a virtual three-dimensional setup model that can dynamically forecast and simulate visual representations of growth and changes in treatment. Cephalogramic data and dental arch data are entered as point data, i.e., as XY coordinate values, to improve storage efficiency. Data for many patients (200 patients on a 1 MB floppy disk) can be stored so that the numerical analysis and visual analysis of changes in morphology and their evaluation can be performed for both forecasts and actual results.

2) The system can be used as a treatment simulator for practitioners and for training purposes or as an educational tool for patients.

3) In the evaluation and diagnosis of different morphologies and their changes, total area superimposed images of specific areas and six-area superimposition images clearly identify orthopedic and orthodontic changes, thereby allowing malocclusion, discrepancy and aesthetics in the relationship between the soft and hard tissues of the teeth, jaws and face to be studied.

4) Traditional analytic methods based on profilograms and polygon tables can also be automatically displayed to augment diagnosis and evaluation.

5) Raw image data such as facial and intraoral photos and X-ray images (cephalograms, panoramas, etc.) are stored on optical still-image disk files which are linked to a relational database to create an image management database. The still-image files and a computer simulator system were also linked together to create an integrated system that allowed data sharing and repeated use of the data.

The field of orthodontics requires that functional occlusion and aesthetics both be achieved. A judgment criteria that can accommodate a wide variety of diagnostic methods and treatment methods are required. Furthermore, goals should be established and diagnosis, treatment plan and treatment should be performed that will provide facial aesthetics and periodontal tissue health. The subject system was developed so that a more comfortable environment can be realized to achieve those goals. The subject system should be further improved by augmenting it with a greater knowledge base and rules, linking with a database and providing it with an inference engine so that the system can use artificial intelligence technology.

In closing this paper, deep appreciation is extended to Professor Kooji Hanada of the Department of Orthodontics, School of Dentistry, Niigata University for his guidance and editing work and to Mr. Yukimune Yasunaga for his assistance.

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References

1) Ascii Publishing Bureau, "Standard MS-DOS Handbook," Tokyo, 1984, Ascii Publishing, 4-512

2) Bainsu Information Center, "dBASE II Bible," Tokyo, 1984, Gijutsu Hyoronsha, 2-345

3) Kiyohito Hikage, Takaaki Miyazaki, Kooji Hanada, "Treatment Methods for Reversed Overbite Using Orthopedic Force and Their Limits," Journal of the Japanese Orthodontic Society, 38:102-103, 1979

4) Kiyohito Hikage, Yukimune Yasunaga, Kooji Hanada, "Clinical Orthodontic Simulation System Using a 16-bit Personal Computer," Journal of the Japanese Orthodontic Society, 43:619, 1984

5) Kiyohito Hikage, "Development of a Computer-Based Clinical Orthodontic Support System," Journal of the Niigata Dental Society, 15: 122-123, 1985

6) Fujio Miura, "Application of a Computer System to the Analysis of Dento-Cranio-Maxillo-Facial Morphologies," Journal of the Stomatological Society of Japan, 39: 541-550, 1972

7) Eiichiro Nakajima, Mamoru Akiyama, [untransliterable first name] Hobo, "Usages of the Rocky Mountain Data System," Tokyo, 1978, Rocky Mountain Morita, 1-60

8) Hiroshi Nezu, Kenji Nagata, [untransliterable first name] Yoshida, Makoto Kikuchi, "Bioprogressive Diagnostics," Tokyo, 1984, Rocky Mountain Morita, 1-169

9) Yoshio Sato, "Introductory Graphics," Tokyo, 1984, Ascii Publishing, 3-255

10) Mamoru Sakuta, Yoshiaki Yamagata, Kazuo Tannne, Yoshihide Yasuda, [untransliterable first name] Yoshida, "Database Management System in Orthodontics," Journal of the Japanese Orthodontic Society, 44: 537-548, 1985

11) Hisashi Shimizu, "Use of Personal Plotters," edited by Graphtec, Tokyo, 1986, Nikkan Kogyo Shimbun Sha, 1-207

12) System Science Laboratory, "RS-232C Communications Handbook," Tokyo, 1985, Gijutsu Hyoronsha, 4-202

13) Kooji Shinoda, "Cephalometry Using a Computer System," Nihon University School of Dentistry, 43: 572-584, 1969

14) Kunimichi Soma, "Study of Growth Forecast Based on Use of Analog Method with Cephalometric Roentgenography," Journal of the Stomatological Society of Japan, 38: 533-555, 1971

15) Satoshi Suzuki, "Use of Computer Systems for Three-Dimensional Model Analysis," Journal of the Japanese Orthodontic Society, 39: 208-228, 1980

16) Junji Sugawara, Yoshinari Kanamori, Toshihiko Sakamoto, "Automatic Extraction of Measurement Points in Mandibula Line Drawings in Cephalometric Roentgenography," Journal of the Japanese Orthodontic Society, 39: 145-156, 1980

17) Junji Sugawara, Toshihiko Sakamoto, "Cephalometric Roentgenography Processing System Using a Line Drawing Input Method," Journal of the Japanese Orthodontic Society, 37: 1-7, 1978

18) Yutaka Takeuchi, Satoshi Suzuki, [untransliterable first name] Nagasaka, Shinji Nakamura, "Cephalometric Roentgenography Analysis System with a Reference Plane Correction Function – Reflections and Improvements Based on Six Years of Clinical Experience," Journal of the Japanese Orthodontic Society, 37: 353-363, 1978

19) Yutaka Takeuchi, "Research on Quantitative Identification of Craniofacial Patterns for Detection of Analogous Cases," Journal of the Japanese Orthodontic Society, 38: 163-189, 1979

20) Kunikazu Teramoto, [untransliterable first name] Ishida, "Linking a Laser-Based Optical Video Disk," Prompt, 4: 80-84, 1985

21) Mitsubishi Electric, "M-Basic plus (III) Syntax Manual," Tokyo, 1983, Mitsubishi Electric Co., 1-296

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22) Mitsubishi Electric, "Multi 16 MS-DOS M-BASIC Compiler Instruction Manual," Tokyo, 1983, Mitsubishi Electric Co., 1-61

23) Nevatia, R, "Image Recognition and Image Analysis for Artificial Intelligence and Computer Vision," compiled by Toshio Minami, Tokyo, 1986, Keigaku Shuppan, 1-239

24) Biggerstaff, R. H., "Computerized Diagnostic Setups and Simulations, Angle Orthodont., 40: 28-36, 1970

25) Bimler, H.P.: "Bimler therapy part 1 (Bimler Cephalometric Analysis," J. Clin. Orthodont., 7: 501-522, 1985

26) Currier, J.H.: "A Computerized Geometric Analysis of Human Dental Arch Form," Amer. J. Orthodont., 56: 164-179, 1969

27) Owen, A.H.: "Diagnostic Block Cephalometrics," J. Clin. Orthodont., 6: 400-422, 1984

28) Ricketts, R.M., Bench, R.W., Hilgers, J.J. and Schulhof, R.: "An Overview of Computerized Cephalometrics," Amer. J. Orthodont., 61: 1-28, 1972

29) Ricketts, R.M., Bench, R.W. Gugino, C.F., Hilgers, J.J. and Schulhof, R.J.: "Bioprogressive Therapy," Calif., 1979, Rocky Mountain D.S. 1-367

30) Ricketts, R.M., Roth, R.H., Chaconas, S.S., Schulhof, R.J. and Engel, G.A.: "Orthodontic Diagnosis and Planning," Calif., 1982, Rocky Mountain D.S., 15-472

31) Savara, B.S.: "The Role of Computers in Dento-Facial Research and the Development of Diagnosis Aids," Amer. J. Orthodont., 61: 231-245, 1972

32) Walker, G.F.: "A New Approach to Analysis of Craniofacial Morphology and Growth," Amer. J. Orthodont., 61: 221-230, 1972

日矯歯誌 46：248～269，1987

仮想三次元コンピュータグラフィックシミュレーションと光ファイル画像データベースを用いた診断と治療計画のための矯正臨床支援統合化システム

日景清人

キー・ワード：仮想三次元コンピュータグラフィックシミュレーション，Visual Treatment Objective(VTO)，不正咬合者のコンピュータ解析，コンピュータ診断，orthodontic clinical simulation system

抄録：本研究の目的は，矯正臨床における診断と治療方針の設定を，セファログラムと歯列のシミュレーション分析で自動化し，同時に写真等の画像生データの管理を，高速検索が可能な光静止画ディスク装置で行うコンピュータ矯正臨床支援統合化システムの実現である．

この目的の達成のために，以下のようにシステムの開発をし，実用化について検討した．

1）セファログラムと上下顎歯列の実物大写真を用い，点データとし，各症例IDとともに1Mディスクで約200人登録，効率的なデータ保存とリアルな再現を考慮し計測点を決定した．

2）各症例についてセファログラムは1枚につき96点で7枚，上下顎歯列データは68点で3経過を登録，分析時にプログラムでセファログラムレース線図形と歯冠パターンによる歯・歯列咬合面展開図をリアルに再現し同期連動して，仮想三次元セットアップモデルを構築，モニターやプロッター上で，数値分析とグラフィックシミュレーションを同時に自動化し症例に適用した．

3）自然成長と成長・治療変化の予測では，リアルな予測画像でVTOを自動構築し，硬組織と軟組織についての診断を定量化した．

4）セファログラムのパターンマッチングでは，全体（TS）と主要6部位重ね合わせ（6S）で，硬組織と軟組織の成長・治療変化の実際と予測について，調和と審美性の改善達成度と必要量をvisualに自動算出した．

5）歯の移動シミュレーションでは，discrepancy，抜歯・非抜歯，歯の移動をComputerized VTOに同期連動し，仮想三次元モデルでindividual ideal archを構築した．

6）プロフィログラムやポリゴン表と11-32 Factorを出力表示し，visualな表示を補った．

7）口腔内，顔面，X線写真の画像生データを光ディスクに記録して画像リレーショナルデータベースを構築し，シミュレーションシステムとリンクして統合化システムとした．

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Integrated orthodontic management system for virtual three dimensional computer graphic simulation and optical video image database

——Supported system for diagnosis and treatment planning——

Kiyondo HIKAGE

Abstract: The purpose of the present study is to research and develop of the integrated computer sytem for practical use of orthodontic diagnosis and planning as well as data analysis in the design of orthodontic treatment and growth change. This computerized analysis sytem was effective to analyze the data which was widely used in the clinical interpretation at the present time. Also, this sytem was capable of simulating visible assessment of the dento-craniofacial complex by using cephalogram tracing line and occlusal arch form line image in the process and forecast of orthodontic treatment and growth change. By using the system hardware consisting of keyboard, digitizer, 24 pin kanji printer, x-y color plotter, color CRT and optical laser disk being connected with a MULTI 16・Ⅱ 16 bits personal computer, virtual three-dimensional analysis was performed by graphic simulation of setup model. Disk storage capacity was sizable with two 1M floppy disk drives and two 10M hard disk drives. 96 landmarks were determined and measured on the cephalogram tracing, and mesio-distal crown width of each tooth were also determined and measured on the picture with identical upper and lower dental arches. The above data were simulated automatically by numerical and visual computer analysis and were automatically drawn out C-VTO (computerized VTO), TS (total area superimposition), 6S (6 area superimposition), polygon, profilogram, 11 factors, 32 factors and tooth-dental arch movement graphic simulation. The advantage of this computerized system was characterized by the reappearance of cephalogram tracing, tooth crown and dental arch. Also, orthodontic and orthopedic changes in hard and soft tissue were expected and evaluated acculately after treatment and even during nontreatment. This integrated management computer system was made up and linked this Orthodontic Clinical Simulator System (OCSS) and optical video image laser disk system for high speed search and record of x-ray, facial and oral photo system to relational data base management system. This system was very useful for orthodontic practice.

緒　言

最近の矯正臨床環境は，技術，知識，概念ともに目覚しい進歩を遂げている．歯科矯正学の領域における計量分析は，1931年，Broadbent, Hofrath による頭部X線規格写真（以下セファログラムとする）の開発に始まり，現在まで顎顔面頭蓋の成長発育の研究や診断，形態変化などの評価を可能にしようとする試みがなされ，多くの分析法が考案され，使用されてきた．

とくに Savara[21], Walker[30] らによりセファログラムのコンピュータ活用[24,29] の道が開かれ，Ricketts, Gusino[28~30] らも bioprogressive therapy system[7,8] という診断・治療計画[26,27]コンピュータシステムと治療システムを完成している．本邦でもコンピュータを用いて，ポリゴン表，プロフィログラム，模型分析や計測点の自動抽出などの試みがなされてきた[4~6,10,13~19]．

一方，パーソナルコンピュータは16ビット時代に入り，8086マイクロチップ・プロセッサが国内の多くの

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メーカーに採用され，各方面の実用に十分耐えるまでに高性能化した．そこで16ビット・パーソナルコンピュータ，ディジタイザー，高解像度カラーCRTモニター，24ドット漢字プリンター，高速カラーマルチペンXYプロッターを用いて，次にあげる目的を達成するためのシステムを開発した[1-3,9,11,12,15,20-23]．

1）各種の分析法のポリゴン表と，プロフィログラムを自動出力すること．

2）セファログラムのトレース線図形を自動構築して，Visualized Treatment Objective（以下VTOとする）による成長・治療予測を表示出力すること．

3）パターンマッチングで歯・顎・顔面・頭蓋・口唇の変化を明らかにし，硬組織と軟組織の調和と異常や審美性をvisualに分析すること．

4）セファログラムと歯列弓の点データより仮想三次元セットアップモデルを構築し，顎骨・歯と口唇の成長変化および治療変化をシミュレーションすること．

5）光静止画ディスク装置による画像データベースをリレーショナルデータベース[13]でリンクし[19,20]，必要な時に即座に原データ（セファログラム，パノラマX線写真，顔面・口腔写真）と上記の分析を同時にモニター上にリアルタイムに表示できるようにすること．

上記システムについて，矯正患者の診断，治療方針の確立への応用について検討したところ，臨床的にも有効性が確認されたので報告する．

システム構成および分析方法

1. 構成機器

今回研究開発したシステムにおけるシミュレーションは，セファログラムと口腔模型の実物大写真を資料とし，デジタイザーから点データをXY座標値で入力し，データディスクに，症例の新規登録時に入力済みの症例ID（identification，以下IDとする）より，経過データ追加時に入力する症例番号からデータディスクより読み出した，生年月日や初診日等と，追加時入力するデータの採取日と自動計算した年齢とともに自動的に保存する．分析時に，セファログラムデータからはトレース線図形を，歯列弓データからは歯・歯列弓咬合面展開図をCRT上にリアルに表示する．

セファログラムトレース線図形と歯・歯列弓咬合面展開図を同期させて，コンピュータグラフィックシ

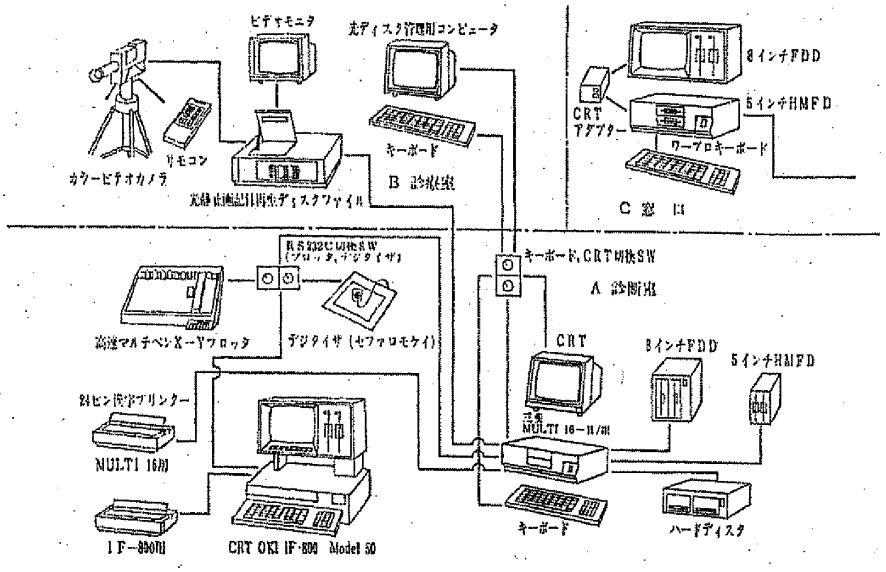


図1 統合化矯正臨床問題解決支援ハイブリッドシステム
A：仮想三次元セファロ模型セットアップシミュレータ解析コンピュータシステム
B：半導体レーザー光線記録再生検索ファイリング光ディスクシステム
C：リレーショナルデータベースによる窓口患者管理システム

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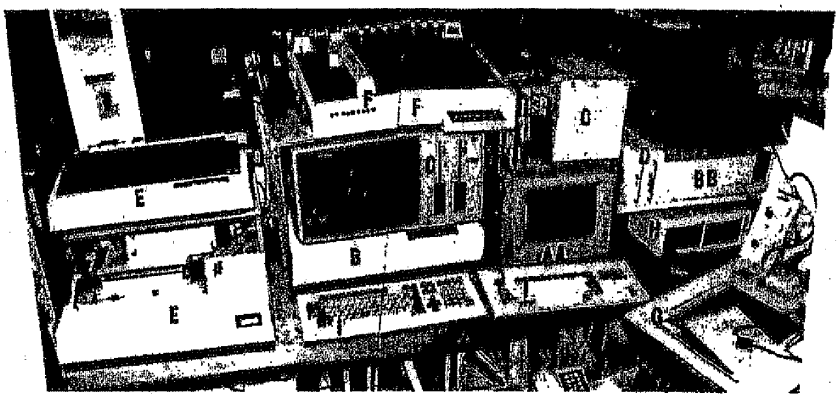


図 2　仮想三次元セファロ模型セットアップシミュレータ解析コンピュータシステム（図1，A）
A：CRT 640×475 ドット8色カラー，AA：CRT 640×400 ドット8色カラー
B，BB：コンピュータ本体，C：8インチFDD 1M×2，D：5インチHMFD 1M×2
E：24ピン漢字プリンター，F：高速マルチペンX-Yプロッタ
G：デジタイザー，H：ハードディスク 10M×2，I：キーボード

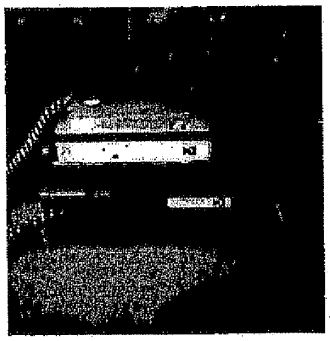


図 3　歯・歯列弓データ入力用
ポラロイドカメラ

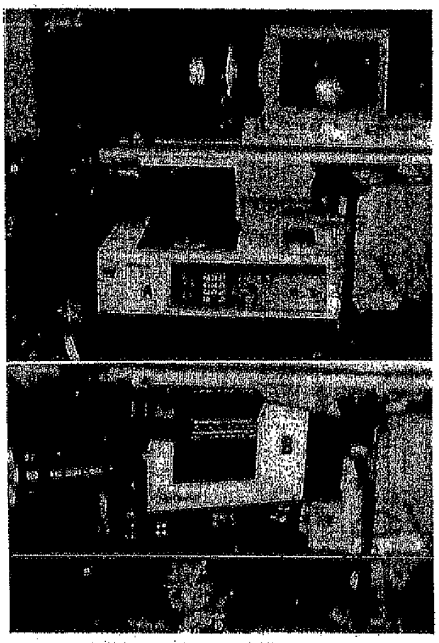


図 4　半導体レーザー光線記録再生検索ファイリング光ディスクシステム（図 1，B）
A：本体，B：三管式カラービデオカメラ

ミュレーションによる仮想三次元セットアップモデルを構築する，また画像生データはレントゲン写真，顔面・口腔写真を三管式ビデオカメラより入力し，光静止画ディスク上に記録，リレーショナルデータベースとリンクして画像データベースを構築し，統合化システムを実現する．

本システムの構成機器は，次の通りである（図1～5）．

1）コンピュータ本体
16bit personal computer
MULTI 16Ⅲ or Ⅱ（三菱電機社製）
IF-800 model 50（沖電気工業社製）

2）デジタイザー
グラディメイト　U4-30（オスコン電子社製）

3）高速カラーXYプロッタ

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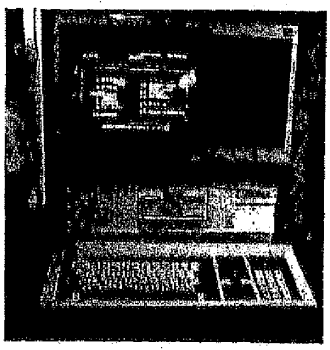


図 5 リレーショナルデータベースによる
窓口患者管理システム（図 1, c）

FP 5301（グラフテック社製）
4）24ピン漢字プリンター
5）ディスク装置
8インチフロッピーディスクドライブ
1メガバイト×2
5インチフロッピーディスクドライブ
1メガバイト×2
5インチハードディスクドライブ
10メガバイト×2
6）光静止画ディスクファイルシステム
TQ-2300 F（松下電器社製）
7）三管式カラービデオカメラ

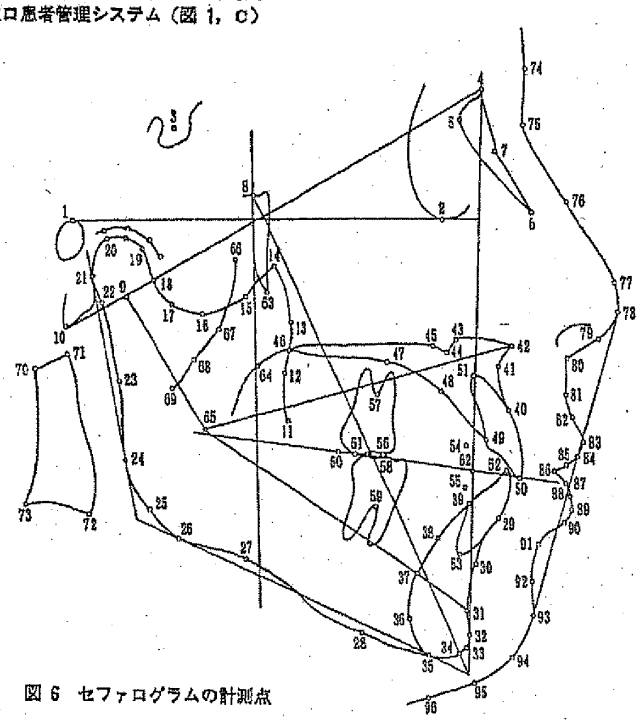


図 6 セファログラムの計測点

1 P	2 OR	3 S	4 NA	5 N2	6 N3	7 N4	8 PT		
9 DC	10 BA	11 Md1	12 Md2	13 Md4	14 Cp	15 Md6	16 Sn		
17 Md8	18 Md9	19 Md10	20 MD11	21 Md12	22 AR	23 Md14	24 Md15		
25 GO	26 Md17	27 Md18	28 Md19	29 Sy1	30 B	31 PM	32 PO		
33 Pog	34 GN	35 ME	36 Sy8	37 Sy9	38 Sy10	39 Sy11	40 Mx1		
41 A	42 ANS	43 Mx4	45 Mx5	46 PNS	47 Mx8	48 Mx9	49 Mx10		
50 Ued	51 Uirt	52 Led	53 Lirt	54 UC	55 LC	56 UM6cd	57 UM6rt		
58 LM6ed	59 LM6rt	60 UMdist	61 LMdist	62 TI	63 PTM	64 SP	65 Xi		
66 Adl	67 Ad2	68 Ad3	69 Ad4	70 Ax1	71 Ax2	72 Ax3	73 Ax4		
74 SF1	75 SF2	76 SF3	77 SF4	78 EN	79 SF6	80 SF7	81 AS		
82 SF9	83 UL	84 SF11	85 SF12	86 EM	87 SF14	88 SF15	89 LL		
90 SF17	91 BS	92 SF19	93 DT	94 POS	95 GNS	96 MES			

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WY-5000（松下電器社製）

8）等倍率ポラロイドカメラ

オルソスキャンカメラ（ユニテク社製）

9）高解像度カラー CRT モニター

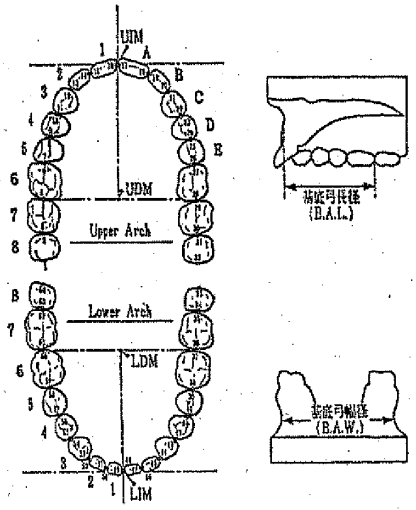


図 7 歯列模型の計測点

2. 計 測 点

セファログラムデータの計測点は，セファログラムトレース線図形の再現と，角度・長さ等の数値分析や各種のポリゴン表の作成に必要な96点を決定し，データ保存効率の向上を図った（図6）．歯列弓データは歯冠パターンによる歯・歯列弓咬合面展開図の再現と数値分析やポリゴン表の作成に必要な点として，おのおのの歯について近遠心接触点の2点，上下顎左右側で第2大臼歯まで萌出の場合は56点，上下顎の咬合時のリファレンスライン設定点として4点，上下顎基底弓幅径と長径用の8点で，合計68点（第3大臼歯まで萌出した場合最大76点）を決定した（図7）．セファログラムの本システムで使用した分析項目の長さ，角度を図 8，9 に示す．

3. 仮想三次元セットアップモデル

セファログラムは各症例につき7枚登録し，1枚につき96点をデータディスクより読み出し，セファログラムトレース線図形を再構築する．同時に Porion, Orbitale, Sella turcica, 上下顎中切歯と第1大臼歯はあらかじめプログラムディスクに18点のパターンデータとして登録してあり，分析時に読み出し，各点に同期させて自動作図出力する．

歯列弓データは各症例につき3経過，すなわち治療前・中・後をデータディスクに登録し，1経過につき

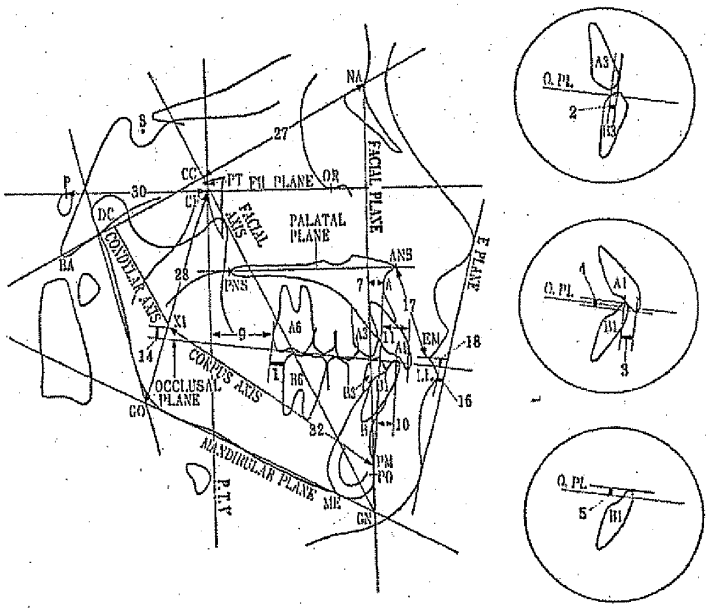


図 8 分析項目（長さ）

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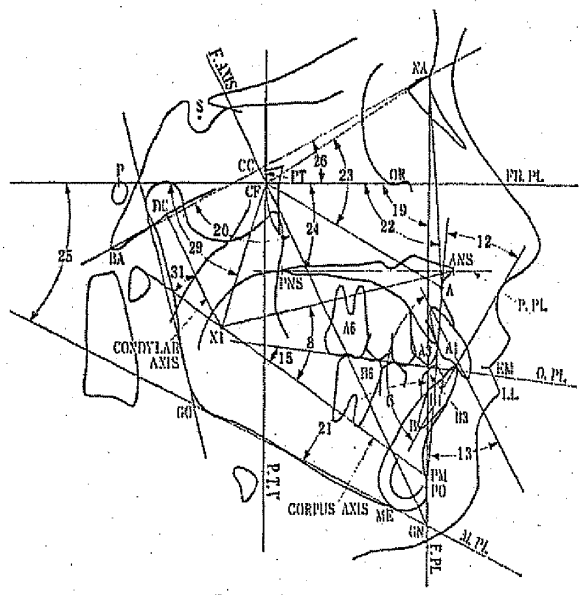


図 9 分析項目（角度）

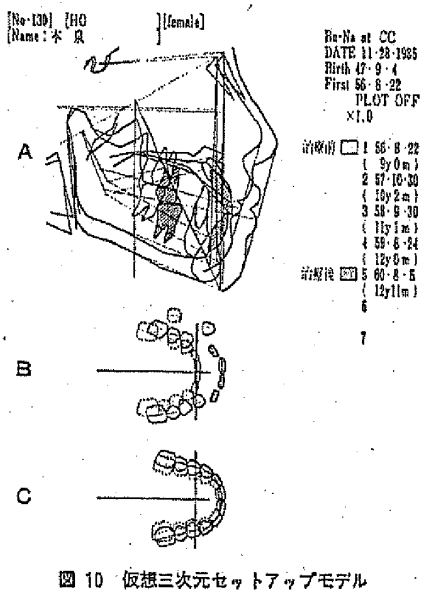


図 10 仮想三次元セットアップモデル
A：治療前後重ね合わせによるコンピュータグラフィックスで構築したセファログラムトレース線図形
B：歯列模型治療前の展開図
実線：上顎，点線：下顎
C：歯列模型治療後の展開図

68点を分析時に読み出し，歯・歯列弓咬合面展開図を構築する．歯冠パターンは各歯につき標準形態を13点で32歯分プログラムディスクにあらかじめ登録してあり，分析実示する時に近遠心接触点で同期させ，長さの倍率に合わせて，歯・歯列弓咬合面展開図を構築する．セファログラムのトレース線図形と歯・歯列弓咬合面展開図を同期連動させるために，中切歯の切縁と第1大臼歯で一致するように補正し，同期連動してコンピュータグラフィックシミュレーションで仮想三次元セットアップモデルを構築し，visual な分析と数値分析を同時に可能にした．

図10は上顎前突症例について，成長・治療変化の実際の仮想三次元セットアップモデルによるシミュレーションである．

4. コンピュータ VTO による成長・治療変化の予測法

Ricketts による VTOの方法を改変し，コンピュータグラフィックスを使用し computerized VTO（以下C-VTO とする）を構築した．96点の点データからセファログラムトレース線図形を自動構築し，成長・治療変化の予測を実現した．図11はその実現のためのプログラムのフローチャートとアルゴリズムである．成長変化を個成長に近づけるために，個成長量=visual norm の成長量×IL (individual length 個体の各部の長さ)/VNL (visual norm length の各部の長さ) と

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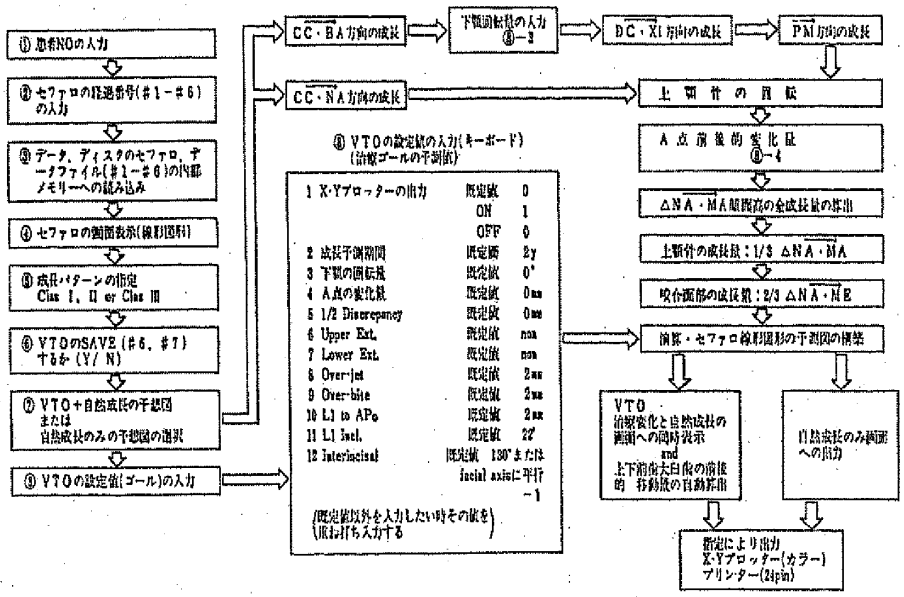


図 11　成長と治療変化の予測のためのコンピュータグラフィックシミュレーションによる VTO 実現プログラムのフローチャートとそのアルゴリズム

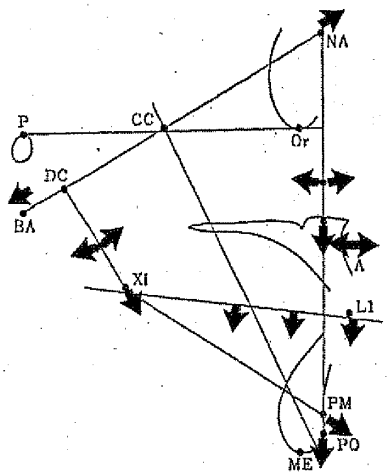


図 12　C-VTO における各部位の成長ベクトルの summary growth algorithm

した．Visual norm とは各年齢における96点によるセファロトレース線図形の visual な平均値で，visual norm length とは visual norm の各部の長さとする．各部とは CC-NA，CC-BA，CC-Xi，Xi-PM，NA-ME，NA-ANS，NA-Tl，CC-GN である．

C-VTO は自然成長（ここでは nontreatment 時の成長とする）および成長・治療変化を予測構築することができる．術者の経験により，対話形式で12項目の設定が可能で各部位の成長と治療の必要改善量を検討しながら予測し，硬組織と軟組織について審美性と調和を達成する過程を明らかにした．

各項目には，理想的ゴールに到達するための値を既定値として設定してあり，術者は経験的な治療改善可能量を考慮しながら各項目を入力してゆく．全項目の設定が完了すると，自動的に VTO を構築し，変化前のセファログラムトレース線図形の上に，CC-NA-BA 重ね合わせ図として表示され，さらにその評価用として6部位による，部分抽出重ね合わせ一括表示図（6S）もメニューでの選択によって構築表示することができる（図11），6部位による重ね合わせ（6 area superimposition）を 6S とし，6S およびその部位とは，1S: NA-BA at CC，2S: NA-CC at NA，3S: E-line at a point of intersection E-line and occlusal plane，4S: mandibular plane at Go' (Go' は point 21-24 line と mandibular plane の交点)，5S: mandibular plane at Pog，6S: palatal plane at ANS とする．

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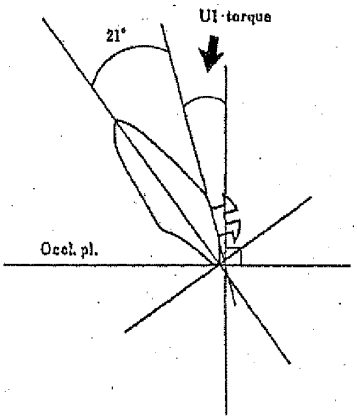


図 13 上顎中切歯のブラケットのトルクの自動算出

VTO 構築のための12項目とその既定値および希望値は次の通りである.

1)「XY プロッタへの出力」の既定値は 0, 出力するときは 1 を入力.

2)「成長予測期間」の既定値は 2 年 (y), 年単位で入力, 3 年以下が望ましい, 成人は 0.

3)「下顎の回転量」の既定値は 0°, 時計方向の回転はマイナス, facial axis の既定値を不変としているが, 回転させて下顎の成長方向を変えたい時, その希望値を入力する.

4)「A点の変化量」の既定値 0 mm, Orthopedic に変化させて, A点を control したい時は希望量を入力する.

5)「1/2 Discrepancy」の既定値は 0 mm. 変化前の萌出 space 不足量の半分, つまり crowding によるオーバーラップ量の総和の 1/2 を入力する.

6)「Upper Ext」の既定値は非抜歯, 抜歯する場合, 第1小臼歯は 4 を, 第2小臼歯は 5 を入力する.

7)「Lower Ext」の既定値は上顎に同じ.

8)「Overjet」の既定値は 2 mm.

9)「Overbite」の既定値は 2 mm.

10)「L1 to APo」の既定値は 2 mm. 咬合平面への下顎中切歯切縁の距離を 1 mm, APo line への距離を 2 mm にしてあり, APo line への距離を変えたい時その長さを入力する.

11)「L1 inclination」の既定値は 22°. 下顎中切歯の APo line に対して希望する角度を入力する.

12)「Interincisal」の既定値は 130°. 希望する角度を入力し, 上顎中切歯を facial axis に平行にしたい時は −1 を入力する.

入力を完了すると, 上下顎中切歯の治療予測変化量と上下顎第1大臼歯の近遠心移動量 (1 : A1, 6 : A6, $\overline{1}$: B1, $\overline{6}$: B6) を自動算出し, 上顎中切歯のブラケットの付加トルク量も自動算出し, 同時に表示する.

以上のように VTO が自動構築される. その順序をフローチャートのアルゴリズム (図11) に従って述べる.

①メインメニューで VTO を選択し予測したい症例を決める. 症例の番号を入力すると症例名と生年月日, 初診年齢等の ID データ, 登録済みセファログラムの撮影日とその時点の年齢, 経過番号が表示される. ②予測したいセファログラムの経過番号を入力する. ③データディスクから目的のセファログラムの点データが内部メモリに読み込まれる. ④画面にセファログラムトレース線図形が構築される. ⑤成長変化のパターンを指定する. ⑥結果を残すか否かを入力する. ⑦成長変化のみの自然成長の出力か, 治療変化も成長に加えて予測するかを入力する. ⑧治療変化も成長に加えて予測する場合は12項目を入力し, VTO 出力を得る. 結果を残す場合, VTO は #6 (経過番号 6) に記録し, 自然成長は #7 (経過番号 7) に記録して, 他の経過セファログラムデータと同様に, 後でいつでも取り出し検討, 分析できるようにした.

C-VTO に用いた成長ベクトルは図12に示す. 治療ゴール達成に必要な上顎中切歯のブラケットの付加トルク量の自動算出方法を図13に示す.

5. 歯の移動分析のためのセットアップモデル

本システムでは discrepancy を自動算出しセファログラムトレース線図形による C-VTO と同期連動させて, 抜歯・非抜歯, 大臼歯・犬歯部の側方移動量, 前歯・大臼歯の前後移動, 下顎前歯の歯軸と APo との前後的位置と咬合面の上下的位置, 軟組織の E-line との距離を同時に検討し, 変化前後を色を変えて, 画面上に残像させながら, それぞれの部位を固定させたり変化させることにより, visual な画像で動的に分析ができる. この歯の移動歯列弓シミュレーションを行うために, 各症例につき三段階の経過データをデータディスクに登録し, 分析時に歯冠パターンデータをプログラムディスクから読み込み, データディスクからアクセスした症例・経過・歯列弓点データの近遠心接触点の位置で, 各歯冠パターンをそれぞれの歯に同期させ, 症例データの歯冠幅径の長さの倍率に合わせてその歯の位置に1歯ずつ構築して, リアルな形態の歯・歯列弓咬合面展開図を再現している.

本システムの discrepancy の自動算出グラフィックシミュレーションの方法を図14-A, B に示す. その7

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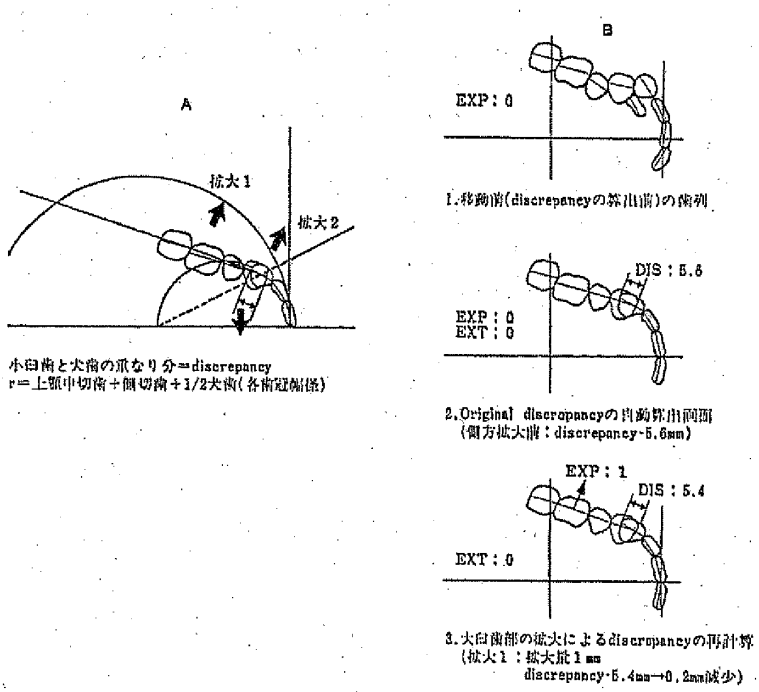


図 14　コンピュータグラフィックシミュレーションによる歯の移動分析における discrepancy の自動算出

ルゴリズムは Bonwill-Hawley の方法を改変した作図法を用い，前歯部は接触点を通る円弧として作図，半径 r は中切歯と側切歯の幅径の和に犬歯幅径の 1/2 を加えた値を既定値とし，プログラム実行時に対話形式で変更して，犬歯部の側方・近遠心移動も可能である（図14-A）．側方の arch form は，本法では犬歯と第1大臼歯の近遠心接触点の中点を結んだ直線とする．図14-B 1は移動前の歯列弓である．図14-B 2は半径 r の円弧上を中点より中切歯，側切歯，犬歯と順に配列し，側方は第1大臼歯をまず直線上に接触点がくるように回転し，次に第2小臼歯，第1小臼歯を配列する．この時犬歯と第1小臼歯のオーバーラップ量，つまり犬歯の遠心接触点と第1小臼歯の近心接触点間の距離が original discrepancy となる（図14-A，B 2）．Total discrepancy は左右の original discrepancy の和とする．図14-B 3 は側方拡大により discrepancy を減少させるシミュレーションで，犬歯部と第1大臼歯部で行うことができ，非抜歯で discrepancy を減少させる必要がある時に行い，とくにⅡ級症例における非抜歯適用の範囲を拡大する必要がある場合に用いる．犬歯部は r を大きくすると拡大し，小さくすると舌側・遠心移動する．第1大臼歯を 1 mm 側方へ拡大すると図14-B 2，3 のように total discrepancy が −5.6 mm から −5.4 mm へ 0.2 mm 減少した．

歯の移動分析シミュレーションの手順を図15に示す．①症例番号を入力すると，氏名と生年月日と年齢が表示される．分析したい経過番号を入力すると，②分析前の歯・歯列弓咬合面展開図とセファログラムの上下顎と中切歯および第1大臼歯が表示される．③Original discrepancy，total discrepancy の算出．④側方拡大により discrepancy を減少させ，その量を自動算出するシミュレーションで，まず非抜歯で拡大のみで discrepancy 解消可能か検討する．不可能であれば，抜歯か大臼歯の遠心移動や他の解決方法を検討する．通常側方拡大は狭窄を伴う歯列に行うが，第2大臼歯が萌出している時は，それも基準に加え，上下顎が最も調和するように，第1大臼歯間の側方拡大量を決める．⑤前歯の前後的位置の決定は，C-VTO を同時に実行して 1/2 discrepancy その他の値を入力して

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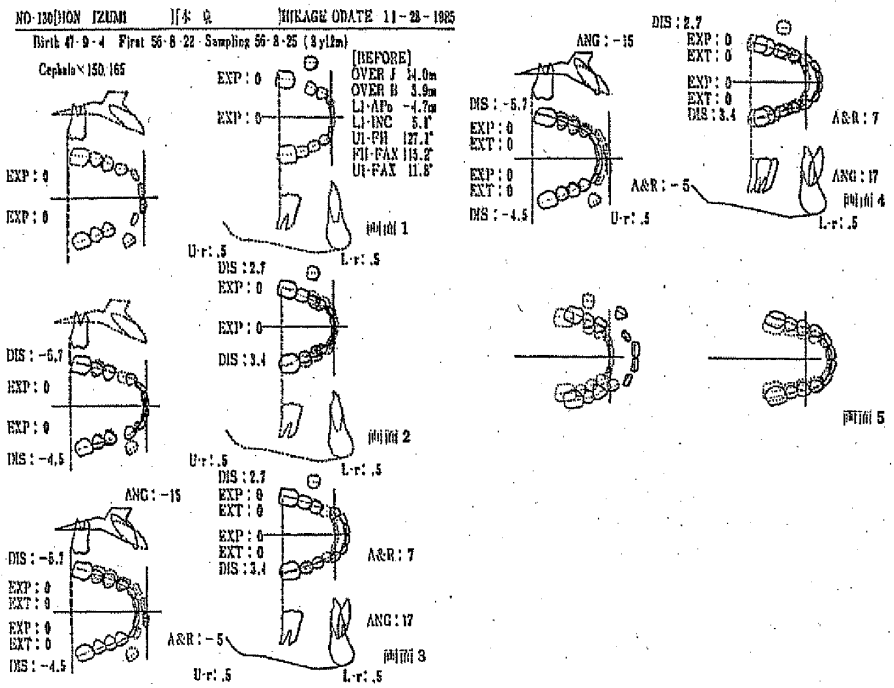


図 15 症例1のコンピュータグラフィックスによる歯の移動シミュレーション

左上 画面1：治療前のセファログラムデータに倍率を合わせて同期させた歯列データの展開図
左中 画面2：対話形式で拡大0の条件での discrepancy の自動算出シミュレーション
左下 画面3：第1大臼歯固定条件における上下顎前歯の retraction と下顎前歯の advancement のシミュレーション
右上 画面4：上下前歯の移動後の第1大臼歯前方移動による space closing のシミュレーション
右下 画面5：治療前後の咬合状態の歯列弓の展開図のシミュレーション

下顎中切歯切縁の APo と咬合平面への距離を決定し，前後的および上下的移動量，傾軸変化量を算出する．その値を参考にして，シミュレータに入力すると，臼歯部の側方拡大と前歯の前後的位置決定後の小臼歯と犬歯のオーバーラップ状態が表示されるので，顎骨内の智歯等の存在状態を考慮して，抜歯・非抜歯を決定する．⑥抜歯の場合はその部位を入力後，再度第1大臼歯固定の状態で表示させる．この時小臼歯と犬歯間に抜歯 space がある場合はそのまま次に進むが，さらにオーバーラップした時は，下顎前歯をもう少し前方の位置に設定するか，または前進させずに第1大臼歯の遠心移動を設定するか，あるいはそれらの両方の移動を設定する．それ以上変更がない時，固定してあった第1大臼歯を近心移動させて space 閉鎖後の状態を確認する．この状態が本シミュレータで到達した individual ideal arch である．⑦分析前の上下顎咬合状態の歯・歯列弓咬合面展開図と治療後の上下顎の咬合状態の予測歯・歯列弓咬合面展開図が表示され，シミュレーションが完了する．

6. 主要6部位重ね合わせ法（6 S）と全体の重ね合わせ法（TS）

本システムでは，Ricketts が報告したような 6 area superimposition (5S)[80]を改変して，次の主要6部位 NA-BA at CC (1S)，NA-CC at NA (2S)，E-line at a point of intersection E-line and occlusal plane (3S)，mandibular plane at Go' (mandibular plane と point 21–24 line との交点) (4S)，mandibular plane at Pog (5S)，ANS-PNS at ANS (6S) について部分的に抽出し，重ね合わせ一括自動表示（6 area superimposition: 6S）し，さらに各種の部位における全体重ね合わせ (total area superimposition: TS) を実現した．各症例について治療前と visual norm，治療前中後，治療前を C-VTO と nontreatment，あるいはすべてを同時に比較することにより，ある基準面

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と点に対する全体的・内部的変化や異常を visual に評価することができる．

1S から 6S の主要 6 部位部分抽出一括表示により，以下のような評価を定量化した．

1S：下顎オトガイ部と上顎第 1 大臼歯の成長および治療変化とその予測および制御必要量，2S：上顎の成長および治療変化方向とその予測および制御必要量，3S：軟組織と硬組織の成長および治療変化とその予測および制御必要量，4S：下顎骨体と下顎顆頭の成長および治療変化とその予測および制御必要量，5S：下顎骨全体と下顎顆頭，下顎前歯，第 1 大臼歯の成長および治療変化とその予測および制御必要量，6S：上顎骨内での上顎前歯と第 1 大臼歯の成長および治療変化のその予測および制御必要量．

7. プロフィログラムとポリゴン表の自動表示

坂本のプロフィログラム，飯塚，石川の報告したポリゴン表や Ricketts の分析法をそのままの形で実現し，さらに計測項目の組み合わせを改変し，すべての経過をカラーで重ねて検討できる要約的な独自のポリゴン表を作製し，独自の分析もあわせて実現した．

プロフィログラムは，とくに日本に多い下顎前突の診断では欠くことのできない最も simple で明解な分析方法であり，上下顎の orthopedic な変化必要量の評価に用いる．

Ricketts の分析法は Dolico, Mesio, Bracky の facial type の 評価を行い，重ね合わせ法と共に上顎前突の診断に用いる．5 factor, 11 factor, internal structure や 32 factor は CRT モニタとプリンターに出力した．

以上の分析は C-VTO，実際の経過の重ね合わせ法によるパターンマッチングや，歯・歯列弓咬合面展開図による分析と併用することで，診断，成長と治療変化の予測や経過の評価を行うための visual な評価を数値分析で補うことで，その評価をより明解にした．

8. 光静止画ディスクファイルによる画像データベース

セファログラム，パノラマX線写真，顔面・口腔内写真を 20 cm スパイラルディスクに記録し，必要な時即座に取り出し，コンピュータシミュレーションと同時に検討したり，結果を記録したり，仮想三次元セットアップモデルをより有効に活用することにした．E-file による自動データベース構築プログラムに通信機能を付加して光ディスクを直接コントロールし，さまざまな検索要求に対応可能にした（図1，4，5）．

9. システムの統合化とリレーショナルデータベース

パーソナルコンピュータ用のデータベース言語（condor s20, dBASEⅡ・Ⅲ, RBASE 4000, 5000等）を使用し，矯正臨床におけるデータマネージメントを行うためのデータベースを作成して，症例の管理やシミュレーションで算出した各症例の角度や長さの結果や治療装置や治療パターンや症例 ID を保存し，それを基にさまざまなデータの加工を行いデータを有効に利用し尽くせる．記録メディアに制限されるが，最大約10億件もの結果が保存可能である．今回の visual norm の統計処理は日本語 E-file で行った．データベ

表 1　7～15歳までの各年齢における主要部位の大きさの平均値と標準偏差（mm）

硬組織	7歳	8歳	9歳	10歳	11歳	12歳	15歳
CC-NA 平均値	52.39	53.53	54.12	54.51	55.75	56.29	58.03
標準偏差	2.32	2.73	2.44	2.65	2.73	2.56	2.83
CC-BA 平均値	42.50	43.47	44.15	44.94	45.98	47.01	50.11
標準偏差	1.77	1.89	1.86	1.88	1.54	2.05	2.70
CC-CD 平均値	26.05	27.08	27.75	28.94	29.54	30.41	32.99
標準偏差	2.24	1.78	1.95	1.82	2.04	2.22	2.09
CD-XI 平均値	27.56	28.60	29.47	30.33	31.02	32.07	34.93
標準偏差	1.74	1.81	1.97	2.11	2.21	2.37	2.70
XI-PM 平均値	56.54	58.13	59.49	60.68	62.19	64.09	68.19
標準偏差	2.64	2.72	2.64	2.55	2.43	2.94	3.30
NA-ANS 平均値	47.81	49.48	51.02	52.34	53.80	55.33	58.23
標準偏差	2.10	2.38	2.43	2.49	2.26	2.56	2.77
NA-TI 平均値	70.38	72.10	73.69	75.87	77.20	79.45	83.44
標準偏差	2.28	2.31	2.39	2.47	2.47	2.73	3.12
NA-ME 平均値	105.63	108.06	110.91	113.56	115.96	118.63	125.58
標準偏差	3.17	2.92	3.25	3.56	3.15	3.88	5.25

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表2 7～12歳までの年間成長量の平均値と標準偏差（mm）

硬組織	7～8歳	8～9歳	9～10歳	10～11歳	11～12歳
CC-NA 平均値	1.14	0.59	0.99	1.24	0.54
標準偏差	1.42	0.92	1.18	1.31	1.08
CC-BA 平均値	0.97	0.68	0.79	1.04	1.04
標準偏差	1.19	0.85	1.27	1.57	1.13
CC-CD 平均値	1.03	0.67	1.19	0.60	0.87
標準偏差	0.82	0.43	0.81	0.83	0.57
CD-XI 平均値	1.04	0.87	0.86	0.68	1.05
標準偏差	0.75	0.40	0.48	0.44	0.55
XI-PM 平均値	1.59	1.36	1.19	1.51	1.89
標準偏差	0.88	0.69	0.55	0.63	1.00
NA-ANS 平均値	1.67	1.54	1.32	1.46	1.53
標準偏差	0.80	0.75	0.64	0.75	0.73
NA-TI 平均値	1.72	1.59	2.18	1.33	2.25
標準偏差	1.08	0.93	0.99	1.24	1.39
NA-ME 平均値	2.44	2.85	2.64	2.41	2.66
標準偏差	1.30	0.99	0.95	1.22	1.48

表3 2年以上の各年齢帯の年間成長量の平均値と標準偏差（mm）

硬組織	12～15歳	9～12歳	8～12歳	7～12歳	7～15歳
	3	3	4	5	8
CC-NA 平均値	0.58	0.72	0.69	0.78	0.71
標準偏差	0.40	0.33	0.27	0.23	0.21
CC-BA 平均値	1.03	0.95	0.89	0.90	0.95
標準偏差	0.47	0.29	0.29	0.23	0.20
CC-CD 平均値	0.86	0.89	0.83	0.87	0.87
標準偏差	0.55	0.23	0.21	0.19	0.20
CD-XI 平均値	0.95	0.87	0.87	0.90	0.92
標準偏差	0.34	0.33	0.31	0.36	0.28
XI-PM 平均値	1.37	1.53	1.49	1.51	1.46
標準偏差	0.73	0.35	0.28	0.27	0.32
NA-ANS 平均値	0.97	1.44	1.46	1.50	1.30
標準偏差	0.45	0.35	0.29	0.32	0.22
NA-TI 平均値	1.33	1.92	1.84	1.81	1.63
標準偏差	0.68	0.61	0.48	0.31	0.24
NA-ME 平均値	2.32	2.57	2.54	2.60	2.49
標準偏差	1.05	0.67	0.64	0.53	0.48

ース言語によるシステムの作成は，項目数が少なければ数分で使用可能で，また途中での変更が可能なので，試運転をしながらデータ項目の追加や削除を行い，時間をかけて十分検討しながら理想のデータベースを構築し，完成させることができる．

データベース言語の採用により類似症例の検索などのように，さまざまに生ずる検索条件で絞り込みの検索やグループ化が可能で，さまざまなバッチ処理や直接のコマンド処理でデータファイルの管理が可能なので，プログラム作成の省力化ができる．データの共有化でデータを種々の形で何度も使用でき，いざとなればデータを高密度に利用することができる（図1, 2, 4, 5）．

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表 4　10歳，12歳，15歳における軟組織の厚さの平均値と標準偏差（mm）

軟組織の厚さ	10歳	12歳	15歳
A-AS 平均値	12.50	13.73	14.77
標準偏差	1.71	1.34	1.72
U1-UL 平均値	13.77	13.51	13.81
標準偏差	1.59	1.70	1.33
L1-LL 平均値	13.70	14.59	15.14
標準偏差	1.35	1.52	1.56
B-BS 平均値	13.67	13.74	14.21
標準偏差	1.99	2.52	1.99
GN-GN' 平均値	7.60	7.90	9.35
標準偏差	1.58	1.77	2.25
PO-PO' 平均値	12.24	12.83	13.39
標準偏差	1.58	1.74	2.41

10. 縦断的経年資料を用いた C-VTO 実現のための visual norm と年間成長量の統計分析（表 1-4）

新潟大学歯学部矯正学教室所蔵の新潟県中魚沼郡川西町の児童 180 名の縦断的経年資料の中から正常咬合者32名（男子16名，女子16名）を選び，セファログラムを資料として統計処理を行った．

硬組織は CC-NA, CC-BA, CC-CD, CD-Xi, Xi-PM, NA-ANS, NA-TI, NA-ME の 8 項目について，7～12歳までと15歳の各年齢別の平均値と標準偏差を算出して，visual norm とした（表 1）．年間成長量は 7～12歳までのそれぞれの 1 年間の平均成長量と（表 2），12歳と15歳の 3 年間の年間平均成長量（3 年間の成長量を 3 分の 1 にしたもの），7～12歳，8～12歳，9～12歳，7～15歳，12～15歳の 5 種の年齢帯の平均年間成長量（表 3）の平均値と標準偏差を算出した．

軟組織は A-AS（A 点の口唇の厚さ），U1-UL（上顎中切歯切縁から口唇ポイント83までの厚さ），L1-LL（下顎中切歯切縁から口唇ポイント89までの距離），B-BS（B 点の口唇の厚さ），GN-GN'（GN 部の軟組織の厚さ），Po-Po'（Po 部の軟組織の厚さ）の 5 項目について 9 歳，12歳，15歳のそれぞれの平均値と標準差を算出した（表 4）．

臨床的応用とその結果

矯正臨床における代表的な，上顎前突，下顎前突，叢生の症例について，本システムを適用し臨床的応用を検討した．

症例 1：上顎前突で初診時 9 歳，女児（図15～19）．Overbite 3.9 mm, overjet 14.0 mm. 下唇が陥凹し，典型的な過度の deep bite と overjet を有し，5 factor は facial axis 85.5°(ほぼ mean), facial depth 88.1°(1SD 以内), mandibular plane 21.1°, lower face height 42.3°, mandibular arc 33.2°（MP と LFH は−2 SD で MA は +2 SD 以上）で Brachy facial pattern（上下的に圧平な顔貌）を有する II 級症例である．図15により歯の移動シミュレーションの手順を説明する．画面 1 は治療前の上下顎骨と上下歯列弓の表示画面である．画面 2 は中切歯と第 1 大臼歯を前後的に固定した discrepancy の自動算出シミュレーションである．下顎の左側の discrepancy は −2.7 mm で，右側は−3.4 mm，上顎の左側の discrepancy は +4.5 mm で右側は +5.7 mm であった．L1-APo −4.7 mm, L1-inclination 5.1° の自動算出値および C-VTO を同時に考慮して上顎前歯の後退量を −5 mm，傾斜量を −15°，下顎前歯の前方移動量を 7 mm，前方傾斜量を 17° と決定し L1-APo を 7 mm 変化させて 2.3 mm とし，L1-inclination は 17° 変化させて 21.7° を得た．画面 4 は上下顎第 1 大臼歯部の前進量をシミュレーションした結果である．画面 5 の左は治療前の上下顎歯列弓の咬合状態で，右が本システムのシミュレーションで得た咬合時歯列弓展開図である．

実際には非抜歯で治療を開始したにもかかわらず，咬合挙上は困難をきわめた．図 17-A は治療開始前で，1 年 2 カ月間の bioprogressive therapy により，overjet が 7 mm 減少し，かなり改善したが，さらに効果的な下顎の成長が必要であったので，図 17-B に達したところでマルチブラケット装置をはずした．そこで咬合力を下顎の前方成長力に変換する方針を立て，咬合力が下顎を前方へ誘導する tooth positioner を使

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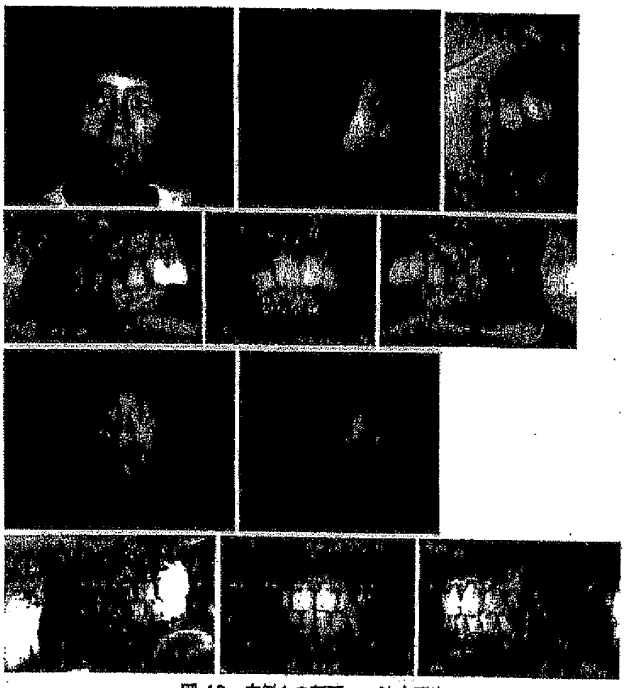


図 16 症例1の顔面・口腔内写真
(A：治療前，B：治療後)

用したところ，予測どおりの良好な下顎の成長が達成された（図17-C）．図17のAからCは初診時（経過1），治療中（経過2），治療後（経過4）のそれぞれのC-VTO画面に表示した実際のデータの線図形である．図17-Dは治療前・中・後つまり図17-A，B，CのNA-BA at CC全体重ね合わせで，図17-Eは6S一括表示画面である．図17-Fは Occusal plane at TI による重ね合わせで，軟組織と硬組織の実際の変化とC-VTOを比較した．つまり図17-C（12歳）と図17-B（10歳）を用いたC-VTOによる予測（10歳の2年後）との重ね合わせで，実際と予測がよく一致し，良好なE-lineと上下唇の調和を達成したことを示している．図18は全体重ね合わせで図19は6S重ね合わせのXYプロッター出力図であり，各部の内部変化が明確になっている．図17-Dおよび図18の重ね合わせ全体表示では，上下顎前歯の overbite と overjet の改善と下顎の成長により全体的に改善されていく様子が明らかになっている．

症例2：構造的下顎前突で初診時8歳，女児．下顎の極端な前上方への偏位がプロフィログラムで示されている（図20-A）．放置すると咬合力が上下顎の成長方向や量に対して悪化力として作用し，上顎には下方へ下顎には前上方に成長方向を変化させ，外科的下顎短縮術が必要となる，比較的重症な限界症例であると思われる．治療は chin cap を base にして acrylic resin mono block（以下 ARMB とする）と組み合わせて，成長方向改善による被蓋改善を試みた．つまり過度の下顎の過成長による前方偏位と過蓋咬合を伴う場合，chin cap 単独で作用させると上顎の成長方向がさらに下後方に変化し増悪必至と診断し，その治療装置は前方牽引を使用する必要があると思われたが，より simple な通常の chin cap と ARMB を用いて治療を開始した．ARMB 装着時に被蓋改善達成後と同様の効果をもたせた．つまり正常被蓋では咬合力と chin cap の牽引力の両方は上顎には前方成長を促進させ，下顎には後方への回転と移動および前方成長制御力を発現させる作用として働くと考えられるので，ARMB にその作用をもたせることで，逆被蓋では上下顎に対して悪化力として働く咬合力と chin cap の牽引力の両方を上下顎の位置改善力に変換させた．つ

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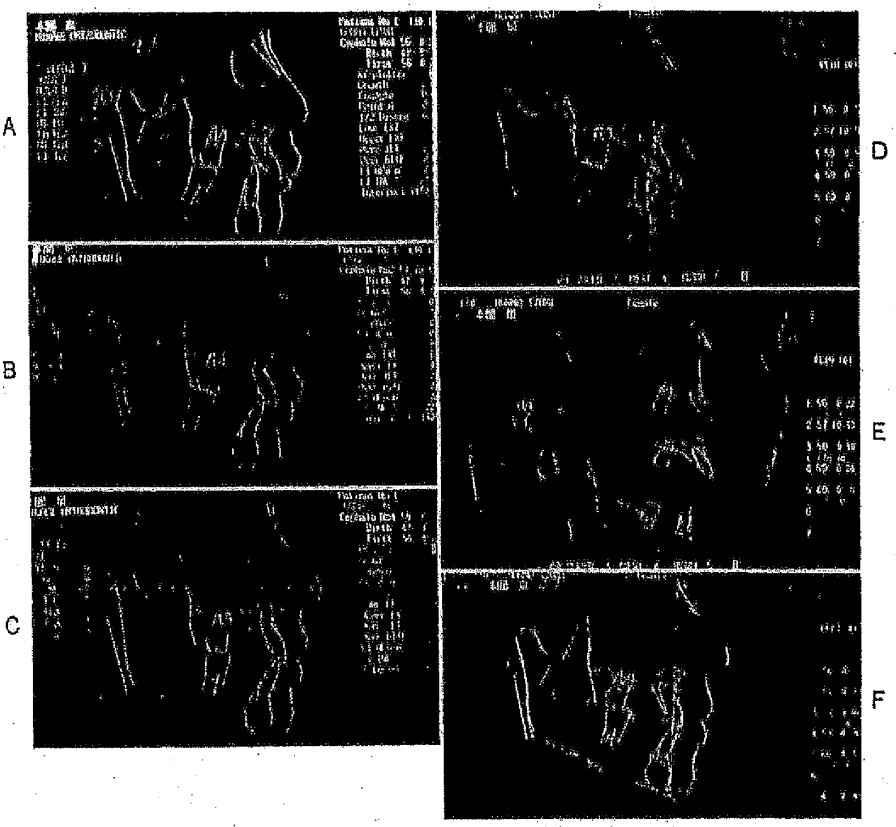


図 17 症例1の C-VTO と重ね合わせ図の CRT 画面

A: 治療前 (9y0m), B: 治療中 (10y2m), C: 治療後 (12y0m), D: 治療前中後の全体重ね合わせ図 (NA-BA at CC), E: 治療前中後の6部位重ね合わせ図 (6S), F: C-VTO と治療後との重ね合わせ図 (occlusal plane at T1)

まりARMR を inclined plane type sliding plate とし force direction converter として咬合力や牽引力の上下成分を前後の水平改善成分に変換させる目的で考案[9]作成し用いた．これにより，2°程度の下顎の後方回転とオトガイ部の後方移動を生じさせて予測どおりの下顎の位置改善と上下顎の成長方向と量を改善し，被蓋改善を達成した．その結果 ∠SNP は初診時 84.3° から 81.3° に 3° 改善した．図20-B は初診時データ（黄）で構築した C-VTO（青）による予測分析例で，12項目の主な設定値は growth 2y, condyle 2°, lower-Ext 4, upper-Ext 4, L1-APo 3.7mm, L1-inc 20°, intericisal は facial axis に平行とした．図21は初診時（赤）と治療中（被蓋改善後緑）と治療中（緑）のデータから interincisal 130°, L1-APo と L1-inc は不変の設定で作成した C-VTO（青）の重ね合わせの XY プロッター出力図である．また図22は治療前（赤）のデータを用いて予測自動算出した nontreatment（緑）の C-VTO と被蓋改善後（青）との6部位重ね合わせ（6S）である．図23-A は治療前の状態で，図23-B は被蓋改善後の状態である．図20-B では下顎の後方回転が必要と考え，時計廻り方向へ 2° 回転させる設定を行って C-VTO を算出したが，実際も mandibular plane が 2° 増加し一致した．図23-C は，被蓋改善後の状態（B）を C-VTO で下顎前歯をその位置に設定して，Interincisal を −1.(−1 は U1 と facial axis とが平行の条件のパラメータ）で，overjet 3.7 mm (over correction), overbite 2 mm の設定で出力した C-VTO の結果である．図23-C

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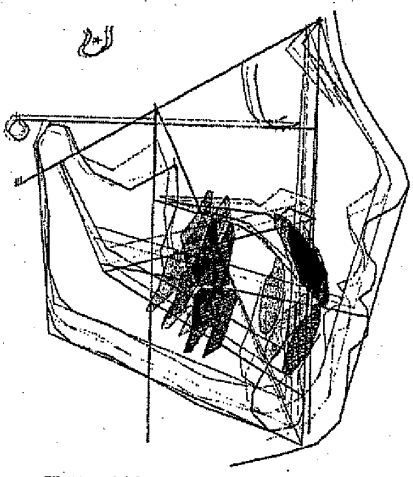
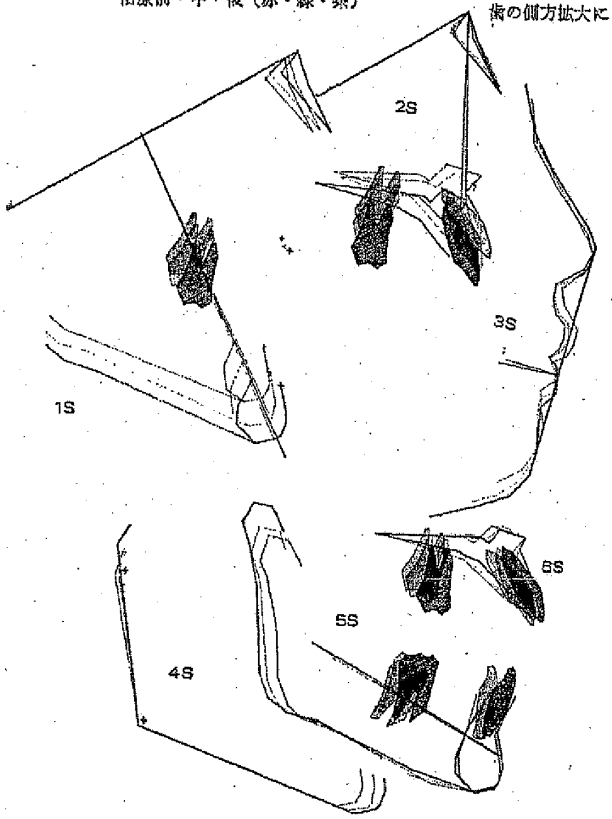


図 18　症例1の NA-BA AT CC による superimposition 線図形出力図
治療前・中・後（赤・緑・茶）

が示すように U1-torque が 25.5° から 6.3° になっている．被蓋改善後の U1 を facial axis に平行にするためには，U1 に 19.2° の reversed torque が必要であり，ブラケットでのトルクは 6.3° を選択すれば良いことを示している．このように C-VTO は初診時の成長・治療変化の予測を行うだけでなく，治療途中でもゴール達成のための必要量を算出シミュレートし，使用ブラケットトルク付加量の検討もした．

症例3：叢生で初診時20歳，女性．前歯部交叉咬合を伴い，discrepancy はそれぞれ上顎 −14.6 mm，下顎 −7.5 mm であった．

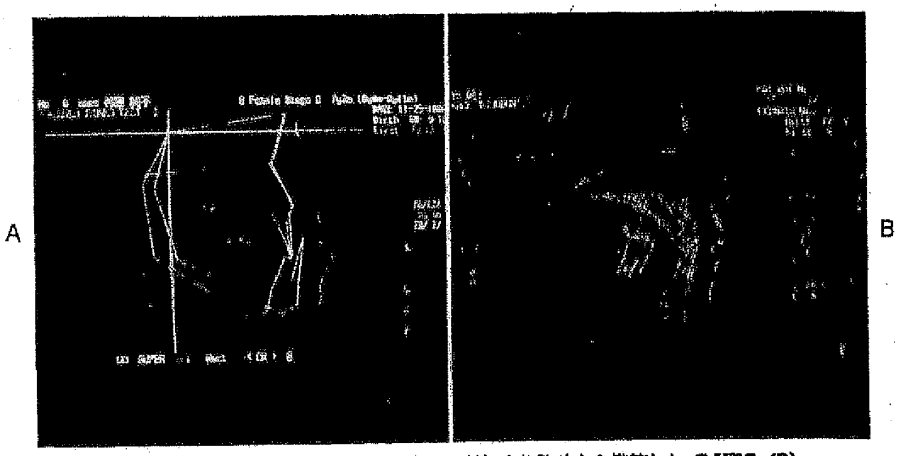
図24-A はその C-VTO で，1/2 discrepancy は −3.5 mm で，下顎は第1小臼歯の抜歯で，上顎は第2小臼歯の抜歯である．その他は既定値をそのまま使用した．図24-B は移動前の歯列弓の状態で，図24-C が discrepancy の自動算出画面である．下顎は左側 −5.3 mm，右側 −2.2 mm，上顎は左側 −9.0 mm，右側 −5.6 mm の結果を得た．図24-D は上顎第1大臼歯の側方拡大による discrepancy の減少量の自動算出



上左　1S: BA-NA PLANE AT CC (CHIN CONTOROL)
上右　3S: E-PLANE (SOFT TISSUE EVALUATION)
下中　6S: MP AT POG (EVALUATION OF LI AND MANDIBULAR GROWTH)
上中　2S: CC-NA PLANE AT NASION (SKELETAL CONTROL OF THE MAXILLA)
下左　4S: MP AT GO (GONIAL ANGLE CHANGE)
下右　6S: PALATAL PL. AT ANS (EVALUATION OF U1 WITHIN MAXILLA)

図 19　部位別重ね合わせ X-Y プロッター出力図

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A B

図 20 症例 2 の初診時のプロフィログラム（A）と初診時から構築した C-VTO（B）

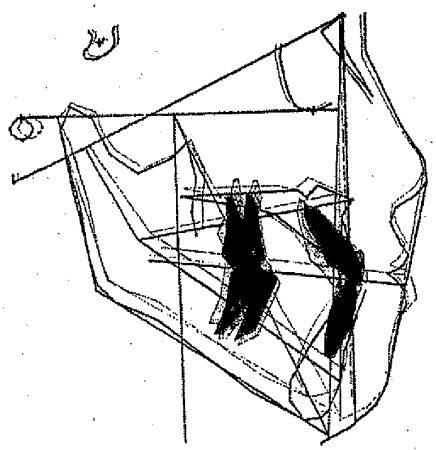


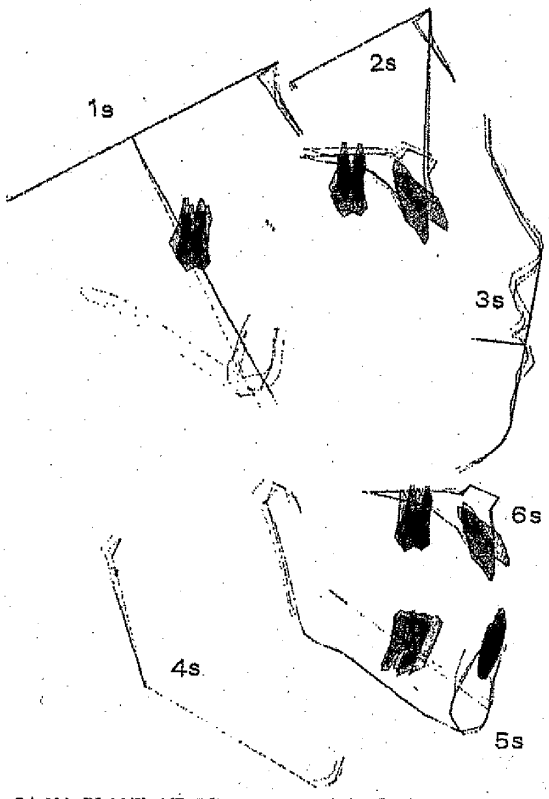
図 21 症例 2 の初診時（赤），被蓋改善後（緑）と C-VTO（青）の NA-BA at PT における superimposition で C-VTO（青）は治療中（緑）を用いて L1 の位置変えずに interincisal 130° の条件で作成した．

と抜歯のシミュレーションで，拡大後の discrepancy の数値の自動算出および抜歯シミュレーションを同時に行った．つまり側方拡大と抜歯の第 1 大臼歯固定で歯生を取り除いた後の抜歯空隙の状態である．下顎左側は 1 mm の側方拡大で 0.2 mm，右側は 0.3 mm，上顎左側は 1 mm の側方拡大で 0.5 mm，右側は 0.2 mm，discrepancy が減少する結果を得たが，抜歯空隙とその他の条件を検討して抜歯と決定した．その結果を用いて，図24-A の C-VTO を予測し，図24-B は図24-D から第 1 大臼歯の固定条件を解除することにより，近遠心移動前後の歯列弓の状態がシミュレーションされ，抜歯空隙は閉鎖され，下顎前歯は 2 mm 後退，3° 舌側傾斜，上顎前歯は 1 mm 前進，6° 唇側傾斜させる結果を得た．図24-F は移動前の上下顎歯列弓の咬合状態と individual ideal arch を達成した移動後の咬合状態の歯・歯列弓咬合面展開図を同時表示して，シミュレーションを完了した画面である．

考　察

Straight wire appliance では bracket の slot に三次元的な形態・構造を付加することにより，術者から arch wire の処理の手間を大幅に軽減させた．また側方拡大や上顎前方および後方牽引装置，functional appliance 等の多くの優れた装置やパーツが供給されるようになり，少しの加工と工夫で orthopedic change や orthodontic change による改善をより効率よく行うことを可能にし，いまや矯正治療の発展は非常に高度で広域に達したといっても過言ではないように思われる．しかしながらいかなる装置も適確な診断と治療方針の設定によって，はじめて本来の機能を発揮することができるわけであり，本システムで実現した歯の移動分析，C-VTO，重ね合わせの自動化は治療開始時の診断・治療計画の決定，成長・治療効果の評価を強力に支援すると思われる．矯正領域へのコンピュータ応用は統計処理によるパターン分析への試み[4,10]や，データベース[10]，セファログラムトレース線図形

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上左 1S: BA-NA PLANE AT CC
(CHIN CONTROL)
上右 3S: E-PLANE
(SOFT TISSUE EVALUATION)
下中 5S: MP AT POG
(EVALUATION OF L1 AND
MANDIBULAR GROWTH)
上中 2S: CC-NA PLANE AT NASION
(SKELETAL CONTROL OF THE
MAXILLA)
下左 4S: MP AT GO
(GONIAL ANGLE CHANCE)
下右 6S: PALATAL PL. AT ANS
(EVALUATION OF U1 WITHIN
MAXILLA)

図 22 部位別重ね合わせ X-Y プロッター出力図

の自動抽出の試み[16,17]等がある．

本システムではパーソナルコンピュータを用いて，今までプロフィログラムやポリゴン表による自動分析しか行えなかったのを，さらに使用しやすく，良好な診断・分析・治療環境を向上させるべくシステム開発・実用化し3年間使用し，改良を重ねた．セファログラムと歯列データは点データで入力・保存し，分析時にセファログラムトレース線図形と，歯・歯列弓咬合面展開図の仮想三次元セットアップモデルを自動構築し，C-VTO，C-VTO との重ね合わせ，実際の治療経過の重ね合わせや，歯牙移動分析グラフィックシミュレーションを構築し individual ideal arch とそこへ至る過程をシミュレーションした．

上顎前突例の図17-Dでは CC-NA と CC での全体重ね合わせから下顎骨の成長改善状態が一目で明らかになり，6S では各部の変化様相が明らかになっている．反対咬合の改善において，図20-A が示すように下顎のオトガイ部が前上方へ変位している症例においては，下顎を後下方へ回転することで上下顎の前後的な改善を C-VTO で自動算出し，治療限界の検討に用いた[9]．また gonial angle の変化においては AR で計測する従来の方法では，変化を十分把握できなかっ

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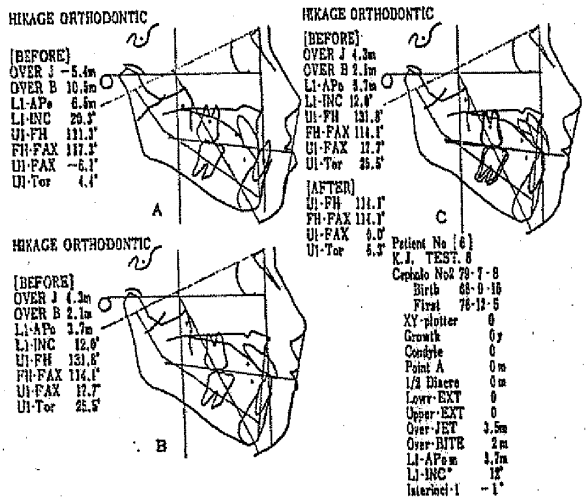


図 23 症例2における被蓋改善後を用いて構築したC-VTOによる前歯のリバーストルク必要量(ブラケット付加トルク)の自動算出

A：治療前（8y3m），B：治療中被蓋改善後（10y10m），C：治療中（B）を用いてL1のAPo-lineに対する位置を不変の条件で作成したC-VTO（U1-torque=6.3°）

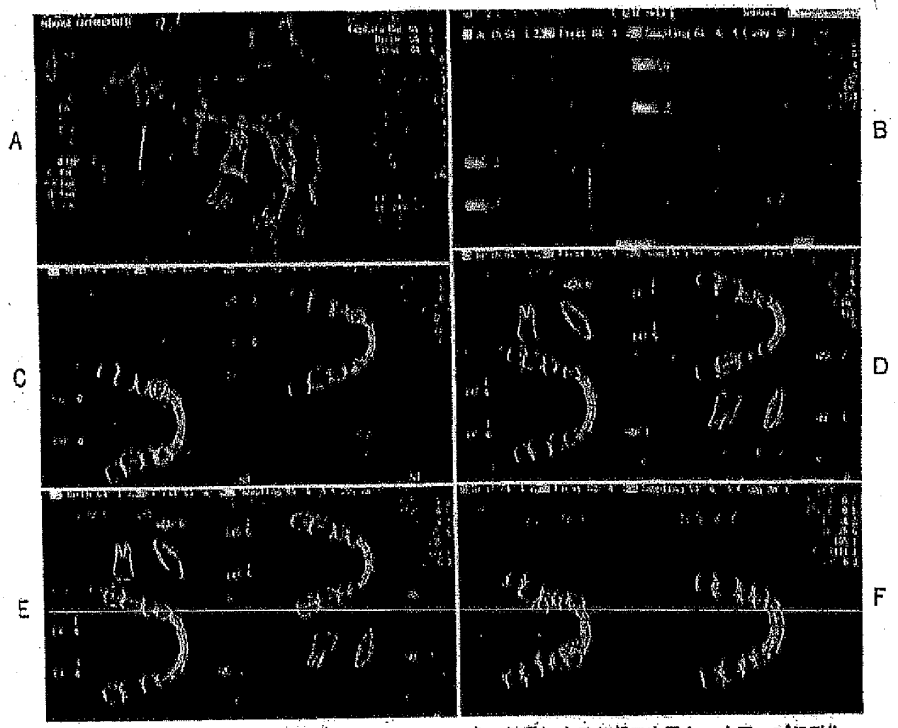


図 24 C-VTO と歯・歯列移動シミュレーションとの連動による仮想三次元セットアップモデル構築と individual ideal arch form へ至る過程の動的解析画面

（A）C-VTO （B）移動前 （C）Discrepancy の自動算出
（D）Discrepancy の側方拡大による減少と抜歯
（E）第1大臼歯の近遠心移動による抜歯空隙の閉鎖
（F）移動前と individual ideal arch 達成後の咬合状態の同時表示

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たが，本システムの主要6部位の重ね合わせの4Sの評価で図22でも明らかなようにgonial angleの減少をvisualに確認できるようになった．図22は赤が治療前で青が実際の被蓋改善後で緑が治療しなかった場合の自然成長の予測である．上顎前歯のトルクの自動算出表示をC-VTO処理で行うので，それに合わせてブラケットを選択できるようになった．上顎前突や下顎前突の程度を∠ANBで従来表現することが多かったが，それだけでは十分でない場合が多く，6S等の評価により，十分表現可能となったように思われる．軟組織のE-lineにおける評価にC-VTOの下顎前歯の位置の設定，抜歯・非抜歯の決定が大きな影響を与え，discrepancyの改善を検討しながら同時に下顎前歯の位置を決定すれば軟組織の状態も自動算出されるので，審美性も常に検討考慮可能になった．また，歯の移動分析は抜歯に関して，側方拡大やその他を試すことにより，非抜歯を十分検討した上で，どうしても必要なら抜歯を決定する．上下顎前歯の位置と複雑な軟組織と硬組織の変化を，下顎前歯の位置の設定で導き出すことができるようになり，硬組織の変化に対応した軟組織の変化を自動的に表示し，シミュレーションした．図17-Fは C-VTO で構築した結果と実際の変化を軟組織で重ね合わせた出力画像であるが，上唇・下唇ともによく一致している．後方回転による下顎前突症例における下顎オトガイ部の前後的位置改善は，今回開発した C-VTO で予測・定量化できるようにしたが，治療で達成する後方移動と顎角部をわずかに小さくする変化や外科的顎短縮術による改善の自動演算に関しては，プログラムをさらに改良して，C-VTO 上で実現する必要があると思われるので今後の課題にしたい．

矯正治療は診断とその改善計画の実行の連続であり，顔面頭蓋，歯列弓，軟組織の形態を評価，成長と治療変化を動的に診断・評価できることは，治療や研究に多大な貢献をもたらす．本研究は，その複雑な手順を自動化する目的でシステムを開発実用化したので，次のようなことが日常臨床でより省力的に行えるようになったと思われる．

1）形態の評価と成長および治療変化の評価のために，セファロトレース線図形と歯・歯列弓咬合面展開図によるコンピュータグラフィックセットアップシミュレーションモデルを構築し，それらを咬合面のreference positionで同期連動させて，仮想三次元セットアップモデルを構築した．それを用いて動的でvisualな成長・治療の実際の変化とその予測についてシミュレーションし，分析検討を可能にした．セファログラムデータと歯列弓データは点データつまりXY座標値で入力，保存効率を向上させているので，多人数の登録（1M フロッピーディスクで 200人）が可能になり，数値分析とvisualな分析で形態とその変化の評価を，実際と予測について検討可能になった．

2）術者の治療シミュレータとして使用すれば，トレーニングや患者の教育マシンの役を果たす．

3）形態とその変化の評価，診断において，各種部位の重ね合わせの全体表示と主要6部位重ね合わせ部分抽出一括表示（6S）は，orthopedic changeとorthodontic changeを明確に表示し，歯・顎・顔面の硬組織と軟組織の関係についての不正，調和，審美性について検討可能にした．

4）プロフィログラム，ポリゴン表による従来の分析法も自動表示して，診断・評価を補強する．

5）セファログラム，パノラマ等のX線写真と顔面口腔内写真の画像生データは光静止画ディスクファイルに記録し，リレーショナルデータベースとインターフェースして，画像データベースを構築して管理した．さらに静止画ファイルとコンピュータシミュレータシステムともリンクすることで統合化システムを構築し，データを共有化させ何度も利用できるようにした．

矯正歯科領域では，機能的咬合と審美性の両方の確保が要求され，多様化した診断方法や治療方法に対応しうる判断基準が必要である．さらに顔面の審美性や歯周組織の健康をもたらすような目標を達成すべく，診断・治療計画・治療を行う必要がある．本システムはそれらの達成のために，より快適な環境を実現できるシステムを目指した．今後本システムにさらに知識ベースとルールを追加し，本システムのデータベースと連結し，推論エンジンをもたせ，人工知能技術を応用したシステムにするため一層の改良を加えていきたいと考えている．

稿を終えるに臨み，ご指導とご校閲を賜った新潟大学歯学部歯科矯正学教室花田晃治教授に深く感謝いたします．また多大なご協力をいただいた安永幸宗氏に深く感謝します．

なお，本研究の一部は第43回日本矯正歯科学会学術大会（昭和59年9月岡山）および新潟歯学会（昭和60年11月新潟）において発表した．

文　献

1）アスキー出版局：標準 MS-DOS ハンドブック，東京，1984，アスキー出版，4-512．

2）バインス情報センター：dBASE Ⅱ バイブル，東京，1984，技術評論社，2-345．

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3) 日景清人，宮崎孝明，花田晃治：Orthopedic force を使用した反対咬合の治療法とその限界〔会〕，日矯歯誌 38: 102-103, 1979.
4) 日景清人，安永幸宗，花田晃治：16ビット・パーソナルコンピューターによる矯正臨床シミュレーターシステム〔会〕，日矯歯誌 43: 619, 1984.
5) 日景清人：コンピューターによる矯正臨床支援システムの開発〔会〕，新潟歯学会誌 15: 122-123, 1985.
6) 三浦不二夫：歯・顎顔面頭蓋の形態分析への電子計算機システムの応用，口病誌 39: 541-550, 1972.
7) 中島栄一郎，秋山 譲，保母幹彌：ロッキーマウンテンデータシステムの利用法，東京，1978，ロッキーマウンテンモリタ，1-60.
8) 根津 博，永田賢司，吉田恭彦，菊池 融：バイオプログレッシブ診断学，東京，1984，ロッキーマウンテンモリタ，1-169.
9) 佐藤義雄：入門グラフィックス，東京，1984，アスキー出版，3-255.
10) 作田 守，山形富明，丹根一夫，保田野秀，吉田建美：矯正歯科におけるデータベース・マネジメントシステム，日矯歯誌 44: 537-548, 1985.
11) 清水久司：パーソナルプロッタ活用法，グラフテック監修，東京，1986，日刊工業新聞社，1-207.
12) システムサイエンス研究所：RS-232 C 通信ハンドブック，東京，1985，技術評論社，4-202.
13) 横田宏司：電子計算機システムによるセファロメトリー，日大歯学 43: 572-584, 1969.
14) 相馬邦道：頭部X線規格写真上での類似法による成長予測の検討，口病誌 38: 533-555, 1971.
15) 鈴木 暁：電子計算機システムの三次元模型分析への応用，日矯歯誌 39: 208-228, 1980.
16) 菅原準二，金森吉成，坂本敏彦：頭部X線規格写真の下顎骨線図形における計測点の自動抽出，日矯歯誌 39: 145-156, 1980.
17) 菅原準二，坂本敏彦：線図形入力方式による頭部X線規格写真の処理システム，日矯歯誌 37: 1-7, 1978.
18) 竹内 豊，鈴木 暁，永坂 信，中村進治：基準平面修正機能をもつ頭部X線規格写真分析システム——6年間の臨床経験にもとずいた反省と改良——，日矯歯誌 37: 353-363, 1978.
19) 竹内 豊：類似症例検出法のための顔面パターンの定量的識別に関する研究，日矯歯誌 38: 163-189, 1979.
20) 寺本邦一，石田成子：レーザーを使った光学式ビデオディスクをつなぐ，プロンプト 4: 80-84, 1985.
21) 三菱電機：M-BASIC plus（Ⅲ）文法説明書，東京，1983，三菱電機㈱，1-296.
22) 三菱電機：MULTI 16 MS-DOS M-BASIC コンパイラ使用手引書，東京，1983，三菱電機㈱，1-61.
23) Nevatia, R.: 人工知能・コンピュータビジョンのための画像認識と画像解析画像認識と画像解析，南條監訳，東京，1986，啓学出版，1-239.
24) Biggerstaff, R.H.: Computerized diagnostic setups and simulations, Angle Orthodont. 40: 28-36, 1970.
25) Bimler, H.P.: Bimler therapy part 1 (Bimler cephalo metric analysis, J. Clin. Orthodont. 7: 501-522, 1985.
26) Currier, J.H.: A computerized geometric analysis of human dental arch form, Amer. J. Orthodont. 56: 164-179, 1969.
27) Owen, A.H.: Diagnostic block cephalometrics, J. Clin. Orthodont. 6: 400-422, 1984.
28) Ricketts, R.M., Bench, R.W., Hilgers, J.J. and Schulhof, R.: An overview of computerized Cephalometrics, Amer. J. Orthodont., 61: 1-28, 1972.
29) Ricketts, R.M., Bench, R.W., Gugino, C.F., Hilgers, J.J. and Schulhof, R.J.: Bioprogressive therapy, Calif, 1979, Rockey Mountain D.S. 1-367.
30) Ricketts, R.M., Roth, R.H., Chaconas, S.S., Schulhof, R.J. and Engel, G.A.: Orthodontic diagnosis and planning, Calif., 1982, Rockey Mountain D.S. 15-472.
31) Savara, B.S.: The role of computers in dentofacial research and the development of diagnosis aids, Amer. J. Orthodont. 61: 231-245, 1972.
32) Walker, G.F.: A new approach to analysis of craniofacial morphology and growth, Amer. J. Orthodont. 61: 221-230, 1972.

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Article Summary

Title: Role of Cephalometry for Planning of Jaw Orthopedics and Jaw Surgery Procedures; Authors : T. Hoffmann, M. Farmand et al.

The diagnostic system Quick Ceph Image employed a computer for processing X-ray images and color S-video images obtained with photo and video cameras. The mages were run through a digitizer tablet. While sitting in front of the monitor, the patient is scanned to produce a real-time profile chart, which is matched to the X-ray profile. The cephalometric analysis can be obtained simultaneously over the X-ray image or the profile picture. In addition, the computer system is able to read frontal images and model pictures, as well as intra-oral images.

The computer system is capable of growth simulation and forecast for modeling orthopedics and surgical procedures. It is possible to simulate relative movement of the teeth. After the successful simulation, the operator superimposes it over the original image and then the program generates automatic correction. The resulting image is fine-tuned manually.

Thomas Hofmann, Mostafa Farmand, Günther Blaseio

Die Rolle der Kephalometrie bei der kieferorthopädisch-kieferchirurgischen Behandlungsplanung

Eine Studie mit Fallbericht unter besonderer Berücksichtigung des Quick Ceph Image™ Programms

Viele Kieferorthopäden und Kieferchirurgen benutzen heute die Kephalometrie als wesentliches diagnostisches Hilfsmittel und als Grundlage zu einer Behandlungsplanung, häufig, ohne sich dabei der jeweiligen kephalometrischen Analyse immanenten Unzulänglichkeiten bewußt zu sein. Dieses Verhalten wurde vor allem durch verschiedene Autoren verstärkt, die eine bestimmte kephalometrische Analyse entwickelten und darauf ihre eigene Behandlungsphilosophie aufbauten.

Obwohl E. H. ANGLE davon ausging, daß bei Ausrichten der Zahnbögen in eine »normale Okklusion« gleichzeitig ideale ästhetische Verhältnisse geschaffen würden, erkannten schon in den 50er Jahren einige Kieferorthopäden und Kieferchirurgen, daß die Gesichtszüge und der Profilverlauf von Menschen mit Normalokklusionen keineswegs notwendigerweise schön aussehen mußten [1]. TWEED glaubte umgekehrt, daß normale harmonische Gesichtszüge mit einer Normalokklusion oder Klasse-I- Malokklusion korrelierten und die unteren Schneidezähne dann über basalen Knochen ausgerichtet wären [2].

1955 berichtete STONER über die Möglichkeit einer quantitativen Weichteilanalyse anhand einer Profilphotographie. Nach einer relativ subjektiven Auswahl von 34 Photographien mit Gesichtern, die er als harmonisch aufgebaut und ästhetisch ansprechend empfand, leitete er daraus verschiedene Winkelmessungen an der Ober- bzw. Unterlippe ab [3].

HOLDAWAY veröffentlichte 1956 eine Weichteilanalyse, die er gleichzeitig zur Diagnostik und als Möglichkeit zur Erfassung von Weichgewebsveränderungen durch Wachstum bzw. Behandlung heranziehen konnte [4]. Als *Holdaway ratio* bekannt wurde, daß der Abstand von der NB-Linie zum unteren Schneidezahn gleich dem Abstand zum Pogonion sein sollte, um möglichst ideale Profilverhältnisse anzutreffen.

RICKETTS beschränkte seine Weichteilprofilanalyse auf den Gesichtsbereich, der durch eine kieferorthopädische Behandlung beeinflußbar war und führte 1957 die E-Linie (esthetic line) ein. Der Abstand der oberen bzw. unteren Lippe zu einer Linie von Nasenspitze zum Weichteilpogonion betrug bei einer Reihe von Filmstars 4 bzw. 2 mm [5]. Ricketts suchte auch anhand von 40 ästhetisch besonders beeindruckenden Gesichtern nach einer Beziehung zwischen unterer Schneidezahnposition, kompetentem Lippenschluß und Harmonie des Gesichtes, betonte aber, daß eine Idealokklusion nicht notwendigerweise ein Kriterium für Schönheit sei.

Dr. Günther Blaseio hat finanzielles Interesse an Quick Ceph Image™

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Im Gegensatz zu den relativ eingeschränkt möglichen Profilveränderungen durch eine kieferorthopädische Behandlung ergab sich durch die Weiterentwicklung der orthognathen Chirurgie für den Behandler die Notwendigkeit zu einer genaueren Diagnose und einer Vorhersage des kieferchirurgischen Endergebnisses unter Berücksichtigung zusätzlicher Aspekte der Gesichtsästhetik. Unglücklicherweise handelte es sich bei den Untersuchungen über die Veränderungen infolge von kieferchirurgischen Eingriffen jedoch überwiegend nur um Erweiterungen bzw. Ergänzungen der Arbeiten, die in der kieferorthopädischen Literatur zur kephalometrischen Analyse bekannt waren [6].

Anfänglich wurde das seitliche Fernröntgenbild nur zur Darstellung der skelettalen Veränderungen nach einer Osteotomie der Mandibula herangezogen. GOLDSTEIN benutzte vielleicht als erster eine Durchzeichnung des seitlichen Fernröntgenbildes, um die skelettalen *und* Weichgewebsveränderungen bei der kieferchirurgischen Behandlung der mandibulären Prognathie darzustellen [7].

Nachdem sich bei Nachuntersuchungen mit verbesserten diagnostischen Verfahren unter Berücksichtigung des Wachstums häufig herausstellte, daß eine skelettale Reaktion auf die kieferorthopädische Therapie ausgeblieben war, erlangte die orthodontisch-kieferchirurgische Behandlung von Dysgnathien in den letzten Jahrzehnten zunehmende Bedeutung. Ein weiterer Grund lag auch in der nunmehr vorhandenen Möglichkeit, skelettale Fehlbildungen bei Erwachsenen unter Einbeziehung gesichtsästhetischer Aspekte ursächlich zu behandeln.

Die Vielzahl der Veröffentlichungen auf dem Gebiet der orthognathen Chirurgie nahm deshalb in den 60er und 70er Jahren sprunghaft zu, selten jedoch gab es Hinweise oder Kriterien für eine Behandlungsplanung unter Berücksichtigung der Gesichtsästhetik. Therapeutische Entscheidungen wurden häufig anhand der kephalometrischen Analyse unter Erzielung der Normwerte getroffen.

Bis etwa 1974 beschränkte sich eine kieferorthopädisch-kieferchirurgische Behandlungsplanung auf eine anteriore bzw. posteriore Bewegung der Mandibula. LINES und STEINHÄUSER erweiterten die kephalometrische Analyse, um alle Möglichkeiten der kieferorthopädischen Chirurgie in eine Behandlungsplanung einbeziehen zu können. Zwar war diese Analyse auf die traditionell bekannten Punkte, Strecken und Winkelmessungen beschränkt, sie führten aber Nachuntersuchungen bei sämtlichen üblichen Standardoperationen der kieferorthopädischen Chirurgie durch und wiesen regelmäßige Veränderungen der bedeckenden Weichteile nach [8]. Allerdings ergaben sich einige Unregelmäßigkeiten, bedingt durch Spaltenpatienten im Probandengut.

Obwohl 1972 ROBINSON versuchte, die quantitativen Weichteilveränderungen bei der chirurgischen Klasse-III-Behandlung in Relation zu den skelettalen Veränderungen zu erfassen, gab es bis etwa 1980 kaum Literaturhinweise, die die Möglichkeit einer Weichteilvorhersage aufzeigten [9, 10, 11, 28]. Bei dem Versuch einer präziseren Weichteilprognose bemerkten die meisten Autoren, daß es eine große individuelle Streuungsbreite im Verhältnis zwischen Hart- und Weichgewebsveränderungen als Reaktion auf die chirurgiche Intervention gab, und die Übertragung der Planung in die eigentliche Operation Schwierigkeiten bereitete.

Die meisten kephalometrischen Analysen benutzen Durchschnittswerte aus einer Normalpopulation als Leitfaden für die Diagnostik einer Gruppe von Individuen mit Extremen. Verfährt man derartig, so erkennt man durch die kephalometrische Analyse weder die individuellen Abweichungen innerhalb der verschiedenen Punkte, Strecken und Winkel, noch die große Variationsbreite, die sich innerhalb einer Normalgruppe verbirgt [6]. Ein Vergleich der kephalometrischen Meßwerte eines Individuums mit kephalometrischen Normwerten resultiert häufig in Abweichungen der Meßwerte, die keine biologische oder klinische Bedeutung besitzen, sich aber in einer Diagnose summieren, ohne wirklich sinnvoll eine Entscheidungshilfe für eine Behandlung zu geben.

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SVAVICEK hat durch die Einbringung eines dynamischen Konzeptes in das ansonsten statische Fernröntgenseitenbild die diagnostischen Möglichkeiten um funktionelle Aspekte erweitert, die bereits im angloamerikanischen Raum in die Diagnose und Behandlungskonzepte von ROTH und GUGINO eingeflossen sind [30]. Trotzdem wäre eine Erweiterung dieser nur zweidimensionalen Konzepte um die dritte Dimension wünschenswert.

Die Variabilität, inwieweit die Weichteile sich nach kieferchirurgischer Lage- und Positionsveränderung des Ober- und Unterkiefers verändern und an neue funktionelle Gegebenheiten anpassen, begrenzt somit eine genaue Weichteilvorhersage. Eine Profilvorhersage, die sich normalerweise auf eine Modelloperation und das Fernröntgenseitenbild des Patienten stützt, hat aber in mehrfacher Hinsicht Bedeutung:

1. Die Notwendigkeit eines kieferchirurgischen Eingriffs zusätzlich zu einer kieferorthopädischen Therapie zur Behandlung der Dysgnathie dem Patienten verständlich zu machen;
2. dem Patienten vor einer Operation einen Anhalt über das mögliche oder zu erwartende Profilresultat zu geben;
3. eine Einschätzung und Abwägung der Behandlungsauswirkungen bezüglich Stabilität und Ästhetik für den Behandler zu erlangen.

Bei den Profilvorhersagen von WORMS et al., EPKER und FISH, MANSOUR, BURSTONE und LEGAN oder PROFITT dienten als Richtlinien bei der Planung Standardnormwerte über das Weichteilprofil und die Position der Schneidezähne im Verhältnis zu den Kieferbasen [9, 12, 13, 14, 15, 33].

Seit 1984 wird in der Literatur über computergestützte Verfahren zur Planung kieferorthopädischer-kieferchirurgicher Eingriffe berichtet [16, 17, 18, 19]. Diese Verfahren bedienen sich meistens der seitlichen Fernröntgenaufnahme oder computertomographischer Daten, um eine Zeichnung (Tracing) oder Vorhersage des chirurgischen Ergebnisses zu ermöglichen. In jüngster Zeit ermöglichen einige Computersysteme eine Simulation und Vorhersage der Behandlungsergebnisse nicht nur am Tracing, sondern auch an der Profilfotographie (Dolphin Imaging System, Orthodontic Treatment Planner, OMS, Quick, Ceph Image) [27].

Eine Vorhersage durchschnittlichen Gesichtsschädelwachstums und kieferorthopädischer Behandlungsergebnisse wird hingegen seit längerem durchgeführt [21]. Vergleiche in Form von tatsächlichen Messungen oder durch Überlagerungen der Vorhersage und der Kontrolldurchzeichnung der Fernröntgenbilder sind dagegen selten durchgeführt worden [21, 22].

Bei Betrachtung der Ergebnisse einer Nachuntersuchung von BENDER ergeben sich für einige Bereiche Unsicherheiten bezüglich der Vorhersagemöglichkeiten des Weichteilverhaltens nach kieferchirurgischen Eingriffen in der Seitenansicht [22]. Die größten Probleme gibt er in Übereinstimmung mit der Literatur bei der Vorhersage von Weichteilveränderungen bei Oberkiefervorverlagerungen an, insbesondere für den Nasenspitzen- und Columellabereich. Dagegen erscheinen sagittale Veränderungen der Weichteile bei Unterkieferrückversetzung mit ausreichender Genauigkeit vorhersagbar [23].

Alle diese Verfahren gehen jedoch weitgehend von rein kieferorthopädischen Gesichtspunkten aus. Sinnvoller wäre es, eine wesentlich größere Anzahl chirurgischer Fälle zu berücksichtigen und alle Bewegungsmöglichkeiten der einzelnen Kiefer mit den entsprechenden Weichteilveränderungen mittels eines geeigneten Computerprogramms zu vergleichen, um die Schwierigkeiten und Unzulänglichkeiten gerade bei komplexen Bewegungen selektiv berücksichtigen zu können. BENDER [24] hat dies zwar versucht, aber die Fallzahl ist sicherlich zu klein. Ein Vergleich seiner Ergebnisse mit denen von LINES und STEINHÄUSER läßt doch einige Unterschiede erkennen [8].

Wenn auch mittels der üblichen Drahtosteosynthese für den Oberkiefer relativ stabile Behandlungsergebnisse erzielt werden konn-

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ten, so wurde gerade der funktionsstabilen Osteosynthese eine verbesserte Stabilität bei Osteotomien der Mandibula nachgesagt.

Ein skelettales Rezidiv nach funktionsstabiler Osteosynthese der Mandibula erscheint aber nur auf einen späteren Zeitpunkt verschoben (> 6–9 Monate postoperativ) [31], ein Zeitraum, der allerdings bei vielen Nachuntersuchungen keine Berücksichtigung findet. Ob sich durch geeignete Verfahren zur prä- und intraoperativen Fixation des gelenktragenden Fragmentes späte Rezidive durch einen unerwünschten Adaptationsprozess am Kiefergelenk vermeiden lassen, ist noch nicht abzusehen.

Die funktionsstabile Osteosynthese der Maxilla mit dicken, stabilen Platten kann sogar eine Verwindung und Verzerrung der Segmente im Oberkiefer bewirken, so daß sich nach der Narkose der Oberkiefer anders darstellt als geplant. Deshalb sollte man bei der funktionsstabilen Osteosynthese im Oberkiefer vergleichsweise dünnere Platten als im Unterkiefer verwenden.

Die vielen Veränderlichen, die auch durch die unterschiedlichen Fähigkeiten und Erfahrungen des Behandlers bzw. Operateurs und der individuellen Reaktion des Patienten darauf hervorgerufen werden, lassen zur Zeit, aufgrund der geringen Anzahl der Untersuchungen und der verwendeten Fallzahlen, standardisierte Ergebnisse oder allgemeingültige Aussagen über die Qualität der jeweiligen chirurgischen Vorgehensweise fraglich erscheinen.

Zusammenfassend erscheinen Weichteilveränderungen nach kieferchirurgischen Operationen abhängig von

1. der Art des chirurgischen Eingriffs,
2. der Operationstechnik,
3. der Dauer des Eingriffs,
4. der individuellen postoperativen Veranlagung des Patienten (response).

Quick Ceph Image™

Die Hardware

Quick Ceph Image™ läuft unter dem Apple Macintosh Betriebssystem auf Macintosh II Rechnern. Mindestens 8 Megabyte Arbeitsspeicher (RAM) werden benötigt; aufgrund der Vielzahl der zu haltenden Bilder werden jedoch 32 Megabyte empfohlen. Das 32 bit Macintosh Betriebssystem Version 7 kann diesen Arbeiitsspeicherbereich linear adressieren. Das unter MSDOS übliche Paging ist nicht nötig. Eine normale 80 Megabyte Festplatte ist ausreichend, eine größere empfehlenswert (*Bild 1*).

Röntgenbilder werden von der Sony Kamera XC77CE (schwarz/weiß), die Farbbilder von der S-Video Kamera EVI 1011E bzw. einer guten Camcorder Kamera mit mindestens 400000 Bildpunkten aufgenommen.

Die erst im Mai 1991 erschienene technisch hervorragende Videokarte RasterOps 24STV (Nachfolger der Karte 364) digitalisiert die Bilder in Echtzeit und löst jeden Bildpunkt mit 24 Bit auf, so daß eine Palette von mehr als 16 Millionen Farben zur Verfügung steht. Das Macintosh Betriebssystem kennt keine Standardbildschirmgröße wie EGA, VGA oder Super VGA und auch keinen Text- oder Graphikmode. Gezeichnet wird ausschließlich im Graphikmode in Fenster (windows), welche dann auf der zur Verfügung stehenden Bildschirmoberfläche erscheinen. Gute Macintosh Programme folgen alle den gleichen »User Interface Guidelines« und sind daher generell leicht zu erlernen.

Quick Ceph Image zeigt Röntgenbilder, Zeichnungen und Text in vielen Fenstern. Diese sind auf dem Monitor frei verschiebbar wie Papier auf einer Schreibtischoberfläche und können nach Belieben vergrößert, verkleinert und gelöscht werden. Mehrere Bilder lassen sich so gleichzeitig beobachten und miteinander vergleichen. Die Verwaltung der vielen gleichzeitig erscheidenden Fenster erfordert einen relativ großen Programmieraufwand, macht die Software für den Anwender jedoch sehr übersichtlich und leicht bedienbar.

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Bild 1: Aufbau des Computersystems in der Praxis mit zwei Videokameras und Reflektorschirm zur Lichtstreuung.

Als Drucker kann der Tintenstrahldrucker PaintWriter von Hewlett Packard empfohlen werden. Die Qualität der Strichzeichnungen ist vergleichbar mit der von Plottern. Im Gegensatz zu letzteren erlaubt ein Tintenstrahldrucker aber auch ein schnelles Ausdrucken von Text und sogar von Photos, so daß man mit einem einzigen Drucker auskommen kann. Bilder mit echter Photoqualität kann man mit sogenannten Sublimationsdruckern erreichen, welche allerdings zur Zeit noch kostspielig sind. Videoprinter sind üblicherweise solche Sublimationsdrukker.

Das funktionelle Konzept der Software

Quick Ceph Image™ ist ein Computerprogramm, das Kieferorthopäden und Kieferchirurgen eine schnelle kephalometrische Analyse mit anschließender Behandlungssimulation erlaubt. Die kephalometrischen Funktionen von Quick Ceph Image basieren konzeptionell auf dem 1986 eingeführten Programm Quick Ceph™. Quick Ceph Image erlaubt zusätzlich die Aufnahme, das Abspeichern, das Vermessen und das Verändern von Röntgenbildern, Kopfphotos, Modellbildern und intraoralen Photos.

Quick Ceph Image benötigt kein Digitalisiertablett. Das Röntgenbild wird mit einer hochauflösenden Schwarz/Weiß-Videokamera aufgenommen, abgespeichert und erscheint direkt auf dem Computerbildschirm, wo der Benuzter die kephalometrischen Punkte und Linien mit der Maus auswählt. Mittels einer zweiten stationären Videokamera wird das seitliche Photo aufgenommen. Dabei sitzt der Patient vor dem Monitor und bringt sein in Echtzeit erscheinendes Profilbild mit der gleichzeitig zu sehenden Profildurchzeichnung des Röntgenbildes zur Dekkung. Die kephalometrische Zeichnung mit den unterschiedlichen Analysen kann danach wahlweise alleine oder überlagert auf dem Röntgenbild oder auf dem Profilphoto abgebildet werden.

Ähnlich der Aufnahme des schwarz-weißen seitlichen Röntgenbildes und des farbigen Profilphotos kann der Benutzer das frontale Röntgenbild und das frontale Photo, fünf schwarz-weiße Modellbilder und fünf intraorale Photos und ein weiteres Röntgenbild wie z. B. eine Panoramaaufnahme einlesen. Verschiedene Modellanalysen wie Zahnbogenlängendiskrepanz und Bolton Analyse sind in Vorbereitung.

Eine Wachstumssimulation, basierend auf Durchschnittswerten unter besonderer Berücksichtigung des dolichofazialen Gesichtstyps und der Wachstumskurven der Bolton Standards, ist möglich. Als Weiterentwicklung kann Quick Ceph Image nicht nur eine Wachstumsvorhersage und Behandungssimulation anhand der Strichdurchzeichnungen durchführen, sondern auch die echten Profilphotographien »wachsen« lassen. Die Wachstumssimulation ist fakultativ und muß daher nicht unbedingt durchgeführt werden,

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um eine kieferorthopädische oder kieferchirurgische Behandlung simulieren zu können. Wachstum und Behandlung sind konzeptionell voneinander getrennt. Einer speziell im deutschsprachigen Raum verbreiteten Kritik an einer Wachstumssimulation darf entgegen gehalten werden, daß die entsprechend den Durchschnittswerten vergrößerten Durchzeichnungen bzw. die vergrößerten Profilphotos sicherlich dem gewachsenen Individuum statistisch ähnlicher sind, als die ursprünglichen unveränderten Bilder.

Eine Behandlungssimulation beginnt mit der Eingabe der Unterkiefer-Zahn-Bogenlängendiskrepanz (ALD) in die »Steiner Box«. Der Ausgleich eines Platzbedarfs kann erfolgen durch Mesialisieren der Frontzähne, Aufrichten der Molaren, Extraktion, Expansion oder Ausnutzen des Mehrplatzes der größeren Milchmolaren. Was im Einzelfall getan werden soll, ist die Entscheidung des Behandlers und nicht des Computers und ist abhängig von: erstens der Ästhetik des Profils (voll, flach), zweitens von der vertikalen Abweichung (brachio-dolichofazial) und drittens von horizontalen Abweichungen (Angle Klasse), wobei einer therapeutischen Entscheidung anhand des Profils letztlich mehr Bedeutung beigemessen wird. Mit der Maus sind diese Begegnungen graphisch sehr leicht durchzuführen, eine Eingabe über die Tastatur ist aber ebenfalls möglich.

Nach dem Ausgleich der Unterkiefer-Bogenlängendiskrepanz wendet man sich der Zeichnung zu, jedoch vorläufig ohne die Überlagerung des Röntgen- oder Profilbildes. In rein kieferorthopädischen Fällen wird man die OK Frontzähne in eine funktionelle Beziehung zu den Frontzähnen stellen und die OK Molaren wenn möglich in eine Klasse I einstellen. Ist eine kieferchirurgiche Behandlung angezeigt, so können die folgenden Bewegungen simuliert werden: Im Unterkiefer: Vor- und Zurückbewegen und Rotation des anterioren Segmentes, Kinnplastik und Autorotation der Mandibula. Im Oberkiefer: Vor- und Zurückbewegung sowie Rotation der gesamten Maxilla oder die getrennte Bewegung eines anterioren und distalen Segmentes. Die Weichteilveränderungen der Strichzeichnung nimmt das Programm automatisch vor, entsprechend der in der Literatur veröffentlichten durchschnittlichen Verhältniswerte [32]. Manuelle Veränderungen am Profil kann aber der Benutzer zusätzlich jederzeit vornehmen.

Ist man mit der Behandlungssimulation anhand der Strichzeichnung zufrieden, überlagert man das noch unveränderte bzw. nur durch die Wachstumssimulation veränderte Profilphoto und drückt mit der Maus die »Auto« Taste. Das Programm führt daraufhin eine automatische Korrektur des echten Bildes durch. Dies ist in weniger als einer Sekunde möglich, trotz umfangreicher Rechenvorschriften (Algorithmen). Eine Anzahl von Stiften, Pinseln und Stempeln (Tools) erlauben dann eine weitere Verbesserung des Bildes mit der Hand. Sogar Nasenkorrekturen, Hautverpflanzungen und die Entfernung von Hautverunreinigungen sind schnell durchführbar. Wie sich in der Praxis gezeigt hat, gibt in vielen Fällen erst die Behandlungssimulation des Photos einen ausreichenden Eindruck von der Ästhetik des angestrebten Behandlungsergebnisses. Speziell in der Kieferchirurgie mit den umfangreichen Bewegungsmöglichkeiten ist die Simulation des Weichteilprofils oft das einzige sichere Mittel, eine Entscheidung für die eine oder andere Operation fällen zu können.

Eine Tabelle mit den Meßwerten der initialen Zeichnung, gegebenenfalls der Wachstumssimulation und der Behandlungssimulation kann in einem Fenster aufgerufen werden. Die Meßwerte beider Simulationen sind auf Anweisung auch als Differenz zur initialen Zeichnung auflistbar. Überlagerungen der fünf von Ricketts vorschlagenen Teilbereiche sind abrufbar. Eine weitere vom Benutzer definierbare Überlagerung zeigt die ganzen Durchzeichnungen. Über 10000 verschiedene Überlagerungsmöglichkeiten sind denkbar und vom Benutzer definierbar.

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Fallbeispiel

Anamnese

Die Patientin ist bei Behandlungsbeginn 17 Jahre alt, hatte mit etwa 12 Jahren ihre Menarche, und das Körperlängenwachstum erscheint abgeschlossen. Der allgemeine Gesundheitszustand ist anamnestisch ohne Besonderheiten. Mit 8 Jahren hatte die Patientin einen Fahrradunfall mit Sturz auf das Gesicht, aber ohne Hinweis bzw. Anzeichen einer Fraktur. Bis vor 3 Jahren war sie ca. 4 Jahre lang alio loco in kieferorthopädischer Behandlung gewesen.

Extraoraler Befund

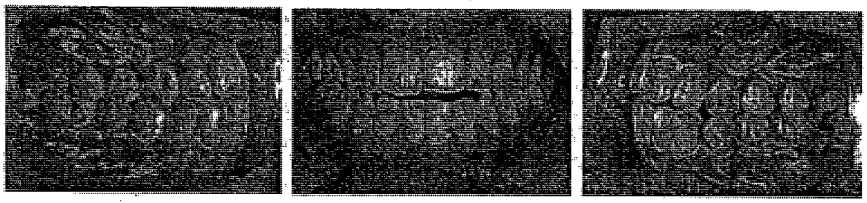
Der Profilverlauf erscheint relativ harmonisch, orthognath mit einer vielleicht mäßig protrusiven Unterlippe. Das Enfacebild läßt eine Asymmetrie im unteren Gesichtsdrittel erkennen. Die Gesichtsproportionen erscheinen harmonisch verteilt, der Lippenschluß ist kompetent (*Bilder 2A + B*).

Intraoraler Befund

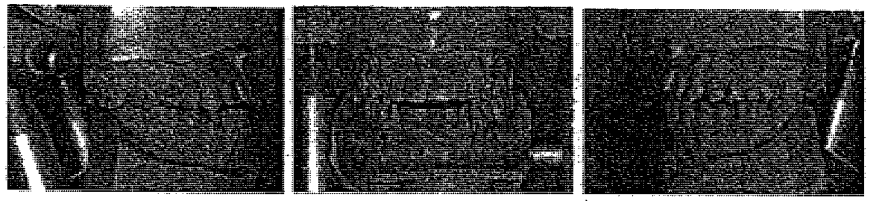
Die Okklusionsbeziehung läßt sich als Angle Klasse III beschreiben. Ein frontal offener



Bilder 2A + B:
Profil- und Enfacephotographie der Patientin.



Bilder 3A–C: Die intraoralen Photographien.



Bilder 4A–C: Die Schädel-gelenkbezüglich einartikulierten Anfangsmodelle in Referenzposition.

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Biß mit einer Abweichung der Mittellinien ist erkennbar. Die Parodontien sind in relativ gutem, entzündungsfreiem Zustand. Diverse marginale Entkalkungen, insbesondere im Prämolaren- und Eckzahnbereich sind sichtbar. Logopädisch läßt sich ein Sigmatismus addentalis diagnostizieren (*Bilder 3A–C*).

Modellbefund/Analyse

Die Schädel-gelenzbezüglich einartikulierten Modelle lassen in RP und IKP eine dentale Klasse-III-Molaren- und Eckzahnrelation erkennen. Der frontal offene Biß ist in RP verstärkt, der Primärkontakt befindet sich auf den zweiten Molaren rechts. Es besteht ein Kreuzbiß im rechten Eckzahnbereich. Oberer und unterer Zahnbogen sind transversal ausreichend entwickelt. Es bestehen Rotationen sowohl im oberen als auch im unteren Frontzahnbereich ohne besondere Beeinträchtigung der Zahnbogenlänge (*Bilder 4A–C*).

Funktionsbefund

Die Mundöffnungsbewegung weicht bei maximal möglichen 46 mm geringfügig nach rechts ab. Die maximale Laterotrusionsbewegung nach rechts ist 7 mm, nach links 10 mm. Das Endfeel ist sowohl bei Öffnungs- wie bei Lateralbewegungen elastisch, aber schmerzhaft. Gelenkgeräusche sind nicht auskultierbar, die Palpation des Muskulatur läßt keine Druckdolenz erkennen, wenn auch die Rechtslateralbewegung gegen manuellen Widerstand schmerzhaft ist.

Röntgenbefund

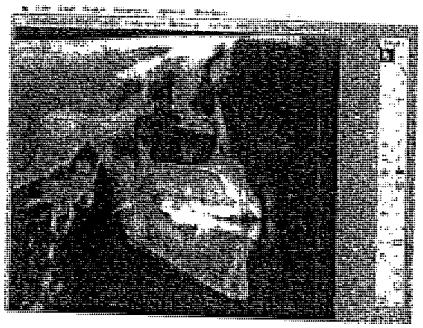
Orthopantomogramm
Alle Zähne einschließlich der Weisheitszähne sind angelegt; der Zahn 46 wurde vor kurzem endodontisch behandelt, apikal ist ein Regenerationsprozeß erkennbar. Der Zahn 17 erscheint elongiert (Frühkontakt!).
Die Mandibula ist relativ symmetrisch, verti-

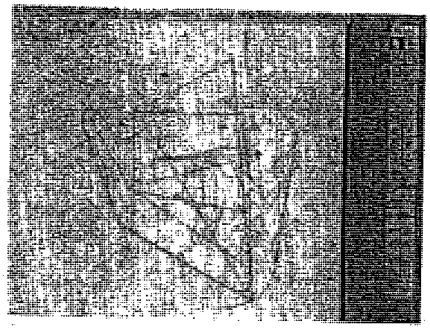
Bild 5: Das Orthopantomogramm vor Behandlungsbeginn.



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Bild 6:
Das initiale kontrastverbesserte Fernröntgenseitenbild mit Durchzeichnung am Computerbildschirm.







Bilder 7A + B: Die kephalometrische Durchzeichnung und das initiale Profilphoto mit Durchzeichnung:

kal im Bereich der Weisheitszähne verkürzt. Beide Kondylen vergleichsweise klein und schmal (*Bild 5*).

Fernröntgenseitenbild und Kephalometrie siehe *Bilder 6 und 7* und *Tabelle 12*.

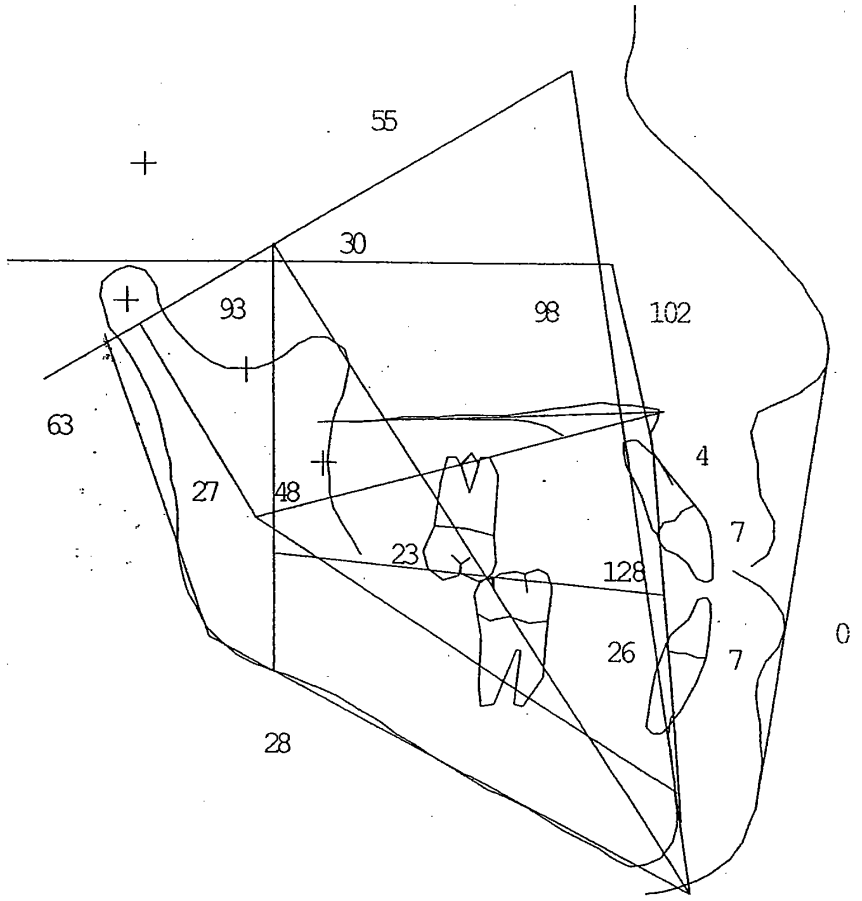
Diagnose

Dentoskelettale Klasse III bei maxillo-mandibulärer Prognathie und Hyperdivergenz, frontal offener Biß, skelettale und alveoläre Mittellinienverschiebung im Oberkiefer nach rechts, Kreuzbiß 13, 44; Dysfunktion überwiegend myogenen Ursprungs.

Behandlungsplanung

1. Orthodontische Vorbereitung mittels Multibandapparatur auf kieferchirurgische Intervention, Nichtextraktionsbehandlung, Koordination der Zahnbögen ohne vertikale Extrusion der Frontzähne, Nivellierung der 2. Molaren im OK (*Bilder 8A–C, 9A + B*).
2. Extraktion der 3. Molaren im UK.
3. OK/UK Osteotomien.
4. Nachbehandlung.
5. Retention.

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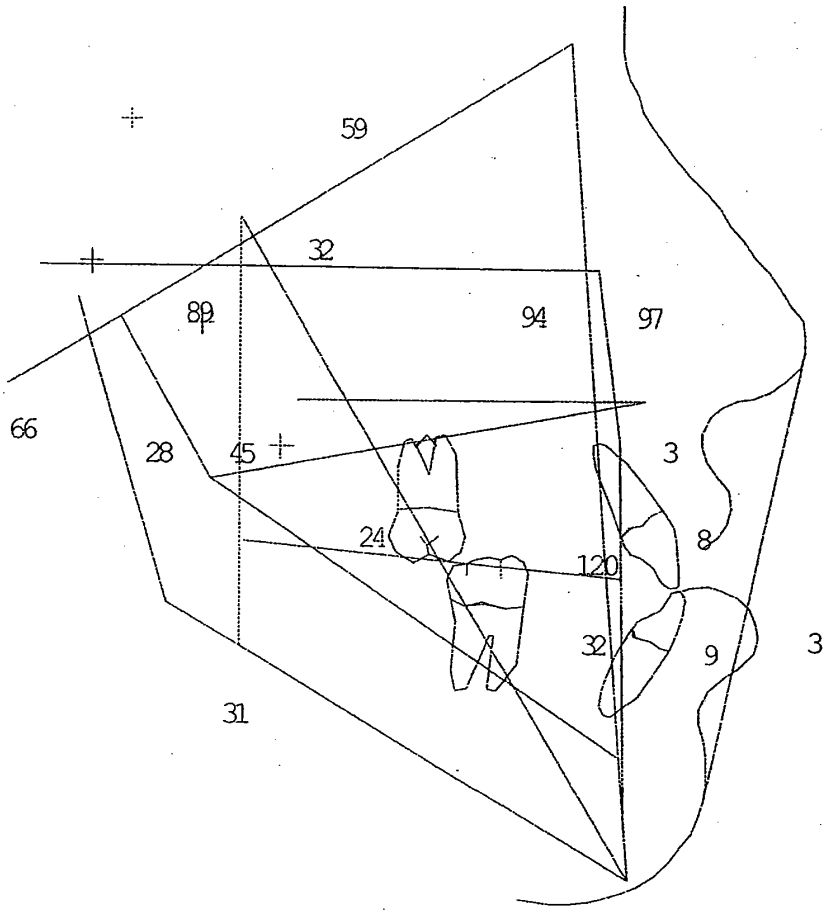


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Tabelle 1: Die kephalometrischen Meßwerte der Rickettsanalyse.

Analysis Ricketts		initial Norm		Clin. Dev.	
Cranial Relations					
Cranial Structure					
Ant Cranial Base	(mm)	54.5	59.4	−2.0	*
Post Facial Ht	(mm)	59.8	54.8	1.5	*
Cranial Deflect	(dg)	30.2	27.3	1.0	
Porion Location	(mm)	−41.8	−38.6	−1.4	*
Ramus Position	(dg)	85.7	76.0	3.2	***
Mx Position					
Maxillary Depth	(dg)	102.1	90.0	4.0	***
Maxillary Height	(dg)	57.8	55.2	0.9	
SN–Palatinal Plane	(dg)	10.1	1.3	2.5	**
Md Position					
Facial Depth	(dg)	98.3	88.3	3.3	***
Facial Axis	(dg)	92.7	90.0	0.8	
Mandibular Plane	(dg)	27.9	24.2	0.8	
Total Facial Ht	(dg)	62.9	60.0	1.0	
Facial Taper	(dg)	53.8	68.0	−4.1	***
MX/MD Relations					
Maxilla					
Convexity	(mm)	4.0	0.9	1.6	*
Mandible					
Corpus Length	(mm)	82.5	73.8	2.0	*
Mandibular Arc	(dg)	26.9	29.8	−0.7	
Maxilla/Mandible					
Lower Facial Ht	(dg)	47.7	45.0	0.7	
Denture Relations					
Mx Dentition					
Mx 1 to APO	(mm)	7.3	3.5	1.7	*
Mx 1 to FH	(dg)	120.7	111.0	1.6	*
Mx 6 to PTV	(mm)	23.5	17.1	2.1	**
Md Dentition					
Md 1 to APO	(mm)	6.7	1.0	2.5	**
Md 1 Inclination	(dg)	25.6	22.0	0.9	
Md 1 Extrusion	(mm)	−2.1	1.2	−1.7	*
Md 1 to Axis-Md 1	(dg)	84.4	90.0	−1.4	*
Mx/Md Dentition					
Interincisor Angle	(dg)	128.1	130.0	−0.3	
Molar Relation	(mm)	−8.7	−3.0	−5.7	***
Incisor Overjet	(mm)	0.3	2.5	−0.9	
Incisor Overbite	(mm)	−2.3	2.5	−2.4	**
Esthetic Relations					
Lower Lip E-Plane	(mm)	0.2	−2.0	1.1	*

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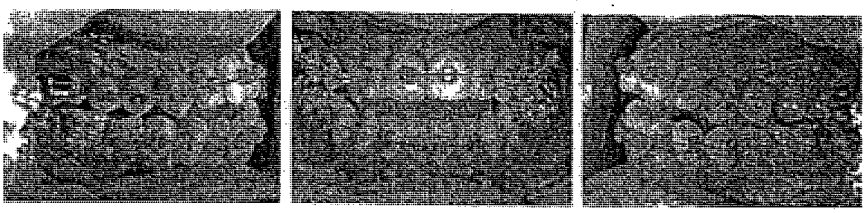


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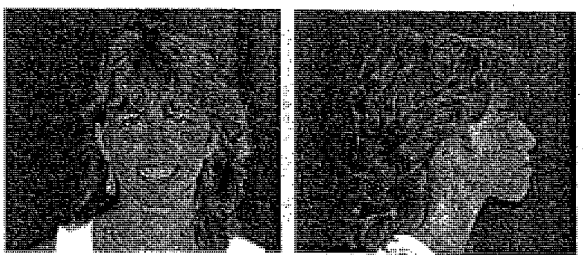
Tabelle 2: Ausdruck der kephalometrischen Meßwerte im Vergleich.

Analysis Ricketts		**1**	**Norm**	Clin. Dev.		**pre-op**	**end**
Cranial Relations							
Cranial Structure							
Ant Cranial Base	(mm)	54.5	51.4	1.3	*	58.9	58.7
Post Facial Ht	(mm)	59.8	54.8	1.5	*	54.4	57.8
Cranial Deflect	(dg)	30.2	27.3	1.0		31.6	31.0
Porion Location	(mm)	−41.8	−38.6	−1.4	*	−31.0	−34.4
Ramus Position	(dg)	85.7	76.0	3.2	***	82.0	79.8
Mx Position							
Maxillary Depth	(dg)	102.1	90.0	4.0	***	97.2	96.7
Maxillary Height	(dg)	57.8	51.2	2.2	**	58.3	54.3
SN–Palatinal Plane	(dg)	10.1	6.3	1.1	*	10.0	6.8
Md Position							
Facial Depth	(dg)	98.3	85.0	4.4	***	94.1	95.5
Facial Axis	(dg)	92.7	90.0	0.8		88.8	92.1
Mandibular Plane	(dg)	27.9	27.5	0.1		30.8	24.6
Total Facial Ht	(dg)	62.9	60.0	1.0		65.6	59.8
Facial Taper	(dg)	53.8	68.0	−4.1	***	55.1	59.9
MX/MD Relations							
Maxilla							
Convexity	(mm)	4.0	2.9	0.6		3.4	1.2
Mandible							
Corpus Length	(mm)	82.5	57.7	5.6	***	83.7	84.2
Mandibular Arc	(dg)	26.9	24.7	0.6		27.7	37.6
Maxilla/Mandible							
Lower Facial Ht	(dg)	47.7	45.0	0.7		44.9	40.7
Denture Relations							
Mx Dentition							
Mx 1 to APO	(mm)	7.3	3.5	1.7	*	8.3	8.9
Mx 1 to FH	(dg)	120.7	111.0	1.6	*	118.7	122.5
Mx 6 to PTV	(mm)	23.5	7.1	5.5	***	23.6	29.5
Md Dentition							
Md 1 to APO	(mm)	6.7	1.0	2.5	**	9.3	6.6
Md 1 Inclination	(dg)	25.6	22.0	0.9		32.3	27.4
Md 1 Extrusion	(mm)	−2.1	1.2	−1.7	*	−3.2	−0.8
Md 1 to Axis-Md 1	(dg)	84.4	90.0	−1.4	*	92.6	85.7
Mx/Md Dentition							
Interincisor Angle	(dg)	128.1	130.0	−0.3		119.8	124.4
Molar Relation	(mm)	−8.7	−3.0	−5.7	***	−9.8	−1.3
Incisor Overjet	(mm)	0.3	2.5	−0.9		−1.1	2.4
Incisor Overbite	(mm)	−2.3	2.5	−2.4	***	−0.4	1.6
Esthetic Relations							
Lower Lip E-Plane	(mm)	0.2	−2.0	1.1	*	2.7	−1.7

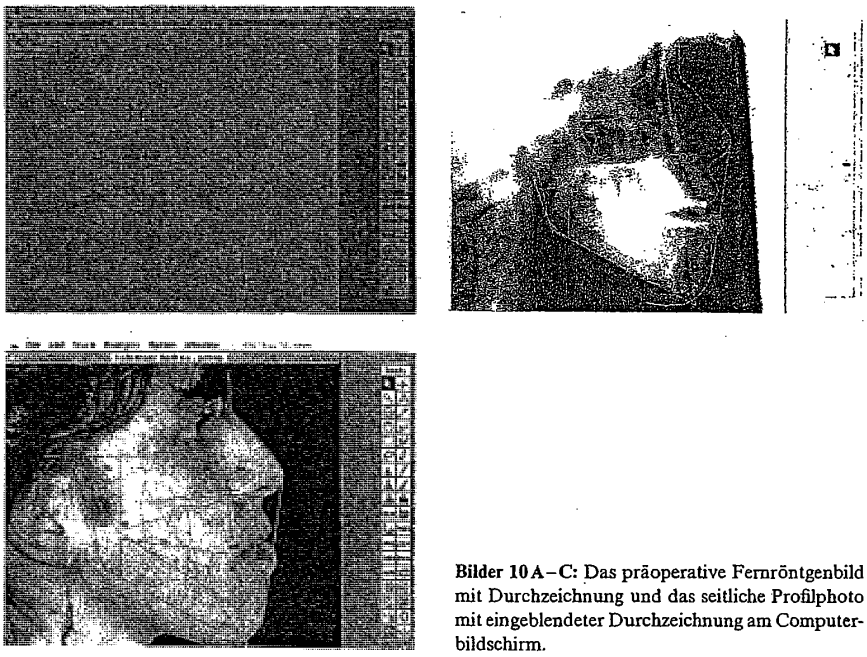
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Bilder 8A–C: Intraorale Aufnahmen bei Beginn der orthodontischen Vorbehandlung.

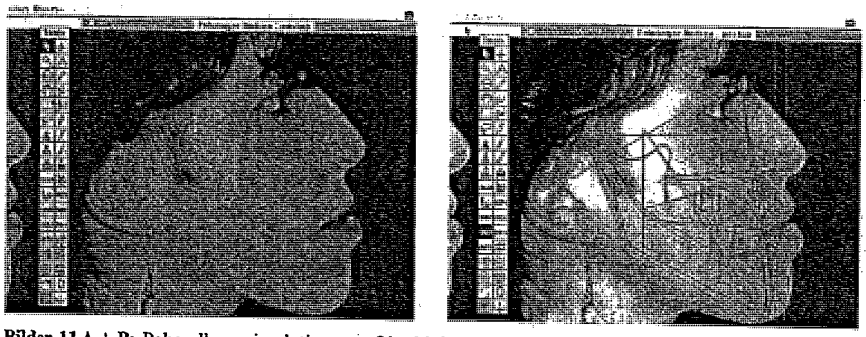


Bilder 9A + B: Die Profil- und Enfacephotographie vor dem chirurgischen Eingriff nach orthodontischer Dekompensation der Zahnbögen.



Bilder 10A–C: Das präoperative Fernröntgenbild mit Durchzeichnung und das seitliche Profilphoto mit eingeblendeter Durchzeichnung am Computerbildschirm.

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Bilder 11 A + B: Behandlungssimulation nur Oberkieferoperation, ausgehend vom präoperativen Profilphoto und Fernröntgenbefund.



Bilder 12 A + B: Behandlungssimulation nur Unterkieferoperation.



Bild 13: Ein Vergleich der beiden Behandlungssimulationen.

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Behandlungssimulation am Fallbeispiel des Quick-Ceph Image-Programms

Folgende Unterlagen der Patienten standen zur Verfügung: Laterale Röntgenbilder und seitliche Dias zu Beginn der Behandlung 1986, unmittelbar vor dem chirurgischen Eingriff 1988 und nach dem chirurgischen Eingriff 1989. Dazu kamen eine frontale und drei intraorale Aufnahmen zu Beginn der Behandlung und ein frontales Röntgenbild vor dem chirurgischen Eingriff.
Erwähnt werden sollte an dieser Stelle, daß die Qualität der Computerbilder am besten ist, wenn diese direkt vom Patienten aufgenommen werden, also ohne das Dazwischenschalten eines Dias oder noch schlechter eines Papierphotos. Da die Operation bereits einige Zeit zurück lag, wurden hier jedoch Dias als das Ausgangsmaterial verwendet. (*Bilder 10A – C, 11A + B, 12A + B, 13*)

Kieferchirurgische Behandlung

Es ist wesentlich, daß vor der denfinitiven orthodontischen Behandlung der Fall mit dem Mund-, Kiefer- und Gesichtschirurgen besprochen wird. Nur dadurch ist es möglich, den Behandlungsplan und -ablauf optimal zu gestalten. Wie bereits beschrieben, wird präorthodontisch eine Profilplanung vorgenommen, in der die chirurgischen Behandlungsmöglichkeiten dargelegt werden. Dabei kommt es neben einer regelrechten Okklusionseinstellung wesentlich auf die Planung des Profils an. Durch die operative Stellungsveränderung der Kieferbasen zueinander, aber auch durch die Neu-Positionierung im Gesicht verändert man das Profil (Obwegeser und Marentette 1986 [26]). Die Zuordnung der Kieferbasen zueinander wird jedoch von der Okklusion bestimmt und weitgehend festgelegt. Somit hat die präoperative kieferorthopädische Vorbehandlung eine unmittelbare Auswirkung auf das postoperative Aussehen des Patienten.

Am Beispiel dieser Patientin soll das Vorgehen nach der Beendigung der präoperativen kieferorthopädischen Behandlung demonstriert werden. Operativ wurden eine klassische Le Fort-I-Osteotomie und gleichzeitig eine sagittale Spaltung durchgeführt. Die Übertragung der Planung in die Operation geschieht mit Hilfe der Modelloperation.

Modelloperation

Kurz vor der Operation wurden neue Modelle angefertigt, die gerade bei bebänderten Patienten mit Sorgfalt hergestellt werden müssen. Eine Verziehung sowohl bei der Abdrucknahme wie bei der Modellherstellung muß vermieden werden. Die Modelle wurden eingesockelt und bei diesen notwendigen bimaxillären Bewegungen schädel-gelenkbezüglich in einen halbindividuellen Artikulator übertragen. Eine Skalierung am Übergang Sockel–Kieferbasis ermöglichte es, das Ausmaß der Bewegung der einzelnen Kiefer zu bestimmen und vorzunehmen. Anschließend wurden die zahntragenden Modellteile des Ober- und Unterkiefers vom Sockel getrennt und in die geplante Position zueinander gebracht. Das genaue Ausmaß der Bewegungen der einzelnen Kiefer wird nach der Profilanalyse, die anhand der Behandlungssimulation durchgeführt worden ist, auf die Modelloperation übertragen.

Zusätzlich wird auch die Bewegung der beiden Kiefer zum Profilverlauf berücksichtigt und in der Modelloperation simuliert. Die Modelloperation muß sehr genau erfolgen, da der auf diesem Modell angefertigte Kunststoff-Splint zur Einstellung des Oberkiefers und damit auch des Unterkiefers dient. Ungenauigkeiten bei der Herstellung und Durchführung der Modelloperation und die Übertragung auf die Operation würden dann ein unbefriedigendes Operationsresultat, wie z. B. schiefe Okklusionsebene oder Mittellinienverschiebung, ergeben.

Nach der Überprüfung der Modelloperation mit dem klinischen Befund wurde der Unterkiefer wieder in die Ausgangslage zurückgestellt. In dieser Stellung wurde ein dünner Kunststoff-Splint angefertigt. Da wir in der Operation zuerst den Oberkiefer osteotomieren, dient der Unterkiefer wie ein Gesichtsbogen mit dem Splint zur Einstellung des Oberkiefers. Die Modelloperation wurde dann durch die Wiedereinstellung des Unterkiefers in die geplante Okklusion vervollständigt und stand bei der Operation zur Verfügung.

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Operation

In einer nasalen Intubationsnarkose wurde nach sterilen Abwaschen und Abdecken des Gesichts die Gesichts- und Kinnmittellinie eingezeichnet. Die Le Fort I-Osteotomie wurde in der von Obwegeser angegebener Weise durchgeführt. Von einer Vestibulumschnittführung von Prämolar bis Prämolar erfolgte eine subperiostale Darstellung der knöchernen Strukturen des Oberkiefers. Die Fossa canina wurde nur soweit, wie es zur Osteotomie notwendig war, freigelegt. Ein Abschieben bis zum N. infraorbitals wurde vermieden. Unter Schonung des Nasenschlauches wird mit der oszillierenden Säge der Oberkiefer in der Fossa canina im Bereich der lateralen Nasenwände osteotomiert und vom Nasenseptum bzw. Vomer getrennt. Mit einem gebogenen Meißel wurde der Oberkiefer im Bereich der Fissura ptergygopalatina vom Hamulus getrennt, ohne diesen zu brechen. Durch eine down-fracture wurde der Oberkiefer vollends vom Mittelgesicht losgelöst und anschließend mobilisiert. Mit Hilfe des Splints erfolgte die Einstellung des Oberkiefers in die geplante Stellung zum nicht operierten Unterkiefer. Der Oberkiefer wurde im Frontbereich 3 mm, im posterioren Bereich um ca. 4 mm nach kranial und im Bereich der Mittellinie um 2 mm nach links gedreht, um eine Übereinstimmung mit der Gesichtsmittellinie zu erhalten. Das präoperativ bestimmte Ausmaß der Kranialbewegung sollte immer intraoperativ anhand der Lippen-Frontzahnrelation überprüft werden. Eine stabile Osteosynthese im Bereich der Fossa canina wurde mit dünnen Titan-Platten vorgenommen. Dabei wird vor allem darauf geachtet, daß es durch die Anbringung und Fixation der Platten nicht zu einer Veränderung der Einstellung kommt. Wir verwenden deshalb immer häufiger neu entwickelte, dünnere Platten (3-D-Platten-System, Farmand), die sich sehr gut dem Knochen anpassen und erst nach der Verschraubung durch ihre Form eine Stabilität hervorbringen.

Nach der Fixation des Oberkiefers, dessen Stellung im Gesicht vor der Osteotmie des Unterkiefers nochmals überprüft wurde, wurde die sagittale Spaltung der aufsteigenden Unterkieferäste in der Originalmethode nach Obwegeser durchgeführt. Der Unterkiefer wurde zurück verschoben und in die Okklusions eingestellt. Nach einer starren intermaxillären Fixation wurden transbukkal am Oberrand zwei Stellschrauben und am Unterrand eine angebracht. Die intermaxilläre Fixation wurde gelöst und die Okklusion überprüft. Eine Vorfixation der aufsteigenden Äste wird routinemäßig nicht vorgenommen. An der Stellung des gelenktragenden zum zahntragenden Fragments des Unterkiefers wird dann die Position des Gelenkes kontrolliert. Die operativen Zugänge wurden mit nicht-resorbierbaren Fäden vernäht.

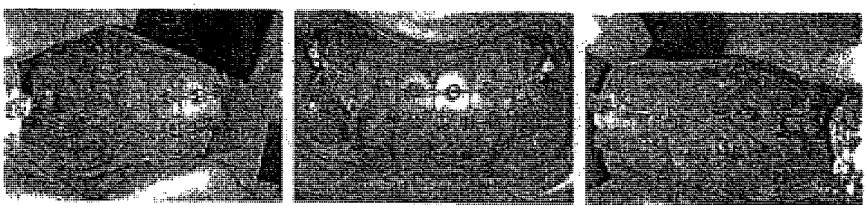
Am ersten postoperatigen Tag wurden leichte Gummizüge zur Führung des Unterkiefers eingehängt. Mit diesen Gummizügen ist es je nach verwendeter Stärke möglich, postoperativ bis zu 4 Wochen kleinere Okklusionskorrekturen durch minimale Bewegungen des Oberkiefers vorzunehmen. Die präoperativ orthodontisch behandelten Patienten sollen bereits in dieser Phase zur besseren Koordination wieder dem Kieferorthopäden vorgestellt werden (*Bilder 14A–C*).

Behandlungsergebnis

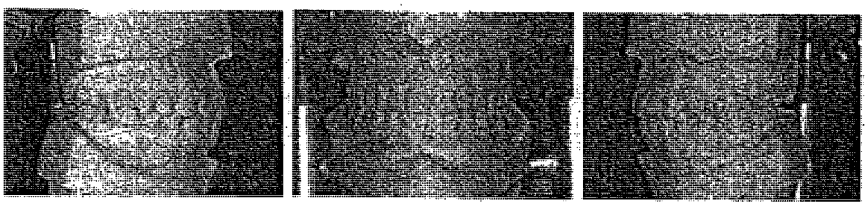
7 Monate nach dem operativen Eingriff konnte nach Entfernen der Bänder und Brakkets ein nach gnathologischen Gesichtspunkten angefertigter Positioner eingesetzt werden, der nach einer Tragezeit von etwa 3 Monaten im Oberkiefer durch eine Retentionsplatte und durch einen direkt geklebten 3-3-Retainer ersetzt wurde.

Aufgrund der durchgeführten orthodontisch-kieferchirurgischen Kombinationsbehandlung konnte ein ästhetisch anspruchsvolles, dental und skelettal überdurchschnittliches Behandlungsergebnis erzielt werden, das über 2 Jahre nach Abschluß der aktiven Behandlungszeit stabil ist. Die Patientin zeigte postoperativ keine Anzeichen einer Dysfunktion der Kiefergelenke, die Mobilität errreichte bald Normalwerte, Sensibilitätsstörungen traten keine auf (*Bilder 15A–C, 16A + B, 17A + B, 18A–C, 19A–C*).

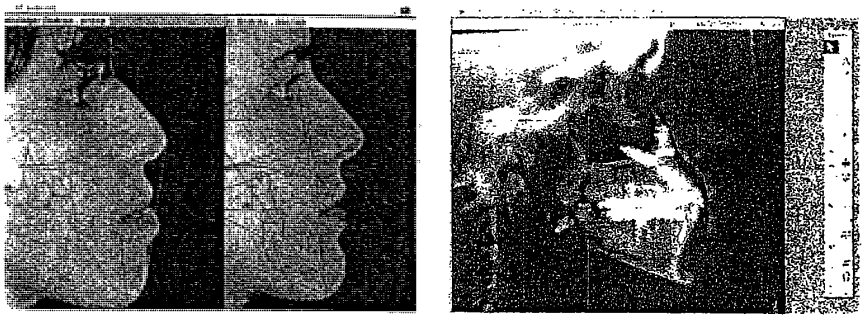
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Bilder 14A–C: Der intraorale postoperative Befund: Leichte Überkorrektur der Mittellinie im Oberkiefer, kurze Kl. II-Elastics zur Okklusionskorrektur.



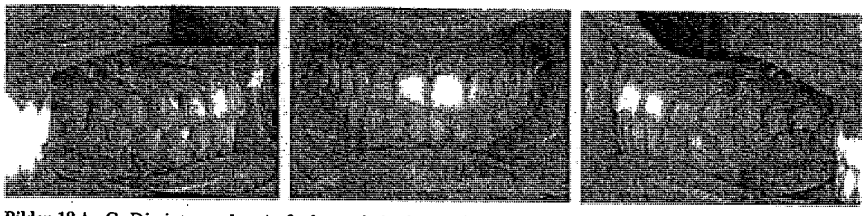
Bilder 15A–C: Die schädel-gelenkbezüglich einartikulierten Modelle bei Abschluß der Behandlung in Referenzposition



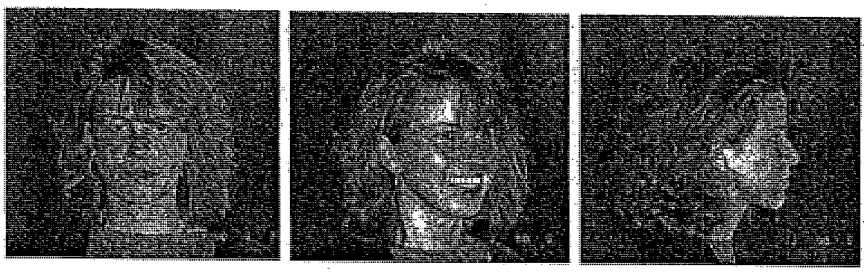
Bilder 16A + B: Das Fernröntenseitenbild bei Abschluß der Behandlung mit Durchzeichnung und der prä- und postoperativen Profilvergleich am Computerbildschirm.

Die Bilder 17A + B: Die Seiten 394 und 395 ▷

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Bilder 18A–C: Die intraoralen Aufnahmen bei Abschluß der Behandlung.



Bilder 19A–C: Die extraoralen Aufnahmen der Patientin bei Abschluß der Behandlung.

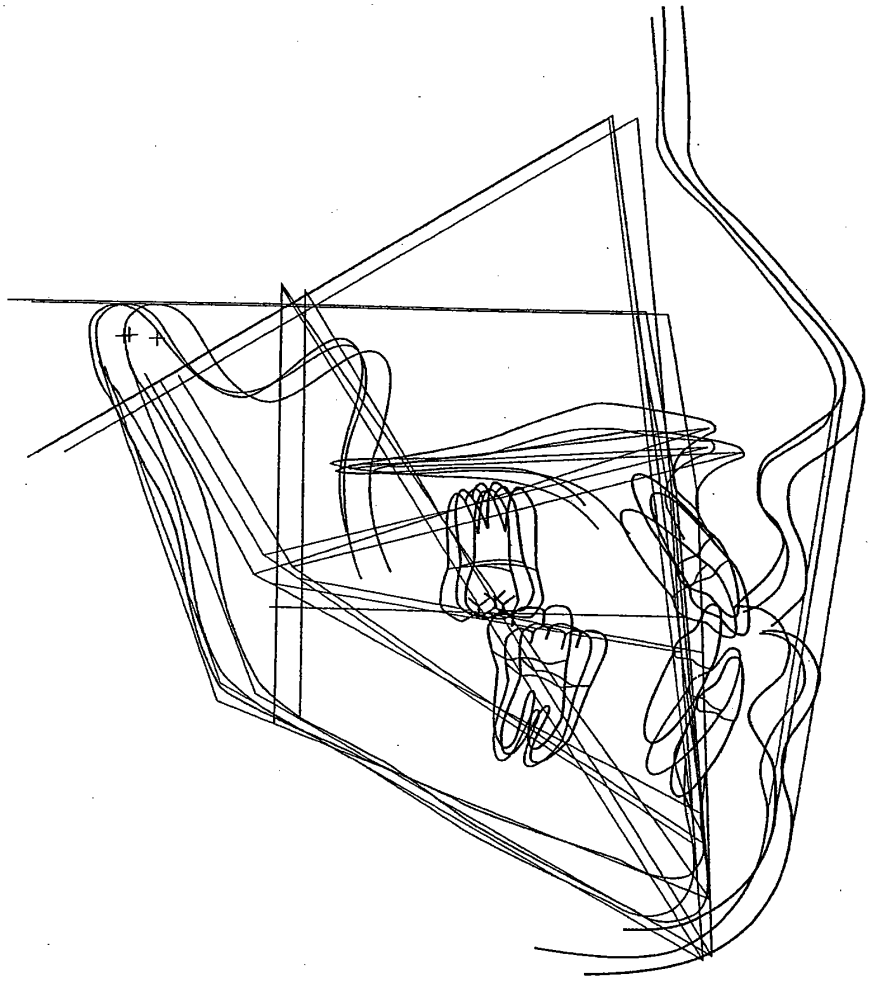
Schlußbetrachtungen

Glücklicherweise gibt es eine große individuelle Schwankungsbreite bei akzeptablen harmonischen oder ästhetisch schön erscheinenden Gesichtern. PECK und PECK zeigten eindrucksvoll, daß die Beurteilung harmonischer und schöner Gesichtszüge auch dem Zeitgeist unterworfen ist [24, 25]. Eine unbefriedigende Gesichtsästhetik ist häufig auch das Resultat eines bestehenden Ungleichgewichts antagonistischer Muskelgruppen während der Wachstumsperiode.

Während die Kieferorthopädie bei ungünstiger Wachstumsrichtung meistens nur zu einer Verbesserung dentaler Beziehungen oder zu einer dentalen Kompensation skelettaler Abweichungen beiträgt [29], ist erst durch eine orthodontisch-kieferchirurgische Kombinationsbehandlung eine kausal orientierte Therapie möglich geworden. Voraussetzung ist eine orthodontische Dekompensation der Zahnbögen, die häufig erst das Ausmaß der Dysgnathie verdeutlicht und den Profilverlauf nachteilig beeinflußt (s. Bilder 2/9). Dabei kann aber heute auf eine prächirurgisch-orthodontische Extraktionstherapie zur Vergrößerung des chirurgischen Manövrierraumes verzichtet werden, wenn, wie im vorliegenden Fall, ein bimaxillärer Eingriff in Betracht gezogen wird.

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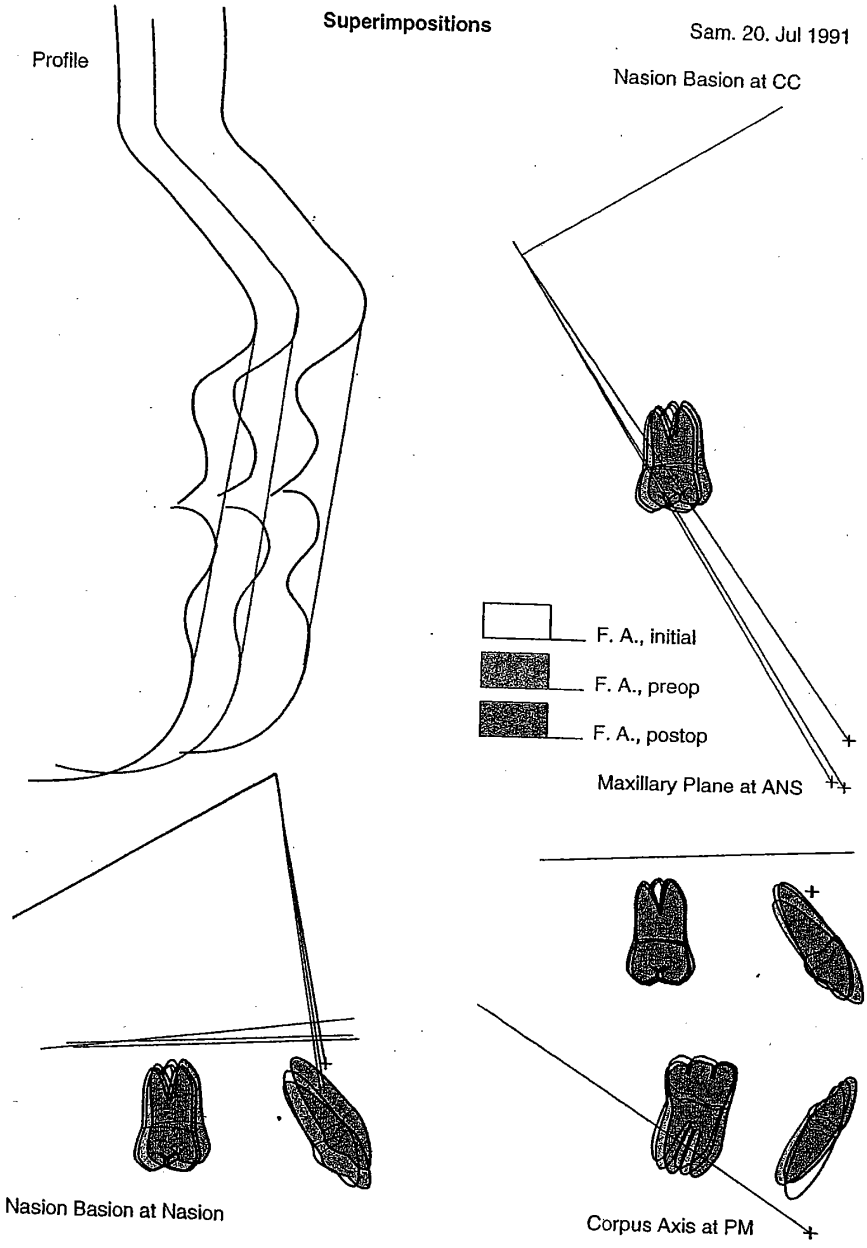


Superimpositions
F. A., initial

Quick Ceph Image™
Sam. 20. Jul. 1991

Bilder 17A + B: Die Überlagerungen nach Ricketts der initialen, präoperativen und postoperativen Fernröntgenseitenbilder.

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Literatur

[1] Riedel, R.: Esthetics and its relation to orthodontic therapy. Angle Orthod. 20: 168, 1950.

[2] Tweed, Ch.: The diagnostic facial triangle in control of treatment objectives. Am. J. Orthod. 55: 651–667, 1969.

[3] Stoner, M.: Photometric analysis of the facial profile. Am. J. Orthod. 41: 453, 1955.

[4] Holdaway, R.: Changes in relationship of points A and B during orthodontic treatment. Am. J. Orthod. 42: 176, 1956.

[5] Ricketts, R.: Planning treatment on the basis of the facial pattern and an estimate of its growth. Angle Orthod. 27: 14, 1957.

[6] Wallen, T., Bloomquist, D.: The clinical examination: is it more important than cephalometric analysis in surgical Orthodontics. Int. J. Orthod., Orthognath. Surg. 3: 179–191, 1986.

[7] Goldstein, A.: Appraisal of results of surgical correction of Class-III-malocclusion. Angle Orthod., 17: 59, 1947.

[8] Lines, P., Steinhäuser, E.: Diagnosis and treatment planning in surgical orthodontic therapy. Am. J. Orthod. 66: 378, 1974.

[9] Robinson, S., Speidel, M., Isaacson, R., Worms, F.: Soft tissue profile change produced by reduction of mandibular prognathism. Angle Orthod. 42: 227, 1972.

[10] Legan, H., Burstone, C.: Soft tissues cephalometric analysis for orthognathic surgery. J. oral Surg. 38: 744, 1980.

[11] Fish, L., Epker, B.: Surgical orthodontic cephalometric prediction tracing. J. Clin. Orthod. 14: 36, 1980.

[12] Mostafa et al.: Automated cephalometric soft-tissue analysis. J. Clin. Orthod. 9: 539–543, 1990.

[13] Mansour, S., Burstone, Ch., Legan, H.: An evaluation of soft-tissue changes resulting from Le-Fort I maxillary surgery. Am. J. Orthod. 84: 37–47, 1983.

[14] Worms, F., Isaacson, R., Speidel, T.: Surgical Orthodontic treatment planning: Profile analysis and mandibular surgery. Angle Orthod. 46: 1, 1976.

[15] Profitt, W., Epker, B.: Treatment planning for Dentofacial Deformities, in Bell, W., Profitt, W., White, R. (Eds.) Surgical Correction of Dentofacial Deformities. Saunders, Philadelphie, 1980.

[16] Walters, H., Walters, D.: Computerised planning of maxillofacial osteotomies: The program and its clinical application. Br. J. Oral Maxillofac. Surg. 24: 178, 1986.

[17] Bhatia, S., Sowray, J.: A Computer aided design for orthognatic surgery. Br. J. Oral Maxillofac. Surg. 22: 237, 1984.

[18] Harradine, N., Birnie, D.: Computerized prediction of the results of orthognathic surgery. J. Maxillofac. Surg. 13: 245ff., 1985.

[19] Chaconas, S. et al.: The Digigraph Work Station. J. Clin. Orthod. 24: 360, 1990.

[20] Ricketts, R.: Cephalometric synthesis. Am. J. Orthod. 46: 647, 1960.

[21] Steinhäuser, E.: Weichteilveränderungen bei korrektiven Osteotomien im Kieferbereich. Dt. zahnärztl. Z. 29: 1065–1073, 1974.

[22] Bender, E.: Vergleich von Weichprofilprädikation mit erzielten Ergebnissen nach korrektiven Osteotomien im Kieferbereich. Med. Diss. Erlangen, 1990.

[23] Rosen, H.: Lip Nasal Aesthetics following LeFort I Osteotomy. Plast. Reconstruct. Surg. 81: 171–179, 1988.

[24] Peck, H., Peck, S.: A concept of facial aesthetics. Angle Orthod. 40: 284–318, 1970.

[25] Peck, H., Peck, L.: Skeletal asymmetry in esthetically pleasing faces. Angle Orthod. 61: 43–47, 1991.

[26] Obwegeser, H.L., Marentette, L.J.: Profile planning based on alterations in the positions of the basis of the facial third. J. Oral Maxillofac. Surg. 44 (4): 302–311, 1986.

[27] Fischer-Brandies, Seeholzer et al.: Vorhersagbarkeit der Weichteilveränderungen mit dem Dentofacial Planner Version 4.22A nach Kieferorthopädischer Erwachsenenbehandlung. Inf. Orthod. Kieferorth. 22: 517–524, 1990.

[28] Neda, K., Kobayashi, M.: Three dimensional prediction of mandibular movement in treatment of prognathism. J. Oral Maxillofac. Surg. 44: 21, 1986.

[29] McLaughlin, R.P.: Okklusionsanomalie und Kiefergelenk – ein historischer Ausblick. Inf. Orthod. Kieferorthop. 20: 351–361, 1988.

[30] Slavicek, R.: Einbringung eines dynamischen Konzepts in die Kephalometrie. Inf. Orthod. Kieferorthop. 14: 69–72, 1982.

[31] Arnett, W., Tamborollo, J.: Progressive Class II-Development, Orthognath. Surg. 2: 4, 11, 695–716, 1990.

[32] Wolford, L.M., Hilliard, R.W., Dugan, D.J.: Surgical Treatment Objective. Mosby, 1985.

[33] Steinhäuser, E.W., Janson, I.M.: Kieferorthopädische Chirurgie, Quintessenz, Berlin 1988.

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THREE-DIMENSIONAL FINITE ELEMENT ANALYSIS OF GLASS–CERAMIC DENTAL CROWNS

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Abstract—Because of the improved esthetic potential of glass–ceramic crowns as dental restorations, they are sometimes preferred over metal–ceramic crowns for restoration of anterior teeth. Because of their relatively high strength, these ceramic crowns are also frequently used for restoration of posterior teeth. However, due to the larger magnitude of biting forces on posterior teeth, intraoral fracture of all-ceramic crowns tends to occur more frequently in posterior crowns (Moffa, 1988). The objective of this study was to determine the relative influence of load orientation and the occlusal thickness of posterior ceramic crowns on the stress distribution which develops under these loading and design conditions. Three-dimensional finite element models for a molar crown were developed to determine the stress distribution under simulated applied loads. Glass–ceramic crowns with occlusal thicknesses of 0.5, 1.5, and 3.0 mm were considered. The largest principal tensile stresses induced in ceramic due to a distributed load of 600 N applied in a cuspal region were approximately 12 and 182 MPa for vertical and horizontal loading orientations, respectively. Stresses which developed in the facial and lingual marginal regions were primarily compressive under vertical loads. However, tensile stresses developed when the load was applied horizontally. Differences in stress distribution within crowns with the three occlusal thicknesses occurred only near the site of loading. Because of the relatively large failure rates of ceramic crowns in the posterior regions, these restorations should be strengthened by improvement in design, composition, and thermal processing conditions. Before any significant progress is made in these areas, these restorations should be used for the anterior teeth. The results of this study suggest that orientation of the applied load has a more important effect on development of large tensile stresses than the occlusal thickness of ceramic.

INTRODUCTION

A castable glass product, which is strengthened during heat treatment by the growth of tetrasilicic fluormica crystals to form a glass–ceramic, was developed by Grossman (1973) and was first used for dental applications by Adair and Hoekstra (1982). This product is gaining in popularity as the material of choice for jacket crown applications. Due to its higher modulus of rupture compared with conventional feldspathic porcelain, this material is used frequently to construct restorations for posterior teeth. Finite element stress analysis has been employed previously to determine the stress distribution in castable ceramic crowns under specific loading conditions. Starling and Cook (1983) used axisymmetric and plane-stress models of a ceramic crown to determine the influence of elastic modulus, cement layer thickness, loading orientation, and loading configuration of the gingival preparation on the resulting stress state. The authors concluded that the stress values determined from the axisymmetric model were in better agreement with the results obtained from mechanical testing and strain gage measurements than the values obtained from a plane-stress model. In their analyses, it was assumed that the applied loading was axisymmetric. However, ceramic crowns used for the posterior teeth are subjected to various types of applied loading which are not necessarily axisymmetric. Since the analysis and design of dental prostheses should be based on the most relevant loading condition, a three-dimensional finite element analysis of these restorations should be employed.

Anusavice and Hojjatie (1988) used a two-dimensional finite element model to determine the influence of the prepared tooth height and applied loading on the stress distribution in ceramic crowns on prepared maxillary central incisors. It was concluded that horizontal load components were major determinants of tensile stresses induced in the ceramic. However, stresses along the mesiodistal direction were not analysed in this previous study.

It is generally believed that if the occlusal thickness of posterior ceramic crowns is less than 1.5 mm, the risk of failure would increase markedly. The objective of this study was to use three-dimensional finite element analysis to test the hypothesis that the orientation of simulated intraoral forces, and not the occlusal thickness, is the principal determinant of high stresses in ceramic crowns.

FINITE ELEMENT MODELS

Three-dimensional finite element models for a mandibular second molar crown were developed and the overall dimensions were selected to be consistent with the values identified by Wheeler (1965) for an average molar crown. In these models it was assumed that the

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enamel in the prepared areas was completely removed and was replaced by castable ceramic crowns with occlusal thicknesses of 0.5 mm (Case I), 1.5 mm (Case II) and 3.0 mm (Case III). Except for this variation in ceramic thickness at the biting (occlusal) region, the three models had identical dimensions in other locations of the crown. The shaded areas for Cases I, II and III shown in Fig. 1 correspond to occlusal regions of dentin. The assumptions used in this study are as follows:

(1) the materials were assumed to be homogeneous, linearly elastic, and isotopic;

(2) the influences of a cement layer and the periodontal ligament were negligible;

(3) residual stresses which are induced in castable ceramic because of contraction differences between the cast crown and shading porcelain and nonuniform distribution of temperature during processing were negligible;

(4) no critical structural flaws were present;

(5) perfect bonding existed between ceramic and dentin;

(6) the external veneer of shading porcelain, which is usually required to achieve acceptable esthetics, was not present.

Mesh generation of the models was accomplished by the use of the MTAB*PRE pre-processing software (1987). This software is capable of generating finite element models using IBM-PC and compatible microcomputers. For preliminary analyses, crown models with 226 nodes and 171 three-dimensional solid elements were developed. Each element consisted of eight nodes and each node could be assigned three translational degrees of freedom (DOF). To improve the geometry of the crown models and to create more realistic topography at the cusp regions, the finite element model for the Case I design was refined. In this refined model, a total of 586 nodes and 456 three-dimensional solid elements (eight-node brick) were employed (Fig. 2). The element-shrink and the hidden-line-removal options of the pre-processing program have been used to generate this figure. All of the nodes in the x–y plane, which correspond to the root portion of dentin, were assumed to be fixed and no translation was allowed in any direction of the Cartesian coordinate system. Locations of some of these fixed nodes are also identified in Fig. 1. The elastic modulus values chosen for ceramic, dentin and pulp were 7.03×10^4, 1.86×10^4 and 2.0 MPa, respectively, and the corresponding Poisson's ratios were 0.28, 0.31 and 0.45, respectively (Anusavice *et al.*, 1986; Anusavice and Hojjatie, 1987, 1988). After generating the finite element model, input data were translated for the SAP86 (1986) microcomputer program. The following analyses were considered in this study:

(a) in the preliminary model, a load of 600 N was distributed along the vertical (z) direction on one cusp and the stress and displacement values were compared for the three design cases;

(b) the analyses described in part (a) were performed except that the load was applied along the horizontal direction;

(c) the finite element model for Case I was refined and the stress and displacement induced in the crown due to the vertical and horizontal loading configurations were compared with those obtained from the previous models;

(d) to determine the influence of the pulp chamber, the same analyses as part (c) were considered by substituting a void region for the pulp chamber.

This study assumed an average biting force of 600 N (Fig. 3) based on the data reported by Craig (1980) and Finn (1978) for second molars under normal mastication. In general, biting forces of this magnitude occur along a vertical direction. However, to determine the influence of loading orientation on the level of stresses, the same amount of load was also applied along the horizontal direction. In static analysis, when the materials are homogeneous, linearly elastic and isotropic, the stresses are directly proportional to the applied loads. Therefore, the stresses calculated in this study for a load of 600 N can also be used to predict the stresses for other magnitudes of applied loads. The three-dimensional crown models for a mandibular second molar were developed to evaluate the manufacturer's recommendations on the design of castable ceramic crowns and to examine the findings from previous studies which are as follows:

(1) the manufacturer of Dicor® castable ceramic crowns recommends maintaining a minimum occlusal thickness of 1.5 mm (Clinical Procedures Manual, Dentsply International, 1984). To determine the influence of ceramic thickness on the magnitude of applied

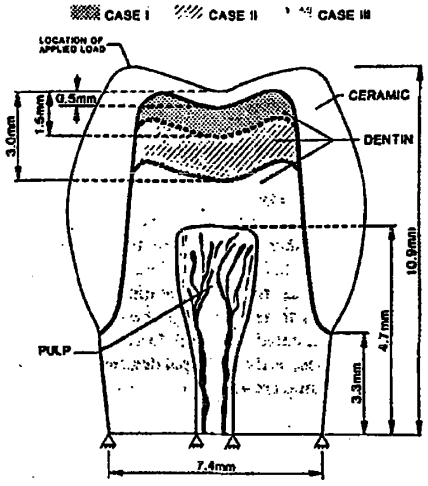


Fig. 1. Cross-sectional view of a mandibular second molar showing the three design cases. Stress distributions were obtained using finite element models with ceramic thicknesses of 0.5 mm (Case I), 1.5 mm (Case II) and 3.0 mm (Case III) in the biting region and for a distributed load of 600 N.

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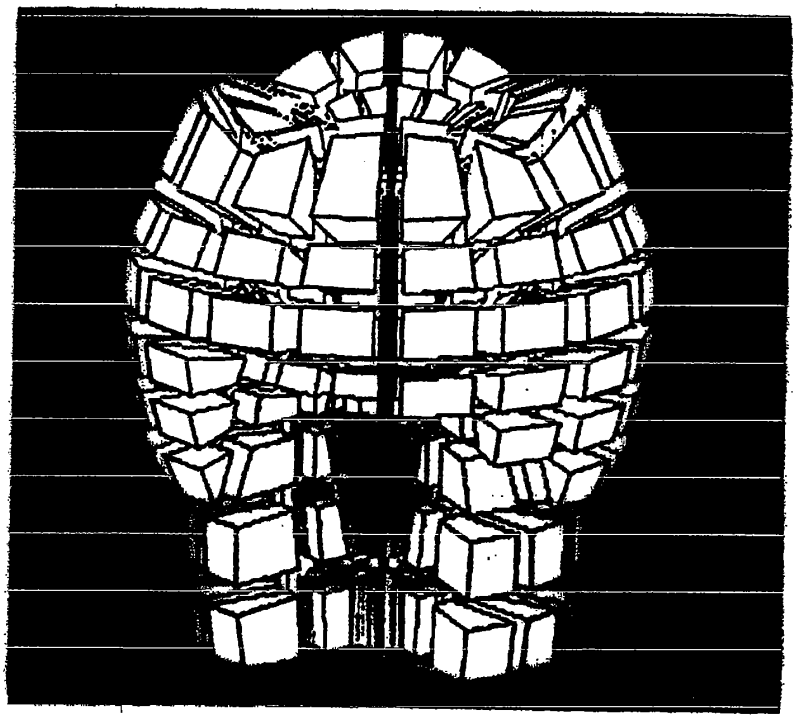


Fig. 2. Three-dimensional finite element model using 586 nodes and 456 solid element (refined model) showing porcelain, dentin and pulp regions.

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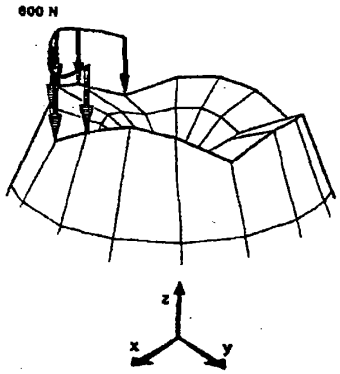


Fig. 3. Locations of the applied loads for the finite element model.

stresses in the crown, three design cases were analysed [analyses in part (a)];

(2) two-dimensional, finite element stress analysis of ceramic crowns for anterior teeth indicate that the loading orientation was a major cause of tensile stresses (Anusavice and Hojjatie, 1988). Analyses in part (b) were performed to evaluate this finding by a three-dimensional model;

(3) The results from finite element analysis are associated with discretization errors which are due to the replacement of a continuous structure by a discrete model and this error should be reduced by mesh refinement (Anusavice and Hojjatie, 1988). Therefore, in the analyses of part (c) the stresses were calculated for a more refined model and the results were compared with those of the preliminary model;

(4) because of the negligibly small elastic modulus of the pulp chamber, it may be hypothesized that the absence or presence of this region within the finite element model will have a negligible influence on the stress distribution in ceramic and dentin. This hypothesis was tested in the analyses of part (d).

The analyses were performed on an IBM PC-AT microcomputer and the outputs from SAP86 finite element analyses were entered into the MTAB*POST post-processing software (1987) to determine the peak values of stress and displacement and to generate stress contours. All components of normal stress (σ_x, σ_y, σ_z), shear stress (τ_{xy}, τ_{xz}, τ_{yz}), principal stress (σ_1, σ_2, σ_3), and maximum shear stress (τ_{max}) and the displacement along the three directions of the global coordinate system were examined by means of stress contours. The results were summarized graphically in terms of σ_1, σ_2, and τ_{max}. For better visualization of the stress magnitudes at the interior points of the crown, the contours were plotted along various cross-sections of the crowns on the color monitor and, with the use of color coding, stresses and displacements at the critical areas such as marginal and pulpal regions were analysed.

RESULTS

For analysis (a) in which the three crown designs were subjected to a vertical load of 600 N, the stress values for all three design cases were nearly identical. The focus of this study is to determine the influence of ceramic thickness and loading condition on the induced stresses in various locations of the molar crown. To accomplish this, the results are presented in terms of principal tensile, compressive and maximum shear stress contours. The peak value of the principal tensile stress (σ_1) for the design Case I (ceramic thickness = 0.5 mm) was 7.7 MPa which occurred at the marginal region (Fig. 4). The stress contours identified by the same letters correspond to the same stress values. The stress magnitudes corresponding to each letter are shown in the table above the figure. The thicker lines identify the location of the nodal points at the crown surface. The stress contours near the marginal and cusp areas which are closer to each other correspond to steeper stress gradients compared with other locations. Similar stress distributions for the principal stress (σ_1) were obtained for the design Cases II and III. For the vertically applied load, the largest compressive stresses were obtained along the z direction. The peak values of the principal compressive stress (σ_2) at the surface for Case I (ceramic thickness = 0.5 mm) was 74.2 MPa (Fig. 5). The corresponding values for Case II (ceramic thickness = 1.5 mm) and Case III (ceramic thickness = 3.0 mm) were 73.8 MPa and 73.3 MPa, respectively. The principal stress distributions (σ_2) for all three design cases were similar.

a = 7.7	b = 4.8	c = 1.9	d = −1.0
e = −3.9	f = −6.8	g = −9.7	h = −12.6

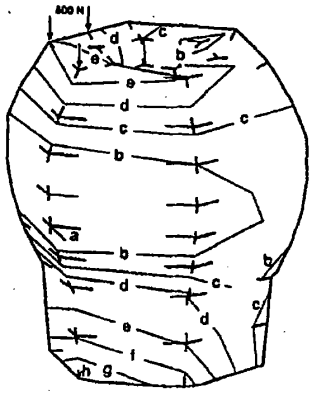


Fig. 4. σ_1-Stress contours for a crown with a ceramic thickness of 0.5 mm in the biting region (Case I) for a distributed vertical load of 600 N. These surface stresses were obtained using a finite element model consisting of 226 nodes and 171 solid elements (preliminary model).

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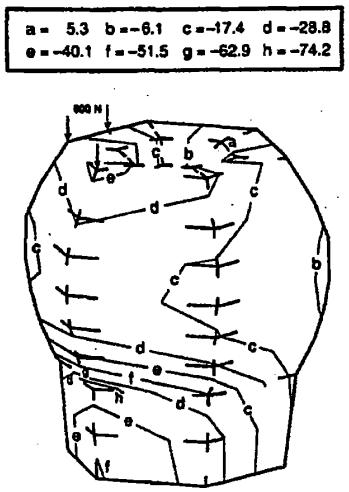


Fig. 5. σ_2-Stress contours for a crown with ceramic thickness of 0.5 mm in the biting region (Case III) for a vertical load of 600 N. A finite element model with 226 nodes and 171 solid elements was used for these analyses.

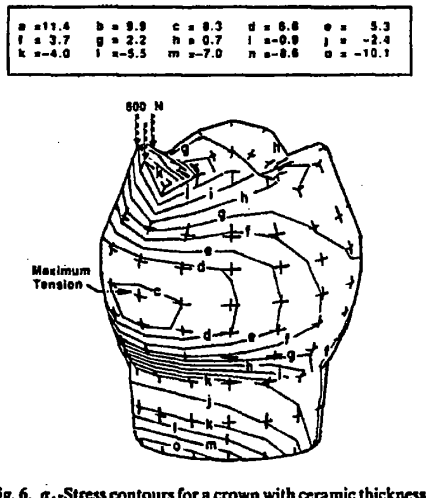


Fig. 6. σ_1-Stress contours for a crown with ceramic thickness of 0.5 mm (Case I) in the biting region for a vertical load of 600 N. These surface stresses were obtained using a finite element model with 586 nodes and 456 three-dimensional solid elements. Contours '*a*' (which represent maximum tension) and '*b*' are hidden from the view of this figure.

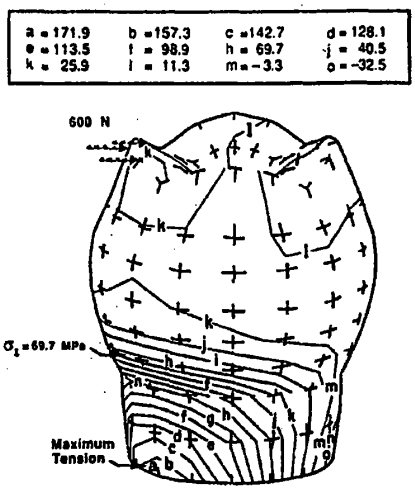


Fig. 7. σ_1-Stress contours for crown with ceramic thickness of 0.5 mm in the biting region (Case I) for a horizontal load of 600 N. A finite element model with 586 nodes and 456 three-dimensional solid elements was used for these analyses.

In analysis (b), the 600 N load was distributed along the horizontal direction at the same location as part (a). Under this loading condition, the peak values of the principal tensile (σ_1) and principal compressive (σ_2) stresses for the Case I were 178.3 MPa and 102.5 MPa, respectively. These stresses were similar for all design cases. To verify the accuracy of these stress values, the model corresponding to Case I was refined and analyses were performed for the same vertical and horizontal loading conditions [analyses in part (c)]. The peak value of principal tensile stress (σ_1) due to a vertical load of 600 N for the refined model was 11.4 MPa (Fig. 6). In this figure, the stress contours '*a*' and '*b*' are hidden from view and do not appear on the figure. However, the location for contour '*a*' (maximum tension) is shown by an arrow. The location of contour '*b*' is near contour '*a*'. Comparison of principal tensile stress values (σ_1) for the refined and unrefined models showed that only a small improvement in accuracy was obtained due to model refinement.

Under the horizontally applied load of 600 N, relatively large magnitudes of tensile stresses occurred in both dentin and ceramic surfaces (Figs 7 and 8). The largest tensile stresses in dentin were produced around the fixed nodes which were located directly below the site of loading. The peak value of tensile stress (σ_1) in ceramic at the marginal area was 69.7 MPa (contour *h* in Fig. 7). The corresponding value in dentin was 171.9 MPa (contour *a*). The largest, principal compressive stress value (σ_2) in ceramic was 116.2 MPa which occurred at the ceramic–dentin boundary (contour *o* in Fig. 8). In general, the stresses developed at the interior of the ceramic and dentin were similar to the surface stresses. Thus, for better visualization of the stress contours, only the surface stresses are used to compare the various design and loading conditions. Analyses performed in part (d) indicated that the pulp chamber had a negligible influence on the stress magnitude for all design conditions.

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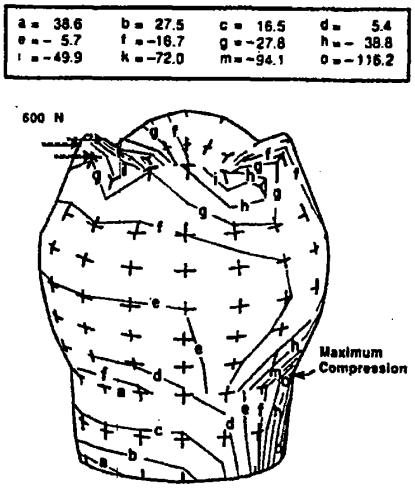


Fig. 8. σ_3-Stress contours for a crown with ceramic thickness of 0.5 mm in the biting region for a horizontal load of 600 N. A finite element model with 586 nodes and 456 solid elements was used for these analyses.

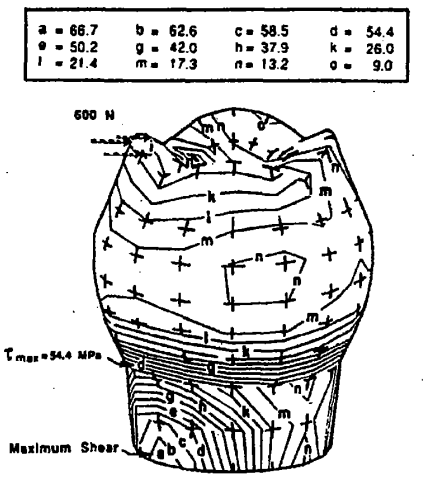


Fig. 9. τ_{max}-Stress contours for a crown with ceramic thickness of 0.5 mm in the biting region for a horizontal load of 600 N. A finite element model with 586 nodes and 456 solid elements was used for these analyses.

The magnitude of the shear stresses due to a vertically applied load were relatively small. However, when the load was applied along the horizontal direction, larger values of shear stresses were observed. The maximum value of shear stress in ceramic which occurred at the marginal area was 54.4 MPa (Fig. 9).

DISCUSSION

A second molar crown has a geometry which is approximately symmetrical with respect to an axis along the occlusogingival direction (z-axis in Fig. 3). However, an axisymmetric finite element model can be used to calculate the stress distribution when loading configurations are also symmetrical about this axis. If cylindrical coordinates (r, θ, z), with z as the axis of symmetry and r as the radial direction are considered, then in the axisymmetric model all the stress and displacement components are independent of angle θ (Timoshenko and Goodier, 1970). An axisymmetric stress condition has only four independent components of stress. In general, intraoral forces which act on dental prostheses are not symmetrically oriented. Therefore, axisymmetric finite element models for molar tooth analyses used previously by Farah *et al.* (1973, 1975), Selna *et al.* (1975), Starling and Cook (1983), and by De Vree *et al.* (1984) have considered an ideal and possibly clinically unrealistic loading condition. Finite element analysis of dental restorations should be based on the most general oral conditions. When generalizing the results from such an analytical study, specific attention should be given to the assumptions and simplifications used (Anusavice and Hojjatie, 1988). In general, biological materials such as dentin are anisotropic, inhomogeneous and exhibit a nonlinear stress–strain relationship. However, in this study dentin was treated like an isotropic, homogeneous and linear material and was assumed to bond perfectly to ceramic. These assumptions were considered because of the lack of reliable mechanical property data for dentin under this condition. For simplification of the finite element model, the influence of the cement layer and critical structural flaws were not considered in this study. It is clear that more accurate stress distributions can be obtained from a three-dimensional model which takes the cement layer into account. However, the model employed in this study was used for a relative comparison of various design geometries in a ceramic crown under comparable loading conditions. Increase in capabilities of microcomputer based finite element programs in the future can make it possible to develop a three-dimensional finite element model that takes the cement layer and the periodontal ligament into account.

Numerous reports exists in the dental literature which describe biting forces on human teeth (Craig, 1980; Gibbs *et al.*, 1986; Proffit *et al.*, 1983). However, most of these reports correspond to axially directed occlusal forces. The maximum biting forces during ordinary chewing vary and may depend on sex, age, tooth location and type of food. Due to the large variability among human subjects, measurement of biting forces is usually conducted on large number of subjects. Gibbs *et al.* (1986) reported that in some bruxer-clencher patients the biting force can be as much as six times larger than that of non-bruxer. A maximum biting force of 4345 N was determined for a

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subject, which was the load applied on the posterior teeth. Graf *et al.* (1974) developed a three-component force transducer to measure occlusal forces in the axial, buccolingual and mesiodistal directions of a first molar tooth in a normal subject. They reported that every chewing stroke was associated with a combination of axial and horizontal forces. In one experiment they measured biting forces performed by chewing medium hard swiss rye bread. For a biting force of 49 N measured along the vertical direction, the corresponding force along the horizontal direction was 19.6 N which corresponds to a ratio of 2.5. Therefore, for a vertical biting force of 600 N used in the present study, a horizontal force of 240 N is expected to be developed. As stated earlier, under the conditions analysed in the present study the stresses are directly proportional to the applied load. Thus, the maximum tensile stress induced in ceramic due to a horizontal load of 240 N is expected to be 72.8 MPa. However, for relative comparison of stresses, produced by vertical and horizontal loads, the same load magnitude of 600 N was applied for each condition.

A comparison of stress contours for the three design cases revealed that reduction of occlusal thickness of ceramic from 3.0 to 0.5 mm had a small influence on the stress distribution, particularly with increasing distance from the occlusal area. For a vertically applied load of 600 N, only small amounts of tensile stress were induced in the ceramic along the vertical direction. The largest compressive stresses occurred in the marginal region where the stress contours for all design cases were nearly identical. Analyses performed in part (a) revealed that stress and displacement for the three design cases were not significantly different. The tensile and compressive strengths of castable ceramic are 69 and 828 MPa, respectively (Clinical Procedures Manual, Dentsply International, 1984). The stresses induced in ceramic due to a vertical load of 600 N applied on a cusp were well below these strength values. However, the analyses in part (b) showed that if the load is applied along a horizontal direction, the tensile stresses induced in ceramic at the marginal region rise above its strength level (Fig. 7). This indicates that loading orientation has a significant influence on longevity of ceramic crowns.

The purpose of analysis (c) was to verify the quantitative results from the previous analyses by increasing the number of nodes and elements. In the refined model, the curvature of the crown at the occlusal region is more precisely modeled. Comparison of the stress contours for σ_1 in the refined and unrefined models showed only a small difference in stresses within cuspal areas. Since the stress contours at the marginal and dentinal regions were similar, the difference in stresses within occlusal regions probably is more related to the change in crown geometry at this region and not to the reduction in discretization error. The results of analysis (c) indicate that the values obtained for analyses (a) and (b) were not associated with large values of the discretization error.

The result obtained from analysis (d) is important relative to the efficiency of the finite element models. When the pulp chamber was replaced by a void region, no significant changes in stress and displacement values were obtained. This implies that for finite element analyses of similar dental restorations, it is not necessary to model the pulp chamber. However, if the pulp chamber is included in the model, relatively larger sized elements can be selected in this region. Therefore, the limited number of nodes and elements which are usually associated with microcomputer programs can be used for more critical areas such as within ceramic marginal regions. From these analyses, it can be inferred that regions with a relatively small elastic modulus which are located farther away from the site of loading can have large elements or in some cases they may be ignored completely in the finite element model. In the previous two-dimensional finite element stress analysis of natural tooth by Atmaram and Mohammed (1981) and ceramic crown by Anusavice and Hojjatie (1988), the influence of the pulp chamber was considered to be negligible. Also, in a three-dimensional finite element analysis performed by Rubin *et al.* (1983), it was found that the pulp chamber had no major influence on the stress distributions. The analyses in part (d) of the present study support this finding.

When the vertical load of 600 N was applied along one cusp, the largest tensile stress which developed in ceramic was 12.0 MPa and occurred near the cuspal region (Case I). The corresponding tensile stress in the marginal area was 4.0 MPa (contour *k* in Fig. 6). However, when the load was applied along the horizontal direction, the tensile stresses induced in cuspal and marginal regions increased to 25.9 and 113.5 MPa, respectively (contours *k* and *c* in Fig. 7). The maximum compressive stresses in ceramic due to vertical and horizontal loading were 70.9 MPa and 116.2 MPa, respectively, in the marginal area. For the horizontally oriented force, the peak value of the shear stress at the marginal area was 54.4 MPa (Fig. 9). If the shear strength of ceramic is considered to be 20,000 psi (137.8 MPa), the ratio of the peak shear stress value to this strength value is 0.39, while the maximum tensile stress of 113.5 MPa induced in ceramic at the marginal area, is approximately 1.6 times higher than the tensile strength value of 69.0 MPa. These results suggest that, in the absence of ceramic flaws along the interior surface or voids within dentin (or cement layer), the regions of castable ceramic crowns which are associated with the highest risk of failure are located near marginal regions and not near cuspal regions. For Dicor®, a tetrasilic fluormica glass–ceramic, Moffa (1988) reported a failure rate for molar crowns of 35.3 % during the first three years. However, little information is available on the mode of failure of these restorations. McInnes-Ledoux *et al.* (1989) and Grossman (1989) have associated the longevity of these crowns with the bond strength of various adhesive materials with ceramic and dentin. In a

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recent study, Kelly *et al.* (1989) have used quantitative fractography by scanning electron microscopy to determine the source of fracture and stress values responsible for fracture in five clinically failed Dicor® ceramic crowns. They concluded that the source of failure in these crowns was at the internal surface of ceramic, often at an intersection of two internal walls of the proposed teeth. The fracture stress in Dicor® was reported to be 55.4 ± 10.6 MPa. In an *in vitro* study, Dickinson (1988) reported that fracture of an anterior Dicor® crown initiated from the incisal edge at the point of loading. However, Hoekstra (1988) showed that under *in vivo* conditions, fracture initiated from the lingual surface and propagated to the marginal area. They reported that failure of a molar Dicor® crown originated from inside the occlusal surface. Unfortunately, these clinical results were reported only for a single crown. In general, clinical failures of ceramic restorations are statistical in nature and determination of the failure modes should be based on a large number of subjects. Since the glass-ceramic material was introduced to dentistry for clinical use only four years ago, few clinical reports on failure are available. At the present time the only reliable study which reports the clinical failure of these Dicor® restoration based on five ceramic crowns, is by Kelly *et al.* (1989). However, to determine the mode of failure of these restorations additional clinical and fractographic data are needed.

It should be emphasised that in the finite element model analysed in this study, the influence of the flaws and the cement layer were assumed to be negligible. Because of these assumptions, no conclusion can be made regarding the failure mode and fracture mechanism of these restorations.

The results of this study support the hypothesis that the orientation of applied forces is a dominant factor in the development of tensile stresses. The reduction of the occlusal thickness of ceramic from 3.0 to 0.5 mm has only a minimal effect on the induced tensile stress state. This insensitivity of induced stresses to changes in the crown dimensions does not appear to justify the recommendation of a minimal occlusal thickness of 1.5 mm. However, to draw a conclusion regarding the mode of failure of these restorations, future three-dimensional studies should also consider the influence of the cement layer, surface flaws, periodontal ligament, and other factors which may be associated with a higher risk of clinical failure.

REFERENCES

Adair, P. J. and Hoekstra, K. E. (1982) Fit evaluation of a castable ceramic. *J. dent. Res., IADR Prog. Abstr.* **61**, No. 1500, p. 345.

Anusavice, K. J. and Hojjatie, B. (1987) Stress distribution in metal-ceramic crowns with a facial porcelain margin. *J. Dent. Res.* **66**, 1493–1498.

Anusavice, K. J. and Hojjatie, B. (1988) Influence of incisal length of ceramic and loading orientation on stress distribution in ceramic crowns. *J. Dent. Res.* **67**, 1371–1375.

Anusavice, K. J., Hojjatie, B. and Dehoff, P. H. (1986) Influence of metal thickness of stress distribution in metal–ceramic crowns. *J. Dent. Res.* **66**, 1173–1178.

Atmaram, G. H. and Mohammed, H. (1981) Estimation of physiologic stresses with a natural tooth considering fibrous PDL structures. *J. Dent. Res.* **60**, 873–877.

Bathe, K. J., Wilson, E. L. and Peterson, F. E. (1974) SAPIV, a structural analysis program for static and dynamic response of linear systems. Report No. EERG 73-11, College of Engineering, University of California, Berkeley, CA.

Clinical Procedures Manual, Dentsply International (1984) Dentsply/York Division, York, PA, p. 7.

Craig, R. G. (1980) *Restorative Dental Materials* (6th Edn), p. 60. Mosby, St Louis.

De Vree, J. H. P., Peters, M. C. R. B. and Plasschaert, A. J. M. (1984) The influence of modification of cavity design on distribution of stresses in a restored molar. *J. Dent. Res.* **63**(10), 1217–1220.

Dickinson, A. J. G. (1988) A comparison of the cerestore and dicor systems. In *Proc. Int. Symp. Alternatives Trad. Porcelain*, Amsterdam, The Netherlands (Edited by Pameijer, C. H.). pp. 1–24.

Farah, J. W., Craig, R. G. and Sikarskie, D. H. (1973) Photoelastic and finite element stress analysis of a restored axisymmetric first molar. *J. Biomechanics* **6**, 511–520.

Farah, J. W., Hood, J. A. A. and Craig, R. G. (1975) Effect of cement bases on the stresses in amalgam restorations. *J. Dent. Res.* **55**(1), 115–120.

Finn, R. (1978) Relationship of vertical maxillary dysplasias, bite force, and integrated EMG. In *Conf. Craniofacial Res.*, Ann Arbor, Michigan (abstract). University of Michigan Center for Human Growth and Development, Ann Arbor.

Gibbs, C. H., Mahan, P. E., Mauderli, A., Lundeen, H. C. and Walsh, E. K. (1986) Limits of human bite strength. *J. Prosthet. Dent.* **56**(2), 226–230.

Graf, H., Grassl, J. and Aeberhard, H. (1974) A method of measurement of occlusal force in three directions. *Hel. Odont. Acta* **18**, 7–11.

Grossman, D. G. (1973) Tetrasilicic mica glass-ceramic method. U.S. Patent 3,732,087, patented 8 May 1973, U.W. Patent Office, Washington, D. C.

Grossman, D. G. (1989) Photoelastic examination of bonded crown interfaces. *JDR Prog. Abstr.* **68**, No. 719, p. 271.

Hoekstra, K. E. (1988) Dicor research facts. In *Proc. Int. Symp. Alternatives Trad. Procelain*, Amsterdam, The Netherlands (Edited by Pameijer, C. H.), pp. 49–77.

Kelly, J. R., Campbell, S. D. and Bowen, H. K. (1989) Fracture-surface analysis of dental ceramics. *J. Prosthet. Dent.* **62**, 536–541.

McInnes-Ledoux, P. M., Ledoux, W. R. and Weinberg, R. (1989) A bond strength study of luted castable ceramic restorations. *J. Dent. Res.* **68**(5), 823–825.

Moffa, J. P. (1988) Clinical evaluation of dental restorative materials—final report, Interagency Agreement No. 1Y01-DE40001-05, Letterman Army Institute of Research, San Francisco, CA.

MTAB*POST (1987) General purpose finite-element solution postprocessor for the IBM-PC and compatible micro-computers. User's Manual, Structural Analysis, Inc., Austin, TX.

MTAB*PRE (1987) General purpose finite-element model generator for the IBM-PC and compatible micro-computers. User's Manual, Structural Analysis, Inc., Austin, TX.

Proffit, W. R., Fields, H. W. and Nixon, W. L. (1983) Occlusal forces in normal- and long-face adults. *J. Dent. Res.* **62**(5), 566–571.

Rubin, C., Krishnamurthy, N., Capilouto, E. and Yi, H. (1983) Stress analysis of the human tooth using a three dimensional finite element model. *J. Dent. Res.* **62**(2), 82–86.

SAP86 (1986) A finite element program for static and

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dynamic analysis of linear structural systems. Installation and User's Manual, Release 3.0, Structural Analysis, Inc., Austin, TX.

Selna, L. G., Shillingburg, H. T. and Kerr, P. A. (1975) Finite element analysis of dental structures—axisymmetric and plane stress idealizations. *J. biomed. Mater. Res.* **9**, 237–252.

Starling, L. B. and Cook, S. D. (1983) An evaluation of stresses within ceramic tooth reconstructive materials. *IADR Prog. Abstr.* **62**, No. 336.

Timoshenko, S. P. and Goodier, J. N. (1970) *Theory of Elasticity* (3rd Edn), p. 380. McGraw-Hill, New York.

Wheeler, R. C. (1965) *A Textbook of Dental Anatomy and Physiology* (4th Edn.), p. 21. W. B. Saunders, Philadelphia.

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different technologies and system designs. Little investigation has been conducted to quantify the relative mechanical strengths of various plate designs and configurations to determine the most effective means of achieving rigid internal fixation of the mandible.

This study compares the relative biomechanical strengths of three different techniques of mandibular fixation using two different plating systems. A beef rib mandibular fracture model with dimensions similar to the human mandible was utilized. Uniform fractures were created using a microsaw. Fixation was then performed using one of three different techniques: six screw eccentric dynamic compression plates (EDCP), six screw reconstruction plates (RECON) and a paired system using a four screw dynamic compression plate with a two screw tension band (DCP + TB). Six models were prepared and tested for each technique using plates from the Synthes/A-O mandibular system and plates from a newly developed mandibular system which incorporates a down sized, low contact titanium plate design for use with 2.4 mm screws. Each of the six systems was tested on six models (n = 36). The plated fracture models were then mounted in an Instron tensiometer and a load applied 3 cm anterior to the experimental fracture site at a rate of 1 cm per minute until failure. Loading data was graphically recorded and evaluation of the mode of failure noted.

The load sustained by the model at the time of failure for the 2.4 mm Low contact systems were: EDCP 13.9 kg (12.5-15.2), DCP + TB 33.1 kg (21.5-46.0) and RECON 17.1 kg (16.0-20.5). Loads recorded for the 2.7 mm systems were: EDCP 33.4 kg (30.0-41.7), DCP + TB 55.5 kg (46.0-60.5), and RECON 30.4 kg (22.0-40.0).

Failure of the 2.4 mm DCP + TB, the 2.7 mm EDCP and the 2.7 mm DCP + TB occurred primarily at the screw-bone interface. Failure of the 2.4 mm EDCP occurred by plate deformation. The 2.4 mm and 2.7 mm reconstruction plates failed by deformation of the plates at the bending joints.

Conclusions: For all tested fixation techniques the 2.7 mm system sustained significantly greater loads than the comparable 2.4 mm system. The 2.4 mm EDCP and 2.4 mm RECON sustained the smallest loads and the 2.7 mm DCP + TB sustained the greatest loads before failure. Failure of the plates (2.4 EDCP, 2.4 Recon, 2.7 Recon) at subfunctional loads indicates fixation that could undergo permanent deformation during function. This problem was always avoided with a paired plate system.

References

Spiessl, B.: Internal Fixation of the Mandible. New York, Springer-Verlag, 1989

Rogerson, K., Agaal, L., Shafer, D.: Mandibular tension band differences with 4 and 6 screw plates. J Dent Res 70:2305, 1991

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CAD-CAM Generated Mandibular Mod... Prototype From MRI Data

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Computer-aided design/computer-aided manuf... ing (CAD/CAM) of three dimensional (3-D) models on radiographic imaging data currently requires ... computed tomography (CT).[1] Although 3-D, com... enhanced MRI images have been developed,[2] the... no reports of MRI data digitized to direct a numer... controlled milling machine. This study utilized co... tional MRI scans to generate an actual three dimen... model of the human mandible.

A phantom model of an edentulous cadaver ma... was cast in poly(methylmethacrylate) (PMMA). ... bone, PMMA is not ordinarily imaged by MRI. ... model was submerged in a 60 mM copper sulfate (C... solution to simulate the soft tissue envelope surrou... the mandible in vivo. Coronal sections of the PM... mandible were imaged at 1 mm increments on a 1.5... General Electric Signa Advantage whole-body MR sy... T1 weighted images were obtained because of in... faster scan times and better anatomic definition; C... generates a more intense signal than water in T1 we... images due to its paramagnetic properties. Films we... veloped directly from the MR system and the image... hand-transferred to bond paper utilizing a referenc... The transferred images were digitized with a digi... pad and puck. 3-D computer images of the digitized... sections were constructed with HURCO ULTIMAX... AutoCAD software on a Nebula XT-12 (IBM compa... computer. The AutoCAD file was then employed to ... a tool path for a HURCO CNC ("computer numer... controlled") Kneetype milling machine. A block of ... wood was positioned and secured onto the HURCO ... and a wood model of the MRI-scanned PMMA ma... was manufactured. This model was foreshortened ... anterior-posterior direction compared to the PM... mandible by approximately 20%.

A customized, true scale model of patient anato... a powerful adjunct to diagnosis and treatment... models aid not only dental implant placement, bu... will allow construction of custom prostheses and p... rication of appropriately formed metallic plates fo... toration of continuity defects. To our knowledge,... models are now available only from CT imaging da... major disadvantage of this technique is the utilizat... ionizing radiation necessary to generate accurate i... and models, typically 25 cGy for 3 mm overlapping ... of the mandible. MRI is a means of obtaining de... anatomic and physiologic patient data in virtually u... ited quantities without exposing the patient to the p... tially harmful effects of ionizing radiation. This i...

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Important Tip About Wearing the Red White & Blue Active Clear Retainer System:

The qualities that make this system of improving your front teeth effective also require care in the seating and removal of the appliances. Never "bite" the Retainer into place. Always seat the Retainer firmly with your fingers using pressure against the biting surface. When removing the Retainer use your fingers on both sides simultaneously and gently pull the Retainer down, if an upper appliance and up, if a lower appliance. By not using these methods you can distort or even rip the material delaying your treatment goals or requiring costly replacement fees.

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JCO INTERVIEWS

Craig Andreiko, DDS, MS on the Elan and Orthos Systems

DR. WHITE What are Elan and Orthos?
DR. ANDREIKO They are two new appliance systems that represent the first time modern CAD/CAM [computer-aided design/computer-aided manufacturing] technology has been applied to both human anatomy and appliance design in the orthodontic field.

DR. WHITE Could you describe Elan more completely?
DR. ANDREIKO Elan is a new dimension in treatment planning. Over the years, treatment planning and appliances have evolved to more completely address the individuality of the patient. Computers now aid in the cephalometric evaluation of the patient and in previewing the anticipated results. Appliances exist that are designed for extraction, nonextraction, expansion, etc. Elan is the first system to integrate the treatment plan and the appliance for a specific patient.

Elan begins with digitizing the skeletal and dental entity of the patient. The system then proceeds to design an occlusion, based on the practitioner's treatment plan and on algorithms developed to mate the three-dimensional positioning of the dentition to the skeletal framework. Next, the system designs and fabricates brackets, wires, and bracket-positioning devices that are essentially reverse-engineered from the desired final results for that individual patient.

It is an evolution of preadjusted appliances. Since the system can capture the "personality" of the practitioner and match this to the individual patient, it is essentially the same appliance he or she is now using, with much more of the guesswork eliminated. This system allows the practitioner to concentrate more on treatment planning and less on adjusting for the mismatch between the appliance and the patient. As Ricketts said, "Begin with the end in mind."

DR. WHITE And Orthos?
DR. ANDREIKO Orthos is a new average prescription and appliance design based on computer analysis of more than 100 cases derived from the Elan technology. It is a coordinated system of brackets, buccal tubes, and wires.

DR. WHITE With the Elan system, how do you establish individual treatment needs such as tip, torque, and in-out positioning for patients?
DR. ANDREIKO The Elan system begins with an analysis to determine the medullary

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center of the mandibular bone. This is converted to a mathematical equation we call Mantrough (Fig. 1)— the keystone of the analysis.

Next, the mandibular teeth are placed on the curve such that the crown long axes are at specified inclinations, as opposed to the facial inclinations that have been used to date. The centric stops (buccal cusps) of these teeth are aligned on another smooth equation derived from Mantrough, such that the roots of the teeth are centered in the bone. The maxillary teeth are then placed in occlusion with the already-set mandibular teeth. Maxillary posterior teeth are placed with respect to centric stops and calculations for molar rotation (Fig. 2). The maxillary anterior teeth are placed from calculations to provide either group function or cuspid rise parameters. Other calculations regarding tooth-size discrepancies, depth of bite, etc., are also done at this time. Essentially, the system does an ideal setup for each case.

DR. WHITE How does the crown long axis differ from the system of measurements Andrews gave us 30 years ago?
DR. ANDREIKO The crown long axis is a line that passes through points of bisection of the incisal edge and the cervix of the tooth, as seen from a mesiodistal profile (Fig. 3). The system works more off the body of the tooth, essentially, but also utilizes specific occlusal landmarks to more accurately control root positioning. Until something like computed tomography or magnetic resonance imaging becomes practical and accurate, I think this is the best that can be done.

DR. WHITE How precise must the appliance be to achieve clinical accuracy?
DR. ANDREIKO The system resolves to about .002" fundamentally, but tolerances can accumulate, and so our goal is to produce occlusions that the practitioner has no desire to adjust through bending the archwire. I think that our advantage here is that the system can view the occlusion from the lingual as well as the labial.

DR. WHITE Where do you place the brackets in the Elan system?
DR. ANDREIKO Mandibular brackets are placed as occlusally as possible for hygiene while assuring clearance from the buccal cusps of the maxillary teeth in the final occlusion. The maxillary brackets are placed fairly centrally, due to the absence of interferences.

DR. WHITE Presuming you can manufacture such accurate brackets and archwires, how can you assure correct placement on the teeth?
DR. ANDREIKO We have developed a single-tooth indirect procedure that will reliably allow the bracket or tube to be placed in the design location. The locating device is constructed on numerically controlled machinery and is not a laboratory procedure.

DR. WHITE I know from our previous conversations that you have a unique background for an orthodontist. Would you describe your experience for our readers?

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DR. ANDREIKO I was introduced to orthodontics as an apprentice tool and die maker at Ormco in 1971. Over the next five years, I progressed through a series of engineering and R&D positions. In 1975, working as a senior project engineer at Ormco, I began designing orthodontic appliances. I developed many products that are now familiar to most orthodontists. Among these are the foil-mesh bonding pads now used by most, as well as braided rectangular wires, brazing technology for assembly of appliances, the metallurgy responsible for today's down-sized appliances, and Ormco's lingual orthodontic system.

DR. WHITE What made you decide to become an orthodontist?
DR. ANDREIKO Part of my responsibility was clinical testing of these products. This meant that I spent quite a bit of time with various practitioners in their offices, observing serial patient visits to examine the performance of these new products. While I understood the intended use of these appliances, there were certain aspects, especially secondary traits, that eluded me. As time went on, I became more and more interested in the clinical aspects, and it became apparent that a formal dental education would be required. In 1983, I decided to leave Ormco and pursue a career in clinical orthodontics.

I graduated from the Loma Linda University general dental program in 1988 and from the orthodontic specialty program in 1991. I will shortly begin treating a limited number of patients as soon as Ormco completes an operatory on the premises. I am also a part-time clinical and didactic instructor at Loma Linda University.

DR. WHITE Was your introduction to orthodontic mechanotherapy via preadjusted appliances, classical edgewise appliances, or a combination of techniques?
DR. ANDREIKO Because of my position at Ormco, I had experience with almost every technique, including Begg. However, the bulk of my experience was with banded Tweed mechanics and later with bonded preadjusted appliance techniques. Of course, the training I received at Loma Linda was based on Bioprogressive principles.

DR. WHITE What were some of the problems you saw with the preadjusted orthodontic appliance?
DR. ANDREIKO In studying dental anatomy to design various appliances, I was impressed with the human variability relative to the geometry required in the appliances. I think this was compounded by the fact that the appliances had to be positioned on the faces of the teeth, which, from an engineer's point of view, is a limitation. Archform and coordination of the mandibular and maxillary archwires was also a difficult parameter to manage.

Positioning of the brackets and tubes was more of an art than a science. In particular, mandibular appliances are often placed more gingivally than the design location, due to a combination of maxillary cusp interference and appliance size. This causes excessive lingual tipping of the crowns and discrepancies in the 1st-order relationships.

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The precision of a high-quality finished occlusion relative to the variation found in the patient population was incongruous with a "one size fits all" approach. I believe that this is a key reason many orthodontists do not use full-size wires. It would seem that a full-size wire is a requirement for the bracket prescription to express its geometry on the occlusion.

DR. WHITE If present preadjusted appliances are so inaccurate, how do you explain the excellent results so many orthodontists achieve?
DR. ANDREIKO Excellent results have been the hallmark of orthodontics. What has happened is that the time and effort required to produce quality results have been reduced. This can be seen in the increased availability of treatment to the public. I also believe that the number of people receiving treatment is going to grow more than just significantly in the ensuing years, and that the orthodontic community must prepare for these increased caseloads.

DR. WHITE With the Elan system, will it be necessary to fill the bracket with wire throughout treatment to fully exploit its potential?
DR. ANDREIKO In certain malocclusions, treatment can be accomplished with round wires. These cases could be treated with undersize wires, just as is now possible. However, filling the slot will provide better detail. In reality, filling the slot should become the preferred mode of treatment with the "accurized" appliance and the newer wire alloys. It seems that the finishing phase may utilize a full-size archwire initially, but the final phase might be done with a smaller wire to facilitate minor detailing and settling of the occlusion.

DR. WHITE If few orthodontists using preadjusted appliances today completely fill the brackets with wire, why would you expect them to use full-size wires with the Elan system?
DR. ANDREIKO Appliances have been designed in the past to allow the practitioner to overcorrect or overcome the clinical side effects of treatment by utilizing the wire size as a tool. Elan systems can provide any overcorrections or clinical side effects, such as additional inclination of incisors in extraction cases, in the slot geometry. Secondly, the smaller wire has allowed the teeth to find an occlusal position through the forces of occlusion when the appliance would have done otherwise. This is less of a concern with individualized appliances.

DR. WHITE As with any preadjusted system, you expect the brackets to effect rotations and vertical positions of the teeth, but what effect does the appliance have on the horizontal relationship between the jaws?
DR. ANDREIKO By more accurately controlling the axial positioning of the mandibular posterior teeth with fill-the-slot mechanics, the width of the arch is more precisely regulated. So while there are no inherent changes in arch width, the cases tend to have more upright mandibular posterior segments, and this leads to a slightly wider arch in some cases.

DR. WHITE What modifications must be made for bicuspid extraction patients or for those

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with mutilated dentitions?
DR. ANDREIKO This system can help in extraction decisions by accurately determining crowding and tooth-size discrepancies. TSD calculations have lacked reliability due to many factors that are not currently included in other calculations, such as arch form and tooth thickness. The system can, for instance, give additional input to the clinician regarding minimizing tooth-size discrepancies based on which teeth are to be extracted before an irreversible treatment plan is instituted. The archwire sequence would depend on the amount of space to close and the practitioner's preference, but I really don't see Elan changing the retraction wire selection very much.

Mutilated occlusions can be analyzed with respect to anticipated restorative dentistry or made to fit as well as can be done within the existing anatomy and software. To be honest, most of our cases have involved minimal restorative work to date.

DR. WHITE What types of wires do you envision using with the Elan system?
DR. ANDREIKO Virtually all types, with an emphasis on the new alloys.

DR. WHITE Can any generic archwire be used?
DR. ANDREIKO That would be a poor use of the system, since the brackets and archwires are an integral design to produce truly coordinated dental arches for that one patient. The appliances are like snowflakes in that they appear similar, yet no two have ever been the same. The system coordinates literally hundreds of parameters in each case.

DR. WHITE How do you plan to make the wires available to the orthodontist? Will you ,supply a full series of archwires at the beginning of treatment, or ship them on an as-needed basis?
DR. ANDREIKO Archwires will be ordered according to treatment plan when the case is sent in, but wires can be fabricated from the data base at any time (templates would be included anyway). Of course, finishing archwires would be provided with every case. I believe that coordinated archforms should be a part of treatment from the beginning, but I also think that they are indispensable at the finishing stage.

DR. WHITE Could you use the custom-made archwires with an ordinary set of preadjusted brackets?
DR. ANDREIKO I think not, for the same reason as above.

DR. WHITE Will the Elan brackets be available in twin, single, or both?
DR. ANDREIKO Currently, the system is available only in the twin configuration, but we have longer-term plans to encompass all techniques, including ceramic and plastic appliances.

DR. WHITE Isn't a twin-bracket system less efficient than a single-bracket system that

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offers greater interbracket distance?
DR. ANDREIKO Practitioners have devised treatment mechanics that function well with both bracket systems. With the new wires, the difference is blurred slightly in some aspects, and the twin bracket systems are still the most popular today.

DR. WHITE What will the slot size be?
DR. ANDREIKO Both .018" and .022" slots are supported currently. I have to say that I gave considerable thought to building only an .020" appliance for ease of manufacture.

DR. WHITE How will this system work for orthodontists who want to use bands on molars?
DR. ANDREIKO Elan will use no bands or convertible tubes. Since the slot geometries of Elan are such that no bends are required, the need for a convertible is gone with today's wire alloys. With the departure of the convertible feature, the tube becomes the smallest bracket in the system, with the greatest pad area. It seems that with the exception of headgear, we may finally see routine fully bonded orthodontics. Of course, the Orthos appliances are designed for banded molars, similar to existing appliances.

DR. WHITE What about hooks?
DR. ANDREIKO Elan will require a master prescription to be on file regarding hooks, slot sizes, etc. However, a mini-prescription sent in with the case could add hooks for surgery or delete them for simple Class I with mild crowding, or anything in between. Hook availability for Orthos will be the same as with current products.

DR. WHITE How viable has the Elan system of brackets and archwires proven in vivo?
DR. ANDREIKO Good question. I should say that we are in our seventh software revision and somewhere in the same vicinity with mechanical upgrades. I think that the analogy of chess-playing computers is a good one. The early programs were slow and could be beaten by many players. Currently, these machines play at the grandmaster level, and I think we are somewhere in this same growth curve. In the beginning, we found weaknesses and, as usual, they took longer to resolve than we had anticipated. So while we have cases in clinical testing, many of them are not of the most recent software and hardware. We need time to evaluate these results and assess the true performance of the current system. But I would like to say that most of the weaknesses identified have been dealt with, and the current cases appear to be progressing quite well.

DR. WHITE How have you been able to measure the Elan's efficacy, efficiency, and cost benefit?
DR. ANDREIKO Of course, you have just defined our goal. We anticipate significant increases in efficiency of treatment. For example, there should be a reduction in the repositioning of appliances, less upsetting of already-acceptable parts of the occlusion, and

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fewer appointments to finish the case. The system will allow the clinician to spend more time designing treatment plans and less time bending wires. This is a continuation in the shift from an art to a science. Realistically, though, these are undoubtedly the most expensive appliances ever built, and the answers are not in yet.

DR. WHITE How will the Elan system compare in price to the ordinary preadjusted appliance?
DR. ANDREIKO We don't really have a firm price yet. We are trying to keep the cost to a minimum so that it can be used more frequently.

DR. WHITE It seems from your description of the Elan system that the loss of a bracket will offer an unusual problem for the orthodontist and patient. How do you plan to remedy this?
DR. ANDREIKO Currently we are providing two complete sets of appliances with each case. In the future, the placement jigs will be reusable with Elan brackets, and I think brackets can be rebondable with the sandblast technique. This is really like most indirect techniques, where the bond is to already-cured adhesive. Worst case would be to reorder.

DR. WHITE What are some of the other problems this sophisticated system may have?
DR. ANDREIKO First, let me say that we greatly underestimated the complexity of this project from the beginning, and we have had many problems/opportunities along the way. And because the system is evolving, it is still possible for software glitches to provide less-than-optimal results, especially in cases like lower incisor extraction, or basically anything we have not written specific code for yet.

Since we work primarily from models, the rule is "garbage in, garbage out". The impression must be pretty good, although the system can repair small voids with the software.

As with anything that is new, there will undoubtedly be a learning curve for the clinician.

Lastly, the appliance won't wear its rubber bands any better than now.

DR. WHITE Can you tell me more about the Orthos project?
DR. ANDREIKO While Elan is a totally customized appliance based on the individual patient's skeletal and dental anatomy, Orthos is an appliance based on norms and averages derived from hundreds of Elan analyses. It contains refinements and upgraded logic from the other currently available prescriptions. The computer logic written to solve functional and static occlusal puzzles and the appliance design software developed for Elan are being used to design the Orthos average appliances. Elan is still under development, but Orthos should be introduced this year.

DR. WHITE How did you determine the significant dimensions necessary for making a more accurate preadjusted appliance?

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DR. ANDREIKO This was a difficult task. I think the answer lies in the basic concepts of mechanical engineering, mixed with generally accepted orthodontic principles of occlusion. The six keys from Andrews were the starting point, but they were not really suited for digital calculations in three dimensions. Basically, the landmarks are chosen to satisfy centric occlusion requirements, as are familiar to your readers, with the addition of skeletal and functional criteria.

DR. WHITE How do these anatomical averages derived from Elan research affect Orthos appliance design?
DR. ANDREIKO We have found several things that affect appliance design and performance:

- By utilizing new rotation-in-slot technology, the lower anterior brackets have been reduced in the faciolingual dimension while, at the same time, the 1st-order relationship between lower cuspids and anteriors has been corrected.
- Mandibular posterior segments have less negative torque than prior designs to keep these teeth from being inclined lingually.
- Orthos archwire forms are taken from skeletal studies and are also "coordinated" mathematically for the first time.
- Molar rotations are calculated from actual anatomy for the first time.
- The mandibular arch has more progressive tip to aid in root paralleling (Fig. 4).
- Mandibular bicuspids have distal root tip to level marginal ridge contacts.
- Upper second bicuspids have distal tip to level marginal ridges between the second bicuspids and the first molars, and they are thicker than the first bicuspids to reduce the need for bayonet bends.
- Upper posterior segments have more buccal root torque to keep the dangling lingual cusps from causing balancing interferences with the prominence of today's expansion mechanics.

DR. WHITE How much difference is there in torque values between Orthos averages and Andrews originals?
DR. ANDREIKO In lower posterior segments the differences exceed 10°, but differences in thickness and angulation are far more significant clinically. For example, clinicians make far more 1st-order bends than 3rd-order bends.

DR. WHITE In the thousands of measurements you've made, have you found any distinct racial differences?
DR. ANDREIKO The Elan system has two basic functions. First is the production of individualized appliances, but the second is equally important. That is to create data bases of these appliances and occlusions that can be analyzed and sorted by many criteria. The first application of this has been studying the difference between races as they relate to

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appliances. We expect to have an Asian version of Orthos soon.

While there are many differences, the most significant are in the mandibular posterior teeth and the maxillary anterior region. For example, the lower first molars in Asian appliances require mesial rotation, due to the prominent buccal cusp, and increases in the maxillary anterior inclinations, due to a generally recessive midface. I have to mention that every bracket, tube, and archwire form is unique to this appliance, and that in the end, the details can add up to make a significant difference.

DR. WHITE Do you think there is a need for systems that reflect these racial norms?
DR. ANDREIKO I think that when the patient pool is of predominantly a single race, the appliance should be designed to impact the fat part of the bell curve. Practitioners using this type of appliance have no more inventory, and the appliances are no more costly than other appliances.

DR. WHITE Using such racial norms would seem little more than continuing with the "one size fits all" concept inherent in most current preadjusted appliances. How do you plan to avoid this problem?
DR. ANDREIKO Racially adjusted appliances *are* a continuance of the "one size fits all" concept. There is room for both average and individualized appliances. Obviously, the individualized appliance brings much more precision, but it is also more expensive. Still, the racially adjusted appliances would offer advantages over current prescriptions by adjusting the appliances to the anatomy.

DR. WHITE One final question: Why do you think the profession should endorse these new appliance systems?
DR. ANDREIKO The history of orthodontics has been one of innovation. One need only look at the appliances and treatment plans available today to see that the specialty has carefully but surely adopted much new technology. We hope that these systems will allow increased availability of orthodontic care over the coming years.

I'd like to leave your readers with a couple of interesting quotations:

"Another excellent way of causing the arch to bend within brackets and anchor sheath and, thus, to enlist force for uprighting, a distal tipping of the teeth (posterior teeth), is to change the positions of the brackets on the bands, thus changing the angles of relation of the slots of the brackets to the long axis of the teeth instead of making the vertical bends in the arch. This permits the use of the arch in its simplest form, or that freest from bends, which, of course, has advantages."[1]
"Theoretically, if all the brackets were to be placed in correct relationships to the respective teeth and if there were to be used a 100 percent elastic arch-bar, ideally formed not only as to gross horizontal form but all of the curvatures, indentations, and fine typal anatomical detail

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that presents for the case, then if the brackets were to continually fit the arch-bar with absolute accuracy, every tooth would receive such pressure as would tend to carry it to its correct location, not only as to position but to axial inclination as well."[2]

DR. WHITE Thank you for your thorough explanations.

DR. WHITE



DR. ANDREIKO



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Elan

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Orthos

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FIGURES

Fig. 1

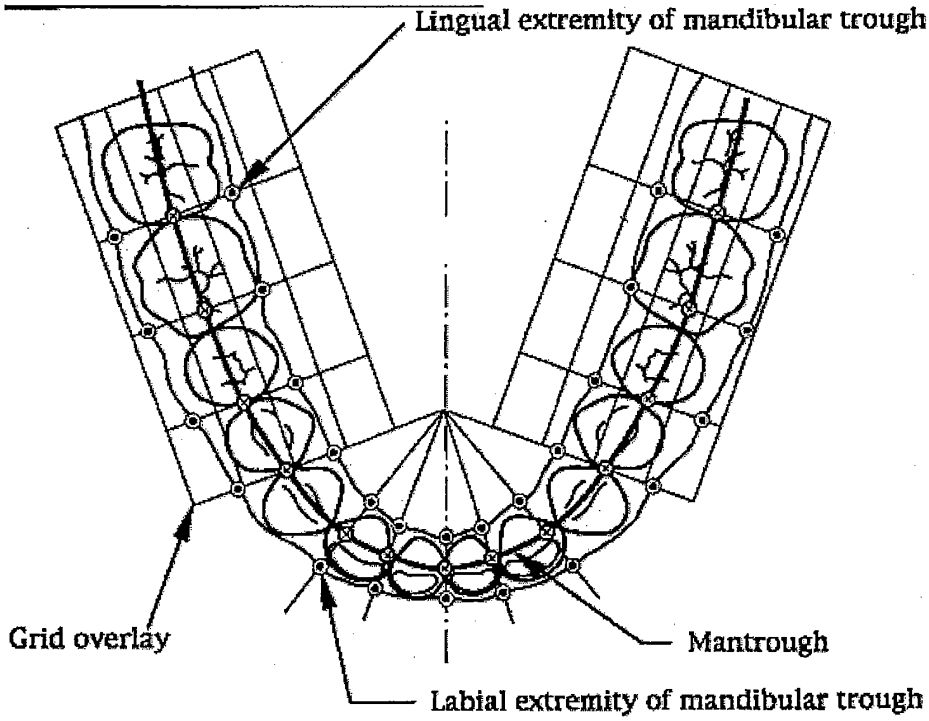


Fig. 1 Development of Mantrough, with grid overlay used for selection of lingual and labial limits.

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Fig. 2

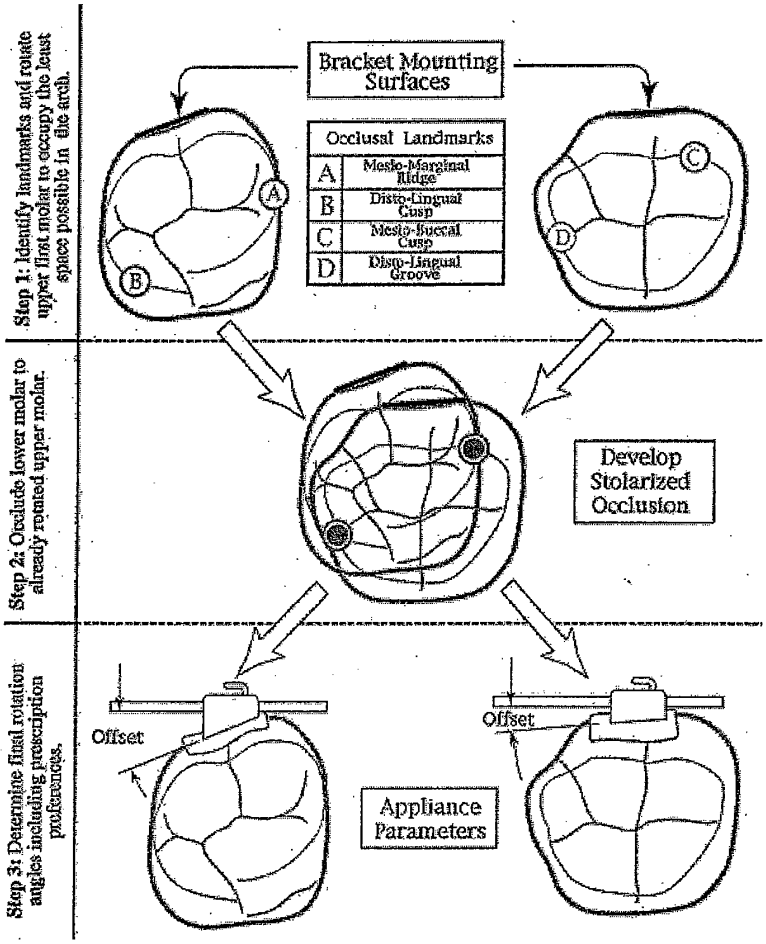


Fig. 2 Explanation of logic used to determine molar rotation angles.

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Fig. 3

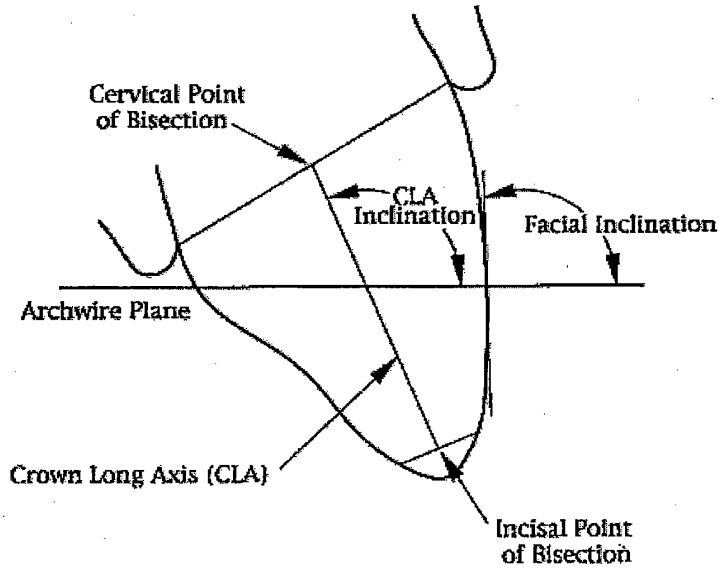


Fig. 3 Derivation of crown long axis, and its relationship to facial inclination.

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Fig. 4

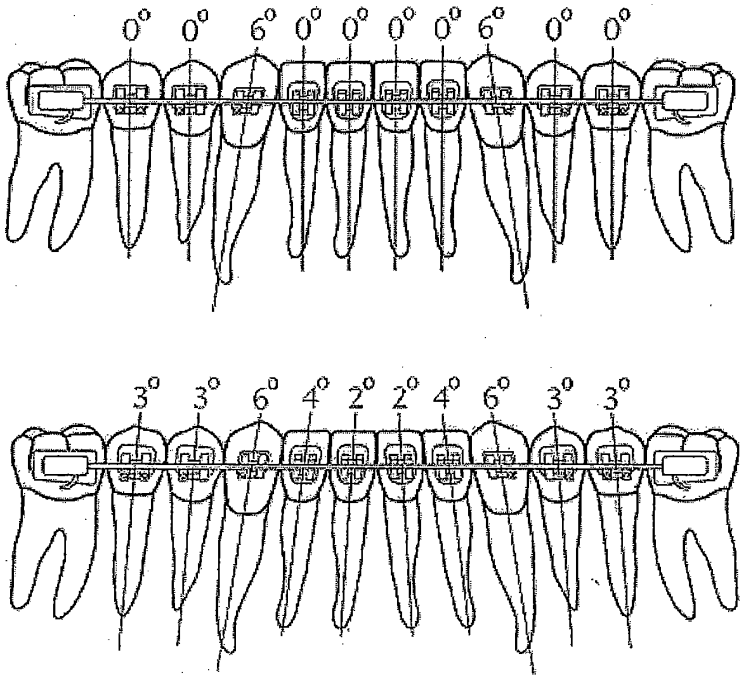


Fig. 4 Effect of progressive tip on root paralleling (top: typical prescription; bottom: Orthos values).

References

1.Angle, E.H.: The latest and best in orthodontic mechanism, Dent. Cosmos 71:260-270, 1929.

2.Steiner, C.C.: Is there one best orthodontic appliance? Angle Orthod. 3:277-294, 1933.

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jco/interviews

DR. HOMER W. PHILLIPS on Computers in Orthodontic Practice

Part 2

DR. GOTTLIEB Is it hard to make a mistake in buying hardware, provided that you've taken care of language capability and bought programs that suit your practice?

DR. PHILLIPS I'd say it is extremely easy to make a mistake. The fact is that at the present time well over 150 brands of microcomputers are being sold around the world. Although most of them are very similar, that isn't a good enough reason to buy just any of them. The microcomputer industry is very young and volatile. Companies come and go very fast. In terms of long-term investment protection and getting value out of your machine and support for it, I could not recommend buying any but one of the most widely sold brands for office use. If I were buying or recommending buying a microcomputer, I would feel hesitant about recommending one other than IBM, Apple, or perhaps Digital. That is not to say that there are not a vast number of other very large capable companies making microcomputers, but for my dollars I wouldn't buy one of them. The models come and go so fast, machines are taken off the market, and there are few things as useless as an orphan computer that no longer has a company behind it. You can just kiss it away if you can't get parts or service when needed.

DR. GOTTLIEB I think we ought to embellish on that a little bit. When that happens, first the company stops making parts, and then they stop servicing that model. When either one of those things occur you're just out of the ball game.

DR. PHILLIPS You really are. And because the prices are not a great deal different from one brand to the other, I think that it is false economy to save $100-500 buying Brand Z when you can buy one of the Big Three for essentially the same price as the others. Any low-volume computer is likely to be taken off the market, and probably would not have much software written for it anyway. Also, be leery of so-called Apple or IBM "compatible" machines. They may not be able to run the particular Apple or IBM program you want.

DR. GOTTLIEB Does what you are saying also apply to the rest of the equipment?

DR. PHILLIPS Yes. That goes for the peripherals— the disk drives and the printers. I

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would only buy the very largest selling ones, because you have to be able to get service on these things. It's not just the loss of dollars in case of an equipment failure; it's the loss of ability to operate the equipment and programs. If you get an off-brand printer that breaks down, chances are extremely good that you will need to buy another printer. I would urge anyone to buy only the largest selling and most widely available and widely serviced equipment.

DR. GOTTLIEB What are the hardware and components that would be involved in an in-house system?

DR. PHILLIPS The basic unit is the Central Processing Unit, or CPU, which does the calculations. Then you would need a storage device of some kind. Those in current use are of two basic types, floppy disks and hard disks. For business applications or to file much patient data you will need a hard disk, which can store a large amount of information in a small space. If you're doing something less involved than that, such as diagnostic programs, a recall system, or an inventory file, you can easily operate with floppy disks.



Loading a floppy disk.

DR. GOTTLIEB What is the difference between them?

DR. PHILLIPS Floppy disks are cheaper than hard disks, but they store much less information per disk. Another difference between the hard and soft disks is the access time, the length of time it takes to get information from the system. A hard disk operates faster and stores more information, but it is considerably more expensive, and, in some cases, it is more difficult to make backup copies of your programs, which are duplicates of the information that you've recorded or stored on the disk. In case something happens to a disk, you need to have the information somewhere else. A good hard disk system will have a reasonably fast way to back up the information, and this is vitally important. A hard disk without a good backup system is a real danger, because you can lose your data. You also need a printer and, in many cases, two printers— a letter-quality printer and a dot-matrix printer.

DR. GOTTLIEB We should mention among the hardware the terminal, the cathode ray

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tube or CRT.

DR. PHILLIPS Yes, the terminal is the most used device to put information into the computer system. It consists of a keyboard and a monitor that looks like a TV screen. The terminal, the CPU, the storage device, and a printer are the basic components of your system.

DR. GOTTLIEB You referred a minute ago to the storage capacity of the system. We usually hear about it in terms of "bits". What is a "bit"?

DR. PHILLIPS "Bit" is an abbreviation for binary digits. It is the smallest discrete piece of information that a computer can handle. You'll hear terms such as 8-bit and 16-bit machines, meaning how much information the CPU can electronically handle at one time. The current state of the art in microcomputers is the 16-bit machine. The earlier ones were 8-bit machines. Those of the future are going to be 32-bit machines.

DR. GOTTLIEB What should an orthodontist be looking for in terms of bits?

DR. PHILLIPS Right now, if you can find the program you want, it doesn't matter a great deal from the operator's standpoint if it runs on an 8-bit or a 16-bit machine. Since 16-bit machines are the current state of the art, many new software programs being written today are for 16-bit machines. However, in catalogs of programs available for microcomputers, you're going to find more written for 8-bit machines such as the Apple than you are for 16-bit machines such as the IBM, simply because 8-bit machines have been on the market longer.

DR. GOTTLIEB And they're not interchangeable?

DR. PHILLIPS Right. There are computers that have both 8-bit and 16-bit processors in them, but if I were buying a machine today I would probably want a 16-bit machine, not because of its inherent benefits to the operator, but simply because more software is being written for them. Also, 16-bit programs can be more sophisticated than those written for 8-bit machines.

DR. GOTTLIEB With the 32-bit machine as imminent as it seems to be, will it outmode a 16-bit machine, which is adequate for an orthodontist's office?

DR. PHILLIPS My thought on obsolescence is that as long as the job that you want accomplished is not obsolete and your computer is doing that job, then it is not obsolete. I have both 8- and 16-bit machines in my office and they're both doing the jobs that I bought them to do, so neither one of them is obsolete as far as I'm concerned.

DR. GOTTLIEB We started with a "bit". What's a "byte"?

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DR. PHILLIPS A byte is a consecutive string of binary digits or bits, typically consisting of 8 or 16 bits. One typewriter character represents one byte of information. In the computer, memory capacity is described as consisting of so many bytes.

DR. GOTTLIEB Another term that an orthodontist will run into is "K". He hears about a 64K system.

DR. PHILLIPS The soft and hard disks we've been talking about are external storage devices. The internal memory or storage capacity of the machine concerns how much information can be stored within the computer itself and is directly available to the processing unit. That internal storage capacity of the machine is what's generally being discussed when people talk about a 64K machine. One kilobyte is conveniently described as 1000 bytes. Actually, one kilobyte is 1024 bytes or 2 to the 10th power. Computer logic is based on the binary system of mathematics rather than the more familiar decimal system. Binary is easy for computers, because the electrical signals for ones and zeros can be electronically generated by a pulse or lack of a pulse of electricity. For a business system you would need at least 64K, preferably 128. Newer programs being written for the 16-bit machines are getting longer and more complex. Soon, 256K or more will likely become standard. External storage is also measured in megabytes, one megabyte equaling approximately one million bytes of storage capacity.

DR. GOTTLIEB How much is enough?

DR. PHILLIPS Memory is cheap. In order not to limit your capabilities with the programs that are now being written, I would want a minimum of 128K. This memory is not stored on a disk. It's stored in what are called RAM chips or random access memory chips, which are the actual little domino-shaped silicon blocks that are in the computer itself. In the past, programs written for microcomputers rarely would need as much as 48K of memory, but many of the current spreadsheet programs and some of the word processing programs require 128K to 196K to operate. These newer, more elaborate programs may soon approach the size of minicomputer programs.

DR. GOTTLIEB Are the systems that you are talking about for an orthodontist able to be added on to if he runs out of capacity?

DR. PHILLIPS Yes. Virtually all of the present day 16-bit computers can be added to up to 512K of internal storage and, to my knowledge, that is more than adequate for any currently available microcomputer programs.

DR. GOTTLIEB Orthodontists will often hear the term "baud rate". What is that?

DR. PHILLIPS There you are getting into the communications aspect of computers. By

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means of machines called modems, and with appropriate programs, you can connect your computer to a telephone line that, in turn, connects it to other computers elsewhere in the country or to data services that provide information such as stock reports or to the New York Times News Service. The baud rate has to do with the speed at which information is transferred over the telephone lines. Typically, for microcomputers, it is somewhere between 300 and 1200, which isn't all that fast.

DR. GOTTLIEB The telephone line slows you down?

DR. PHILLIPS That's right. If you're paying for connecting to a news service by the minute, the baud rate becomes significant; but, if you get a machine that has a faster baud rate, many of these services charge you more per minute, because they are expecting to make so much per hour.

DR. GOTTLIEB Do you look upon the computer and modem as a particularly good application for orthodontists who have multiple offices?

DR. PHILLIPS This would depend very much on the specific situation. For someone with three to six offices and a host computer at the main office, certainly they would want to include information from the branch offices in the overall business system, and the modem is one way to do that. But there are other ways. I'm afraid I'm inclined to be simplistic about these things. I like to do things with the least possible complications. So when you think about modems and transferring information from one office to the other, my thought is, "What is a reasonable length of time to get this information from one place to the other—what's a workable time frame?" Determine that, then decide how to do it. For instance, in most cases, I feel that a very practical way to do it, which might be simpler and have fewer problems, would be to use floppy disks at the branch offices and physically transport those disks back to the main office and integrate the information there. I would be inclined to do that, frankly, because to me it's a more failsafe method and would not have the same potential for electronic and operator problems. Modems are useful, but they are not real fast and they involve another layer of technology both from the operator's standpoint and the equipment standpoint. So, if physically transferring disks between offices works, which it would in most cases, that's the way I would do it. I would have a personal computer with a disk drive in the branch office, enter the data, and physically bring it back to the other one.

DR. GOTTLIEB There is a lot of talk about computer break-ins by creative young people. Is this a serious problem for an orthodontic office? How can one guard against it?

DR. PHILLIPS That need not be a problem at all. First of all, for a computer system to be vulnerable to such a break-in, your computer must be connected by a modem to a telephone line; and your system must be turned on and data or programs must be on line for an

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electronic intruder to gain access to them. The first line of defense against this happening is simply not to have a modem. Second, do not leave the equipment turned on 24 hours a day. If you need a modem and you do leave it on all the time, the next security step is to have multiple passwords built into your programs, and to change them at frequent intervals. A much more likely source of data loss in an orthodontic office is from the use of the machine by unauthorized personnel in your building who gain access to the computer. The answer to this problem, again, is to have multiple passwords in the programs, change them often, and be very selective about who knows them. It is possible to physically lock the machines in some cases.

DR. GOTTLIEB How long a life should the software and the hardware have to be cost-effective?

DR. PHILLIPS In an orthodontic office, chances are your computer will not run all the time. Even if you turn it on in the morning and leave it on all day, you're not actually running it all the time. So, for the work load that most practices have, the computer itself will last almost indefinitely. The things that are apt to have a service life are the disk drives and the printers. These are the more mechanical parts of the system. If you get five years' use out of a floppy disk drive without appreciable problems, I think you are doing well. If you use a printer a lot, I think you're going to need service on it once a year. With appropriate use of backup copies, the software should last indefinitely. I don't plan on using one soft disk that has an applications program on it more than a year. I'll make copies and use them alternately to reduce the wear per copy. I have a master copy of each of my programs and working copies, which are used only to make additional working copies. There is a certain amount of wear and tear, particularly if you're using a floppy disk, because the read/write head contacts it, causing friction, and dust and dirt can get to it. The hard disk system operates as a sealed unit that pretty well isolates the disk from all environmental dust and grime. If all goes well, the read/write head does not contact the surface. Therefore, somewhere between five and seven years is a reasonable length of time to expect to have a fairly service-free operation from a hard disk. This type of storage device does not travel well. It should be moved as little as possible.

DR. GOTTLIEB An orthodontist could expect to get five to seven years out of equipment if he were to buy today?

DR. PHILLIPS I would say so. That presupposes that you're using it in a reasonable fashion. You can think of it somewhat like fine photographic equipment. You do want to protect it from dust and from obvious things like coffee spills, and you don't want to drop it. But as long as it stays in the same place and is kept relatively dust-free, you can expect to get a very long service life out of it. These pieces of equipment, particularly the disk drives, don't take kindly to exposure to a lot of dust, and most dental offices have a fair amount of dust,

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from plaster or whatever. I recommend that the equipment be covered any time it is not in use.

DR. GOTTLIEB You were talking earlier about dust, which is an enemy of computers. What about when you have the office cleaned and the cleaning people are creating a lot of dust?

DR. PHILLIPS If the equipment is covered at any time it is not actually in use, you don't seem to have problems. The people that have problems with computers in dental offices by and large are those that are very nonchalant about them and never take any precautions at all to keep dust out of the machinery. For instance, if you're using floppy disks, any disk that is not actually in use in the disk drive should be in a closed container. It should never simply be left out on a table. While all the equipment should be covered when not in use, it very definitely should not be covered when it is in use, because heat is a very big potential source of problems with computers. Free air circulation is mandatory when the computer is in use. You should take precautions not to put folders or books or anything else over vents in the computer housing. The vents should be un-obstructed while in use, but totally closed when not in use. In an orthodontic office, plaster dust in the air can be one of the main problems, so do not put your computer in the lab, even though you may have more room for it there.

DR. GOTTLIEB There is, of course, a double problem there. Computer systems are noisy, and you might want to get them to some place other than where you are working.

DR. PHILLIPS This is true. High-speed printers are extremely noisy, and cooling fans in the CPU are noisy, too. So a remote location is sometimes advisable. However, this has to be tempered with the need for accessibility.

DR. GOTTLIEB And when you say accessibility, I think we probably ought to point out that when you start something printing, frequently you need to watch it at the beginning and see that it's printing what you want.

DR. PHILLIPS That's why you can't put it back in the utility room.

DR. GOTTLIEB Does the general office temperature also affect the computer?

DR. PHILLIPS With the present design of the machinery a constant temperature isn't essential. If the room temperature is within the human comfort range, let's say 70-85 degrees, it will cause no problems for the computer if it has adequate ventilation. If you have a computer that is full of additional printed circuit boards, all of which generate heat, additional cooling may be needed. If the computer does not have a cooling fan, I would advise adding one if several additional circuit boards are installed.

DR. GOTTLIEB Can you have humidity problems?

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DR. PHILLIPS In a dental office with controlled relative humidity, this shouldn't be a problem. Humidity that is comfortable for the orthodontist and the patients should be OK for the computer.

DR. GOTTLIEB Do you recommend a separate room or closet for the computer?

DR. PHILLIPS I don't think that's necessary. Present equipment will stand up very well in an environment that is comfortable for people.

DR. GOTTLIEB What are the electrical problems that you can have?

DR. PHILLIPS Historically, a computer was connected to a dedicated line, with nothing else on the electrical circuit. In my office, I have such a line for my computer. However, if you go to any microcomputer store in the country, I doubt very seriously that anyone will ever mention that you should have a dedicated electrical line. If you ask them about it, they may not know what you're talking about, or they will say you don't need it, and that's probably true. The only reason for one is to help control the variation of the voltage that gets to the machine, but the way that the power supplies of most computers are made now they can handle a fairly sizable range of voltage fluctuation. Beyond that, you can buy inexpensive surge protectors that will, within limits, control the variation of the voltage getting to the machinery. My recommendation is to buy a surge protector and not concern yourself with a dedicated line.

DR. GOTTLIEB Are the reasonable ones good enough?

DR. PHILLIPS I would say for somewhere in the $100 range you could get one that would be adequate. A more likely source of electrical problems in most areas is static electricity. If you're in a climate where static electricity is a problem in the office in the cooler months of the year, you need to make some provision for controlling the static electricity in the vicinity of the computer. This can take the form of grounding the computer itself and installing a grounded floor mat in the area of the computer. A charge of static electricity can damage your software.

DR. GOTTLIEB You mean just by walking across a carpet and touching the computer?

DR. PHILLIPS Yes. I feel that if you are in an environment where that is routinely a problem in the winter months, I would want the area grounded. At least, the carpet should be treated with an anti-static spray.

DR. GOTTLIEB Could the data be lost that was being entered at the time you had the static charge?

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DR. PHILLIPS It certainly could. A discharge of static electricity when the disk drive is in operation can cause loss of data.

DR. GOTTLIEB Would you recommend turning off the computer before dusting it or cleaning the face of the terminal?

DR. PHILLIPS That would be a good idea.

DR. GOTTLIEB What about during an electrical storm?

DR. PHILLIPS An electrical storm can stop a program, damage it, or damage the computer itself. So the prudent thing to do in an electrical storm is to turn off the equipment and come back to it later.

DR. GOTTLIEB It can do anything from knocking out your equipment to knocking out the data that you're putting in at the time, and everything in between, whether you have a surge protector or not?

DR. PHILLIPS Right. A lightning strike can overcome the surge protector. It would be pretty rare that you couldn't afford to stop working for a little while until the storm went by.

DR. GOTTLIEB Is being too close to fluorescent fixtures a hazard?

DR. PHILLIPS Yes and no. Chances are you're not going to have any problem with the disk drives or the computer itself using a fluorescent light in the area. Computers are pretty well protected along that line. Where you can have a problem, and I can speak from personal experience, is if you are using a digitizer with an electromagnetic radiation pickup mechanism. The ballast box of a fluorescent fixture emits electromagnetic radiation, and it can enter spurious data through a digitizer. So any fluorescent light in the area of a digitizer needs to be shielded.

DR. GOTTLIEB How close?

DR. PHILLIPS For room light, I'd say three or four feet away. The light source for the digitizer itself must be immediately under the digitizer, so it has to be shielded.

DR. GOTTLIEB How about the magnetic field around a motor of any kind?

DR. PHILLIPS Yes, that can cause a problem. A large number of microcomputers have an electric motor in them, and of course the disk drives have electric motors. The cooling fan has an electric motor. But just as a matter of good practice, I would not have anything magnetic or electrical closer to the computer than I had to. For instance, some of the copy holders for typing use a magnet to hold the paper down. Well, the first thing you should do is

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throw the magnet away. The last thing you want around your disk drives is a magnet. That's a guaranteed data destroyer.

DR. GOTTLIEB Even a magnet of that size?

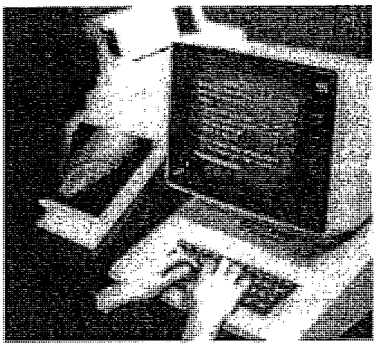
DR. PHILLIPS Oh, yes. No other magnets should be near any magnetic storage device. I would make a real effort to see that no permanent magnets and nothing that emits electromagnetic radiation is near the computer if at all possible, particularly if you are using a digitizer.

DR. GOTTLIEB We've covered a lot of hazards. Are there any others?

DR. PHILLIPS Those are the main things. The electronic hazards are the main ones—static electricity and actual magnets or radiating equipment. The obvious things beyond that are just good housekeeping practices such as clean handling of all the equipment. Don't touch the disks with your fingers. You don't want oil on them. You don't want cigarette ashes on them.

DR. GOTTLIEB We've spoken about the environment for the computer; let's talk about the physical conditions for operating it. For example, if you put the terminal on a normal desktop and have your keyboard at that height, you can create problems for the operator.

DR. PHILLIPS Yes, you can, and the trend today is to have a detachable keyboard so that you can have a more comfortable arrangement. However, you still need to be able to see the monitor, so the environment, including a comfortable chair, is very important if much work is done at the keyboard.



Operating the computer.

DR. GOTTLIEB One of the most significant considerations is that the ceiling lights not reflect off the screen, or you really create a problem.

DR. PHILLIPS Yes, many of the screens at the present time are built with a sloped

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surface to cut down glare, and some of them are adjustable so that you can tilt the screen one way or the other to get a better viewing angle as well.

DR. GOTTLIEB Do you have any feeling for whether amber type on the screen is better than white?

DR. PHILLIPS I think either a green or an amber screen is preferable to the plain black-and-white screen. There's a certain amount of strain involved. Monitors are not all equally easy to read, so it's pretty important to have one that displays characters distinctly, or you are going to find yourself straining to see what's on the screen. Also, whoever is operating the equipment in the office should not be expected to operate it all day long. If you have such a load that the computer needs to be used five hours a day, I think it's preferable that more than one person share that task. I think about an hour at a time is as much as you would want to do.

DR. GOTTLIEB How big should the screen be? How many characters and lines should you have for orthodontic office use?

DR. PHILLIPS For prolonged use, a 12" (diagonal measurement) screen is easier on the eyes than a 9" one. The typical screen today can accommodate lines 80 characters long and display a minimum of 24 lines. The typical typewritten page has about 60 characters in a line, so an 80-character screen will pretty well handle anything you want to do. For doing some bookkeeping functions with a spreadsheet that might be 200 characters wide, you need a program that will allow you to scroll horizontally to see beyond the 80-character limit. Originally, programs were written for a 40-character line length, because the Apple computer that started the micro revolution was designed to be used with a TV set as the monitor, and the TV set could handle only 40 characters per line. To see text on the screen as it would appear on a printed page, 80 characters are needed.

DR. GOTTLIEB In speaking about printers, you said an office probably needs both a letter-quality printer and a dot-matrix printer. Why was that?

DR. PHILLIPS Dot-matrix printers are generally inexpensive and rather fast, but the appearance of the text is not equal to the best typewriter quality. A letter-quality printer should produce text equal in quality to that produced on a good office typewriter. Letter-quality printers are often slower than dot-matrix types, and they are fairly noisy, but they are the usual way, at the present time, to get true typewriter quality printing from your computer. The dot-matrix printers are coming closer to giving that quality by a variety of mechanical innovations such as having the dots overlap. This comes closer to the appearance of a fully formed character, but is still not quite the same. Ink-jet printers hold a lot of promise for fast, high-quality print, but at present they are expensive and are not widely

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available for use with microcomputers. They also have the advantage of quiet operation.

DR. GOTTLIEB Still, why have two printers?

DR. PHILLIPS You might want to have two printers for two reasons. You probably will want any correspondence going out of your office to look at least as good as it did before you had the computer, so you'll probably want a letter-quality printer for that. On the other hand, much of the information that you will generate in the office such as reports that will be used internally can be satisfactorily produced on the faster dot-matrix printer using cheap continuous-fold paper. Anything involving graphics— pie charts or bar charts— requires a dot-matrix printer simply because at the present time letter-quality printers aren't capable of doing good graphics. If you're doing diagnostics and want a printout of what amounts to a tracing, you need a dot-matrix printer with graphics capability.

DR. GOTTLIEB Also, you can keep letterheads in a letter-quality printer and not have to be changing the paper in order to generate letters on the same machine as reports and bills.

DR. PHILLIPS That's true. The computer may be exceedingly fast, but if someone is having to constantly change from a letterhead to another form to a third form to a fourth form, you lose the advantage of the speed of the computer, so this is another reason for having more than one printer. Realistically, you must expect to pay for some redundancy in your computer installation, just as you do with your dental equipment. Who operates a modern office with only one dental chair?

DR. GOTTLIEB A big area we ought to talk about in regard to printers is service.

DR. PHILLIPS Of all the pieces of equipment in your system, the printer is most likely to need service. And, depending on the type of printer you have, this may be a problem. I would want to buy a printer locally and have it serviced by the place where I bought it. Most dot-matrix printers are small and light enough so that you can very easily pick one up and take it to the shop yourself to have it fixed. A letter-quality printer may weigh 50-80 pounds and you're probably not going to want to pick it up and take it over there, so it would be desirable to buy it from a place that will come to your office to service it.

DR. GOTTLIEB Would you recommend having a service contract for other parts of the system?

DR. PHILLIPS Service contracts are generally available for the major brands of computers and for the peripheral devices from the same manufacturer. I would recommend a service contract if the system is to be used daily for essential office business.

DR. GOTTLIEB From the company or from the retailer or from somebody else?

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DR. PHILLIPS They are available from several sources, but I would want one that a local store would honor, whether it was their own service contract or from the manufacturer. I would only buy a service contract that the local dealer tells you in writing he will honor, because you don't want to be sending your equipment across the country to be worked on.

DR. GOTTLIEB You also need to have enough such dealers that if he goes out of business you can transfer that contract to the next dealer.

DR. PHILLIPS That's right. You have to expect to have service at some point.

DR. GOTTLIEB Is the equipment that an orthodontist is apt to be looking at likely to have that built in?

DR. PHILLIPS Yes, if it's one of the major brands.

DR. GOTTLIEB In summary, would you say that you would definitely have a service contract on your CPU and on your printer, but not necessarily on your CRT's?

DR. PHILLIPS That's right. I wouldn't worry about the CRT. Those things are cheap enough so that if you need to you can buy another one. Beyond that, they are not apt to have problems in the first place.

DR. GOTTLIEB But even with the accessibility now of a lot more service organizations, you wouldn't be without a service contract and just depend upon calling them in when you had a problem?

DR. PHILLIPS In the first place, I wouldn't recommend that you try to automate everything in your office at the same time. It's impossible to do. I would start with something simple, get one program running adequately before I'd go to the second program, and so on. The time would come when I had enough programs running that it would be a bother if something broke down and I couldn't get it fixed right away. This is the point where I would be interested in a service contract. If I bought my first small computer and was doing very limited work on it, I might be inclined not to start with a service contract. I would wait until I had enough going that it would be a real problem if something broke down. My own experience has been that these systems are really very reliable if they are treated with care. They don't have the number of breakdowns that the larger systems had a few years ago.

DR. GOTTLIEB What happens when the computer is down, not working?

DR. PHILLIPS Whether this is a serious problem depends on how long you can afford to have it out of operation, and this in turn depends on what programs you're running. If you are running strictly diagnostic, recall, and inventory programs, you can usually go a week or so

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without having any adverse effect on your practice. Someone in the office will probably have to put in more time doing those tasks manually or simply delay doing them. But for something as timely as your appointment book, you just can't afford to be without it. If you computerize your practice or parts of your practice, you have to expect that sometime something is going to fail. So, if you absolutely cannot afford being down or out of operation at all, the only way around that is to have redundant systems, to have a minimum of two of everything; that's the only way you can solve that problem. And you scale it from there. If you can afford to be without a printer for three days, you may not need two printers. If it's disk drives, chances are you don't want to be without them at all, so you would want to have a spare one or access to another one— a loaner or something of this sort. It makes a certain degree of sense to me to have two of several things in the office, since the price is low.

DR. GOTTLIEB Another alternative would be to find somebody in your area who has the same equipment, but then you generally get relegated to times when they're not using their equipment, which is not the most convenient arrangement, except perhaps to print out your data.

DR. PHILLIPS That's right. It is a good option to have an arrangement with someone else.

DR. GOTTLIEB Sometimes there are organizations of owners of a particular system that can be helpful in that type of emergency, or in finding or sharing software packages.

DR. PHILLIPS These are often called users groups, made up of people who have a high interest in operation of the equipment. Very often you can find people who are more than willing to talk with you and help you with whatever you are doing. It almost verges on a cult.

DR. GOTTLIEB The other major thing we ought to speak about is backup.

DR. PHILLIPS Backup is of major importance if you're doing anything on the computer that you don't want to lose, or that you can't afford to lose. You need multiple copies of your information, and any computer system worthy of the name will have backup procedures that are easy to operate, by which you may make copies of your programs and your data.

DR. GOTTLIEB You back up everything— your programs, your data— everything is duplicated.

DR. PHILLIPS That's right. The hardware and programs should be such that the backup is easy, and it must be an absolute operating requirement in the office that these backups are made at stated intervals. That's a necessity. If you're not going to do that, you shouldn't have a computer.

DR. GOTTLIEB At what intervals should you do this?

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DR. PHILLIPS This depends again on the program. For financial information, I would want it backed up every day. On the diagnostic systems, backup copies will be made anytime I have entered enough information that it would be a bother to me to sit down and do it again if I lost it, meaning generally in the range of 10 or 15 headplates. You're not apt to lose this information, but if I did it wouldn't kill me to sit down and do that many of them over again. I wouldn't want to do 50 of them again.

DR. GOTTLIEB Is the backup itself time consuming?

DR. PHILLIPS This depends on your system. Since a hard disk stores so much information, a poor backup system can be very time-consuming. It rarely takes more than a minute to completely copy one floppy disk.

DR. GOTTLIEB And how are you backing up the hard disk?

DR. PHILLIPS The type of backup will vary with the brand of hard disk that you buy. There are a lot of different systems. Some people go to the extreme of backing up a hard disk with a hard disk. That's a beautiful way to do it, but expensive. There are also machines for backing up hard disks on tape, which are usually fairly practical, and they are even getting into things now such as storing backup data on video disks or tape, both of which hold a tremendous amount of information.

DR. GOTTLIEB Is it practical to back up hard disks with floppy disks?

DR. PHILLIPS Generally I'd say no, from the standpoint of time required. Backup procedures should be fast and easy, to encourage an operator to do it often. A hard disk can easily hold the equivalent of 50-100 floppy disks. That's a lot of disks to handle and file, so I wouldn't want to do it. Videotape may be the best bet for backing up a hard disk.

DR. GOTTLIEB Let me point out that, if you try to use your videotape machine for other purposes and you make any change in the adjustments, you can get into deep trouble. It was reported in our newsletter that one company is going out of business because it could not interpret the data on its videotape after somebody changed the adjustment on the machine. Unless you are aware that the change was made and unless you are able to realign the machine to be compatible, you are in very grave danger of having discovered one of the ways of losing your data. One additional trick that we learned with those videotape machines is that you can buy a videotape head cleaner that goes a long way toward keeping the machines in alignment and improving the reliability of the transfer.

DR. PHILLIPS Well, that's certainly worthwhile to know. There are a number of ways that you can lose data. One of them obviously is by not having any backup. Just as other

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businesses can't afford to lose their receivables, so an orthodontist can't afford to lose patient data and receivables. If you lost your data, you'd be hard pressed to recover all of it. Such losses have put retail companies out of business. So you need a reliable backup system.

DR. GOTTLIEB You really need to have a double backup system, with copies both on and off the premises.

DR. PHILLIPS That is true. Ideally, I would say that you should store one backup copy in a closed container, in a room in the office other than where the computer is located, and have another copy that you don't keep in the building at all. That's something you can only do with a computer. You can't take all your office information home very well unless you're using a computer.

DR. GOTTLIEB It's one of the beauties of the computer that you can keep all of your data safe from fire, vandalism, and theft, which you can only do marginally even with fireproof files.

DR. PHILLIPS That's right. I think for some people that might be justification alone for using a computer. It's the one way that you can really take all your information up to that date home with you.

DR. GOTTLIEB But you must do it systematically or routinely.

DR. PHILLIPS Some systems back up automatically every so often, but by and large it's something that you must keep track of and do.

DR. GOTTLIEB Is there something in the system that tells you that you backed up, that the data is transferred and you're OK?

DR. PHILLIPS Usually there is. On most of the smaller systems it is not automatic. On most of the micros you have to check it, but there are ways to do it. For instance, on the IBM-PC system there is a program that does a disk comparison and will tell you that you have indeed made a backup copy and that it is accurate, or that it is not. If you don't have such a program, the only way you would know would be to run the whole backup disk to see if the data is there.

DR. GOTTLIEB I think part of computer phobia is, "Is the data still there, and can I still get it out of that box?"

DR. PHILLIPS You can't see it and you can't feel it, so is it there? That's right. You have to learn to accept the fact that it's there even though you can't see it. There is another layer of complexity between the person and the data, and you have to get to the point where the

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machinery is invisible to you before you can be comfortable with it. Until you get to the point where you're putting information in and it comes out again without worrying too much about it, the computer will bother you. It's very much like driving a car. After you've been driving a few years, you don't give a lot of thought to every single procedure you do in getting from the office to the house. You do it almost automatically.

DR. GOTTLIEB It takes less time than most people think, I believe, to get comfortable with the thought of putting data into an invisible form, but you can make it visible— you can have what are called hard copies printed out.

DR. PHILLIPS That's true, and for many programs you should have a hard copy, in my estimation.

DR. GOTTLIEB If you really were concerned about it, you could back up both ways perhaps for awhile.

DR. PHILLIPS Yes, you could do that. I think it wouldn't take long before you stopped doing it, because it is unnecessary, but it could give you a sense of security. I have an aversion to looking at large stacks of computer printouts, so I don't print things out unless I have to. Usually, I will ask someone to print a certain thing and place it in the patient's file, and we print certain things for consultations, but that's the extent of our diagnostic printouts. If I ever want a copy of something I print it out, but I don't do many.

DR. GOTTLIEB Do you have any feelings on the question of buying or leasing?

DR. PHILLIPS I think that depends on the person's tax situation. Leasing is a viable option, particularly for things like printers. As far as the computer itself is concerned, unless there is a tax advantage to leasing, which for some people there certainly will be, I would buy. I have only one leased item. That is my letter quality printer, and the reason is that, of all the pieces of equipment, printers are the ones that are most apt to wear out. They also keep coming down in price, and printing technology keeps getting better. My letter-quality printer at the time I leased it sold for $3,300. Now, something like two years later, you can get one that is pretty comparable to it for approximately half that price.

DR. GOTTLIEB Does your lease payment include service?

DR. PHILLIPS No, I still have to pay for service.

DR. GOTTLIEB Is the cost of the leasing and the service just slightly more than the cost of buying the equipment, or substantially more?

DR. PHILLIPS Leasing is considerably more expensive. The cost of service is the same

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whether you are leasing or buying. Printers type very fast, and this causes a lot of wear and tear. You have to plan on replacing them from time to time. For this reason, I think leasing is a pretty good way to obtain them. With the price coming down, it may become more economical to buy one and plan on replacing it. Just a few years ago that wasn't the case.

DR. GOTTLIEB Would you see any virtue in an orthodontist waiting a little bit before buying a computer, to see if the price of the various components will come down?

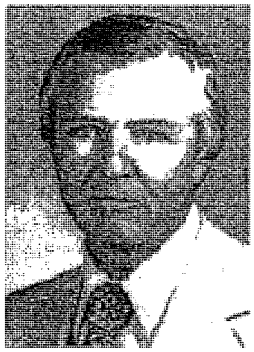
DR. PHILLIPS No. A few years ago, I think that was reasonable to do. But now the price of the equipment, both hardware and software, is cheap enough that I really don't see any reason to wait. If there is some job you really want to do and a program to do it is available, then I would go ahead and start, because you can only get so far in developing your computer knowledge by reading about it and talking about it. The only way you really get into it is to actually get your hands on the equipment and begin. There's always going to be next year's model, but unless you start, you never put the power of the computer to work, no matter what's coming.

DR. GOTTLIEB The average car on the road is seven years old right now, and there have been a lot of models since that time.

DR. PHILLIPS That's right. And people are still getting to work in the old ones.

DR. GOTTLIEB Homer, I want to thank you for this comprehensive discussion on the state of the art of computers in orthodontic practice.

PHILLIPS



Dr. Phillips is in the private practice of orthodontics at 8211 Roughrider, San Antonio, TX 78239.

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The author of this is an orthodontist – attorney (Laurence Jerrold, DDS, JD)

The problem, electronic data transmission and the law

"Larry, I need a few minutes to pick your brain." The phone call was from one of my former students, let's call him Jim, who was calling me about a case that he had just taken diagnostic records on. From the way he was describing it, it was a tough case and being new to practice, Jim just wanted to be sure of his diagnosis and treatment plan. We can all recall those times, fresh out of school and first beginning to realize not how much we had learned, but just how much orthodontics we didn't know. Had he been practicing locally, he could have gathered up the patient's models, x-rays, and photos, and either just stopped by the office, dropped in at the school, met me somewhere for lunch, etc. The problem was that Jim was practicing out of state, way out of state, like across the country. "No problem," I said, "Just scan everything into your computer, send it to me, and while its on the screen, we can talk."

The question you should all be asking yourselves is not "How do you do that scanning thing?" or "So what was so tough about the case?" What you should be saying is "If I do this, will I be guilty of having practiced orthodontics in a state in which I am not licensed to do so?" Enter the era of teledentistry.

Years back, we consulted with one another through the mail, then by phone, and eventually via the fax. Technology today affords us the same luxury through a myriad of electronic gadgetry. We now use modern technology to effect medical/dental data transfers for administrative purposes; we can also provide specialty consultations without having to transport either the patient or the physician; and finally, we are able to actually diagnose a patient who is seated thousands of miles away via technologically advanced video imaging and fiberoptic communication systems.

Medicine is ahead of dentistry in this area. Physicians today can provide high-quality medical expertise to remote sites that in turn may help to reduce the costs of health care. A patient's progress can be monitored remotely thus allowing for earlier hospital discharge, which again might help to reduce the costs of delivering affordable quality health care. It is a boon to authorized persons seeking medical records, laboratory results, pathologic information, radiographs, pharmaceutical information, etc., when one is off site and needing to access this data. It also enhances medical education so that state of the art medicine, because of telemedicine, is now immediately available to locales that previously may have been deprived of timely access to this information.

As with most things there is also a potential downside to telemedicine. Practitioners involved with providing care, advice, etc., through this medium may be exposed to potential liability in the areas of malpractice; licensure and credentialing issues; data security, privacy,

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and confidentiality matters; and issues relating to storage, retention, and maintenance of medical records.

As you know from reading this section of AJO/DO, there is no duty owed any person, unless a doctor-patient relationship has been established. Although it is relatively easy to establish this relationship face-to-face, it is much harder to do so through a modem. The problem is that if it can be shown that a doctor-patient relationship was established with technology used as the medium; and that the information transfer resulted in diagnosis or treatment that fell below the established standard of care, then the potential for liability becomes a real threat. If it can be shown that the consulting practitioner rendered advice directly to the patient, reviewed the patient's records for a fee, or made a recommendation to the requesting doctor on which the consulting practitioner expected the former to rely, than it could be argued that a doctor-patient relationship existed that in turn would gives rise to the duty to conform to an established standard of care.

It is highly conceivable that a plaintiff will claim that the teledental consultation was negligent in that it did not allow for an appropriate diagnosis to be made, which led to an inferior treatment plan that resulted in the claimed injury. Another potential basis for a malpractice suit would be one in which the claim of negligence stems from any actions taken as a result of technically induced flaws or inaccuracies in the data transmitted. Another scenario could involve the loss of stored or retained records that may compromise the orthodontist's ability to compare and evaluate a patient's dentofacial growth and development and ultimately result in the claimed injury.

Teledentistry may very well complicate the issue of venue—the state in which the malpractice suit will be brought. Suppose a patient who lives in Oregon, goes to an orthodontist in Washington and is treated, through teledentistry, by another orthodontist in Georgia. Further suppose that the diagnosis or the treatment recommended, results in an injury. Where will the lawsuit be filed, Washington, Oregon, or Georgia? Will this problem contribute to what is known as forum shopping, which is each side looking at the differences in the state laws governing malpractice in an effort to choose the most advantageous forum relative to such things as statutes of limitations, laws relating to the potential for recovery, laws concerning who can testify as an expert, etc.?

Another area for potential litigation is the situation in which, as noted above, some of the patient's diagnostic data have been flawed either in storage or transmission. Not only may the doctor be found liable, but the manufacturer who made the equipment and/or the consultant who recommended the system may also be exposed to liability relative to the malfunction or the software problem encountered.

Given that there exists all of these potentials for liability, are there steps that we can take

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to better posture ourselves before we enter this brave new world of teledentistry? Let's use the hypothetical situation I initially posed. The first thing I would do is to make sure that I kept my own chart on Jim's patient. Based on the data he sent me for review, I would first generate, as best I could, a hard copy of the data. Then I would develop a chart that documented my diagnosis, treatment plan, mechanotherapeutic recommendations, etc. I would also routinely correlate the quality of all data transmitted through periodic testing by comparison. In addition, I wouldn't do anything different. By this I mean that if the quality of an x-ray was poor in my office and I would have retaken it, then if a transmitted x-ray is not of sufficient diagnostic quality, don't use it, request that a new one be taken before rendering help. I would strictly adhere to some back-up protocol.

After this I would make sure that once I got involved in "treating" Jim's patient I would make it a point to familiarize myself with the laws in Jim's state that govern how long those records would have to be maintained both in his state and in my own. In this way I would be sure of maintaining them for the longer retention period of both state laws. Next I would make sure, regardless if I was in full-time academia or in private practice, that my liability insurance would cover me should an adverse event occur because of my teledental activities. Finally, I would have Jim ask his patient to sign a consent form acknowledging the limited services I was providing or have Jim add my name to his consent form regarding his treatment of this patient.

COMMENTARY

Where does all of this leave us? As with any new environment we must learn to become comfortable within those new surroundings. Because of state's sights issues, we must acknowledge that what is allowed in one jurisdiction may not be allowed in another. California, as an example, has a consultation exception to its licensing laws whereas other states require the consulting physician to have a license to practice in that state. Congress has a task force, The Joint Working Group on Telemedicine, working on issues relating to Telemedicine. The Federation of State Medical Boards has addressed this issue and has recommended issuing a limited national license. The American College of Radiology has already formulated guidelines dealing with issues in telemedicine. In addition, The Center for Telemedicine Law's Licensure Task Force is already influencing state laws regarding modifications concerning licensure requirements.

Again, where does this leave us? The AAO should address this issue through a policy statement, possibly in the Guidelines for Clinical Practice that was recently completed. State components should address their medical counterparts and offer to assist them as they develop the laws that will eventually filter down and affect us. Clinically, we should not rush into using the available technology without having due respect for the potential consequences of our actions. How many times have you thought you had a treatment plan all set based on

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the diagnostic records only to discover that when you are face to face with the patient, there is something that is different and your treatment plan changes. Teledentistry won't allow for that.Twenty years from now this may not be an issue or cause for thought, but for right now...

References

1. American College of Radiology, Standard for Teleradiology; Res.26-1996.

2. Cepelewicz BB. Telemedicine liability: Strategies to minimize risk. Medical malpractice law and strategy, Vol. XV No. 2 December 1997

3. Sfikas PM. Teledentistry: Legal and regulatory issues explored. J Am Dent Assoc 1997;128:1716-8.

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1: Br J Orthod. 1989 May;16(2):85-93. Related Articles, Links

An assessment of the fit of a parabolic curve to pre- and post-treatment dental arches.

Jones ML, Richmond S.

Department of Child Dental Health, Dental School, Heath Park, Cardiff.

Study casts of the teeth are routinely used for diagnosis and to assess treatment change: the crowding of the teeth or shortage of space available within the dental arch is usually assessed visually. A full cast analysis program has been developed previously, making use of the three-dimensional Reflex Plotter linked to a computer. This study examines the validity of the fit of computer generated parabolic curves to dental arches, as performed in the measurement of crowding. Using a visual analogue method it was found that the parabola appeared to fit lower post-treatment dental arches best. However, reservations regarding the fit of symmetrical curves are expressed and other solutions suggested.

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An Assessment of the Fit of a Parabolic Curve to Pre- and Post-Treatment Dental Arches

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Abstract. *Study casts of the teeth are routinely used for diagnosis and to assess treatment change: the crowding of the teeth or shortage of space available within the dental arch is usually assessed visually. A full cast analysis program has been developed previously, making use of the three-dimensional Reflex Plotter linked to a computer. This study examines the validity of the fit of computer generated parabolic curves to dental arches, as performed in the measurement of crowding. Using a visual analogue method it was found that the parabola appeared to fit lower post-treatment dental arches best. However, reservations regarding the fit of symmetrical curves are expressed and other solutions suggested.*

Index words: Reflex Plotter, Study Casts, Orthodontics, Crowding, Parabolic Arch.

Introduction

Probably, the first and most important assessment any orthodontic clinician makes in his diagnosis of a dental malocclusion is that of the tooth crowding present. On the basis of such an assessment and taking into account the various treatment aims the space requirements in the arches may then be approximated. These are frequently crucial assessments used to decide whether or not tooth extraction is appropriate, and for something so important it seems extraordinary that it is usually made by means only of a visual estimate of a study cast of the teeth, occasionally supported by crude measurement. This deficiency in orthodontic diagnosis has been realized for some time and almost since researchers started collecting data on the sizes of teeth (Black 1902) others have attempted to derive indices to estimate tooth space requirements in the developing dental arches and thus help in the orthodontic treatment planning (Pont, 1909; Hogue, 1912, 1917; Hixon and Oldfather, 1958; Tanaka and Johnston, 1974).

Perhaps the various methods of analysing or measuring crowding may be classified into two principal types:

(1) simple crowding or space requirement analyses: usually consisting of a tooth to tooth discrepancy or width ratio analysis;
(2) arch length analyses: where an ideal curve is fitted to the dental arch and the discrepancy between the sum of the tooth widths and the fitted curve is used to analyse the degree of crowding present.

It is the latter method of crowding assessment with which this paper is concerned.

Review of the Literature

Any review of arch length analyses must principally concern itself with a review of the search for the 'perfect' universal dental arch shape. Such a model curve should then be simple to fit to any dental arch and the difference in length between the ideal curve/arch (first molar to first molar) and the actual summed mesio-distal tooth widths should be equal to the arch length discrepancy or crowding apparent. In the search for this ideal arch most researchers have used various sized samples of untreated perfect occlusions as the source for their trial fitting of curves. Usually, they have concerned themselves with the arch form from first molar to first molar the problem becoming more difficult if second and

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TABLE I *Principal authors who have published work on fitting ideal curves to dental arches*

Author	Form of ideal curve	Area of fit
1. Angle (1906, 1907)	Parabola	Middle curve of dental arch
2. Williams (1917)	Circle	Incisor tips only
3. Stanton (1922)	Ellipse or parabola	Outer cusps and incisal edges
4. Izard (1927)	Ellipse in 75%	Middle curve of arch
	Parabola in 20%	
	'U' shape in 5%	
5. McConnail and Shurr (1949)	Catenary curve	Average fit to arch form
6. Muslich and Ackermann (1973)	Catenary curve	Average fit to arch form
7. Wheeler (1950)	Parabola	Anterior of arch
Ramsden (1964)	Parabola	Anterior of arch
8. Sicher (1952)	Ellipse	Best fit to upper dental arch
	Parabola	Best fit to lower dental arch
9. Herren et al. (1973)	Interpolation of small straight lines	To fit middle curve
10. Mills and Hamilton (1965)	Parabola	—
11. Currier (1969)	Ellipse	Outer curve of dental arch
	Parabola	Middle curve of dental arch
12. Hechter (1978)	Parabola	Middle and outer curve of dental arch
13. Lu (1964)	Polynomial equation of the fourth degree	Middle curve
14. Brader (1972)	Trifocal ellipse	Middle curve
15. Begole (1979)	Cubic interpolatory spline	—

third molars are included. Perhaps the very earliest ideal arch is the Bonwill Hawley arch; this is based on descriptions provided by Hawley in 1905 suggested by the work of Bonwill in 1886. Hawley proposed a geometric method for predetermining the dental arches, the ideal arch being based on an equilateral triangle whose base represented the intercondylar width of the mandible. The six anterior teeth were thought to be arranged on the arc of a circle whose radius was determined by the combined width of the incisors and canines, the premolars and first molars forming a line, with second and third molars turned towards the centre. Hawley did, however, advise against employing this method too literally in determining arch form, though he felt it might be a useful guide in the assessment of the malalignment and malposition of teeth.

Where one is to be concerned with the fitting of a curve one must define precisely where it is to be fitted: to inter-tooth contact points, buccal cusps, or lingual cusps—and perhaps even more important precisely where on the cusp it is to be fitted. The use of different points on the tooth crown surface may alter the nature of the ideal curve and this may offer some explanation for the great variety of ideal curves suggested by researchers, although based on essentially similar material. Table I summarizes the main authors who have published accounts of the fitting of curves to the arch; included is the type of curve fitted and the precise part of the dental arch to which it was intended to fit. It is of interest that most authors have found considerable variations within the different samples of occlusion that they analysed. These differing samples also presumably having an effect on the curve selected by the authors.

It may be noted from Table I, that there has been considerable interest in fitting ideal curves to dental arches: examining the literature it would appear that the three principal types of curve that have been used and recommended by research workers have been either some form of an ellipse, a parabola, or a catenary curve.

Examining the work of many of the early authors who have recommended the ellipse it is apparent that they have often used different foci, fitting the resultant form to various and different parts of the dental arch, there being difficulty in the universal fit of an ellipse to all dental arches.

The catenary curve, originally suggested by McConnail and Shurr (1949), has had its advocates over the years although its usefulness is perhaps best summed up by Rudge (1982) and Rudge et al. (1983) who, in a comparison of different types of arch, found that although the use of a catenometer was the most reproducible method, questioned the validity of its fit: the curve when adjusted to lie over the incisal edges tending to fall lingually in the premolar area and when fitted to the premolar region tending to overlap the incisal edges; he doubted the usefulness of this curve in the clinical situation especially for the less experienced operator. Therefore, amongst the simple ideal curves this leaves the parabola. This particular arch form has often been recommended in the literature as a

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useful and valid curve to fit to dental arches: the earliest author suggesting this ideal arch form being Angle in 1907, and the most recent being Hechter in 1978. Both Currier (1969) and Hechter (1978) introduced computers into their analysis of arch form.

Currier (1969) examined 25 ideal casts and precisely defined the outer, middle and inner curves of the dental arch thus:

(1) the outer curve to be to the buccal cusp tips of molars and premolars and incisal edges of canines and incisors;
(2) the middle curve to be to the central fossae of molars, fissures of premolars and angular on canines and incisors;
(3) the inner curve to be the most lingual aspects of all the teeth.

Overall in his study he found the ellipse had the best mathematical 'goodness of fit' to the outer and the parabola the best to the middle curve of the teeth. Neither of these two significantly fitted his defined inner curve.

Hechter (1978), with a prize winning piece of research, also investigated the fit of a number of curves and found that the parabola showed the best 'goodness of fit' to upper and lower arch-middle and outer curves, providing that second and third molars were not included (one must, of course, bear in mind that most crowding assessments would be made before the full eruption of the second molars). He suggested, therefore, that clinically the parabola may at present be the most useful predetermined arch shape.

In summary, therefore, in the assessment of arch length discrepancy a very large number of curves have been used to predetermine the ideal arch. Evidently, from the volume of literature on the subject the search continues, with research workers examining more and more complex mathematical arch forms (Lu, 1964; Brader, 1972; Begole, 1979). It would appear, however, that the most frequently recommended curve to fit to the dental arches in the assessment of crowding has been the parabola, it being usually fitted to the middle curve of the dental arch as in Fig. 3, the middle curve having arguably the greater clinical validity in such an assessment. For this reason, together with its ease of mathematical application, the parabola was selected as part of a study cast analysis system to be used in later projects (1984, 1985, 1986, 1987) by the authors. The present study is concerned with the validity of the parabola in this chosen role as assessed by a number of orthodontic clinicians making a visual assessment.

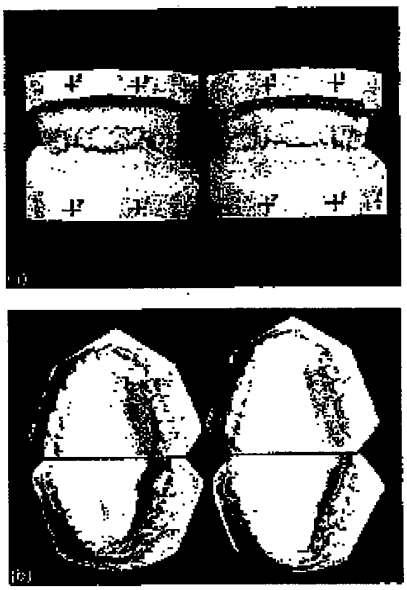


FIG. 1 (a) An example of pre- (left) and post-treatment (right) casts as used in study (in occlusion). (b) Pre- and post-treatment study casts viewed apart for fit of curves (refer to Fig. 4).

Methods and Materials

To investigate how appropriate the fit of a parabolic curve is to the dental arches for crowding assessment in malocclusions the data for 28 pairs of casts were drawn randomly from previously digitized and stored material from the 'Barry Project' (Richmond and Jones, 1986; Richmond, 1987). In this project, 151 consecutively referred and orthodontically-treated malocclusions had the occlusal change and tooth movement assessed on pre- and post-treatment study casts (Fig. 1); 110 points on each pair of casts being digitized by means of a three-dimensional Reflex Plotter linked to a Hewlett Packard Series 35 computer (Fig. 2). All data was stored on disc. This subsequent archive material was then used to derive measurements of clinical interest relating to the precise tooth movement and dental changes brought about by the orthodontic treatment (Fig. 1). The plotting and measurement of study casts together with the derivation of software and measurement error has previously been described by these authors (1984, 1985, 1986,

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TABLE 2 (a) *The measurement error as previously calculated for reflex plotter (Richmond 1984)*

		Range
Absolute error for machine		0·13–0·36%
Pointing error	x axis	0·03–0·11 mm (SD 0·03)
	y axis (depth)	0·02–0·31 mm (SD 0·06)
	z axis	0·03–0·12 mm (SD 0·06)

(b) *Intra-observer error in millimetres of four measured variables. Sample of 30 casts randomly drawn from original data and redigitized some weeks later (Richmond 1987)*

	n	Mean diff.	SD of diff.	SE	Significance
Overall mesio-distal tooth widths (upper)	30	−0·01	0·71	0·12	NS
Overall mesio-distal tooth widths (lower)	30	0·06	0·58	0·10	NS
Length of fitted parabola (upper)	30	−0·16	0·66	0·12	NS
Length of fitted parabola (lower)	30	−0·12	0·39	0·07	NS

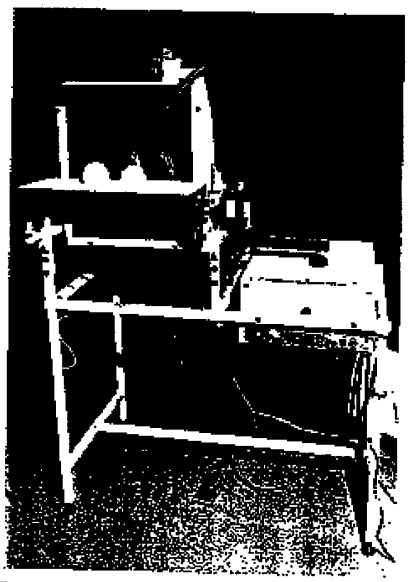


FIG. 2 Reflex plotter used for study casts set up for measurement.

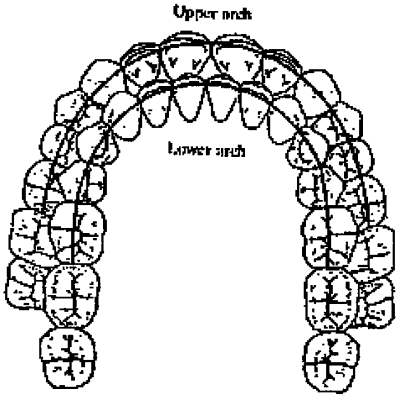
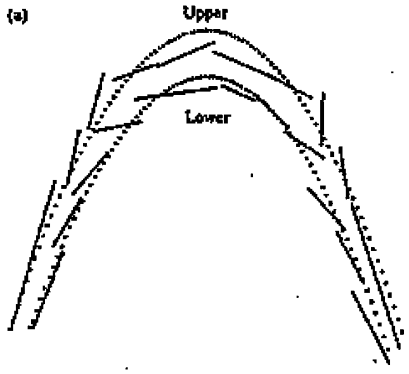


FIG. 3 Diagram to illustrate upper and lower dental arches in plan view: in each arch an ideal curve has been fitted to pass through the middle curve of the teeth.

1987). Table 2 summarizes the error analysis of both the machine and the variables measured.

As discussed earlier the tooth crowding assessment for upper and lower dental arches (1st molar–1st molar) form part of this program being based on a routine to achieve the best 'goodness of fit' of a parabola to the middle curve of each dental arch as projected to a functional occlusal plane defined by molar and premolar cusps (Jacobsen 1975). The program calculated the quadratic fit of each curve to each upper and lower dental arch and was plotted as in Fig. 4 (at ×2 magnification); there were thus plotted records for 14 subjects (or patients) with pre-treatment and post-treatment study casts ($n = 28$), a two-dimensional plan view

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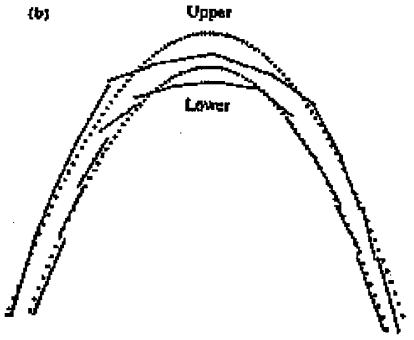


FIG. 4 (a) Plotted tooth widths and fitted parabolas for upper and lower dental arches—pre-treatment casts from example in Fig. 1b. (b) Plotted tooth widths and fitted parabolas for upper and lower dental arches—post-treatment casts from example in Fig. 1b.

TABLE 3 *Analysis of variance for upper and lower arches*

	Source of variation	Sum of squares	DF	Mean square	*F*	Significance
Upper arch	Subject	23371·9	13	1797·8	11·5	***
	Observer	6887·8	2	3443·9	22·0	***
	Time	1371·5	1	1371·5	8·8	**
	Subj. obs. interaction	3821·5	26	146·9	0·9	0·5
	Subj. time interaction	13469·4	13	1036·1	6·6	***
	Obs. time interaction	3717·9	2	1858·9	11·9	***
	Residual	13104·0	84	156·0		
Lower arch	Subject	18289·6	13	1406·9	7·6	***
	Observer	6867·4	2	3433·7	18·7	***
	Time	6738·7	1	6738·7	36·6	***
	Subj. obs. interaction	7463·9	26	287·0	1·5	0·07
	Subj. Time interaction	6876·1	13	588·9	3·1	***
	Obs. time interaction	3275·4	2	1637·7	8·9	***
	Residual	15462·0	84	184·1		

*** $P < 0{\cdot}001$; ** $P < 0{\cdot}01$.

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TABLE 4 *Components of variation analysis for assessment of closeness of fit of parabola to casts (based on 14 subjects, 28 pairs of casts)*

From analysis of variance	Pre-treatment		Post-treatment	
	Upper	Lower	Upper	Lower
(a) Mean square due to variation between observers	4995·8	4436·7	307·0	614·7
(b) Mean square due to interaction obs. × subj.	153·9	346·6	168·7	223·5
(c) Mean square within observers and subjects	185·1	177·0	126·8	191·1
(d) Corresponding SD within-observer variation	13·6	13·3	11·3	13·8
(e) SD for reproducibility of a single measurement by an arbitrary observer	16·9	18·9	12·3	14·7
(f) Overall SD produced from (e)	17·9		13·6	

of the dental arches together with fitted parabola being plotted in each case. The plotted arch forms plus fitted ideal parabolic curve correspond to the diagram in Fig. 3.

Three observers, orthodontic clinicians, read each plotted record twice to assess the closeness of fit of the parabola to the upper and lower dental arch forms (represented by a linear plot across the mesio-distal width of each tooth in that arch—Fig. 4). They were assessing how appropriate the fit of the parabola was to the mean middle curve of the arch in each case and used a visual analogue scale of length 100 units.

Results

1. The visual analogue data assessing the fit of the computer generated parabola to 28 pairs of casts by three observers twice was analysed using the S.P.S.S.X. package on a multics mainframe computer system. The data was taken down by subject, time (1 = pre-treatment, 2 = post-treatment), observer, and repeat reading. A mean reading and standard deviation based on six observations (three observers × two repeat readings) was aggregated for each subject for upper and lower arches.
2. The three-way analysis of variance of upper and lower arches by subject, observer and time was performed as in Table 3. This method of analysis has been previously described (Armitage, 1971).
3. The reproducibility of the parabola fit assessment method was similarly examined using the analysis of variance for pre- and post-treatment casts separately. It may be remembered that the three observers scored each set of casts twice. The most useful of the information obtained is shown in Table 4.

Discussion

The validity of fit of the parabola to the middle curve of the dental arches

On examining Table 3, as one might expect, the dominant source of variation was between subjects, highly significant differences between observers and between types also emerging from this analysis. However, substantial interaction effects are apparent (Armitage 1971)—for example a highly significant (13 d.f.) subject × time interaction means that curve fitting pre- and post-treatment varies between the 14 subjects in a way that is greater than the within observer variation (measuring the same cast twice) (84 d.f. residual). This is not unexpected, but makes the F ratio for the effect of time (the effect of treatment on parabola fit) unreliable. Statistical advice suggested that a better assessment might be based on:

$$F = [(\text{MS due to time})/(\text{MS for time}) \times \text{subject interaction}]$$

This would give an F value of 3·32 for the upper arch and 6·49 for the lower arch. This latter figure is significant at the 0·05 level. The former just fails to be statistically significant. Such an approach is equivalent to a t test on 14 pairs of values, and indeed if this is done a similar result is achieved—a better fit with the parabola being apparent on the treated cases especially in the lower arch. In both pre- and post-treatment casts the parabola was better in the lower arch. These findings would be in broad agreement with the observations of previous researchers. Hechter (1978), although fitting his parabola to the outer curve, found an improved fit in post-treatment arches, which he attributed to the improved dental arch symmetry; Sicher (1952) found that the parabola fitted the

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lower dental arches, in his sample of occlusions, far better than the upper.

The V.A. measurement error

Viewing the results as regards the intra-observer reproducibility of the parabola assessment: three observers viewed the plots for 14 subjects twice with a 1-week interval. Table 4 summarizes the data. Line (d) shows the standard deviation reflecting variation between repeat assessments of the same plotted casts by the same observer. The four SD estimates are very similar and a produced value of 13·04 is appropriate. In line (e) an estimation of reproducibility corresponding to the situation in which the observer is chosen arbitrarily is shown. Here of course, the variation is greater: the SD estimates are no longer so homogenous and it is clear that the main difference is between pre- and post-treatment casts—the reliability of the assessment technique is better on the finished or post-treatment casts and this is probably largely related to the effect of the archwire creating a more uniform arch form (and also flattening the curve of spee), thus considerably easing the assessment of fit of the parabola for the observers. The upper/lower arch differences are similar, not showing a significant critical ratio. Overall, it is apparent from the data that occasionally gross inter-observer disagreement on fit of the parabola has occurred and this subjective assessment may not have great objective reliability. One may conclude that the observers show great variability both between themselves and between observations as to what constituted a good or poor fit of parabola to the dental arch. However, where the best reproducibility occurred (in the post-treatment lower dental arches) it was found that the best parabola fit also occurred.

In summary the visual analogue measurements showed great variation as regards reproducibility between observers and duplicate measurements. However, the study adequately demonstrates that the observers found the parabola best fitted treated arches and more closely approximated the middle curve of the lower arch: the parabola, therefore, showed the best fit to post-treatment lower arches when assessed by three clinicians.

One may, therefore, expect when using the fit of a parabola to assess crowding on serial casts for there to be some positive bias towards reading space or reduced crowding in the pre-treatment cases dependant purely on the improved fit and reduced residual in the post-treatment cases. In cases where the fit of the parabola was less certain this was usually demonstrated as an overlap beyond the anteriors—a phenomenon previously reported by Rudge et al. (1983) when he was trying to fit other ideal curves.

Where such curve fitting may prove particularly useful is in the comparison of post-treatment and post-retention dental arches where one might anticipate the mean change in arch form to be less.

It is apparent from the previous literature review that in the assessment of arch length discrepancy a very large number of curves have been used to predetermine the ideal arch. Evidently, from the volume of literature on the subject the search for this perfect curve continues. The parabola has been amongst the most popular of ideal curves used by past researchers and would appear from previous research to be no less appropriate in its fit to the dental arch than any other symmetrical shape. In the present study the fit of the parabolic ideal curve seemed to work well enough for the assessment of crowding particularly in the lower arch and, in fact, this observation has been previously made by Sicher (1952), although on different material. He similarly found in his study that the best fit of the parabola occurred to the lower dental arch.

In the visual analogue assessment in the present study, it is apparent that the three observers found it far easier to visualize the fit of a parabolic curve to an already aligned arch (as in the post-treatment casts) and, indeed, the intra-observer error was much reduced in this situation. No doubt this is due to the reduced mental agility required to fit a curve to an aligned post-treatment arch rather than a malaligned and disrupted pre-treatment dental arch.

However, as a concept it would seem unlikely that a predetermined 'ideal arch form' applicable to both the upper and lower dental arches of all individuals exists and the finding of White in 1978 (examining 24 ideal occlusions) that only 6 per cent of dental arches tested were symmetrical is perhaps of some relevance to the problem. Begole (1979) interestingly has presented a computer fitted curve especially designed to attempt to solve these problems of asymmetry. She made use of the cubic interpolatory spline, a mathematical model of a physical device used by draughtsmen to draw smooth curves through a limited number of defined points (by coincidence a similar curve has been used to show the middle curve of the dental arch in Fig. 3). The measurement of a similar computer generated cubic spline curve provides an arch length to assess the available space. Obviously, a computer program to incorporate the fitting of such a curve in the assessment of crowding would be far more complex than the fitting of a parabolic curve. However, in the light of the present study, it may

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prove worthy of further investigation; theoretically the fit should be more consistent in the upper dental arch and the flexibility of fit to pre- and post-treatment dental arch forms may well have greater validity in any serial analysis of the change in crowding from study casts.

Conclusions

1. This study would agree with others in that the parabola best fits the middle curve of lower dental arches (from first molar to first molar).
2. The parabola fits post-treatment dental arches more consistently than pre-treatment arches and this is undoubtedly related (at least in part) to the arch form applied in the fixed appliance cases.
3. In the visual analogue assessment system used in this study the reproducibility was best in post-treatment arches.
4. The parabola probably fits as well as any ideal symmetrical curve and is adequate in crowding analysis.
5. The incorporation of a more flexible 'curve form' (allowing for arch asymmetries) into tooth crowding analysis systems should theoretically improve the fit particularly in upper pre-treatment dental arches and, thus, reduce bias in serial assessment of tooth crowding. Such a method could also be extended to include second and third molars.

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References

Angle, E. H. (1907)
Treatment of malocclusion of the teeth, 7th edn,
S. S. White Dental Company, Philadelphia.

Armitage, P. (1971)
Statistical methods in medical research,
Blackwell Publishing, Oxford, 198–200.

Begole, E. A. (1979)
A computer program for the analysis of dental arch form using the cubic spline function,
Computer Programs Biomedicine, 10, 136–142.

Black, G. V. (1902)
Descriptive anatomy of the human teeth, 5th edn.
S. S. White Dental Company, Philadelphia.

Bogue, E. A. (1912)
A collection of orthodontical data,
Dental Record, xxxii, 875–876.

Bogue, E. A. (1917)
Orthodontia of the deciduous teeth,
Dental Cosmos, lix, 246.

Bonwill, W. G. A. (1886)
Geometrical and mechanical laws of articulation,
Transactions of the Odontological Society of Pennsylvania, 1886–87–88, 281–301.

Brader, A. C. (1972)
Dental arch form related to intraoral forces: PR=C,
American Journal of Orthodontics, 61, 541–561.

Currier, H. H. (1969)
A computerised geometric analysis of human dental arch form,
American Journal of Orthodontics, 56, 164–179.

Hawley, C. A. (1905)
Determination of the normal arch and its application to orthodontics,
Dental Cosmos, 47, 541–557.

Hoster, F. J. (1978)
Symmetry and dental arch form of orthodontically treated patients,
Journal of the Canadian Dental Association, 44, 173–184.

Herren, P., Schmeker, R., and Jordi, T. (1973)
Arch shape and space balance determined by the Arcogramme Technique,
Transactions of the European Orthodontic Society, 49, 61–73.

Hixon, E. H. and Oldfather, R. E. (1958)
Estimation of the sizes of unerupted cuspid and bicuspid teeth,
Angle Orthodontist, 28, 236–240.

Isard, G. (1927)
New method for the determination of the normal arch by the function of the face,
International Journal of Orthodontics, 13, 582–595.

Jacobson, A. (1975)
The 'Wits' appraisal of jaw disharmony,
American Journal of Orthodontics, 67, 125–138.

Jones, M. L. (1987)
A quantitative three dimensional assessment of treatment change in a consecutively referred sample of malocclusion from a Welsh Town,
PhD thesis, University of Wales.

Jones, M. L. and Richmond, S. (1986)
The performance and use of the 3D cast analysis system,
British Journal of Orthodontics, 13, 54.

Jones, M. L. and Richmond, S. (1985)
Initial tooth movement: force application and pain—a relationship?,
American Journal of Orthodontics, 88, 111–116.

Lu, K. H. (1966)
Analysis of dental arch symmetry,
Journal of Dental Research, 43, 780 [abstr.].

McConnell, M. A. and Sherr, E. A. (1949)
The ideal form of the human dental arcade with some prosthetic application,
Dental Record, 69, 285–302.

Mills, L. F. and Hamilton, P. M. (1965)
Epidemiological studies of malalignment—a method for computing dental arch circumference,
Angle Orthodontist, 35, 244–248.

ALN121598

ClearCorrect Exhibit 1002, Page 1628 of 3373

Moyers, R. E. (1988)
Handbook of orthodontics, 4th edn.
Year Book Medical Publishers, Chicago.

Nasich, D. R. and Ackerman, J. L. (1973)
The Cullinometer; a reliable device for estimating dental arch perimeter,
American Journal of Orthodontics, 63, 366–375.

Peat, A. P. (1989)
Der Zahn—Index in der Orthodontie,
Zahnärztliche Orthopädie, 3, 306–321.

Reynolds, W. M. (1964)
Co-ordinated archep; an investigation into the form and interrelationship of orthodontic arch wires,
MSc thesis, Temple University.

Richmond, S. (1984)
The feasibility of categorising orthodontic treatment difficulty—the use of three-dimensional plotting,
MSc dissertation, University of Wales.

Richmond, S. (1987)
Recording the dental cast in three dimensions.
American Journal of Orthodontics, 92, 199–206.

Richmond, S. and Jones, M. L. (1985)
A comparison of two and three-dimensional incisor angles.
British Journal of Orthodontics, 12, 90–96.

Richmond, S. and Jones, M. L. (1986)
The development of 3D cast analysis system,
British Journal of Orthodontics, 13, 53.

Robertson, N. R. E., Jones, M. L., Richmond, S., and May, E. (1987)
The screening and categorization of patients: a case for natural selection?,
British Journal of Orthodontics, 14, 182–186.

Rudge, S. J. (1981)
A computer program for the analysis of study models.
European Journal of Orthodontics, 4, 225–231.

Rudge, S. J., Jones, P. T., Hepenstal, S., and Bowden, D. E. J. (1983)
The reliability of study model measurements in the evaluation of crowding,
European Journal of Orthodontics, 5, 225–231.

Sicher, H. (1952)
Oral anatomy, 2nd edn,
C. V. Mosby Company, St Louis.

Stanton, F. L. (1922)
A consideration of normal and abnormal dentures as a problem of three dimensional spaces and its bearing on orthodontic classification and terminology,
International Journal of Orthodontics, Oral Surgery, and Radiology, viii, 185–204.

Tanaka, M. M. and Johnston, L. E. (1974)
The prediction of the size of unerupted canines and premolars in a contemporary orthodontic population.
Journal of the American Dental Association, 88, 798–801.

Wheeler, R. C. (1950)
A textbook of dental anatomy and physiology, 2nd edn,
W. B. Saunders Company, Philadelphia.

Williams, P. N. (1917)
Determining the shape of the normal arch.
Dental Cosmos, 59, 695.

White, L. W. (1978)
Individual ideal archet,
Journal of Clinical Orthodontics, 12, 303–308.

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Computerized interactive orthodontic treatment planning

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Computer programs for digital computers are now being used in orthodontics for cephalometric analysis and for data-retrieval systems. Cephalometric analysis using a computer program is a relatively well-defined problem. The skeletal landmarks are converted into coordinates in a geometric space and an analysis is chosen. A computer program can then be written to calculate the desired angles and distances. If standards are available for the analysis, then the results can be compared to a table of standards that are already stored in the computer.

Intervention by the clinician is not required once the coordinate points are selected and the data are entered into the program. This process results in time saving to the busy clinician. It takes approximately 30 to 60 seconds to digitize a lateral head film. The data retrieval systems that are currently in use are located in major teaching centers and are used for rapid access to large banks of growth and cephalometric data. Record systems also fall into the retrieval system area, and some of these are now available as a service to the orthodontic clinician in practice via various entry modes.

Computerized patient diagnosis has long been worked at in medicine and is beginning to take strides in orthodontics. Computerized programs for diagnosis go a step beyond a data-retrieval system, since they require the definition of meaningful criteria to establish conclusions about the stored data base. The treatment planning of an orthodontic patient must be preceded by three distinct steps: (1) records, such as models, head films, etc., are obtained; (2) data are collected from these records and directly from the patient; and (3) data and/or secondarily derived data are compared with standards to establish a differential diagnosis for the patient.

The computer program performs well in the storing of vast amounts of data and organizing them rapidly into predetermined categories. The drawing of conclusions for a differential diagnosis and treatment planning is a more sophisticated problem. At the present state of the art there has been only limited success in achieving these goals. It is fair to state that although the computer program can greatly aid in amassing and organizing the diagnostic data base information, it is still the clinician who must assimilate and soundly interpret the results.

The field of computerized orthodontic treatment planning is at present one of the

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fall into four major categories: data-storage and retrieval systems, analytic systems, simulations, and real-time systems.

There is almost no mention in the literature of the use of computer systems for interactive simulation programming to aid the researcher or clinician in orthodontic treatment planning for the patient. The major thrust of the computer applications to orthodontics has been in an area that is loosely termed computerized cephalometrics. This category of applications involves two areas. The first is the study of growth and development and growth prediction of the facial skeleton on both a longitudinal and a cross-sectional basis to see if growth trends and patterns can be established. The second is the cephalometric anaylsis of patients who are to be treated orthodontically with comparison of measurements to available standards. The latter use has gained some prominence with its availability as a commercial service to practicing dentists and orthodontists.[2] Although the dental literature contains no direct references to interactive uses of computers in treatment planning, some of the reported work on simulations and analysis does help to support the basic concepts that are utilized in this project.

The use of computer programs developed to do a cephalometric analysis has been reported by several investigators.[3–6] A lateral head plate tracing is converted into X-Y coordinate points, either by hand or by an electronic digitizer. A digitizer is a device that converts X-Y coordinate points on a graph to electronic signals that signify the numerical coordinate locations of these points in a geometric space. This is usually done by placing a pointing device at the location to be converted and transmitting this location to an electronic device that converts the physical location to an electrical analog and thus to an X-Y coordinate. These data are then fed into a digital computer.

Once the data are stored in the computer in its X-Y coordinate form, any number of mathematical manipulations can be performed to measure the angles and distances between sets of points. If a data bank of standards is available,[7–9] then the measured data can be compared to the standards and, relative to the standard, "diagnostic" information is obtained. The concept of digitized information has been used in the study of dental arch form.[10, 11] The arch form is digitized by inputting the cusp tip X-Y coordinate positions, and measurements of arch form and arch width are done automatically by a computer program.

In the case of simulation,[11] if a curve for the arch form has been predetermined, then teeth can be moved along the curve and arch length or available space can be determined. The drawback to this type of simulation is that the mathematical general curve shape for the arch form that is fitted to the X-Y coordinates is either parabolic[11] or a trifocal ellipse,[12] which is an approximation to the arch form. To date, no major study has shown that the arch form for the human dentition actually approaches a mathematically defined curve in its entirety.

An in-depth review of the literature revealed that no satisfactory model has been developed that includes as components the facial skeleton, dentition, and soft-tissue drape of the face. However, models for the individual component parts (lateral skull, soft tissue, arch form, frontal skull) have been reported on in the literature.[10–13]

The study of growth and growth prediction using the digital computer has been limited. The major thrust has been on skeletal patterns of lateral head films.[9, 13, 14] These studies generally look at the changes of the lateral facial skeleton with age to get at the problem of growth prediction.[16, 17]

In general, it can be stated that the use of computers to analyze orthodontic data base

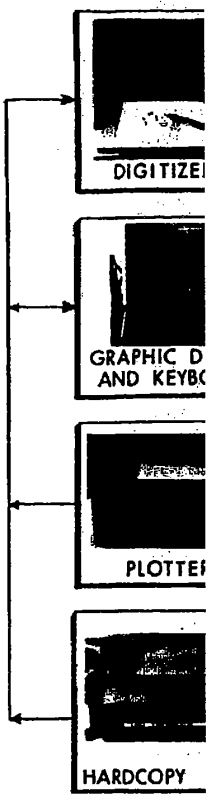


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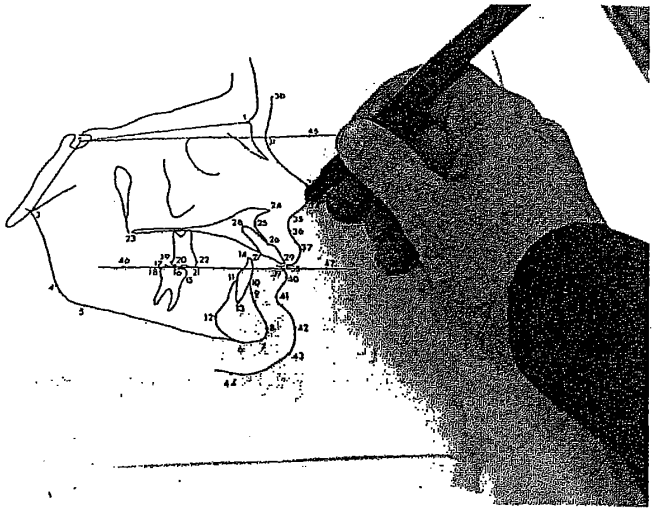


Fig. 3. Digitizing points for input to the computer program. Also illustrated is the point set used to construct the graphic display and calculations.

needs of interactive orthodontic treatment planning. The system is illustrated in Fig. 2. The heart of the system is a Computer Automation Alpha-16 mini computer with 24k of memory. The computer acts as the central processor for the peripheral equipment that interfaces with it, including the orthodontist.

The major communication device used by the operator is a Tektronix 4010-1 graphic display terminal and keyboard. It is via this terminal that the operator commands the system program operation, interfaces with the treatment-planning program, and is able to view the graphic simulation that is provided. The digitized data are entered into the system via a Summagraphics tablet digitizer. The digitizer converts the x-y Cartesian coordinates to electronic data signals and inputs the data directly into the computer. This is done by touching the pen-sensing device to the desired location on the digitizer tablet as shown in Fig. 3.

A Houston Instrument Digital Plotter is used to obtain final hard copy actual-size (1:1) tracings of the treatment plan. Copies of the graphic terminal display can be obtained by utilizing the Tektronix 4610 hard copy unit. These copies are approximately three-quarter scale (1:0.75). The data and programs are stored on a Diablo Series 40 disk drive with a storage capacity of 50,000K bits. The disk file system is directly addressable for programs and data. The entire system is capable of communication via telephone modems to large data banks that are stored on the University of Connecticut Univac 1106 computer system. The system is also capable of operation by remote operators via a modem telephone system.

The software that has been utilized in the system can actually be divided into two parts—the executive software and the treatment-planning software. Since it is not the purpose of this article to discuss the specific technical details of the executive software, suffice it to say that the program is written in the BASIC computer language and that

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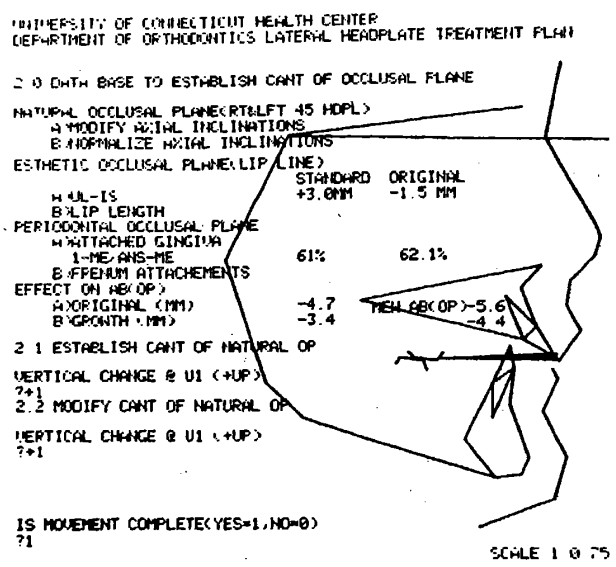


Fig. 5. Establishing a treatment occlusal plane. Data are inputted at 2.1 and 2.2 as noted by (?). Effect of change on A-B to occlusal plane is noted in new AB (OP).

reference is a fixed plane that is offset from the S-N line by 7 degrees. The human engineering aspects of the program have been designed to make operation as simple as possible.

The treatment planning program

Prior to going into a detailed description of the treatment planning program, it is important to set some philosophical ground rules. It is not the purpose of this article to substantiate or disprove any given assumptions used for treatment planning but, rather, to develop a logical systems engineering approach which is applicable to treatment planning in keeping with the specific needs of the individual patient. The mathematics and geometry of the situation can only describe the size, position, and angular relationships of the parts in space. This can be done with a computer program, but the final judgment and integration of the data still cannot be defined to the discrete levels required by the program, and thus these decisions have been left for the trained orthodontic clinician to make.

The program is designed to work with the clinician. It organizes and presents the primary data base information in a meaningful form. It calculates and organizes secondary or derived data base information. It alerts the operator to the important criteria for each decision and computes updates of the required measurements. The program then displays and simulates what the operator desires on the graphic display and recomputes the effect of the change on the relevant measurements.

It is fundamental to understand that the computer with its program is an *aid* to the orthodontist and, as such, is only one facet of the complete treatment-planning process.

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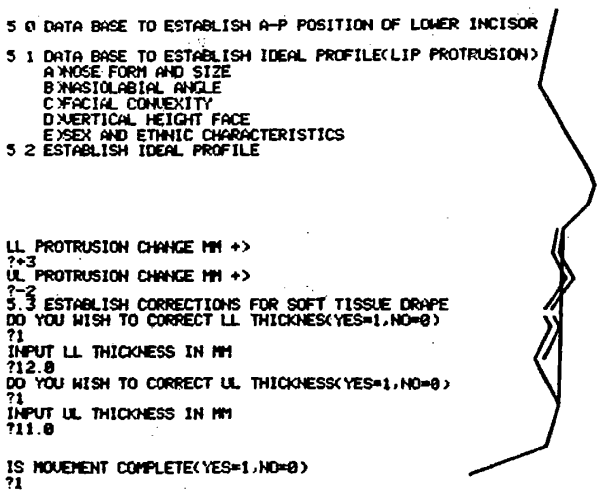


Fig. 7. Establishing ideal profile. Data for lip protrusion changes are entered in 5.2 and simulated. Step 5.3 allows for corrections of soft-tissue drape calculations if desired.

growth construction. Cranial base growth is along the S-N line. Midfacial growth occurs as horizontal increments to A point and vertical increments to ANS. The mandibular prediction is along the Y-axis angle to Frankfort horizontal. The input scheme selected allows the input of any type of growth data that the operator desires.

The second step (2.0 as noted in Fig. 5) of the program requires the operator to establish a cant for the treatment plane of occlusion as shown in Fig. 5. This decision is divided into two parts (2.1 and 2.2, as shown). Initially, the clinician determines the patient's natural plane of occlusion, using data base information. Once this has been done, the clinician considers the other factors that might enter into modification of the occlusal plane. These factors are esthetic considerations, periodontal considerations, and denture apical base relationships. As illustrated in Fig. 5, the data base, along with the standards and measured values, is displayed on the screen.

As the operator modifies the cant of occlusal plane, the new measurements are printed on the display. The simulation moves the occlusal plane as the operator indicates, so that he can see what the change will entail. In the sample case depicted in Fig. 5 the natural plane of occlusion was moved +1 mm. flatter than the inputted occlusal plane (center rotation is the mesiobuccal cusp of the maxillary molar and change measured in millimeters at the maxillary incisor) (Step 2.1). After consideration of the modification factors, it was decided to move the plane +1 mm. flatter than the natural plane as illustrated (Step 2.2). Once the treatment occlusal plane has been selected at the end of this step, it is used for all the calculation and simulation that follows.

The third step of the program (Step 3.0) is to establish mandibular rotation. Since the hinging of a mandible open or closed usually requires a growing patient, except in cases to be treated surgically, growth is included in this step. As shown in Fig. 6, the data bases

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The advantages

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1. A more thorough data base that is integrated with the treatment plan.
2. A detailed treatment plan that has included all steps for examination.
3. A graphic visualization of the projected treatment changes.
4. A simulation that allows changes to be made easily.
5. Control of the decisions by the orthodontic clinician.
6. Storage and retrieval of data as required for each step.
7. A time savings to the busy clinician since, when he sits down to do the treatment plan, the data are presented in an orderly and organized fashion.

It may not be too far in the future that the cost and technical advances in computer terminal technology will put a computer terminal or computer system in the realm of the private practitioner's office. Certainly, the costs have come down considerably in the past several years and will continue to do so as the usage rate increases. This will certainly increase both the demand and the feasibility of such a system.

REFERENCES

1. Faber, R. D.: Computers in dentistry, unpublished data, University of Maryland, 1972.
2. Rocky Mountain Data Systems: RMDS computerized cephalometric manual, ed. 2, August, 1972.
3. Cleall, J. F., and Chebib, F.: Coordinate analysis applied to orthodontic studies, Angle Orthod. **41:** 214-218, 1971.
4. Walker, G., and Kowalski, C. J.: Computer morphometrics in craniofacial biology, Comput. Biol. Med. **2:** 235-249, 1972.
5. Solow, B.: Computers in cephalometric research, Comput. Biol. Med. **1:** 41-49, 1972.
6. Krogman, W. M.: Use of computers in orthodontic analysis and diagnosis: A symposium, AM. J. ORTHOD. **61:** 219-254, 1972.
7. Walker, G.: Cephalometrics and the computer, J. Dent. Res. **46:** 1211, 1967.
8. Ricketts, R. M.: The evolution of diagnosis to computerized cephalometrics, AM. J. ORTHOD. **55:** 795-803, 1969.
9. Solow, B.: Automatic processing of growth data, Angle Orthod. **39:** 186-197, 1969.
10. Currier, J. H.: A computerized geometric analysis of human dental arch form, AM. J. ORTHOD. **56:** 164-169, 1969.
11. Biggerstaff, R. H.: Computerized diagnostic setups and simulations, Angle Orthod. **40:** 28-36, 1970.
12. Brader, A.: Dental arch form related with intraoral forces: PR = C, AM. J. ORTHOD. **61:** 541-561, 1972.
13. Walker, G., and Kowalski, C. J.: A two dimensional coordinate model for the quantification, description, analysis, prediction, and simulation of craniofacial growth, Growth **35:** 191-211, 1971.
14. Savara, B. S.: Use of computer techniques in the study of growth, Adv. Oral Biol. **4:** 1-9, 1970.
15. Parin, V. V., and Bayevskiy, R. M.: Introduction to medical cybernetics, National Aeronautics and Space Administration, NADS TT F-459, July, 1967.
16. Greenberg, L. Z., and Johnston, L. E.: Computerized prediction: The accuracy of a long-range forecast, AM. J. ORTHOD. **67:** 243-252, 1975.
17. Shulohof, F. J., and Bagha, L.: A statistical evaluation of the Ricketts and Johnston growth forecasting methods, AM. J. ORTHOD. **67:** 258-276, 1975.

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Case Reports on Tooth Positioners using LTV Vinyl Silicone Rubber

by

Katsuyuki KAMADA, Takahiko TAMURA*, Yuichiro HAMA*, Toshio KOIKE*, Takashi KANDA*, Michiyoshi TAKAHASHI*, Yutaka NAGATA* and Minoru NISHIYAMA***

Introduction

Remarkable progress has been made recently in the techniques and methods of orthodontics, especially in clinical orthodontics. It is also true that the labio-lingual system, which was once epoch-making, has been replaced by the full-banded system, which is frequently used today [1].

Since both techniques have their merits, it is difficult to say which is better.

The labio-lingual system requires a light and continuous orthodontic force, and therefore it seldom harms the teeth or periodontal tissue. It has also other advantages, including the fact that oral hygiene is relatively easy, and the patient is seldom affected by caries, etc. On the other hand, when a general improvement of occlusion is sought, occlusion in delicate movements of the teeth becomes difficult. Therefore, the range of treatment by this system is necessarily limited. This is why the full-banded system is being used more frequently, and numerous cases have already been reported.

It is no exaggeration to say that the present level of orthodontics has been made possible because of many years' accumulation of knowledge by researchers.

As the quality of dental materials improves and develops steadily, the tooth-positioner has come to be used as a new kind of removable orthodontic appliance which permits movement of the teeth.

It was invented by H.D. KESLING [2–4] in 1945, and in those days it was used for the closure of small spaces, the improvement of axis-inclination, and for better contact in occlusion. However, recently, it has become possible to use it more positively [9–11,13,14].

The authors now introduce cases in which tooth-positioners were applied, discuss the effects of the new technique, and make some reports.

Case No. 1

Patient: S.S., a girl, 10 years and 3 months old.

Chief complaint: Anterior protrusion.

Family history: Slight anterior protrusion is observed in her mother's teeth, and the face of the elder sister of the patient's father looks very much like that of the patient. Therefore, hereditary factors should be taken into consideration.

Medical history: Nothing worth special mention.

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Fig. 1 Case No. 1. Photographs of the face (before treatment)

Symptoms:

Facial examination: No asymmetry can be seen from the front view, while a lateral view shows protrusion of the lower face (Fig. 1).

Oral examination: Dental age—Hellman's dental age IV-A. No missing teeth. Maxillary anterior teeth show a tendency to protrude. Interdental space is seen between the protruding anterior teeth. Superior labial frenum is abnormal. Oral hygiene comparatively good (Fig. 2).

Occlusal appearance: In the maxillary, a 2.5 mm space between the two central incisors and a 1 mm space between the central and lateral incisors. No special asymmetry, such as space, crowding, etc., in the lower jaw. Midline shows no deviation both in the upper and lower jaws. Molar relationship of buccal segments—Angle's class I. Overjet 7 mm. Overbite 4 mm.

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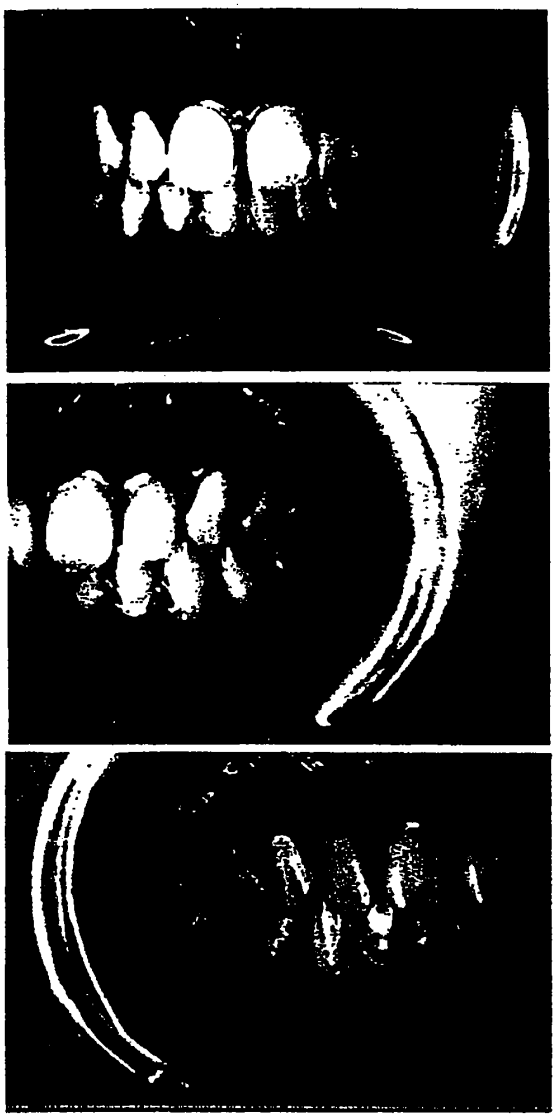


Fig. 2 Case No. 1. Oral photographs (before treatment)

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Roentogenocephalometric analysis: As shown in Table 1, abnormality was recognized both in the patient's skeletal pattern and denture pattern.

Diagnosis: Angle's class I with upper incisal protrusion.

Treatment plan: As a result of an analysis of the data, the decision was made first to extract the upper and lower first premolars, and to carry out treatment by the full-banded system. However, the patient's parents were firmly opposed to the extraction of permanent teeth, they would not give their consent to our proposal to put in an orthodontic appliance for fear of poor esthetic appearance, and asked us only to ease her feeling of uneasiness caused by the protrusion, and to close the space between the maxillary anterior teeth. So we changed our original plan and began treating her with a removable orthodontic appliance.

In order to ease the feeling of protrusion in the maxillary anterior teeth and to close the space between them, we attempted to retract the protruding anterior teeth.

Treatment: As the superior labial frenum was abnormal between the two central incisors, a frenectomy was performed. Then a removable tooth-positioner was made [5–11,12,13] and fitted to the mouth. It was first applied to close the space between the maxillary anterior teeth and to improve the overjet and overbite (Fig. 3).

Since it was a remarkable case of maxillary protrusion, a slit was made between the maxillary anterior teeth of the tooth positioner for the purpose of achieving adequate orthodontic force [7,9,14]. As this treatment proved effective after five months, the first tooth-positioner was replaced by a second. Since an improvement in overjet had been achieved, no slit was made on the positioner this time. In the sixth month after the application of the second tooth-positioner, a third positioner, for the final aim of retention, was applied (Fig. 4).



Fig. 3 Tooth-positioner applied

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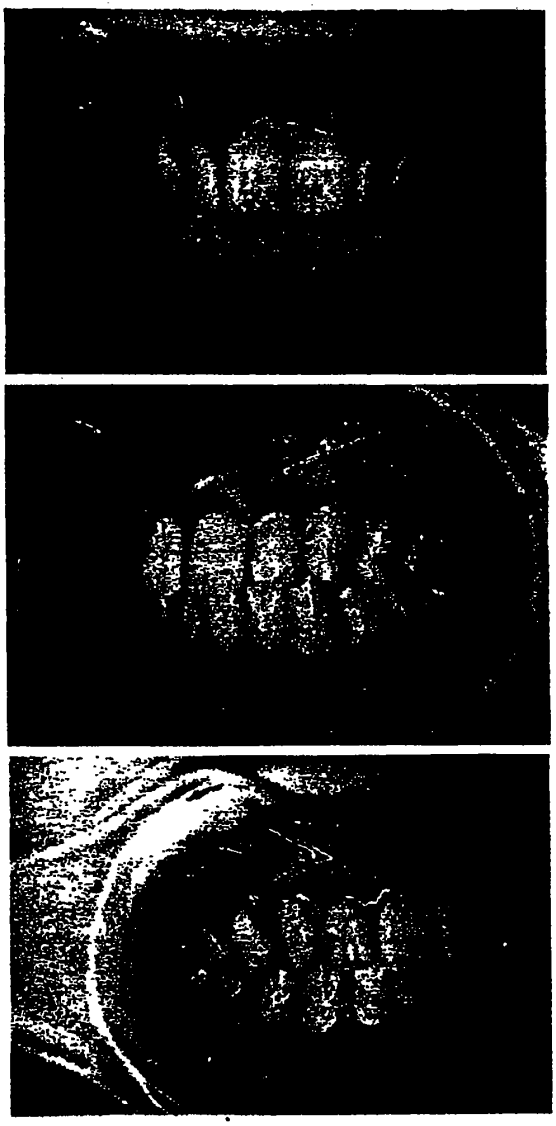
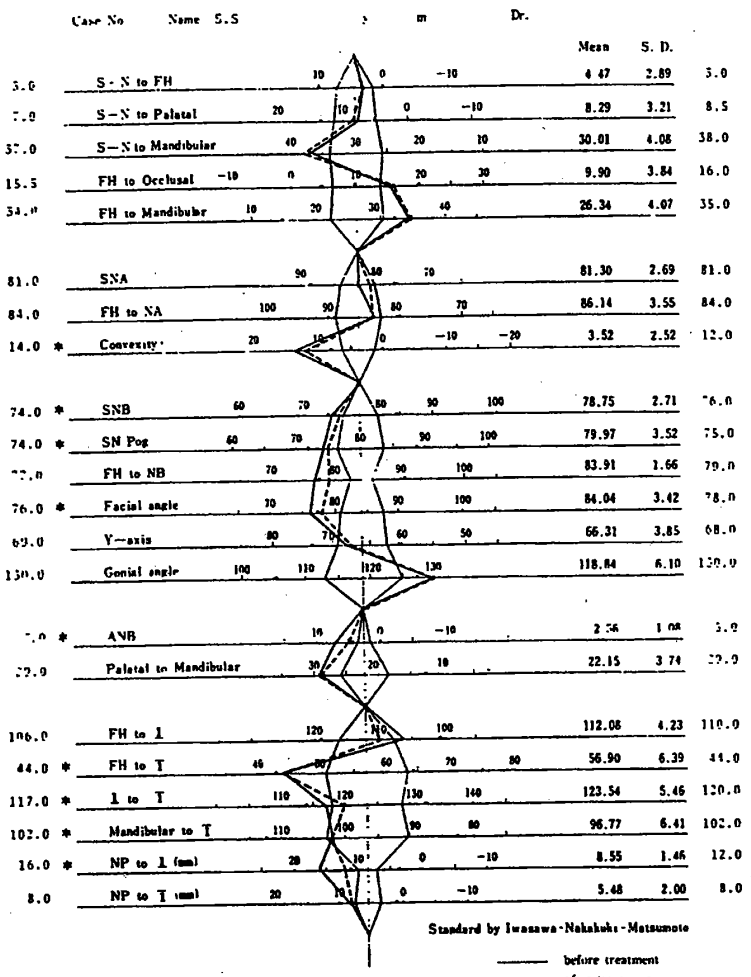


Fig. 4 Oral photographs (after treatment)

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Table 1 Case No. 1. Roentgenocephalometric analysis (before and after treatment)



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Case No. 2

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The roentgenocephalograms taken at the end of the treatment revealed that the change observed in the skeletal pattern was negligible (Table 1). However, since change was observed in FH to $\underline{1}$ and 1 to $\overline{1}$, it was recognized that the treatment had proved effective in modifying the denture pattern.

On oral examination, molar relation showed good class I with the overjet decreased from 7 mm to 2 mm, the overbite from 4 mm to 2.5 mm, and we concluded that the primary purpose of the treatment had been achieved.

Case No. 2

Patient: N.K., a girl, 11 years and 7 months old.

Chief complaint: Anterior protrusion.

Family history: Nothing worth special mention.

Medical history: Same as above.

Symptoms:

Facial examination: From the front, no asymmetry, but from a lateral view, protrusion in the middle face (Fig. 5).

Oral examination: Dental age—Hellman's dental age III B. Maxillary anterior teeth protruding. The upper left canine is erupting (Fig. 6).

Occlusal appearance: Midline of both the upper and lower jaws shows no deviation. Molar relation—Angle's class II. Overjet 6 mm and overbite 3 mm (Fig. 7).

Roentogenocephalometric analysis: As shown in Table 3, there was abnormality particularly of the upper face, but no major abnormality of the lower face. In denture pattern, abnormality in FH to $\underline{1}$.

Diagnosis: Angle's class II, div. 1, malocclusion.

Treatment plan: As she was a non-extraction case, treatment was aimed mainly at improving the maxillary denture pattern.

Since the molar relation was Angle's class II and ANB was large, plans were made to improve the relation of tooth axes of the maxillary anterior teeth after correcting the molar relation using head gear.

Treatment: Bands were set at $\underline{6}\ \underline{6}$, and head gear was used for more than 14 hours a day. Since the patient was co-operative, the class I molar relation was obtained.

Later, according to the conventional method, a tooth-positioner was made. Because the overjet was large, a slit was made between the maxillary anterior teeth of the tooth positioner, as in the previous case. Since the treatment proved effective in the anterior teeth, the first tooth-positioner was replaced by a second seven months later. No slit was made this time, as there was an improvement in the overjet. Six months later, a third tooth-positioner was applied to correct the midline and the mesial rotation of the right maxillary canine (Fig. 8). Before the third positioner was applied, the shape of a left maxillary canine was made using a wax block, to guide eruption (Fig. 9). A slit was made on the canine of the third tooth-positioner before it was applied (Fig. 10). Six months later, normal occlusion could be observed, as shown in Fig. 11.

When the condition before and after treatment was compared and examined by the roentgenocephalometric method (Table 2), the treatment could be seen

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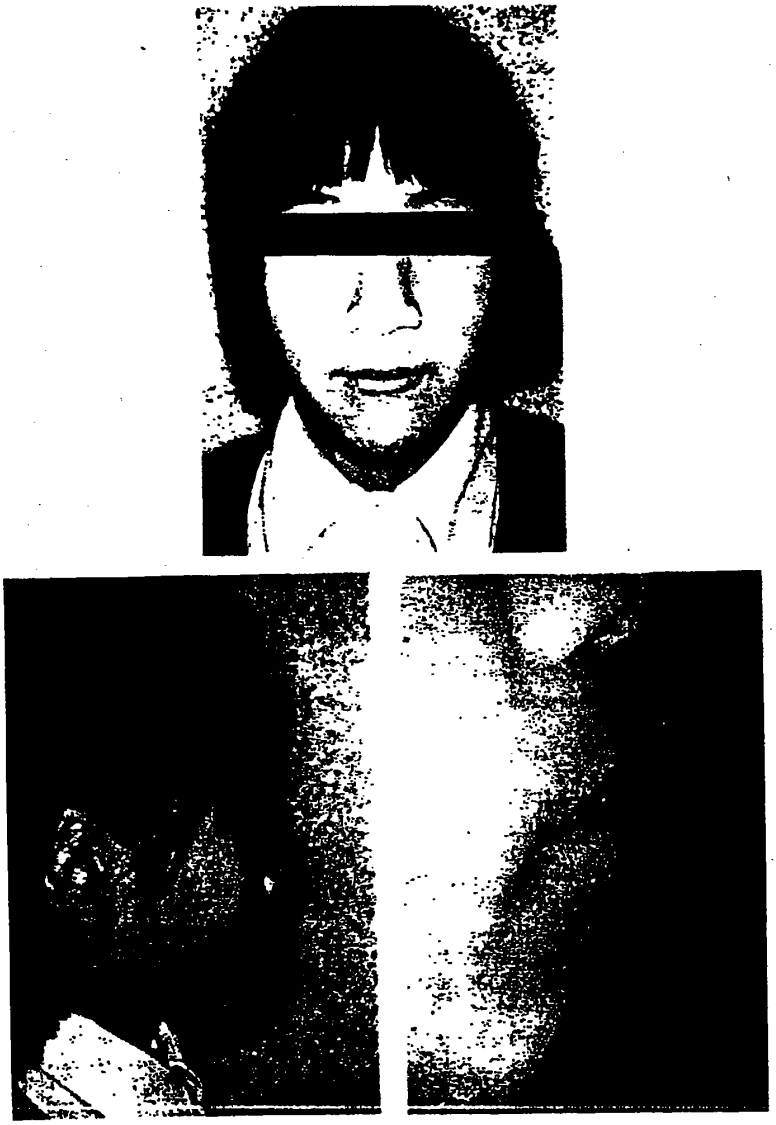


Fig. 5 Case No. 2. Photographs of the face (before treatment)

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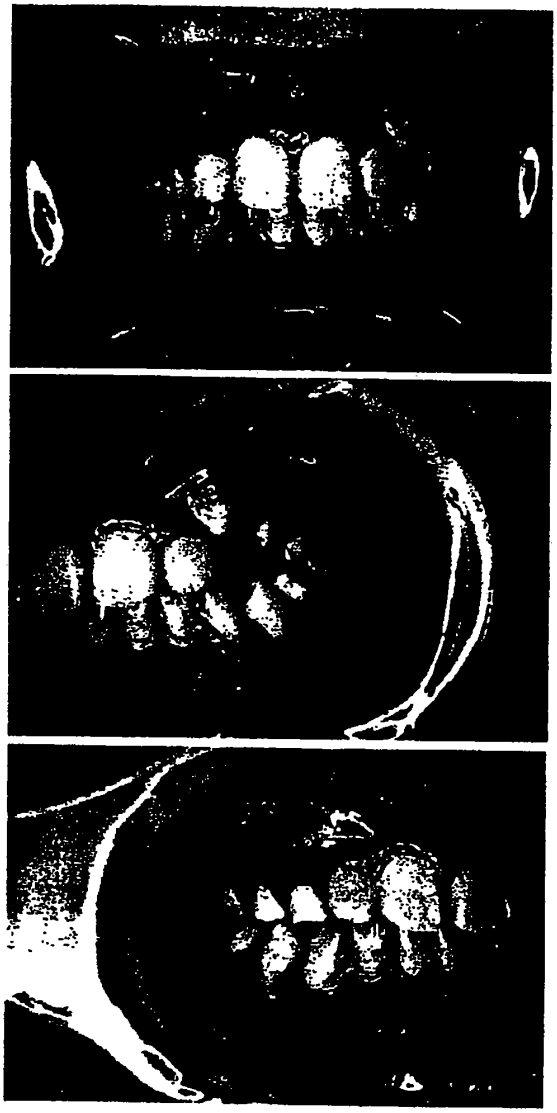


Fig. 6 Case No. 2. Oral photographs (before treatment)

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Fig. 7 Case No. 2. Oral photograph (Lateral view before treatment)

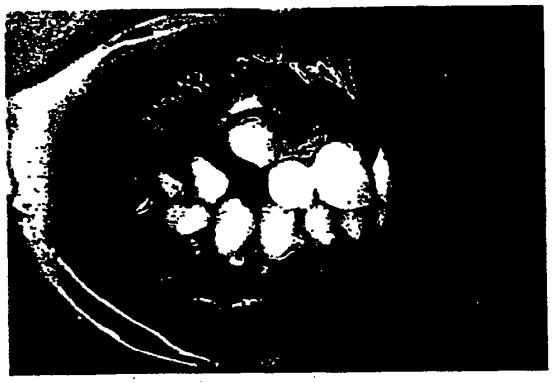


Fig. 8 Case No. 2. Oral photograph (Eruption of right upper canine)

to have been effective, in both the skeletal pattern and the denture pattern.

Case No. 3

Patient: H.T., a boy, 10 years and 4 months old.

Chief complaint: Anterior crossbite.

Family history: Nothing worth special mention.

Medical history: Same as above.

Symptoms:

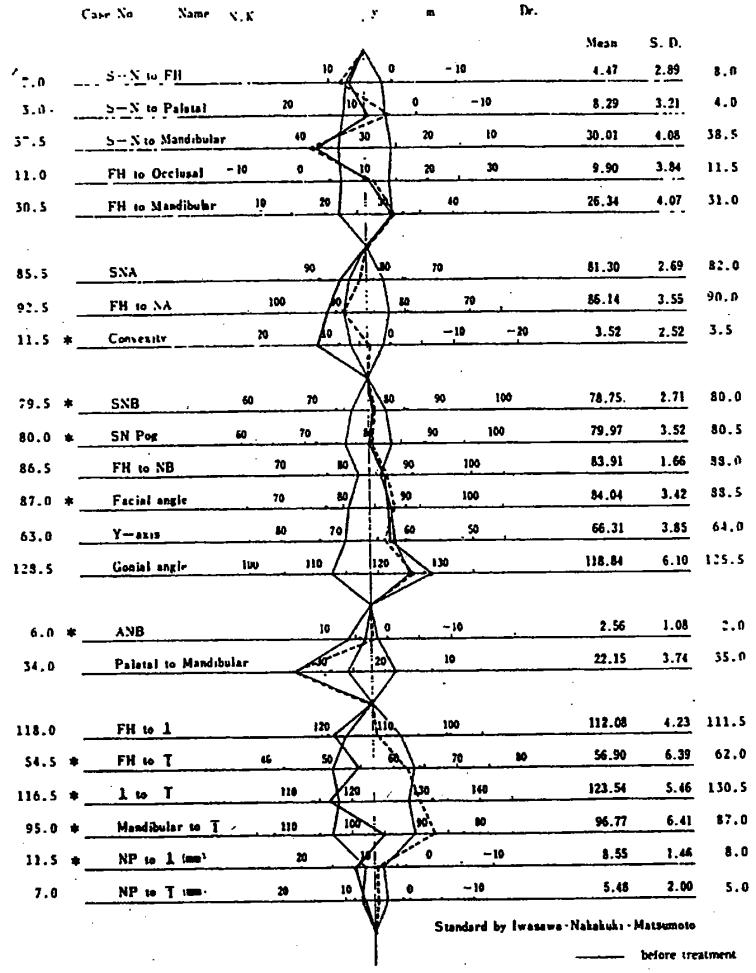
Facial examination: No asymmetry could be seen from the front, but a concavity could be seen in the middle face (Fig. 12).

Table 2 Ca

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7.0	S–N
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11.5 *	Conv
79.5 *	SNB
80.0 *	SN P
86.5	FH to
87.0 *	Facia
63.0	Y–ax
128.5	Gonia
6.0 *	ANB
34.0	Palat
118.0	FH t
54.5 *	FH t
116.5 *	1 to
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11.5 *	NP t
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Table 2 Case No. 2. Roentgenocephalometric analysis (before and after treatment)



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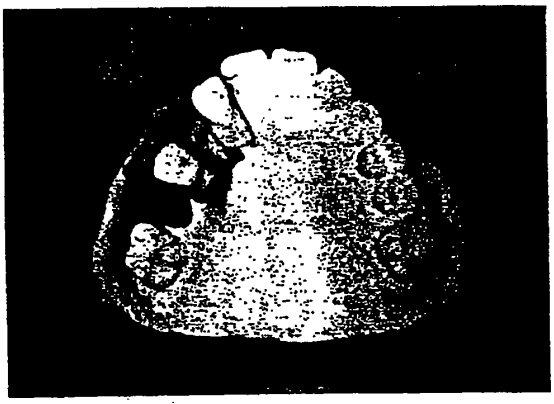


Fig. 9 Case No. 2. Right upper canine set up



Fig. 10 Tooth-positioner applied

Oral examination: Dental age III B according to Hellman's dental age. Caries and other diseases not observed. but the upper incisors occluded lingually with the lower incisors. Because of poor oral hygiene. brushing instructions were given before treatment started (Fig. 13).

Occlusal appearance: Upper incisors showed crossbite. but midline showed no deviation. Molar relation—Angle's class I. Overjet 2 mm. Overbite 6 mm.

Roentgenocephalometric analysis: As shown in Table 3, only a slight irregularity was found in the upper jaw. but remarkable irregularities were observed mainly in the denture pattern.

Diagnosis: Angle's class I with anterior crossbite

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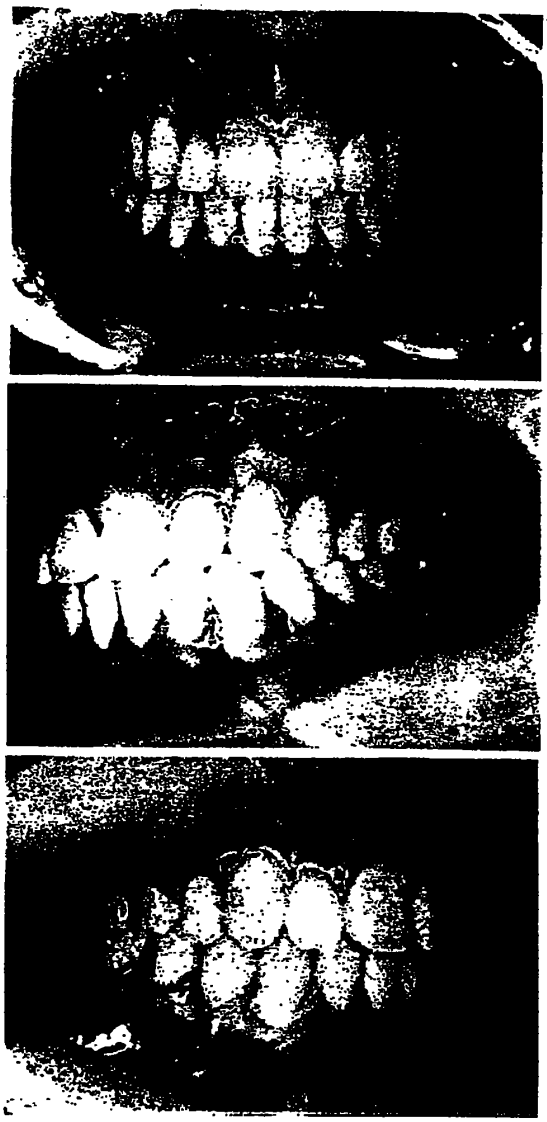


Fig. 11 Case No. 2. Oral photographs (after treatment)

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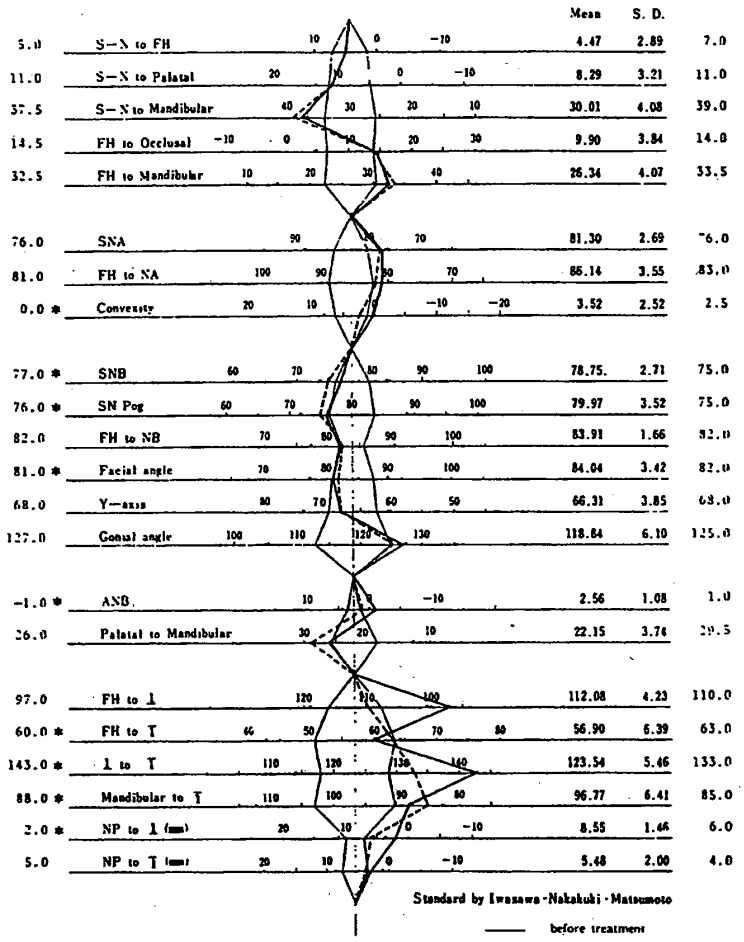
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Table 3 Case No. 3. Roentgenocephalometric analysis
(before treatment, and 2 months later)

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2	11.0
8	39.0
4	14.0
7	33.5
9	76.0
5	85.0
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52	75.0
6	82.0
2	92.0
55	68.0
10	125.0
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4	29.5
23	110.0
39	65.0
46	133.0
41	85.0
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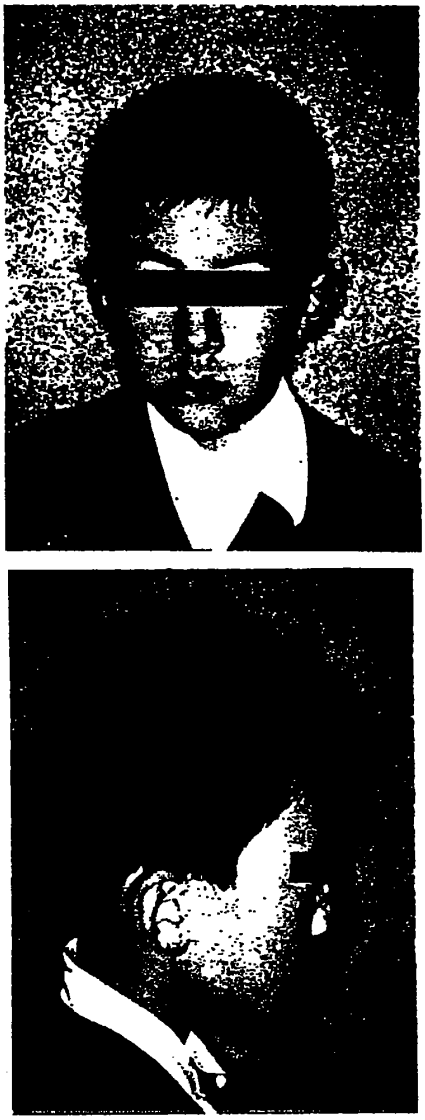


Fig. 12 Case No. 3. Photographs of the face (before treatment)

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Fig. 13 Case No. 3. Oral photographs (before treatment)

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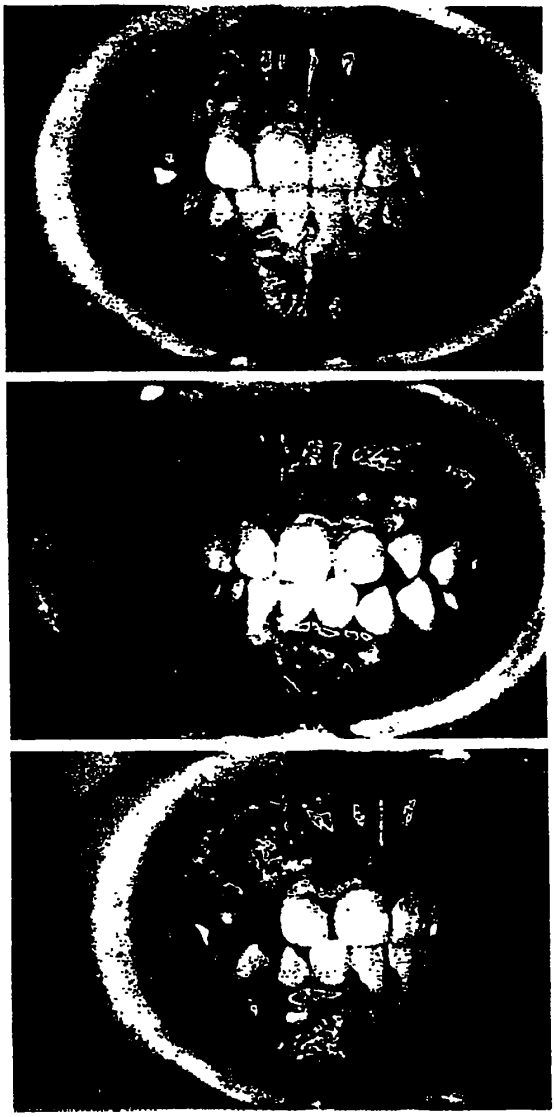


Fig. 14 Case No. 3. Oral photographs (10 months later)

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Treatment plan: As he was a non-extraction case, the patient was to be treated mainly to improve his denture pattern. Because of deep overbite in his anterior teeth, it was difficult to place the bands and brackets in position on incisors; and because of his poor oral hygiene, the decision was made to correct, by the use of a tooth-positioner, the deep overbite and overjet of the anterior teeth, which was the patient's chief complaint.

Treatment: Using a tooth-positioner made in the conventional way, overbite and overjet in his anterior segments were corrected in two months. A second tooth-positioner has since been applied for retentive purposes, and as an eruption guide (Fig. 14).

Roentgenocephalometric analysis: The roentgenocephalograms taken at the end of the treatment revealed scarcely any change in skeletal pattern, but an improvement was seen in the denture pattern. The overjet and overbite were somewhat corrected. Favorable results have thus been obtained (Table 3).

Discussion and Conclusions

The authors applied tooth-positioners using LTV vinyl silicone rubber, and drew the following conclusions about this kind of appliance:

1) It is possible to improve axis inclination substantially by the use of tooth-positioners. These can be used not only for the treatment of maxillary protrusion and cross-bite, but also for prosthetic treatment and in pedodontics.
2) Tooth-positioners can be used with various extra-oral appliances, including a chin-cap and head gear [10]. They can also induce normal development in comparatively easy cases of skeletal abnormality.
3) By using tooth-positioners, dentisits can give patients with poor oral hygiene the necessary guidance during treatment, and can avoid periodontal diseases, caries, etc. In the case of anterior cross-bite, they can avoid the extremely difficult task of setting up a bracket position, because of the occlusal interference of the teeth with each other, and can also save complicated manipulation, such as wire-bending. As a result, treatment can be shorter.
4) By using this kind of tooth-positioner, injuries to periodontal tissue, which may occasionally be caused when mechanical orthodontic appliances are used, can be avoided.
5) Unlike the material used for conventional tooth-positioners, the one used in the present tooth-positioners (LTV vinyl silicone rubber) is easy to handle in the laboratory, and the time required to make it is short. Since it can be adjusted to highly variable changes, the range of appliance is larger than for the conventional one. It can be used effectively not only as a retainer, but also in active treatment.
6) Tooth-positioners using this material can induce the eruption of teeth in cases requiring serial extraction.

Although the above-mentioned merits can be seen in this type of tooth positioner, its effectiveness in vertical translation is slight [14], despite its high effectiveness in horizontal translation. As for other removable appliances, therefore, it is essential to keep the application time of this type of positioner strictly accurate. It is doubtful whether this positioner should be used for

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patients suffering from nasal disease, etc.

We have so far discussed the advantages and disadvantages of tooth-positioners using LTV silicone rubber. We should like to record more cases of treatment with this type of tooth-positioner, to examine the distribution of various cases treated with this appliance, and to examine the diseases for which it is useful and to try to find more effective uses for it.

References

[1] Enoki, K. 1981. The history of orthodontics, Orthodontics, 2nd ed., Ishiyakushuppan, Tokyo, 3–6 (in Japanese)

[2] Kesling, H.D. 1945. The philosophy of tooth positioning appliances, *Amer. J. Orthodont.*, 31, 297–304.

[3] Kesling, H.D. 1946. Coordinating the predetermined tooth positioner with conventional treatment, *Amer. J. Orthodont.*, 32, 285–293.

[4] Kesling, H.D. 1956. The diagnostic set-up with consideration of the third dimension, *Amer. J. Orthodont.*, 42, 740–784.

[5] Sugimura, H. et al. 1966. Materials for tooth positioners, *J. Jap. Orthod. Soc.*, 25, 106–114 (in Japanese).

[6] Yoshii, O. 1973. Studies on orthodontic rubber materials (Part 3), *J. Stomatol. Soc. Jpn.*, 40, 103–121 (in Japanese).

[7] Nishiyama, M. et al. 1977, published in 1979. Construction of tooth positioners using LTV vinyl silicone rubber, *J. Nihon Univ. Sch. Dent.*, 19, 93–102.

[8] Nishiyama, M. et al. 1979. Studies on vinyl silicone rubber—Its composition and basic properties, *JDMA*, 35, 370–377 (in Japanese).

[9] Yoshii, O. 1980. The development of new orthodontic treatment—The outline of dynamic positioners with Orthocon, *DE*, 54, 1–13 (in Japanese).

[10] Yoshii, O. 1980. New orthodontic device—dynamic positioner (D.P.) II. Practical application and construction of D.P., *The Nippon Dental Review*, 454, 107–130 (in Japanese).

[11] Yoshii, O. 1980. New orthodontic device—dynamic positioner (D.P.) III. Case reports of reversed occlusion, *The Nippon Dental Review*, 457, 146–164 (in Japanese).

[12] Kesling, H.D. 1945. The philosophy of the tooth positioner appliance, *Amer. J. Orthodont.*, 31, 297–304.

[13] Kamada, K. et al. 1982. Construction of tooth positioners with LTV vinyl silicone rubber and some case reports, *J. Nihon Univ. Sch. Dent.*, 24, 1–27.

[14] Yoshii, O. 1983. The early treatment case of anterior crossbite with dynamic positioners, *Dental Diamond*, 18, 16–22 (in Japanese).

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Construction of Tooth Positioners with LTV Vinyl Silicone Rubber and Some Case Reports

by

Katsuyuki KAMADA and Minoru NISHIYAMA***

Introduction

In the orthodontic field, attention has recently begun to center on active treatment with tooth positioners, appliances with elasticity made of rubber materials used for orthodontic force in place of conventional metal wires[1–7].

Tooth positioners were contrived by KESLING as retainers to be used after the use of metal wires in active treatment[8,9]. Nowadays, it is used for closing the spaces due to band removal after active treatment, for the minute regulation of the occlusal relationship and for aftercare as a retainer. Not only that, as it is possible to regulate malocclusion by moving teeth with rubberlike elasticity applied in place of metal wires or brackets, it is beginning to draw attention as a new active treatment appliance to be substituted for conventional metal wires.

With regard to the materials for tooth positioners to be used as active treatment appliances, various kinds of materials have been applied since KESLING contrived them[10–12], but few materials satisfy the necessary conditions for tooth positioners[10]: 1) easy manipulability, 2) elasticity and hardness, 3) tastelessness and odorlessness in the oral cavity and 4) durability. Polyurethane rubber and heat-vulcanized silicone (HTV) rubber which are tasteless, odorless and superior in elasticity, have recently been developed[1,4–7], but these materials require special mold materials and equipment in the preparation process which is also very complicated, so their use has not been widespread as yet.

Therefore, for several years the authors have been studying their practical application and trying to develop a material that is easy to manipulate and superior in physical properties[2,3,13]. As a result, the authors have developed a clinically applicable method of tooth positioners with low temperature vulcanized (LTV) vinyl silicone rubber. The following is an outline of its physical properties, the method for its preparation and some case reports.

Materials and Properties

Though silicone rubber is roughly classified into two types (HTV rubber and room temperature vulcanized (RTV) rubber), the silicone rubber that the authors have introduced into the dental field[13] is not HTV rubber that requires a high temperature to vulcanize (1st vulcanization 150°C and 2nd vulcanization 250°C,

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**西山 稔: *Dept. of Dental Materials, Nihon University School of Dentistry, Tokyo, Japan.*

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Table 1 Physical properties of LTV vinyl silicone rubber (T-Fix)

Item	Regular type	Hard type
Specific Gravity	1.12	1.21
Hardness (Shore Hardness)*	43	55
Tensile Strength (kg cm^{-2})*	50	58
Elongation (%)*	380	240
Young's Modulus (kg cm^{-2})	16	28
Elastic Strain (%)	3.6	2.7
Permanent Deformation (%)	0.1	0.1
Water Absorption (mg cm^{-2})**	0.02	0.02

* Storage in 37°C water, 90 days
** Storage in 37°C water, 30 days

but LTV vinyl silicone rubber (T-Fix)[a] that vulcanizes at 80–150°C. Some facts about the material are as follows:

1. Composition

The base material is a thixotropic paste of dimethylvinyl siloxy polydimethylsiloxane: Vi-PDMS, with chloroplatinic acid: H_2PtC_6 (catalyst) added, and the hardener is a liquid composed of polyhydromethylsiloxane: PHMS and Vi-PDMS.

2. Mix ratio and vulcanization

The standard mixing ratio of the base material and the hardener is 10:1 (weight percent), and the mixture has a 24-hour pot life at room temperature (25°C).

Vulcanization finishes in a short time (20 minutes at 100°C and 10 minutes at 150°C), when the mold materials have good thermal conduction, but in the case of plaster molds in a water bath, using a dental flask, the adequate vulcanizing time is 60–90 minutes at 100°C.

The vulcanization mechanism is an addition polymerization[13], and no by-products are produced. Consequently, shrinkage due to vulcanization can hardly be seen. But careful treatment is necessary because its vulcanization is liable to be incomplete if it comes in contact with either sulfer, phosphorus, nitrogen compound, organometallic salt or flux.

3. Harmfulness

The present material is not considered harmful. It has passed notification test No. 434 issued by the Ministry of Health and Welfare in Japan. Furthermore, the authors are convinced, from the data obtained through the clinical application of the tooth positioner made of the present material, that it does not cause redness or tumors of the oral mucosa nor does it cause an uncomfortable feeling when applied.

4. Physical properties of the set product

There are two types of the present material; regular and hard. Table 1 shows the physical properties of the respective set products.

Method for Preparing a Tooth Positioner

The method for preparing a tooth positioner with LTV vinyl silicone rubber (T-Fix) is as follows: The working process, from set-up model to wax model for mak-

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ing a tooth positioner. follows the conventional method[5,8–10], but the subsequent process was contrived by the authors.

1. Preparing a set-up model

In the process of preparing tooth positioners. the first thing to do is to make a set-up model of the supposed dental arch after treatment. A set-up model is prepared by separating the upper and lower plaster models and arranging them in the ideal position to serve the purposes of treatment. The method is as follows:

1) Making plaster models

Plaster models are prepared by taking impressions of the patient's upper and lower jaws with alginate impression material. First, an ordinary plaster mixture is filled to a height of 5–8 mm from the cervial upper margin to be cured. After curing, a separator is applied up to the molar portions and then the models are filled with an α-plaster mixture. The application of the separator is to get a horizontal division, a standard level on the plaster model, separating the dental arch and base, which is necessary in preparing set-up models.

2) Mounting the plaster model on an articulator

The trimmed plaster model is mounted on an articulator to reproduce occlusal conditions.

3) Die division

The dental arch is separated from the division line of the model (Fig. 1). After the dental formula is written on the labial surface of each die, the dental arch is separated at the contact surface of the lower central incisor using a fretsaw in the direction of root to crown in accordance with the principle of rearrangement. Next, each die in an irregular position on the separated dental arch is cut from the root section to just before the contact point (Fig. 2) to be separated with fingers (Fig. 3).

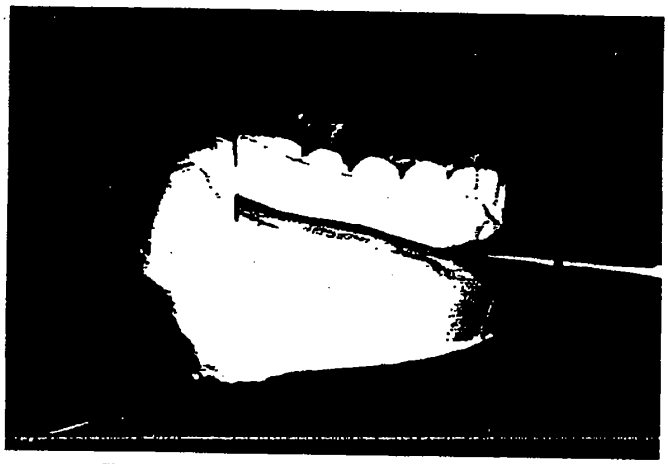


Fig. 1 Separation between a part of the dental arch and base

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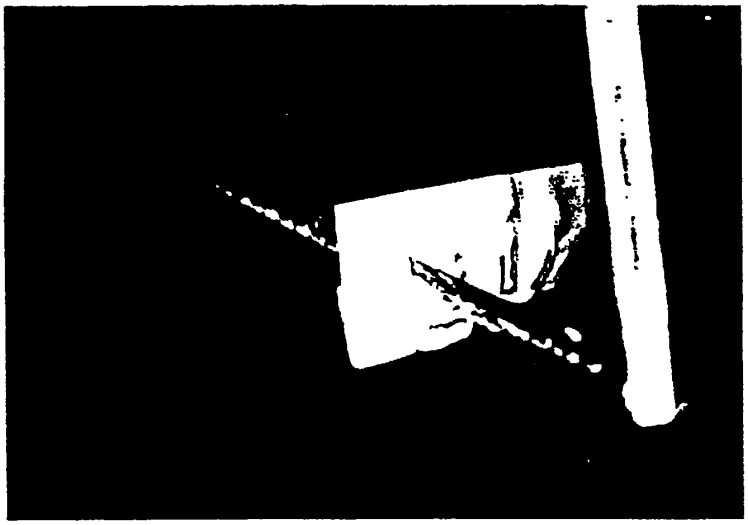


Fig. 2 Vertical separation of the dental arch by the use of a fretsaw

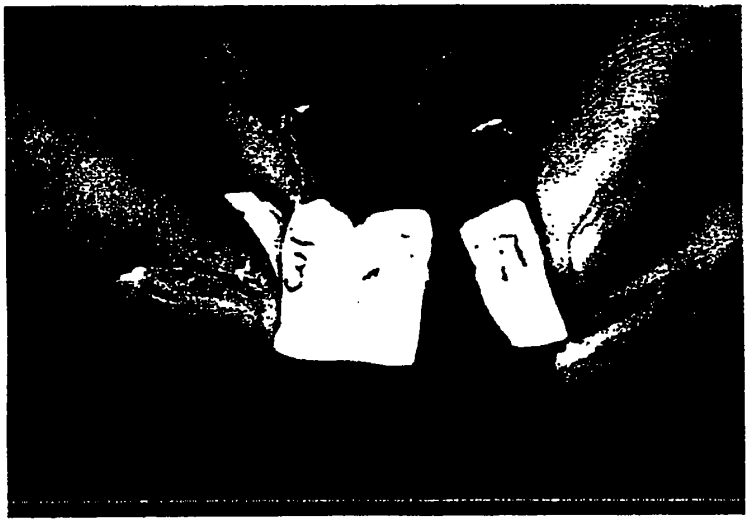


Fig. 3 Individual separation with fingers

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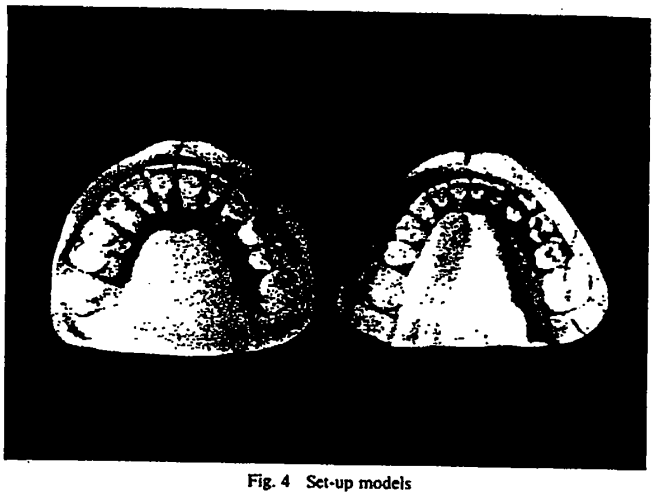


Fig. 4 Set-up models

The portions or numbers of teeth to be separated is decided according to the purpose or plan for treatment. The mesiodistal surface of each separated die is individually carved to make the die root similar to a normal root and each die base is reduced by 2 mm.

4) Die rearrangement

The separated dies are rearranged in accordance with the treatment plan on the articulator. To move the teeth, the aim points are put on the opposite side. So, the rearrangement is carried out from one side of the lower dental arch to the other. The rearranged dies are fixed with paraffin wax, referring to the gingival condition before separation, and then with the lower dental arch used as standard, one side of the upper dental arch is rearranged and then the other. Finally, wax gum festooning is performed to complete the set-up model (Fig. 4).

Then, using the set-up model mounted on the articulator, bite raising is carried out, approximately 4 mm at the anterior tooth portion, to take a wax bite.

2. Making working models

The set-up model is duplicated with alginate impression material and an α-plaster mixture is filled into the impression surface to make a working model (Fig. 5).

3. Making a wax model of the tooth positioner

The upper and lower working models are fixed with the wax bite taken in 1. 4), to make a wax model of the tooth positioner (Fig. 6).

4. Making a plaster mold

Wax models, invested in plaster with a dental flask in accordance with the conventional method is soldered to be a plaster mold, to which an alginate separator is applied. . . . Even without an alginate separator, the silicone product is easily taken

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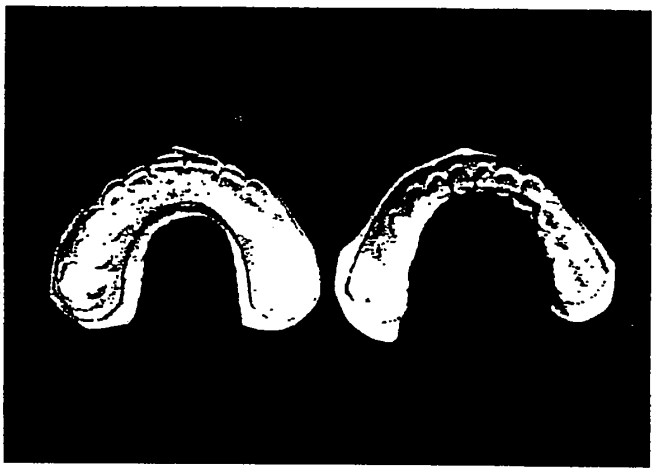


Fig. 5 Working models

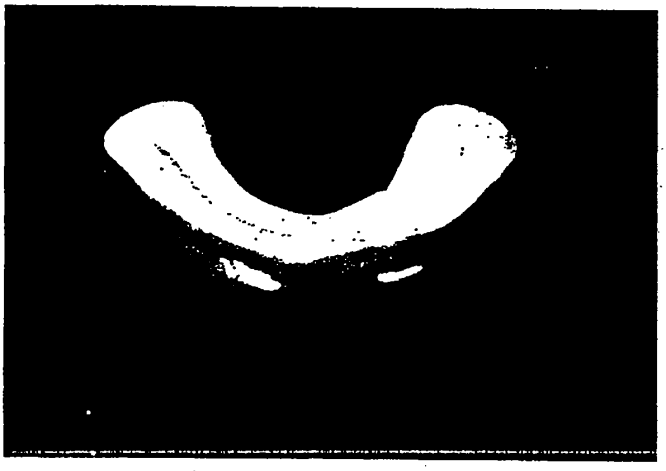


Fig. 6 Wax model of a tooth positioner

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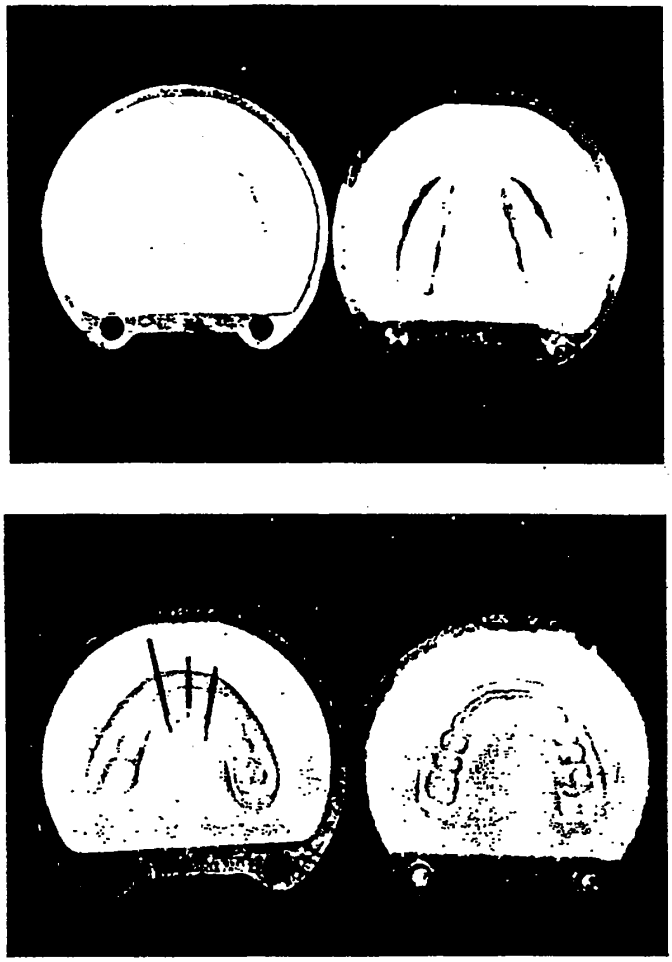


Fig. 7 Split plaster molds

out of the mold, but the lubricity of the set product surface seems to be somewhat inferior as compared with those with an alginate separator applied.

On the other hand, as shown in Fig. 7, bottom, the tooth positioner when completed may have some air holes between the upper and lower incisal edges if 2 mm ϕ wires are inserted beforehand when the wax model is made.

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5. Filling with a silicone mixture

The base material and hardener are well mixed in a ratio of 10:1 and then the plaster mold is filled with the silicone mixture (Fig. 8) with a syringe (Figs. 9, 10). The silicone mixture is thixotropic and easily pushed out into the mold with a syringe or piled up in the mold with a spatula. Again, as the mixture has a 24-hour pot life at room temperature there is no hurry about the manipulation of mixing and filling.

6. Vulcanization of silicone

After finishing the filling of the mixture the flask, with both trays put together, is pressed at (50–60 kg·cm²) and is held with a clamp and heated in a 100°C water bath for 60–90 minutes. Dry heating is also allowed. If a polymerization pressure pot for dentures is used, the heating time can be shortened to 10 minutes.

7. Takeout and polish

When vulcanization is completed the flask is taken out of the water bath to be cooled, still clamped. It is not always necessary to leave it to cool at room temperature. Quick cooling in water does not have any effect on the set product.

Vulcanized silicone, when cooled, having preferable elasticity, is easily taken out of the flask with its upper and lower trays split (Figs. 11, 12). Again, there is no fear of injuring the plaster mold in the takeout precess, so the same plaster mold can produce more than two tooth positioners.

Flashes due to the splitting of the mold are very thin (30–50 μ), and there is little fear of causing dimensional changes in the height of the bite.

Polishing is almost unnecessary. The flashes are cut with scissors and their traces are restored with sandpaper cones to complete the tooth positioner (Figs. 13, 14). It is possible to increase the lubricty of the surface, if necessary, by coating it with glazing silicone (Fig. 15) and leaving it in the drier for 30 minutes at 100–130°C (Figs. 16, 17).

The merits of preparing tooth positioners with LTV vinyl silicone (T-Fix) are as follows:

1) The plaster mold is easily filled with the mixture with either a syringe or spatula.
2) The mixture, having a 24-hour pot life at room temperature, is extremely preferable in manipulation.
3) Vulcanization is completed in 60 minutes at 100°C.
4) The set product is tasteless and odorless and shows preferable rubber-like elasticity.
5) There is no need for special mold materials: plaster molds will produce preferable set products.
6) The set product is easily taken out of the plaster mold.
7) There is no fear of injuring the plaster mold in the takeout process, so the same mold can produce more than two set products.
8) Set product surfaces have good lubricity.
9) Flashes due to the splitting of the mold are very thin (30–50 μ), and there is little fear of causing dimensional changes in the height of the bite.
10) Partial arrangement of materials, different in mechanical strength, is possible.

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Fig. 8 LTV vinyl silicone mixture



Fig. 9 Mixture is filled into mold by syringe

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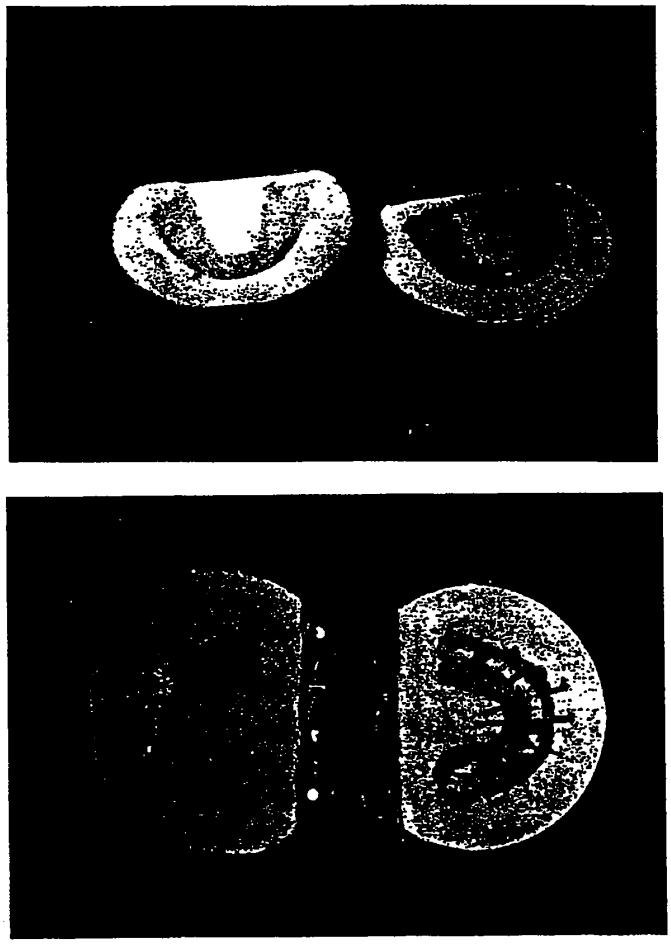


Fig. 10 Mixture is filled

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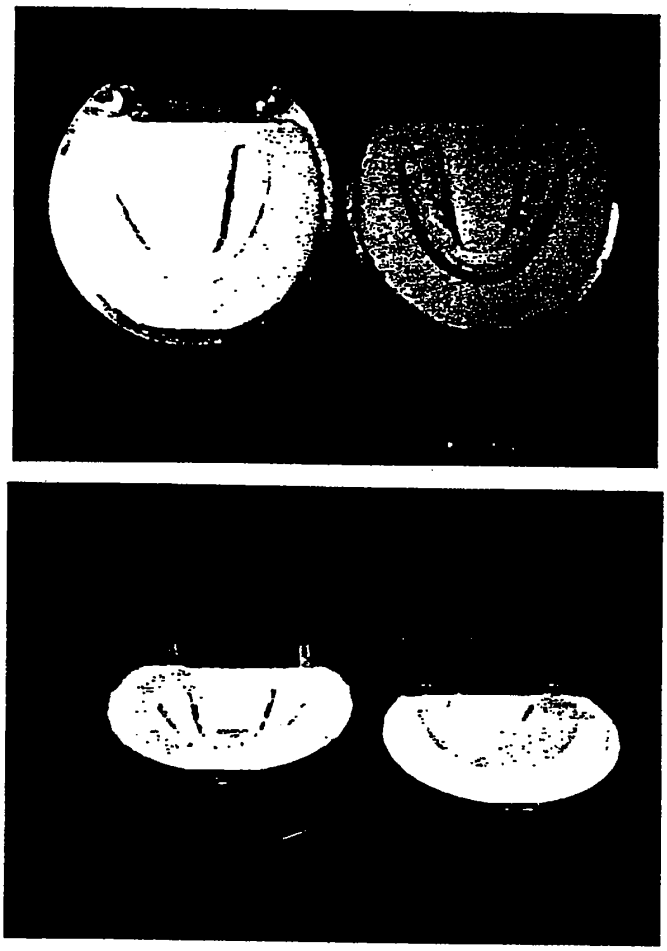


Fig. 11 After curing flasks are separated

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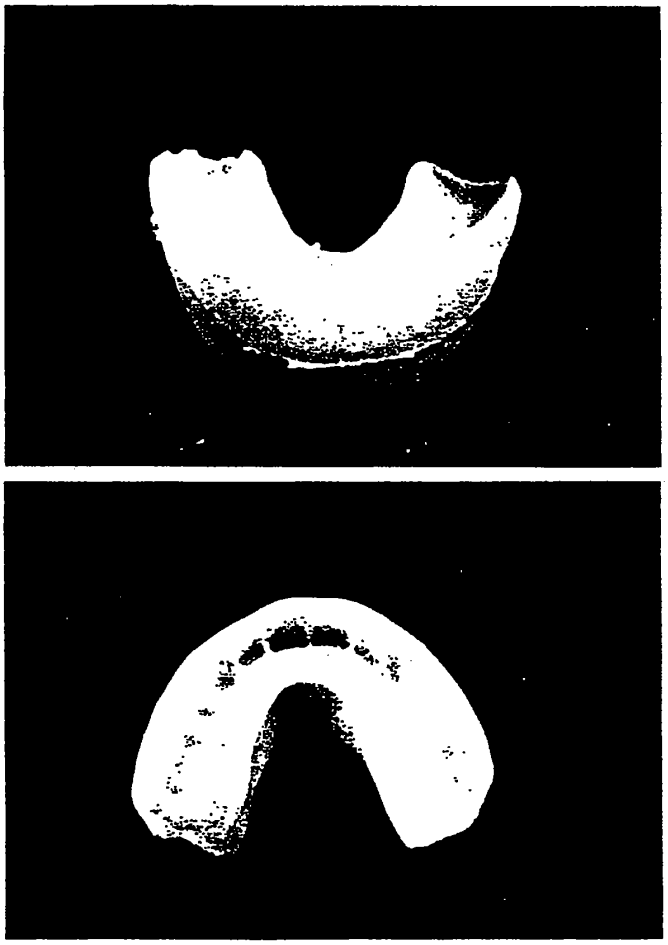


Fig. 12 Tooth positioner immediately after takeout

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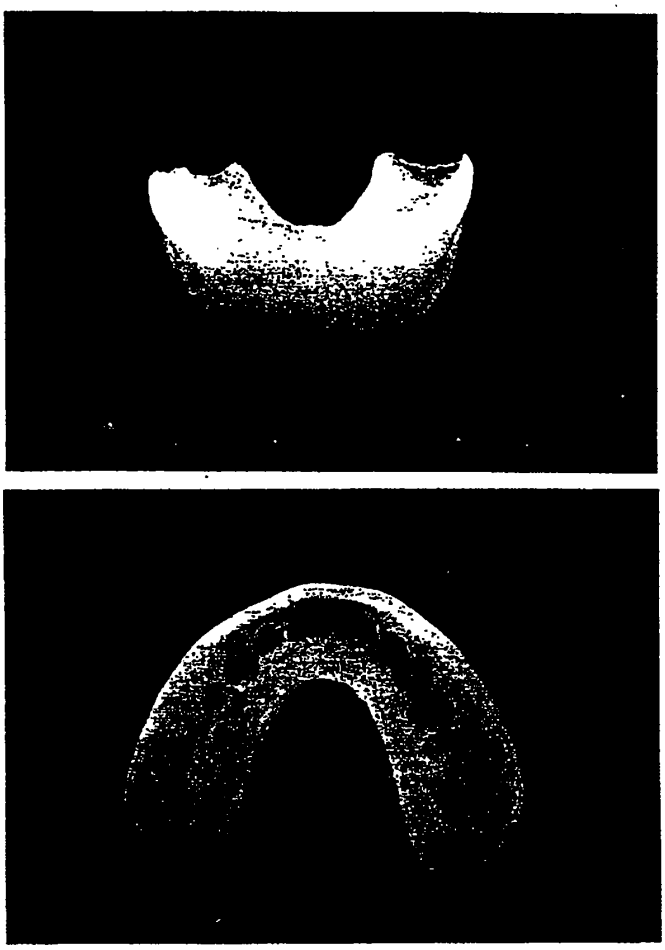


Fig. 13 Completed tooth positioner (Regular type)

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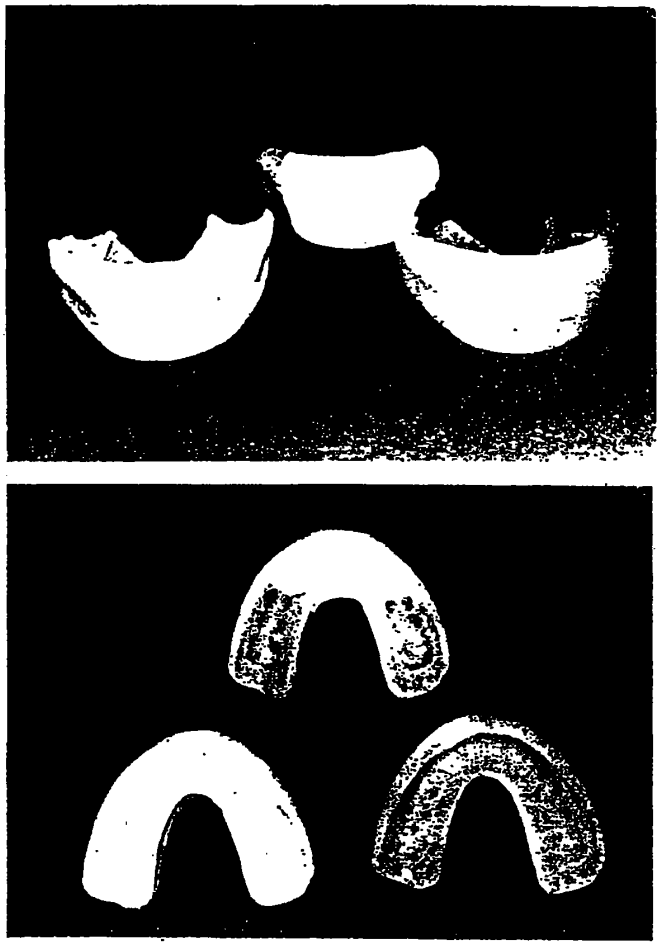


Fig. 14 Completed tooth positioners (Left: hard type, Center: combination of regular and hard types, Right: regular type)

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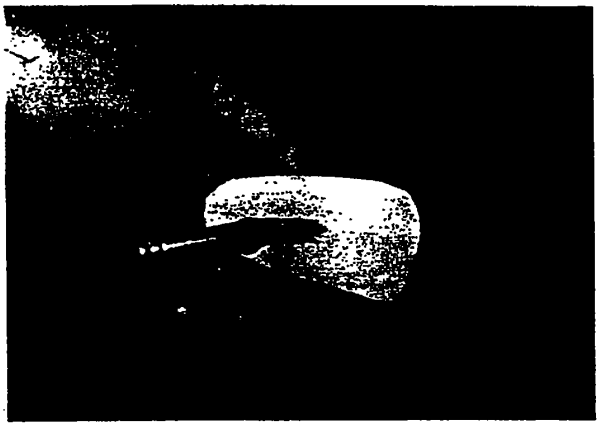


Fig. 15 Coating of glazing agent

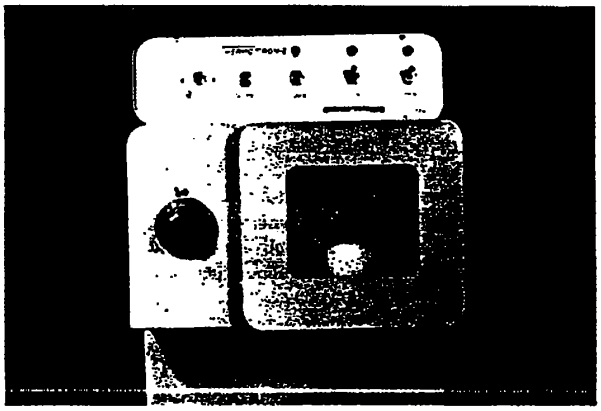


Fig. 16 Vulcanization of glazing agent

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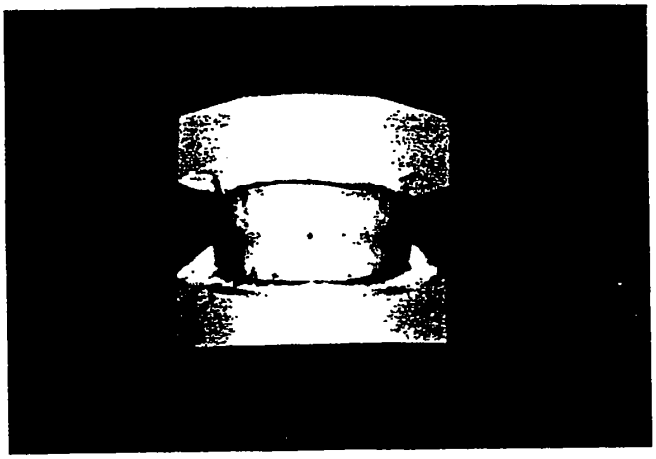


Fig. 17 A tooth positioner in position on the set-up model

Case Reports

The following are outlines of adaptive cases for tooth positioners. the period to start application. practical instructions and four representative clinical cases selected from more than 80 the authors have previously treated. Case I: maxillary protrusion. Case II: reversed occlusion. Case III: a tooth positioner used as an active retainer. and Case IV: a tooth positioner used in the process of periodontal treatment.

1. Adaptive cases

Adaptive cases for tooth positioners are malocclusions mainly due to odontogenic and functional factors. of which careful analysis and accurate diagnosis are required.

Adaptive cases are as follows: odontogenic and functional maxillary protrusion. mandibular protrusion. deep overbite. cross-bite. denture guidance. adjustment of slightly rotated teeth and inclined teeth. closure of spaces between teeth. adjustment for preferable intercuspal relationships and retention.

2. Period to start application

Orthodontic treatment is most frequently performed in the mixed dentition period. which is considered to be the most suitable period to start treatment. So it is in the case of tooth positioners whose clinical effect is heightened when applied in this period.

3. Practical instructions

When removable appliances such as tooth positioners are applied. the patients' cooperation is urgently required. so much so that parents should be well informed as to the purpose and meaning of such appliances.

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4. Case repor

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The longer the tooth positioner is applied the better. The orthodontic force of the tooth positioner depends upon its rubber-like elasticity that gives a continuous light force to the teeth. Patients, therefore, are requested to come once a month for the following checks: whether the appliance is being used correctly, kept clean or damaged and when treatment should proceed to the next step. The orthodontic force should be adjusted by the selection of materials in accordance with the amount of tooth movement on the set-up model.

4. Case reports

1) Case I

This was a girl, 10 years and 6 months of age on her first visit. Her chief complaint was protrusion of the upper incisors (Fig. 18). The occlusal findings were of an Angle Class I, 6 mm overjet.

From the cephalometric analysis results, it was diagnosed as maxillary protrusion mainly caused by an odontogenic factor due to excessive labial inclination of the upper incisors.

The treatment plan was to perform lingual movement and space closure of the upper incisors. That is, in the 1st stage: space closure and improvement of the overbite and overjet, in the 2nd: achievement of a preferable intercuspal position, and in the 3rd: retention. A tooth positioner was prepared for these purposes. A set-up model was also prepared in accordance with the 3 stages of the treatment plan.

Treatment required 10 months in the 1st and 2nd stages and 7 months in the 3rd (observation period).

Fig. 19 shows the tooth positioner mounted in the oral cavity in the 1st stage of treatment. In such a remarkable case of maxillary protrusion, the maxillary portion of the tooth positioner should have some slits to divide its orthodontic force so that the lighter force can be given to the teeth[5].

Fig. 20 shows the oral cavity after treatment: the upper incisors moving in the lingual direction, the spaces closing, the overbite and overjet improved and the intercuspal position becoming preferable. The results proved to be satisfactory.

2) Case II

This was a boy, 9 years and 8 months of age on his first visit. His chief complaint was lower lip protrusion (Fig. 21). The occlusal findings showed an Angle Class III tendency. The upper right and left central incisors and the lateral incisors showed reverse overjet. Again, from the fact that a construction bite could be taken with the mandible retracted, it was diagnosed as functional reverse occlusion. Cephalometric analysis also disclosed a slight inferior growth of the maxilla.

Like Case I, the treatment was planned in 3 stages. The 1st stage was to improve the malalignment of the anterior teeth as quickly as possible and to remove the obstruction of premature contact. The labial expansion of the 4 upper incisors and the lingual movement of the 4 lower incisors were performed for rearrangement. In the 2nd stage, a set-up model was prepared for the purpose of improving the molar occlusal relationship and to guide the eruption of the buccal segments. Using a model with the anterior overlap improved, the upper and lower first molars were rearranged to be in the normal position. At the same time, the missing areas of the right and left deciduous 2nd molars were filled with wax equivalents of permanent

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Fig. 18 Case I (Top) Anterior view before treatment (Center and Bottom) Lateral views before treatment



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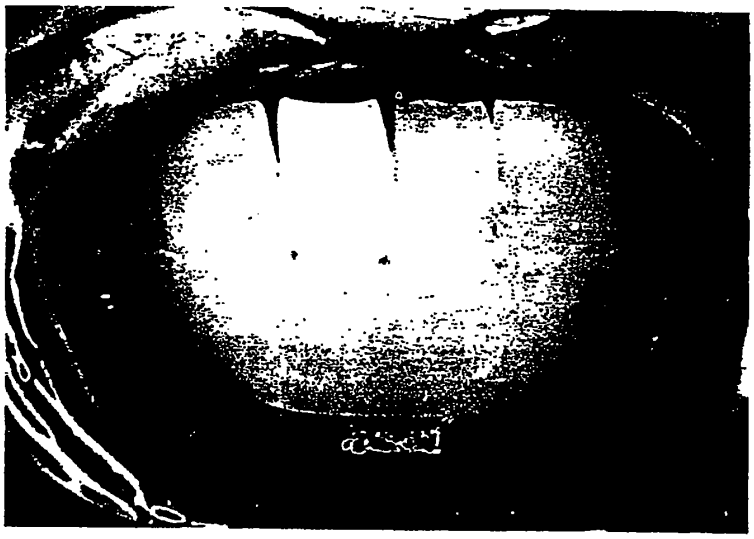


Fig. 19 A tooth positioner with slits

crowns that would erupt later to guide the eruption of the buccal segments.

Fig. 22 shows the oral cavity a month after the tooth positioner was mounted. The overlap of the 4 upper incisors has improved.

Fig. 23, the oral cavity after 15 months showing a preferable anterior occlusal relationship. Hereafter, the treatment is expected to proceed to the 3rd stage, final retention, after the eruption of the lower mandibular second premolars.

3) Case III

This was a case in which a tooth positioner was used as an active retainer in a boy, 9 years and one month of age on his first visit. His chief complaint was lower lip protrusion diagnosed as Angle Class III. The full band system was applied to the treatment and the active treatment period was 19 months. The purpose for the tooth positioner in this case was to improve and retain the intercuspal position of the buccal segments (Fig. 24). A stable occlusal relationship was obtained 3 months after the application of the tooth positioner and the total retention period was 8 months (Fig. 25).

4) Case IV

This was a 33-year-old man for whom a tooth positioner was used for the purposes of closing the spaces between his teeth, improving the intercuspal positions and reducing the patient's feeling of a double protrusion (Fig. 26, top).

This is one of the clinical cases most frequently seen, in which a malocclusion such as malposition of the teeth and axiversion causes and aggravates periodontal disease. In such cases, the malocclusion should be improved to promote treatment

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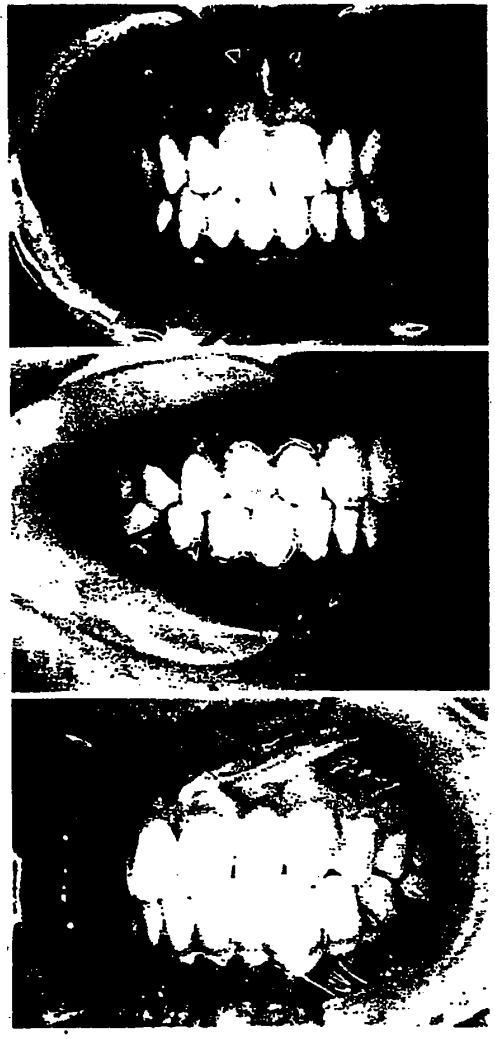
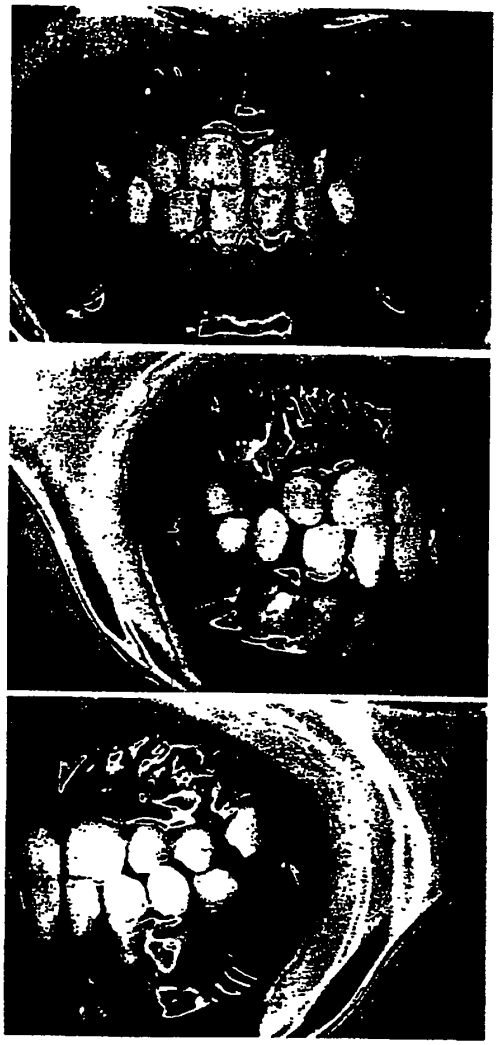


Fig. 20 Case 1 (Top) Anterior view after treatment (Center and Bottom) Lateral views after treatment

Fig. 21 Case
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Lateral

Fig. 21 Case II (Top) Anterior view before treatment (Center and Bottom) Lateral views before treatment

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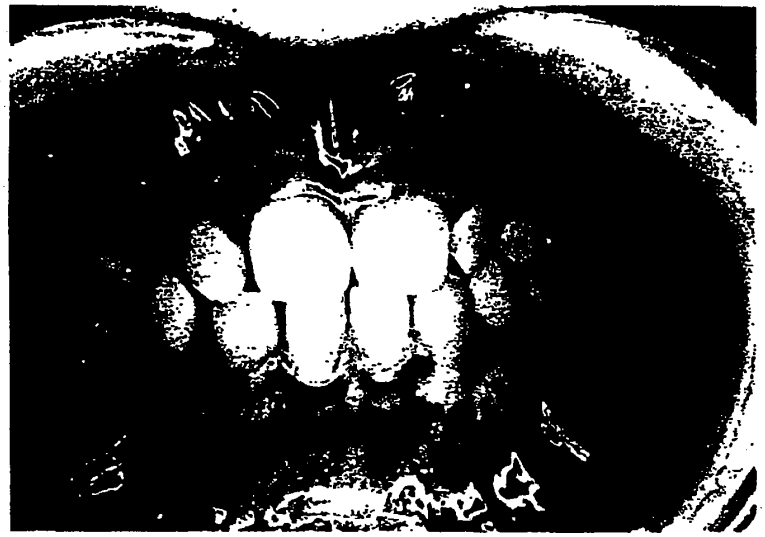


Fig. 22 Case II Anterior view after one month

of the periodontal disease. Fundamental treatment of the disease is of course necessary, but its effects are heightened by the simultaneous use of orthodontic treatment.

Fig. 26, top, shows the oral cavity immediately after fundamental treatment for the periodontal disease was finished. The anterior overlap is insufficient, double protrusion and spaces between the teeth are observed and the intercuspal position of the buccal segments is unstable.

The treatment plan was to improve the abnormalities shown above, to give preferable influence not only to the anterior teeth but also to the periodontal tissues of the molar teeth and to secure the remarkable effects of treatment, functionally and aesthetically. Patients are always very much interested in aesthetic improvements. In the present case, from the beginning, the set-up model was arranged to show the normal overlap.

Fig. 26, bottom, the oral cavity 4 months after the application of the tooth positioner showing that a stable occlusal relationship was obtained. The treatment was followed by fixation through periodontal treatment.

As shown above, the present material has excellent rubberlike elasticity and a wide area of action which makes it possible to move the teeth to a greater degree as compared with the existing materials for tooth positioners. Considering these merits and its preferable manipulability, wide application would be expected regarding tooth movement.

Fig. 23
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Fig. 23 Case II (Top) Anterior view after 15 months (Center and Bottom) Occlusal views after 15 months

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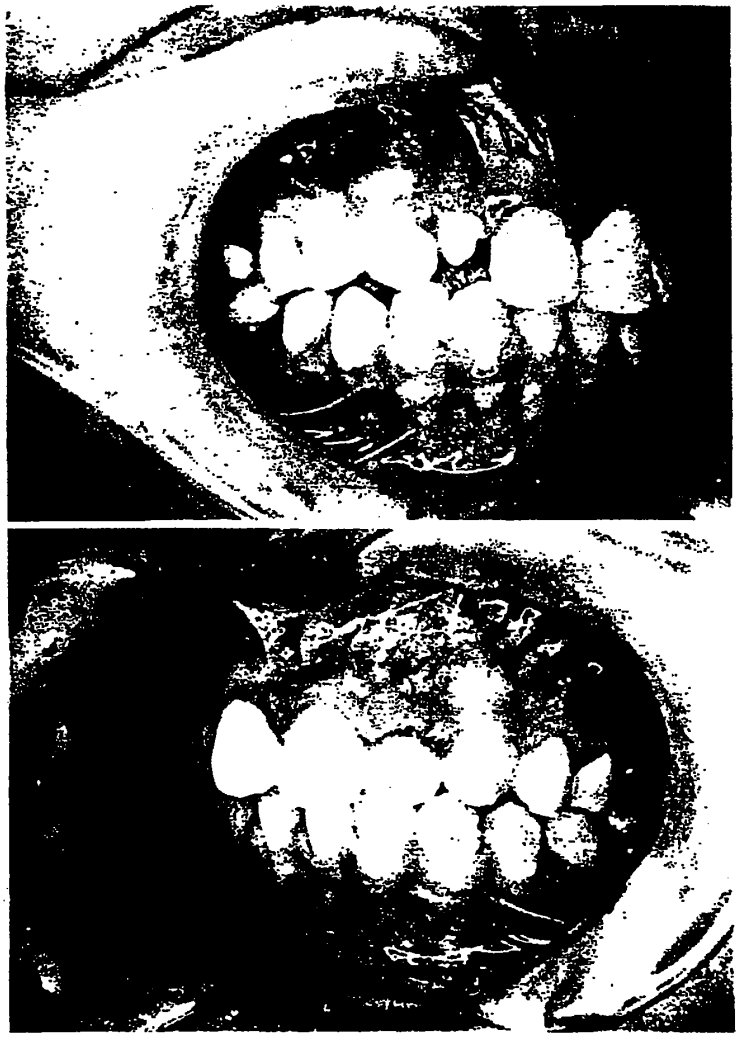


Fig. 24 Case III (Top and Bottom) Lateral views before setting of the tooth positioner



Fig. 25 Cas

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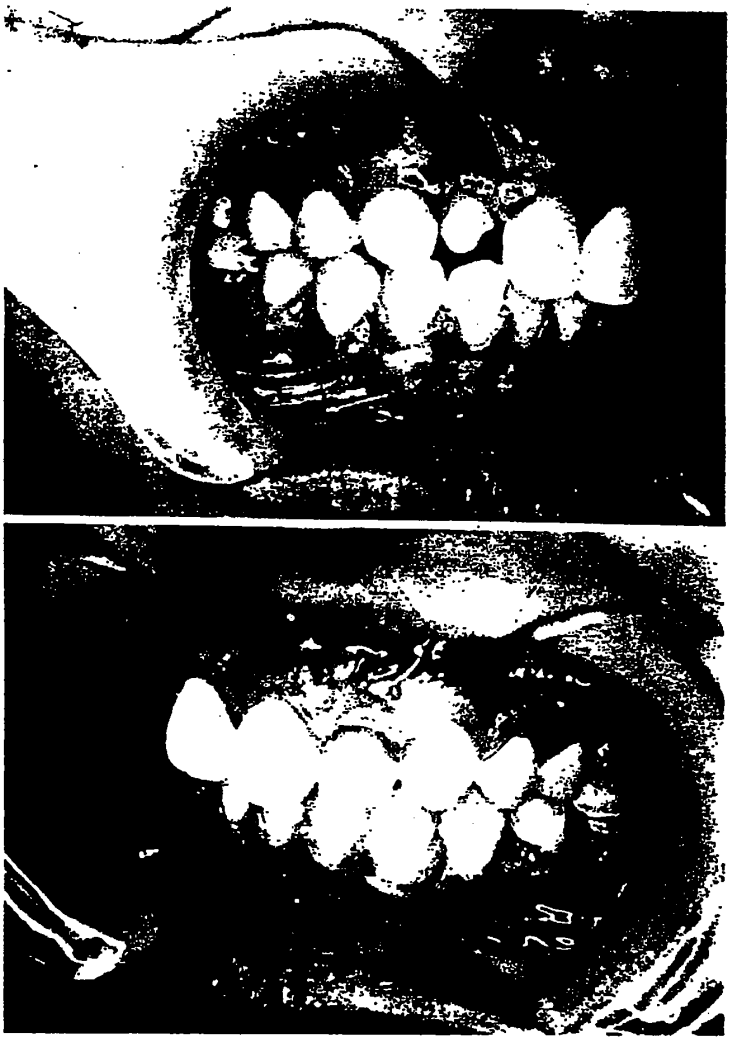


Fig. 25 Case III (Top and Bottom) Lateral views after treatment with the tooth positioner

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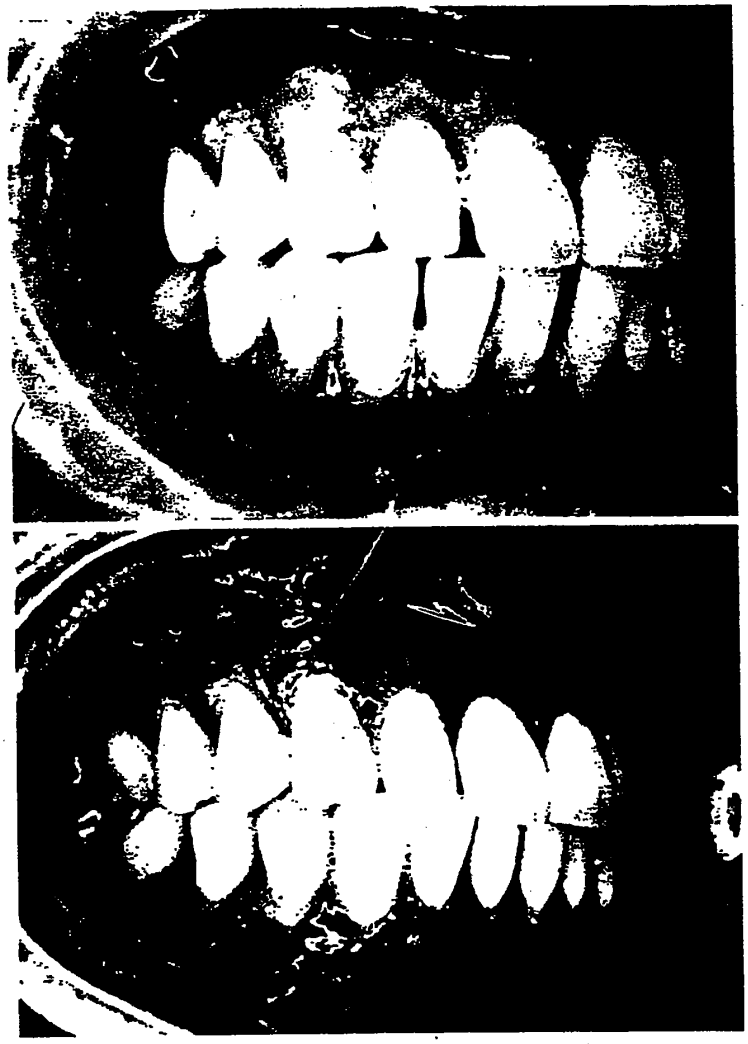


Fig. 26 Case 1V (Top) Lateral view before treatment with the tooth positioner (Bottom) Lateral view after treatment with the tooth positioner

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Conclusion

This paper introduced the properties of LTV vinyl silicone rubber as a new type of dental material, the method for preparing tooth positioners with this material and some case reports. As we have seen, the present material is easy to manipulate and has excellent physical properties especially in elasticity. Again, because the present material has preferable adhesiveness to methacrylate resin[13], it is possible to make various kinds of dental appliances with this material used together with denture relining material, denture splint material and other methacrylate resins. Its wide application, therefore, would be expected.

References

[1] Yoshii, O.: Studies on orthodontic rubber materials (Part 3); *J. Stomatol. Soc. Jpn.*, Vol. 40, 103–121, (1973). (in Japanese)

[2] Nishiyama, M., Kamada, K. and Horiuchi, S.: A new construction of tooth positioners with LTV vinyl silicone rubber; *J. Nihon Univ. Sch. Dent.*, Vol. 19, 93–102, (1977, published in 1979).

[3] Nishiyama, M. et al.: Studies on tooth positioner materials—Application of LTV vinyl silicone rubber—; *Nihon Univ. dent. J.*, Vol. 53, 491–498, (1979). (in Japanese)

[4] Yoshii, O.: New orthodontic device-dynamic positioner (D.P)—I. Approach to the proposal of D.P and transparent silicone rubber; *The Nippon Dental Review*, No. 452, 61–74, (1980). (in Japanese)

[5] Yoshii, O.: New orthodontic device-dynamic positioner (D.P)—II. Practical application and construction of D.P; *The Nippon Dental Review*, No. 454, 107–130, (1980). (in Japanese)

[6] Yoshii, O.: New orthodontic device-dynamic positioner (D.P)—III. Case reports of reversed occlusion; *The Nippon Dental Review*, No. 457, 146–164, (1980). (in Japanese)

[7] Yoshii, O.: New orthodontic device-dynamic positioner (D.P)—III. Case reports of reversed occlusion (Part 2); *The Nippon Dental Review*, No. 458, 112–129, (1980). (in Japanese)

[8] Kesling, H. D.: The philosophy of tooth positioning appliances; *Amer. J. Orthodont.*, Vol. 31, 297–304, (1945).

[9] Kesling, H. D.: Coordinating the predetermined and tooth positioner with conventional treatment; *Amer. J. Orthodont.*, Vol. 32, 285–293, (1946).

[10] Sugimura, H. et al.: Materials for tooth positioners; *J. Jap. Orthod. Soc.*, Vol. 25, 106–114, (1966). (in Japanese)

[11] Prescott, M. A. and Fartman, A.: Construction of silicone rubber tooth positioners in your own laboratory; *J. Practical Orthodont.*, Vol. 2, 456–460, (1968).

[12] Wells, N.E.: Application of the positioner appliance in orthodontic treatment; *Amer. J. Orthodont.*, Vol. 58, 351–366, (1970).

[13] Nishiyama, M. et al.: Studies on vinyl silicone rubber—Its composition and basic properties—; *JDMA*, Vol. 35, 370–377, (1979). (in Japanese)

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Three-dimensional Measurements of the Occlusal Surfaces of Upper Molars in a Dutch Population

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The occlusal surfaces of the first upper molars of a Dutch population were measured three-dimensionally by moiré contourography. Cusps and ridges were higher than those of a Japanese population, but distances between cuspal tips were smaller. Differences in occlusal form may influence jaw movements in the two populations.

J Dent Res 63(11):1298-1301, November, 1984

Introduction.

A detailed three-dimensional description of the micro-relief of the molar occlusal surface has been difficult to obtain. We have already reported sex differences of the micro-relief and the relation between the height of cusps and the size of the tooth in a Japanese (Mongoloid) population in which the teeth were measured three-dimensionally by moiré contourography (Kanazawa *et al.*, 1983; Sekikawa *et al.*, 1983). In the present study, the molar teeth of a Dutch (Caucasoid) population from the Bolk collection were also measured with the same method, and results obtained were compared with those for the Japanese population.

Materials and methods.

Materials used were the teeth collected by the late Professor L. Bolk of the Department of Anatomy, University of Amsterdam. The collection was obtained at the time of the closing of two large cemeteries in Amsterdam. It contains a large number of skulls with complete dentitions. The teeth were extracted and sorted according to tooth type, and were stored in black wax plates. Most of the teeth were obtained just after or before eruption and had suffered no attrition. This large collection of teeth has been used for anthropological research by several authors. For instance, Jørgensen (1955) studied the frequency of the Dryopithecus pattern in lower molars. Fujita (1965) discussed the tooth shape difference between the Japanese and the Dutch, and concluded that Japanese teeth have a rather well-developed crown as compared with the root, while the Dutch have a smaller crown and a longer root.

In three-dimensional measurements, it is of importance to measure complete teeth with little attrition, because the heights of cusps or the depths of grooves and the micro-relief patterns must be measured accurately. Therefore, the number of extracted teeth which are available for measurement is unavoidably limited. However, the specimens used in this study are considered to be sufficient in number and in quality for our purposes. The specimens used were 21 upper right first molars and seven upper left first molars of unknown sex.

Plaster casts were made directly from the teeth with the use of a vinyl silicone impression material (Fig. 1). Their crowns were photographed by moiré contourography. Since details of the moiré apparatus and the photographic technique have already been published elsewhere (Ozaki *et al.*, 1984), here we describe them briefly.

A cast of a molar tooth was set in the position of the standard tri-cuspal plane (Korenhof, 1960; Ozaki *et al.*, 1977), where the cuspal tips of protocone, paracone, and metacone were set in the same plane parallel to the horizontal grating. The camera used was a Nikon F-2 with a Micro-Nikkor 105 mm lens and PN-11 closing-up ring. The grating had a pitch of 0.2 mm. The distance between the principal point of the lens and the center of the light was adjusted to 260.0 mm, and that between the lens and the grating was 260.4 mm. Contour interval in this condition was 0.200 mm between the first and the second fringes. The film used was Kodak Tri-X Pan, which was developed at ASA 1600. Photography was carried out in a darkroom with f/32 at 1/2 second of exposure.

A moiré photograph (Fig. 2) obtained from each tooth was enlarged eight times and put on a digitizer connected to a microcomputer into which coordinate values of the eleven measuring points (Fig. 3) were entered at an accuracy of 0.02 mm. The heights of the points were obtained by means of counting contour lines from the deepest point in the occlusal surface (fossa mesiobuccalis). Interpolation of the contour interval was made to the accuracy of 0.05 mm. From these three-dimensional coordinate values, all the distances between measuring points were calculated.

Results.

Macroscopically, the teeth had rather high cusps and conspicuous main and accessory ridges (Fig. 1). The hypocone sometimes had a developed accessory ridge and was distinctly separated from the other three cusps by the distal lingual groove, which was usually deep, like a fissure. Averages of mesiodistal and buccolingual diameters were 10.6 ± 0.40 (S.D.) mm and 11.1 ± 0.68 (S.D.) mm, respectively. The buccolingual diameter was smaller than the Japanese average of 11.8 mm.

The oblique ridge is formed by the continuation of the central ridge of metacone and the distal accessory ridge of protocone. This pattern of formation had hardly any variability in these materials. In the Japanese population, however, cases in which the distal accessory ridge of the metacone takes part in this oblique ridge were found in 13% of subjects (Sekikawa *et al.*, 1983). The Dutch specimens contained no types with reduced metacone and hypocone.

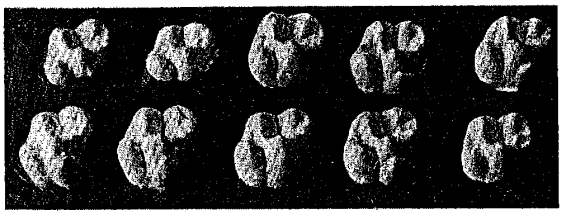


Fig. 1 – Upper first molars in Bolk's collection used in this study.

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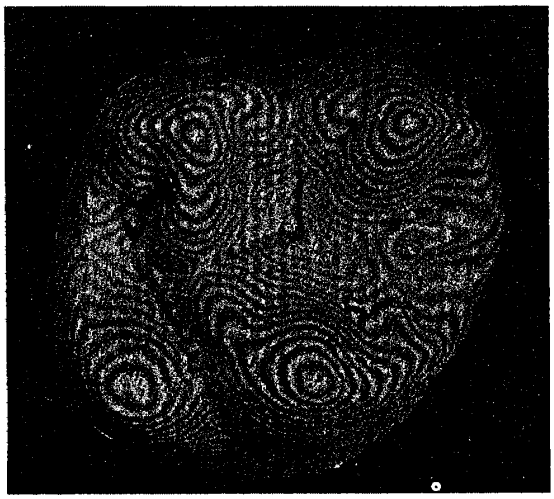


Fig. 2 – An example of a moiré photograph of the occlusal surface of an upper first molar used for measurement in this study. Contour interval is 0.2 mm.

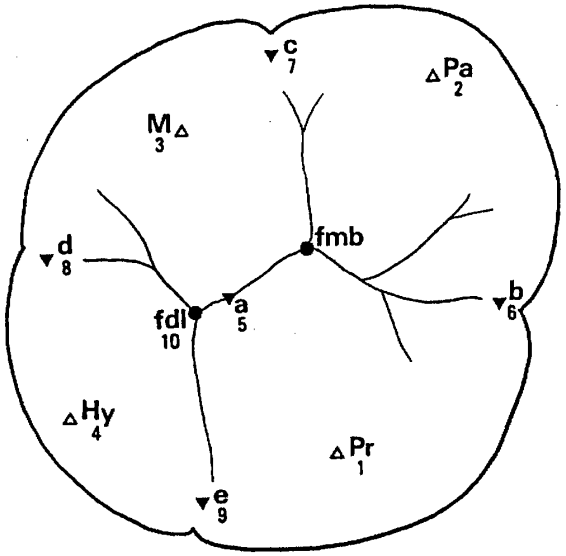


Fig. 3 – Measuring points on the occlusal surface of an upper first molar. Pa, Paracone; Pr, Protocone; M, Metacone; Hy, Hypocone. *a*, the lowest point on the oblique ridge; *b*, *c*, *d*, and *e*, the lowest points of marginal and cutting edges between four cusps. *fdl*, fossa disto-lingualis; *fmb*, fossa mesio-buccalis.

Table 1 shows the means and standard deviations of heights of measuring points and distances between them. Item 1 is the height of three cusps (protocone, paracone, and metacone) which have the same values because their tips are positioned on the same horizontal plane. Items 2 to 8 are the heights of other points. Items 9 to 63 are all the distances between the measured points comprising items 1 to 8. The mean height of the three cusps was 2.96 mm, which is much higher than the corresponding average

TABLE 1
MEAN AND S.D. (IN mm) OF 63 ITEMS ON THE OCCLUSAL SURFACE OF THE UPPER FIRST MOLAR IN A DUTCH POPULATION

No.	Items	Mean	S.D.	No.	Items	Mean	S.D.
1	3 Cusps	2.96	0.26	33	b-Hy	7.99	0.55
2	Hy	2.06	0.36	34	b-fmb	4.05	0.35
3	a	1.22	0.23	35	b-fdl	6.71	0.47
4	b	1.30	0.37	36	b-a	5.73	0.41
5	c	1.61	0.23	37	c-Pa	2.70	0.30
6	d	0.61	0.46	38	c-Pr	6.20	0.47
7	e	1.16	0.35	39	c-Me	2.23	0.25
8	fdl	0.07	0.28	40	c-Hy	7.30	0.40
9	Pr-Pa	6.01	0.49	41	c-fmb	2.67	0.33
10	Me-Pa	4.75	0.41	42	c-fdl	4.93	0.31
11	Me-Pr	6.12	0.55	43	c-a	4.04	0.30
12	Hy-Pa	8.54	0.49	44	c-b	5.58	0.37
13	Hy-Pr	4.24	0.39	45	d-Pa	7.55	0.44
14	Hy-Me	5.88	0.43	46	d-Pr	6.03	0.47
15	fmb-Pa	3.30	0.32	47	d-Me	3.35	0.38
16	fmb-Pr	3.56	0.38	48	d-Hy	3.47	0.48
17	fmb-Me	3.04	0.37	49	d-fmb	4.66	0.37
18	fmb-Hy	5.28	0.38	50	d-fdl	2.13	0.41
19	fdl-Pa	6.45	0.43	51	d-a	2.86	0.35
20	fdl-Pr	3.92	0.40	52	d-b	8.52	0.51
21	fdl-Me	3.51	0.35	53	d-c	5.40	0.38
22	fdl-Hy	2.43	0.30	54	e-Pa	7.34	0.40
23	fdl-fmb	3.22	0.35	55	e-Pr	2.63	0.25
24	a-Pa	5.38	0.37	56	e-Me	5.55	0.39
25	a-Pr	3.46	0.41	57	e-Hy	1.65	0.31
26	a-Me	3.01	0.32	58	e-fmb	4.16	0.38
27	a-Hy	3.31	0.25	59	e-fdl	2.23	0.37
28	a-fmb	2.14	0.31	60	e-a	2.60	0.28
29	a-fdl	1.11	0.20	61	e-b	6.42	0.44
30	b-Pa	3.65	0.44	62	e-c	6.53	0.37
31	b-Pr	4.08	0.46	63	e-d	4.08	0.46
32	b-Me	6.90	0.50				

of 2.46 mm for the Japanese population (Table 2). Almost all the distances had smaller values as compared with those of a Japanese population.

Fig. 4 shows the items with significant differences between the two populations at the 1% level of probability. The population difference is especially great for the distance items between the three main cusps and between Pa and Hy. Items referred to the points *c*, *d*, and *e* showed no significant differences. These points are considered to have rather high variability in their position.

Fig. 5 shows the significant correlation coefficients at the 5% and 1% level between the first 29 items. Items 1 to 8 showed significant correlations within the same height group. Items 9 to 29 were also highly correlated with items within the distance group. Especially, items 9, 10, 11, 12, 14, 16, 19, and 24 (which are larger distances than the others) had high correlations with many items of the distance group. On the other hand, items 13, 15, 17, 22, 27, and 29 (which are smaller distances and contain more variable points) had only weak correlations with other items. Significant correlations between height and distance items were very few. This tendency was also found in a Japanese population (Kanazawa *et al.*, 1983; Sekikawa *et al.*, 1983).

Discussion.

Three-dimensional measurement of the teeth has been considered to be of importance in tooth morphology (Lavelle, 1978). However, to date, the measurement of the tooth has been limited to a one-dimensional (or caliper)

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TABLE 2
MEANS AND S.D. OF 33 ITEMS ON THE OCCLUSAL SURFACE OF THE UPPER FIRST MOLAR IN TWO POPULATIONS

Items	Item Number in This Study	Dutch Mean	Dutch S.D.	Japanese Mean	Japanese S.D.	Inter-population Difference
3 cusps	(1)	2.96 #	0.26	2.46	0.23	**
Hy	(2)	2.06 #	0.36	1.88	0.33	*
a	(3)	1.22 #	0.23	0.81	0.21	**
b	(4)	1.30 #	0.37	0.96	0.35	**
c	(5)	1.61 #	0.23	1.39	0.26	**
d	(6)	0.61 #	0.46	0.45	0.35	
e	(7)	1.16 #	0.35	1.02	0.26	*
fdl	(8)	0.07	0.28	0.17 #	0.28	
Pr-Pa	(9)	6.01	0.49	6.88 #	0.55	**
Me-Pa	(10)	4.75	0.41	5.10 #	0.49	**
Me-Pr	(11)	6.12	0.55	6.78 #	0.56	**
Hy-Pa	(12)	8.54	0.49	9.09 #	0.63	**
Hy-Pr	(13)	4.24	0.39	4.35 #	0.48	
Hy-Me	(14)	5.88	0.43	6.15 #	0.63	*
fmb-Pa	(15)	3.30	0.32	3.98 #	0.39	**
fmb-Pr	(16)	3.56 #	0.38	3.54	0.37	
fmb-Me	(17)	3.04	0.37	3.68 #	0.51	**
fmb-Hy	(18)	5.28 #	0.38	5.17	0.53	
fdl-Pa	(19)	6.54	0.43	6.94 #	0.51	**
fdl-Pr	(20)	3.92	0.40	4.83 #	0.61	**
fdl-Me	(21)	3.51 #	0.35	3.32	0.41	*
fdl-Hy	(22)	2.43	0.30	2.95 #	0.40	**
fdl-fmb	(23)	3.22	0.35	3.47 #	0.46	*
a-Pr	(25)	3.46	0.41	3.48 #	0.35	**
a-Me	(26)	3.01	0.32	3.26 #	0.39	**
b-Pa	(30)	3.65	0.44	4.09 #	0.63	**
b-Pr	(31)	4.08	0.46	4.45 #	0.61	**
c-Pa	(37)	2.70	0.30	2.82 #	0.29	
c-Me	(39)	2.23	0.25	2.38 #	0.32	*
d-Me	(47)	3.35	0.38	3.65 #	0.52	**
d-Hy	(48)	3.47 #	0.48	3.39	0.49	
e-Pr	(55)	2.63	0.25	2.74 #	0.35	
e-Hy	(57)	1.65 #	0.31	1.58	0.30	

The symbol # indicates the larger value in the two populations. Asterisks denote the significant inter-population differences at the level of 5% (*) and 1% (**), respectively.

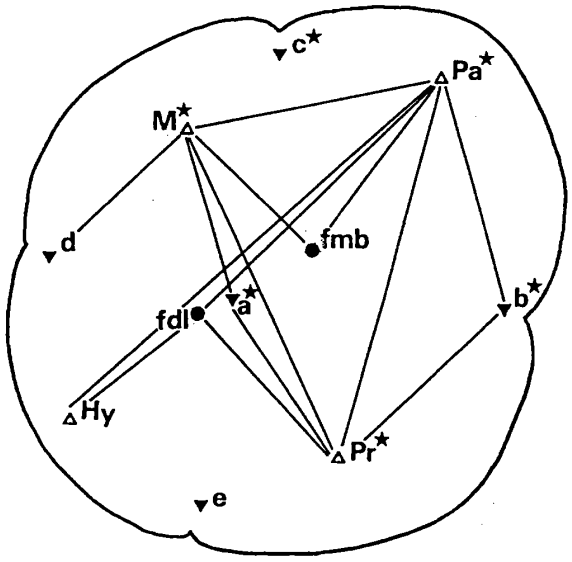


Fig. 4 – Schematic diagram showing differences of items used in this study between two populations. Asterisks and lines denote height of points and distances between them, respectively, having significant differences at the level of 1%.

method or a two-dimensional geometrical analysis. For instance, mesiodistal or buccolingual measurements of tooth crown size, classification of groove pattern of the occlusal surface by means of macroscopic observation, quantitative analysis of anomalous tubercles, determination of the frequency of occurrence of non-metrical characters, and so on, have been carried out. These studies are not sufficient to describe the detailed three-dimensional relief of the occlusal surface. Groove patterns, for example, are far more complicated from the three-dimensional point of view than what would be imagined from two-dimensional illustrations in a textbook.

Recent development of the three-dimensional measurement technique is found in various fields such as holography, rasterstereogrammetry, and stereophotogrammetry. These techniques have just started to be applied to tooth morphology. The moiré method is one of those techniques, which is able to obtain successive contour lines directly on an object (Takasaki, 1970). It has been quite widely used (Drerup *et al.*, 1983), especially in the medical field. For dental morphology, this technique has not been used because of the difficulty of obtaining the fine pitch of contour lines. The contour interval, 0.2 mm in this study, is thought to be necessary to represent minute relief and is sufficient to measure the depth of the occlusal surface with the aid of the interpolation method. A finer pitch would lead to difficulty in counting contour lines.

Fujita (1965) measured the teeth in Bolk's collection and compared them with those of Japanese subjects. Japanese teeth have larger crowns and shorter roots than Dutch teeth, and thus Japanese teeth are thick and short in general form, while Dutch teeth are slender and long. One of our findings was that the occlusal surfaces in Japanese molars have long intercuspal distances and low cusps, while those in Dutch molars have short intercuspal distances and high cusps. There might be common genetic or developmental factors of tooth formation in the findings of these two studies.

We have shown that the correlation between items of height and distance is low. This indicates that the factors controlling the heights of the cusps and the transverse sizes of the crowns are nearly independent of each other. This kind of independence between tooth dimensions was found also in the human incisor, where mesiodistal diameter is independent of the buccolingual diameter (Kolakowski and Bailit, 1981). The variability of the crown form can be explained by developmental studies such as differentiation potential of inner enamel epithelium and accretion rate of enamel (Butler, 1955; Keene, 1982).

The height of the cusp is considered to have functional effects on occlusion, especially on jaw movements such as the sagittal condylar path, incisal path, side shift of the mandible, curve of Spee, and, moreover, on the form of the facial skeleton. However, anthropological surveys of these functional or morphological differences in relation to crown relief have not yet been done. Further studies on these aspects are needed from the functional point of view.

Acknowledgments.

We are indebted to the late Prof. J. van Limborgh, University of Amsterdam, for giving us an opportunity to make

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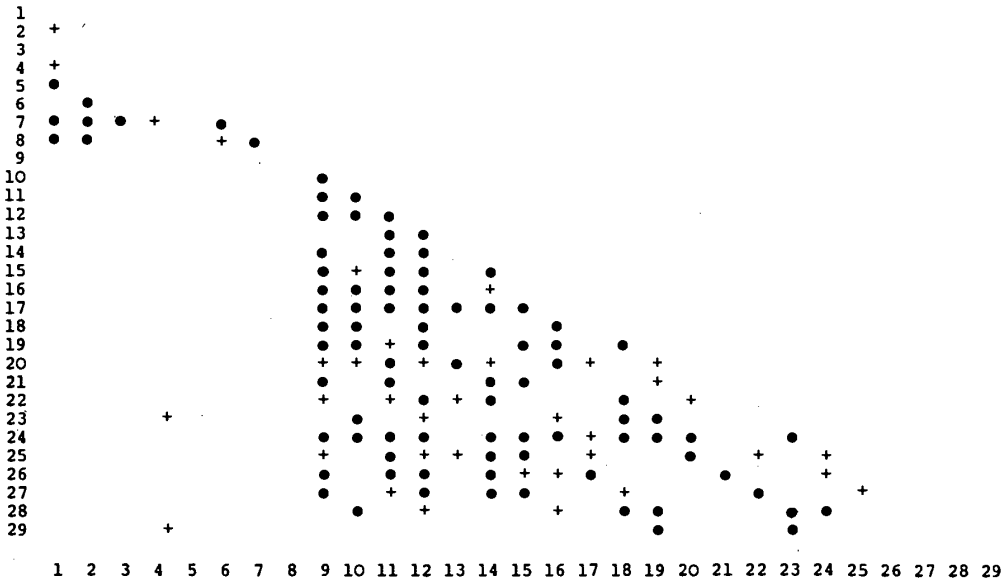


Fig. 5 – Schematic representation of correlation matrix of first 29 items. Items from 30 to 63 are omitted for simplification of the Fig. Symbols represent significance levels, + = 5% and • = 1%.

casts of teeth in Bolk's collection. Thanks are also due to Dr. H. Sakura, National Museum of Science, for his discussions.

REFERENCES

BUTLER, P. M. (1955): The Ontogeny of Molar Pattern, *Biol Rev* 31:30-70.

DRERUP, B.; FROBIN, W.; and HIERHOLZER, E. (1983): **Moiré Fringe Topography and Spinal Deformity.** Stuttgart and New York: Gustav Fischer Verlag, pp. 3-257.

FUJITA, T. (1965): Ha no Hanashi (The Tooth). Tokyo: Iwanami Publishing Co. Ltd. (in Japanese), pp. 60-63.

JØRGENSEN, K. D. (1955): The Dryopithecus Pattern in Recent Danes and Dutchmen, *J Dent Res* 34:195-208.

KANAZAWA, E.; SEKIKAWA, M.; and OZAKI, T. (1983): Three-dimensional Measurement of the Occlusal Surface of Upper First Molars in a Modern Japanese Population, *Acta Anat* 116: 90-96.

KEENE, H. J. (1982): The Morphogenetic Triangle: A New Conceptual Tool for Application to Problems in Dental Morphogenesis, *Am J Phys Anthropol* 59:281-287.

KOLAKOWSKI, D. and BAILIT, H. L. (1981): A Differential Environmental Effect of Human Anterior Tooth Size, *Am J Phys Anthropol* 54:377-381.

KORENHOF, C.A.W. (1960): **Morphogenetical Aspects of the Human Upper Molar.** Utrecht: Uitgeversmaatschappij Neerlandia, p. 103.

LAVELLE, C. L. B. (1978): An Analysis of Molar Tooth Form, *Acta Anat* 100:282-288.

OZAKI, T. and KANAZAWA, E. (1984): An Application of Moiré Method to Three-dimensional Measurement of the Occlusal Aspects of Molars, *Acta Morph Neerl-Scand* 22:85-91.

OZAKI, T.; OHNUKI, E.; and TSURUOKA, M. (1977): Occlusal Surface Index of the Molars in Indians, *J Anthrop Soc Nippon* 85:237-243.

SEKIKAWA, M.; OZAKI, T.; and KANAZAWA, E. (1983): A Study on the Cuspal Ridges of the Upper First Molars, Proc. 25th Meeting of Jpn Assoc Oral Biol 263 (in Japanese).

SEKIKAWA M.; AKAI, J.; NAMBU, A.; KANAZAWA, E.; and OZAKI, T. (1983): Three-dimensional Measurements of the Occlusal Surface of Lower First Molars in a Modern Japanese Population, *Jpn J Oral Biol* 25:737-744.

TAKASAKI, H. (1970): Moiré Topography, *Appl Optics* 9:1457-1472.

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Original Articles

THE PHILOSOPHY OF THE TOOTH POSITIONING APPLIANCE

H. D. KESLING, M.D.S., LA PORTE, IND.

THIS new appliance grew out of a desire to create some simple appliance that would influence all of the teeth to flow into their best possible position with relation to one another without any interference from bands or wires, that would be effective under functional forces, that would produce arch form in accordance with type, that would further attain the desired harmony between facial features and tooth arrangement, and that would serve as a retainer to conserve all the advantages gained above. As this appliance was developed, it was found to be most practical for the final artistic positioning and retention of the teeth after basic treatment had been accomplished.

In the last few years we have heard much about lack of bony base, mesial drift, bimaxillary protrusion, bimaxillary bony retrusion, and so forth. All of this has been expressed because of a realization of a lack of harmony and balance between the teeth, the jaws, and the features of the face. Perhaps no two operators would agree upon a certain pattern or profile as a typically beautiful face. It is quite encouraging that those teeth that have sufficient space in the denture to assume an upright position over their bony bases produce a pleasing profile and dentures of which the teeth are stable under functional forces. Perhaps this will be the media by which orthodontists in general will finally agree to some extent as to what constitutes balance and harmony of the dentures and facial contour.

Except in the presence of abnormal muscular habits, teeth that are unhampered by proximal contacts or inclined plane interference tend to assume positions which are stable as well as in balance with one another and with the immediate tissues surrounding them. Therefore, the diagnosis and plan of treatment of the average orthodontic case is greatly simplified when we accept our limitations of bone development and leave in each arch only those teeth

Read before the Fall Meeting of the New York Society of Orthodontists, Nov. 14, 1944.

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which will have sufficient space to be positioned upright and properly rotated, with correct proximal contacting. Then with the mechanics we have at hand, we can place the maxillary denture in its proper relation to the mandibular. With the exception of cases with exaggerated bone deformities, orthodontic cases have a very favorable prognosis when treated in this simple and realistic manner. It would be ideal to have a case treated from start to finish with an appliance that did not interfere with the proximal contacting of the teeth nor increase their mesial-distal dimensions. To date, the profession has not

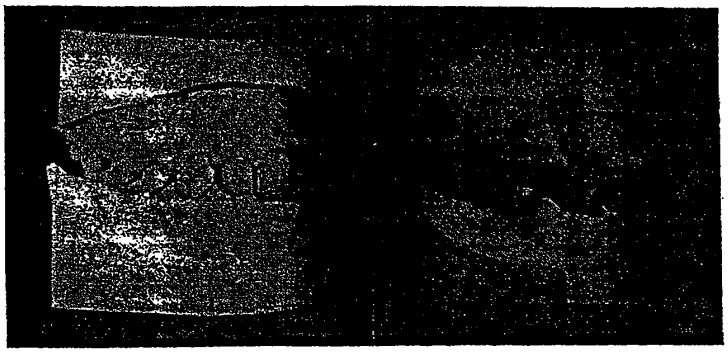


Fig. 1.—Basic treatment. Right, original model. Left, basic treatment model.

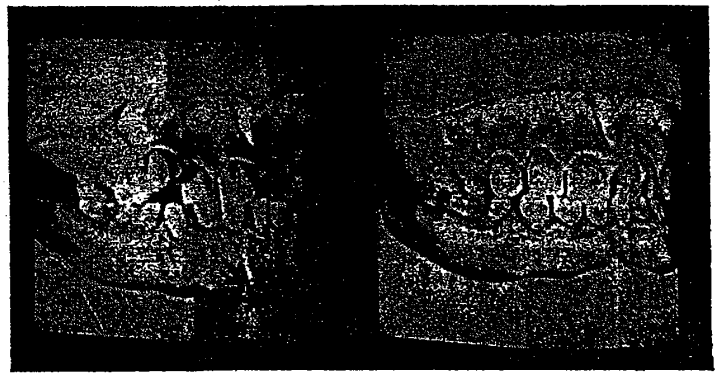


Fig. 2.—Basic treatment. Left, original model. Right, basic treatment. Note spaces.

been favored with an appliance that would adequately control the teeth that required major movements without banding or capping these teeth. We have in the "Tooth Positioning Appliance" an active treating appliance for the final artistic positioning of the teeth as well as an effective retaining device. This appliance allows the teeth to flow into their most ideal position without interference from bands, caps, or wires. Also, this appliance is most effective under functional forces.

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The proved practicability of the Tooth Positioning Appliance is for the final artistic positioning and retention of the teeth of cases that have already had basic treatment completed with a conventional type appliance. Basic treatment need only be carried until each tooth is properly rotated and is approaching its desired position. Arch form need not be ideal, slight spaces may remain, overbites may still be exaggerated, and mesial-distal or buccal-lingual relationships of the maxillary teeth to the mandibular need not be perfect so long as the cusps are starting into their proper inclined plane relationships.

At this point all of the bands and wires are removed and impressions are taken immediately. From the impressions two sets of models are prepared from hard plaster. The art portions of these models should be carved and proportioned like those of any display or study models of orthodontic cases. One of the models is used to make the setup and the other is used as a control. The teeth are dissected from the setup model and are rearranged in wax on these bases to the desired arch form, axial positioning, and occlusion. This gives the operator a chance to express himself in detail as to the arch form and tooth positioning he would prefer for each patient. All orthodontic treatment is tooth positioning, but here is a practical reason for positioning with the hands plaster teeth which are an exact reproduction of the crowns of the teeth in the mouth.

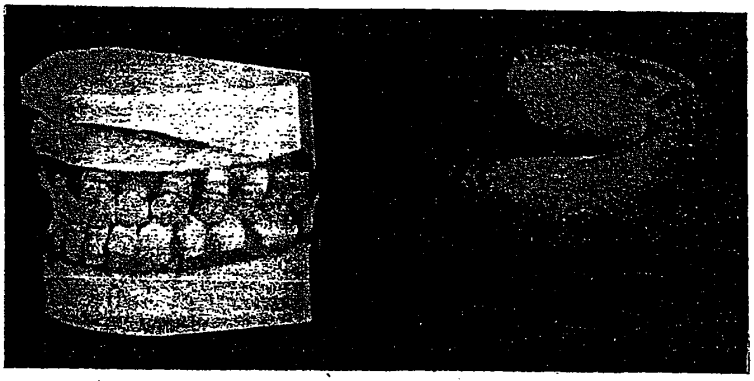


Fig. 3.—Setup and positioner. Left, setup model. Right, Tooth Positioning Appliance.

When completed, this setup model is used as a pattern over which the Tooth Positioning Appliance is constructed. The setup models are articulated on an anatomic articulator and the bite is opened to the physiologic rest position. The Positioner is a one-piece pliable rubber appliance that is made to completely fill the freeway space between the upper and lower dentures as well as to cover the labial, buccal, and lingual surfaces of both the maxillary and the mandibular teeth.

If basic treatment has been properly accomplished, each tooth will have sufficient space in the arch. The material of the Positioner allows it to stretch over the teeth, and while it is being worn its resiliency influences each tooth

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toward its position in the predetermined pattern, or setup. Experience has shown that in this way arch forms may be modified, slight rotations may be accomplished, and axial position influenced.

In the past after orthodontic treatment has been completed, the average orthodontist has depended upon Nature to settle the teeth into positions of balance and harmony. Examination of a cross section of orthodontic cases throughout the country reveals that this procedure has been disappointing, even where treatment has been carefully executed.

When the Positioner is applied at the end of major tooth movements, it takes advantage of the fact that in this condition the teeth are most susceptible to its gentle forces. The teeth are unstable from previous manipulation and respond to the influence of the Positioner very readily. Not only does the Positioner maintain the advantages gained by the conventional treatment, but the teeth are actually influenced toward more harmonious and stable positions through its wearing.

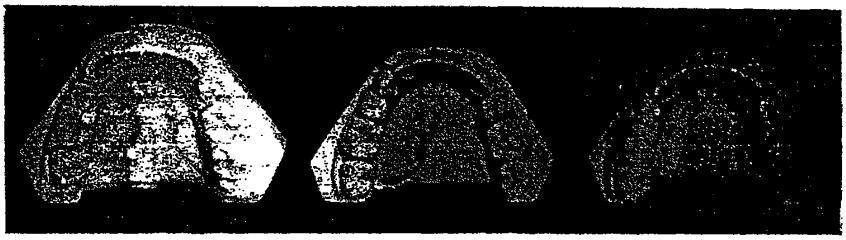


Fig. 4.—Changing arch form. Left, basic treatment model. Center, setup model. Right, model after treatment with Positioner.

Orthodontic service is certainly a personal service, and we can personalize it even more by developing a distinctive arch form and tooth arrangement according to type for each individual under treatment. With the predetermined pattern it is possible for the operator to shift the teeth within reason into any desirable position, and, in proportion to his artistic ability, to give each case a distinctive, artistic touch.

Every orthodontist has hoped to develop for each of his patients an arch form according to type. In the main this has failed, because, in a high percentage of the cases treated, arch forms have been produced that would allow the teeth to assume positions which would least resist the desired tooth movements. Thus, arch forms frequently have come to be a result of expediency rather than a true development according to type. In fairness, we must give credit to the rare orthodontist who takes the trouble and succeeds in developing each arch form in accordance with type after major tooth movements have been achieved.

Not infrequently, teeth of individuals under orthodontic treatment are tipped into abnormal axial positions. This is especially true in the molar and premolar areas where the teeth are invariably tipped buccally. With the Tooth Positioning Appliance, this condition can be corrected in the setup, and in the mouth

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the Positioner will influence the teeth, not only by reducing the arch width, but also by the functional forces working through the occlusal surfaces of the teeth, their roots being thrown buccally and their crowns lingually. Teeth so positioned with the Tooth Positioning Appliance will more nearly approximate the axial positioning of the same teeth in nonorthodontic normals.



Fig. 5.—Mesial-distal correction. Left, basic treatment model. Right, model after correction *with Positioner.*

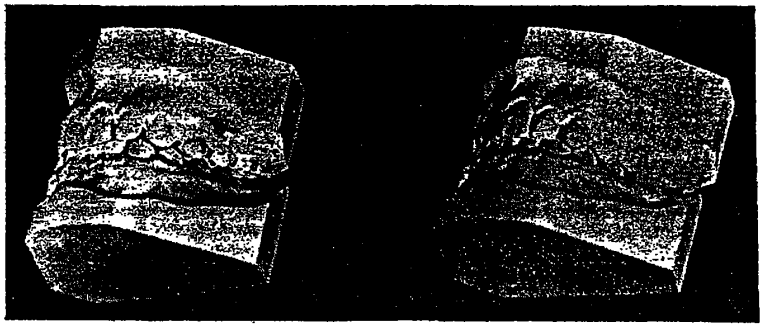


Fig. 6.—Buccal-lingual correction. Left, basic treatment model. Right, model after correction with Positioner. Note space closure.

As basic treatment is completed in severe Class II, Division 1 cases, the maxillary anteriors often assume a lingual axial inclination. This position is inevitable because of the distance the incisal edges of these teeth must travel lingually in order to reach Class I relationship to those of the mandibular incisors. When using the Tooth Positioning Appliance it is quite convenient to exaggerate the labial axial inclination of these teeth on the setup, and

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through the appliance influence them into their normal positions. This same condition will often prevail in cases where it is necessary to eliminate some of the dental units in order to complete basic treatment properly.

When using the Tooth Positioning Appliance for the final positioning of the teeth, it is not necessary that all of the teeth completely interlock in inclined plane relationship before basic treatment is discontinued. If the maxillary buccal teeth are approaching their normal relationship both buccolingually and mesiodistally to their antagonists in the mandibular arch, the teeth can be forced into the Positioner, and it will influence all the teeth toward their complete interdigitation. If it is necessary to shift the mandible laterally or mesially in order to engage the Positioner, the proper force for positioning these teeth will be brought into play when the patient, after seating his teeth into the Positioner, carries the mandible back into its normal position. The functional forces will add greatly to reduce this type of discrepancy, if the patient is not lazy and works against any shift of the mandible created by the Positioner.

There are some types of major tooth movements that the conventional type of appliance has utterly failed to produce. Deep overbites are corrected not by the depression of the anterior teeth but by the elevation of the other teeth to their line of occlusion. There surely are cases of closed-bite malocclusion in which the most favorable treatment would be the depression of the anterior teeth rather than the elevation of the posterior teeth. Since the pressure required to elevate teeth is very light compared with that necessary to depress teeth generally speaking, all conventional types of appliances elevate the posterior teeth in these closed-bite cases rather than depress the anterior teeth.

When dealing with such cases the intelligent arrangment of the teeth on the setup would be an almost end-to-end relation of the anterior teeth. A Positioner processed from such an arrangement and worn by the patient would not only throw all the occlusal forces onto the anterior teeth, but also through the elasticity of the appliance would give additional "kick" to this depressing action. No other appliance previously available to the profession has such possibilities. Only as the anterior teeth are depressed would the Positioner influence the posterior teeth to any great extent. Certainly the most active force would be toward the depression of the anterior teeth.

Open-bite malocclusions have been difficult to handle with the conventional type appliance, and although in cases carefully treated the anterior teeth have been brought into the line of occlusion, this is usually entirely accomplished by the elongation of the anterior teeth. Invariably the faces of individuals with open-bite malocclusion are long and the mandible has the appearance of being depressed even though a few of the posterior teeth are in occlusion. The ideal treatment of such cases would be the depression of these posterior teeth and not the elongation of the anteriors. To date, there is not sufficient practical evidence that this can be accomplished, but certainly the Positioner offers the best possibilities of such a correction. It would be expecting too much to think that the Positioner, even under functional forces, would accomplish this result. The most favorable results so far have been accomplished with the

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COORDINATING THE PREDETERMINED PATTERN AND TOOTH POSITIONER WITH CONVENTIONAL TREATMENT

H. D. KESLING, D.D.S., M.D.S., LA PORTE, IND.

IT SHOULD be the ambition and determination of every orthodontist to treat each of his patients in such a manner as to produce the best possible results in tooth arrangement with the least inconvenience to himself and his patient. Any discussion among orthodontists is sure to reveal numerous theories concerning the proper age for treatment and the mechanics for producing any given result. Orthodontic literature presents a variety of techniques for the management of the different types of cases. Colleges offer specialized courses covering the mechanics of various appliances. Nevertheless, much of each orthodontist's time is consumed making appliance adjustments which will contribute little or nothing definite to the final result. There is no way of measuring the inefficiency of orthodontic operations, but a fair estimate would reveal that not more than 15 per cent of the time is spent on operations that are necessary and which will contribute directly to the final result. In the past, it was the common practice to make adjustments weekly, or even daily. This did not allow sufficient time for the tissues to repond fully to the pressures which were being exerted by the appliance before additional changes were administered. With the materials and appliances available today it is possible to make adjustments that will be active over a period of weeks. Barring accidents, so long as these adjustments are carrying the teeth toward the desired results, there is no need for more frequent adjustments.

Calvin Case developed stationary anchorage by preparing rigid attachments for groups of teeth and pinning this anchorage against individual teeth for movement. Using these mechanics, he attempted to move only individual teeth but did not attempt to coordinate group tooth movements. Angle, Ketcham, Mershon, and others visualized the possibilities of group tooth movements. Through appliances which these men developed, we are able to treat cases in much less time through reciprocal tooth movements. Among Tweed's many contributions was his technique for successfully developing and using dynamic or complete arch stationary anchorage. This anchorage paved the way for successful mass movements of teeth. A further step forward, in line with these previous developments in orthodontics, is possible when we develop a predetermined pattern of the proposed tooth positions prior to treatment and coordinate this pattern with treatment. This pattern can be used as a guide for basic treatment through conventional appliances and later utilized for the construction of the positioner.

Read before a meeting of the Southern Society of Orthodontists, Jan. 28 and 29, 1946.

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Temptation to start treatment before the permanent canines and premolars have erupted is prompted by the idea that more space is needed for these erupting teeth. If this space could be created, it would allow these teeth to assume better positions as they erupt. However, in the writer's experience, this course of treatment has invariably led to disappointment. In crowded arches, unless the first molars are tipped forward, space is gained only by "ballooning out" the teeth and supporting alveolar process, either labially or buccally, without any development or modification of the apical base. This seems to hold true regardless of the age at which treatment is undertaken. Clinical experience proves that it is more practicable to close wide spaces caused by removing teeth than to attempt to create even slight spaces.

Since treatment during the transitional period cannot be considered final, it would seem advisable to undertake major tooth movements after the permanent canines and premolars have erupted into the mouth. Only emergency cases should have earlier treatment. In these cases the early treatment should be considered only as an attempt to aid Nature through the developmental stage. To complete treatment successfully, not infrequently these cases will need major tooth movements after the premolars and permanent canines have erupted.

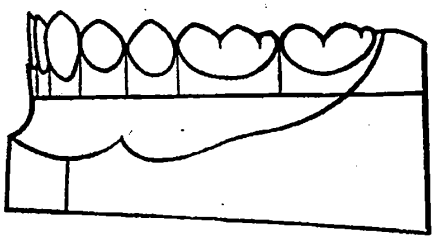
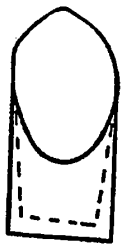


Fig. 1.



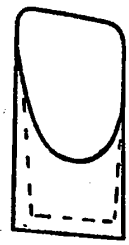


Fig. 2.

Fig. 1.—Diagram of case showing vertical and horizontal saw cuts.
Fig. 2.—Diagram of individual teeth, dotted line showing desirable trimming on mesial, distal, and root end.

The predetermined pattern, or setup, for the case should be developed as a part of the preliminary study and used as a guide in diagnosis. Nothing an operator can do can be as enlightening for this purpose as the preparation of such a setup. In treatment we strive to coordinate tooth anatomy with the existing basal bone. There is no better way to visualize this coordination than through the predetermined pattern prepared before treatment is undertaken. If the technique of the setup is carefully executed and care is taken to preserve the tooth anatomy on the plaster models, the result will be sufficiently clear-cut as to leave no doubts as to the most desirable course of treatment.

The predetermined pattern is made by dissecting the teeth from a plaster model, and, after trimming them, rearranging the teeth in wax into the desired arch form, axial positioning, and interdigitation (Figs. 1 and 2). The operator is free to move the teeth, within reason, to any position which he thinks

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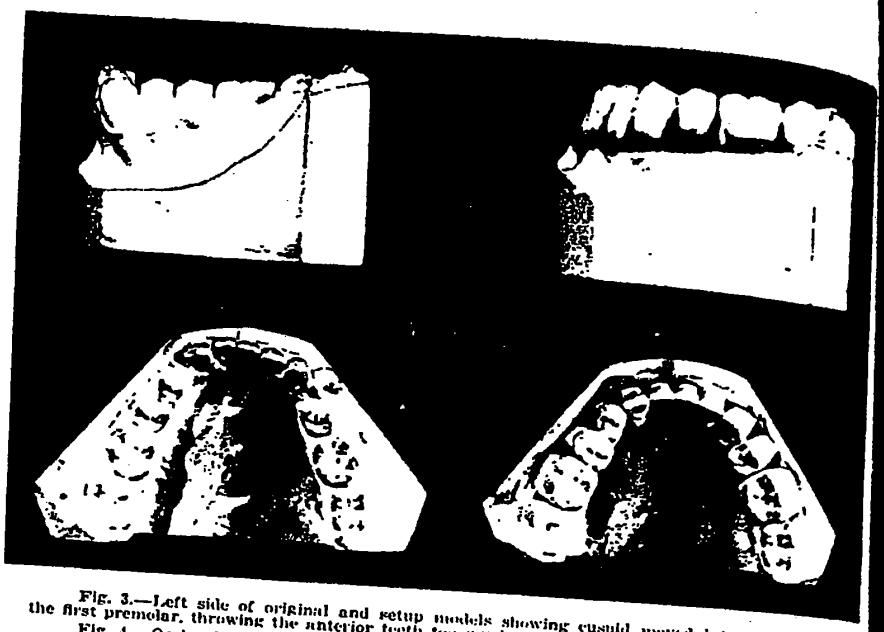


Fig. 3.—Left side of original and setup models showing cuspid moved into the space of the first premolar, throwing the anterior teeth too much to the lingual.
Fig. 4.—Occlusal view of models shown in Fig. 3.

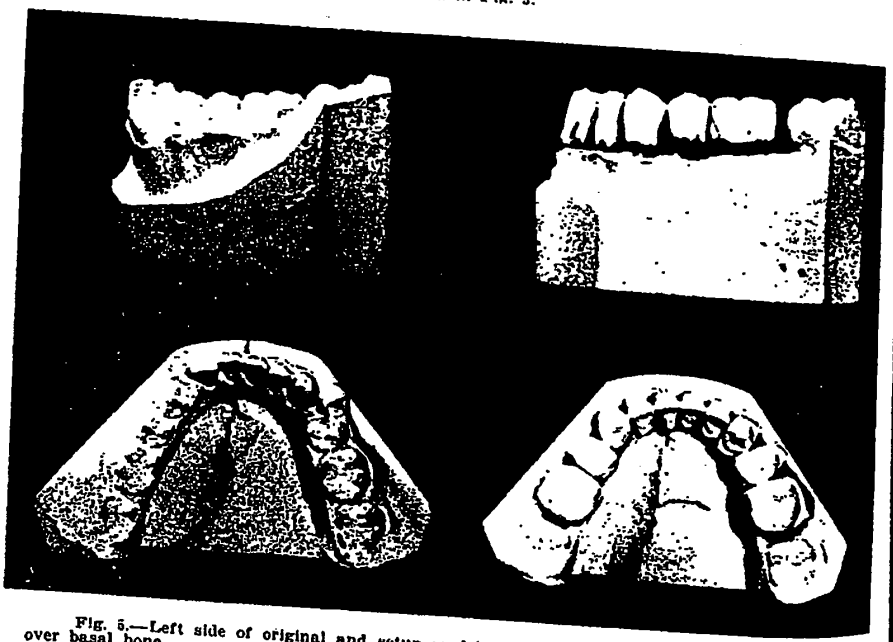


Fig. 5.—Left side of original and setup models showing correct positioning of the teeth over basal bone.
Fig. 6.—Occlusal view of models shown in Fig. 5.

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Fig. 7.—X-ray sho

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By knowing the exact movements necessary for completion of treatment, anchorage problems become simplified. In order to control the teeth, it is necessary to have some rigid attachment to each individual tooth. At the present time there is no practical means of attaching to the teeth other than by banding. Perfect bands do not necessarily mean good orthodontics nor the most desirable finished result. At the best, bands and attachments can only be considered temporary and as a means, during treatment, of attaching to the individual teeth. Many operators overestimate the necessity of making and placing perfect bands and devote more time to this part of the technique than to the more important part—the manipulation of the appliance. Usually the leveling off and lining up of the teeth can be accomplished with one adjustment, by applying a very small high-tempered arch wire. This is only possible if enough time is allowed for the tissues to repond to this light force.



Fig. 7.—X-ray showing second premolar and cuspid roots after treatment.

Treatment of both arches can be carried on together, bearing in mind that mandibular teeth should advance toward the predetermined pattern and ...ary anchorage somewhat ahead of the maxillary teeth. Adjustments ...l be made which will definitely cause the teeth to progress toward the pre...ined pattern and which will not cause unnecessary tooth movements in ...er directions. With the mechanisms we have at hand for creating such ...ts, it is quite possible to make adjustments that will be active over a ...l three or four weeks. Such an adjustment need not be unusually severe ...ch a nature that the action will be continuous. Too frequent ad... are a waste of time and a source of discomfort to the patient. Most ...s have had experiences where it has been impossible to see a patient ...d of eight to ten weeks because of illness. When the patient returned, ... that had taken place in the absence of regular appliance adjustments ...ingly good.

...t learn the possibilities of our treating mechanism. We must make

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Fig. 8.—Tooth-positioning appliance.

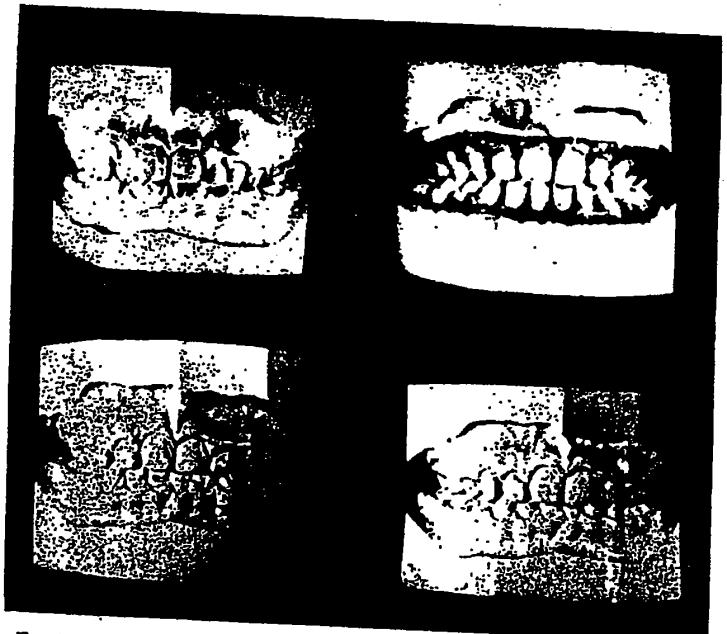


Fig. 9.—Front view. Upper left, original. Upper right, setup model. Lower left, basic treatment. Lower right, finished case.



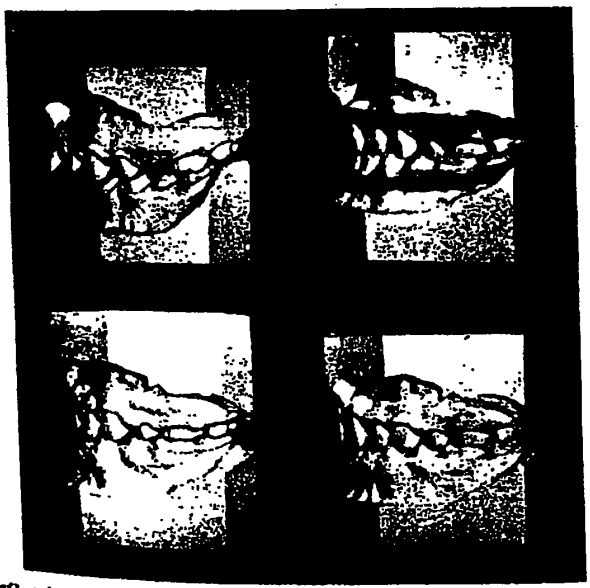
10.—Right side. Upper left
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11.—Left side. Upper left,
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Fig. 10.—Right side. Upper left, original. Upper right, setup model. Lower left, basic treatment. Lower right, finished case.



Left side. Upper left, original. Upper right, setup model. Lower left, basic treatment. Lower right, finished case.

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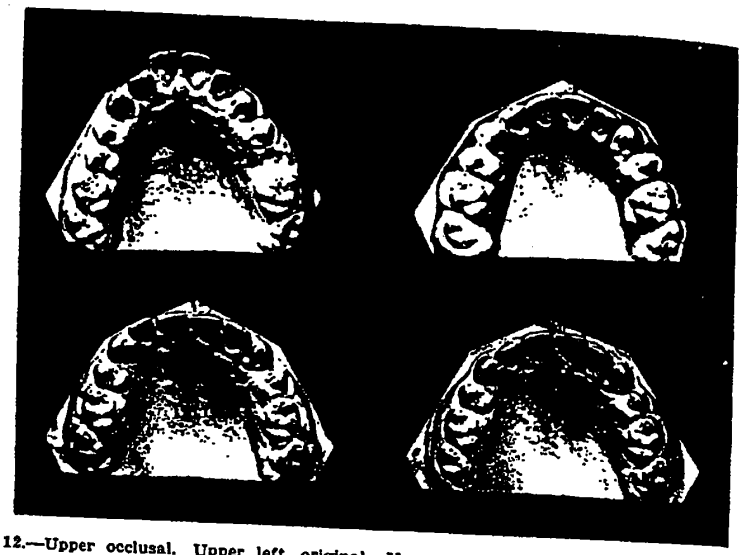


Fig. 12.—Upper occlusal. Upper left, original. Upper right, setup model. Lower left, basic treatment. Lower right, finished case.



Fig. 13.—Lower occlusal. Upper left, original. Upper right, setup model. Lower left, basic treatment. Lower right, finished case.

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adjustments accordingly and allow enough time for this stored-up energy to create tissue changes and desired tooth movements. There is less damage to tissue when we know by a predetermined pattern the desired position of each tooth and through the mechanism carry the tooth only toward that predetermined position.

Major tooth movements are completed when the teeth are properly rotated and approaching their normal axial inclination and interdigitation. It seems entirely unnecessary to prolong conventional treatment after these positions have been accomplished. It is necessary, however, in the case of extractions, to parallel the roots of the teeth that are being moved into the space of an extracted tooth (Fig. 7).

During basic treatment the predetermined pattern should be duplicated in artificial stone and these models used to fabricate a tooth-positioning appliance for the final artistic positioning (Fig. 8). As the end of conventional treatment approaches, the function of the tooth-positioning appliance should be explained, both to the parents and to the child. The patient should be informed of his responsibility with regard to the wearing of this finishing appliance. The operator, the patient, and the parents should collaborate on a definite schedule for the patient's wearing of the Positioner. The patient should practice four hours of exercise wearing daily as well as wearing the Positioner while sleeping at night. To be most effective, the appliance should be placed immediately after the removal of the conventional appliance. At this time the teeth are unstable from active treatment and are susceptible to the gentle forces of the tooth-positioning appliance.

If the Positioner is worn as directed, slight rotations will be corrected, spaces will be reduced, and the arch form and axial positioning of the teeth will approach that of the predetermined pattern in three or four weeks' time. At this time it will be necessary to decide whether the patient is to wear the Positioner as a retainer for a few weeks or whether it is a case that is going to require prolonged retention. If it is the latter, a conventional type of retainer should be constructed and cordinated with the Positioner.

Orthodontic treatment should be instigated at the most opportune time. With the exception of emergency cases this would be when the premolars and permanent canines are erupted. At this time it is possible to develop a predetermined pattern of the case. This will serve as a valuable diagnostic aid, as a guide through basic treatment, and as a form over which the tooth-positioning appliance can be constructed. With the predetermined pattern the operator can more efficiently plan and execute the major tooth movements with fewer appointments and less inconvenience to himself and the patient. Many of the one hundred results to be shown in the clinic session of this meeting have been accomplished with from fifteen to eighteen basic treatment appointments. It seems well within the realm of possibility that in the future most orthodontic cases can be successfully treated with twelve to fifteen basic treatment appointments. This can be accomplished, however, only if the operator first determines the goal and then coordinates all of his efforts toward that end.

916 Indiana Avenue

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The Speed Positioner

PETER KLEEMANN, DDS, MS
CHRISTIANE JANSSEN

Since the introduction of the positioner by Kesling in 1945, various methods of fabrication from elastic materials including rubber, thermoplastic vinyl, and resin have been described.[1,2] In 1977, a highly elastic silicone elastomer made of polydimethyl silicate was introduced.[3-8] Today, silicone materials can be made by a number of vulcanization methods, with catalysts such as peroxide, platinum, and tin.

Although the common silicone elastomers are biologically inert and have excellent mechanical properties,[9,10] they have not been widely used in orthodontic practices. Reasons may include the time and cost of fabrication, the uncertainty of clinical performance, and the need for patient cooperation. These problems have been solved in our office by the Speed Positioner.

The Speed Positioner is a highly efficient and precisely fabricated appliance designed to establish and retain gnathologic functional occlusion during the final phases of orthodontic treatment (Fig. 1). It can be made in the office, without alginate impressions, from a clear or transparent silicone elastomer called Odontosil.* This material vulcanizes without added pressure or temperature, using a platinum-hydroxyl-group vinyl siloxane hardener that is biocompatible and hypoallergenic. Odontosil resists shrinkage and, like other silicone elastomers, displays a high resetting ability, permanent elasticity, high tear resistance, and stain resistance; it is odorless, tasteless, and disinfectable.

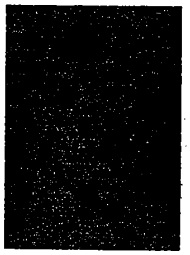
When coupled with miniaturized brackets, the Speed Positioner provides three-dimensional control and allows individual tooth movements of as much as 3mm. Appliances with maximum interbracket distance, such as SPEED,** Ultra-

*Dreve-Dentamid, Max-Planck-Strasse 31, 59423 Unna, Germany.

**Strite Industries Ltd., 298 Shepherd Ave., Cambridge, Ontario, N3C 1V1 Canada.



Dr. Kleemann



Ms. Janssen

Dr. Kleemann is in the private practice of orthodontics at Duisburgerstrasse 84, 46535 Dinslaken, Germany. Ms. Janssen is a certified laboratory technician in Dr. Kleemann's practice.

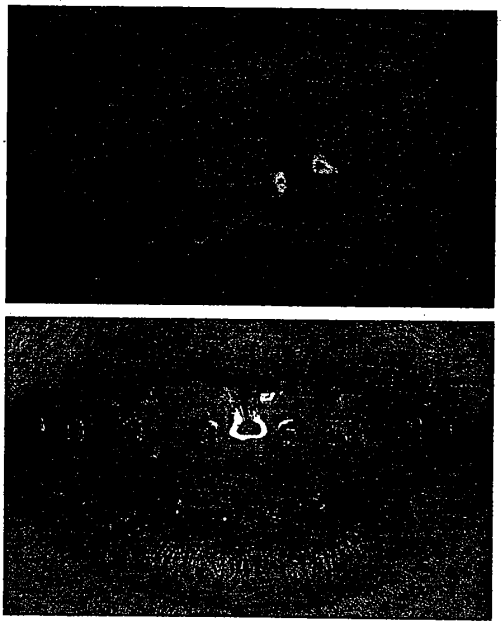


Fig. 1 Speed Positioner.

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Mini-Trim,*** Mini-Dyna-Lock,† Mini-Mono-Line,‡ Mini-Twin,†† Mini-Friction-Free,‡‡ Mini-Taurus,§ and Mini Diamond,§§ are preferable because they extend the working range of the positioner and improve patient comfort.

Positioner Fabrication

1. Precise impressions of the upper and lower arches are required with the bonded miniaturized brackets in place. Sharp tie-wing edges and hooks should be removed or reduced by grinding, and severe undercuts blocked out with elastic O-rings or Hug-Caps# (this blocking is not necessary with the SPEED appliance).
2. A split-tray impression technique will ensure accurate reproduction. Take a pre-impression of each arch using soft Zerosil* silicone putty. With a scalpel, trim away any elastomer tags or undercuts that could hinder the repositioning of the tray (Fig. 2). Blow-dry the pre-impression tray and reinsert it. This hard tray will then guide a thin, thixotropic silicone elastomer impression material around the teeth and brackets. Use the hydrophilic, fast-setting Zerosil Supersoft* to create the actual impression.
3. After the impression material has set, remove the hard tray, then carefully peel the silicone

***Dentaurum, Inc., 10 Pheasant Run, Newtown, PA 18940.
†3M Unitek, 2724 S. Peck Road, Monrovia, CA 91016.
‡Forestadent USA, 10240 Bach Blvd., St. Louis, MO 63132.
††"A"-Company, 11436 Sorrento Valley Road, San Diego, CA 92121.
‡‡American Orthodontics, 1714 Cambridge Ave., Sheboygan, WI 53082.
§RMO Inc., P.O. Box 17085, Denver, CO 80217.
§§Ormco, 1717 W. Collins Ave., Orange, CA 92667.

#Kreative Koncepts, 105 E. First St., Hinsdale, IL 60521.
*Dreve-Dentamid, Max-Planck-Strasse 31, 59423 Unna, Germany.



Fig. 2 A,B. Hard pre-impression tray made with Zerosil silicone putty. C. Elastomer tags and undercuts trimmed away with scalpel.



Fig. 3 Surface tension of silicone reduced with KKD Release Spray.

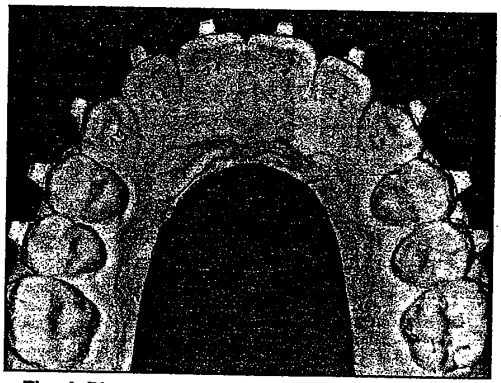


Fig. 4 Plaster cast removed from silicone tray.

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Fig. 5 Individual teeth marked (A), cut away from plaster cast (B), and ground with conical bur (C).

material toward the lingual, away from the teeth and brackets. Replace the silicone tray in the hard tray. Reduce the surface tension of the silicone by spraying it with KKD Release Spray** (Fig. 3). Let the impression stand for an hour.

4. A high-quality, Class IV synthetic superstone plaster (Tewestone***) is recommended for exact reproduction of the miniaturized bracket outlines. After the plaster has set, carefully remove each cast from the silicone tray (Fig. 4). Mark the individual teeth, cut them away from the cast, and grind the apical areas with a conical bur (Fig. 5). Replace the individual teeth in the silicone trays, and pour in wax to make setup models (Fig. 6).

5. Take a centric bite registration using a transparent, fast-setting silicone material (Regofix*). Because of the elasticity of this material, it is important that the patient close to the correct position just short of occlusion. The bite registration will resist deformation and can be kept as a permanent occlusal diagnostic record. Take an arbitrary facebow registration, then replace the archwires and reactivate them as necessary.

6. Using the centric bite registration and facebow, mount the setup models on a semi-adjustable articulator such as Dentatus**** (Fig. 7). Position the teeth according to gnathological

*Dreve-Dentamid, Max-Planck-Strasse 31, 59423 Unna, Germany.
**Kentzler-Kaschner Dental GmbH, Muehlgraben 36, 73479 Ellwangen, Germany.
***Kettenbach GmbH, Postfach 61, 35713 Eschenburg, Germany.
****Knapstein-Import, Ostwall 237, 47798 Krefeld, Germany.

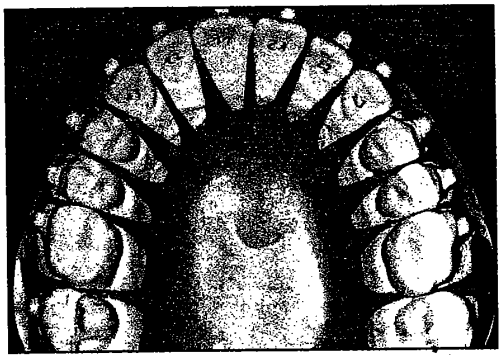


Fig. 6 Individual teeth replaced in silicone tray and poured with wax.

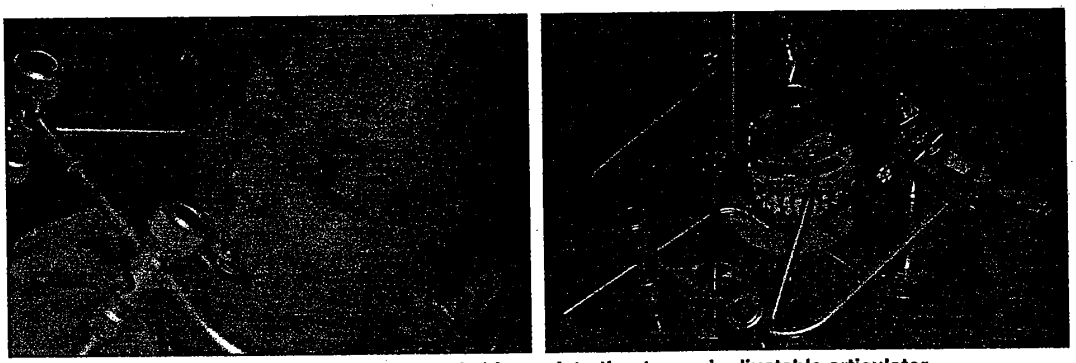


Fig. 7 Facebow transfer of centric bite registration to semi-adjustable articulator.

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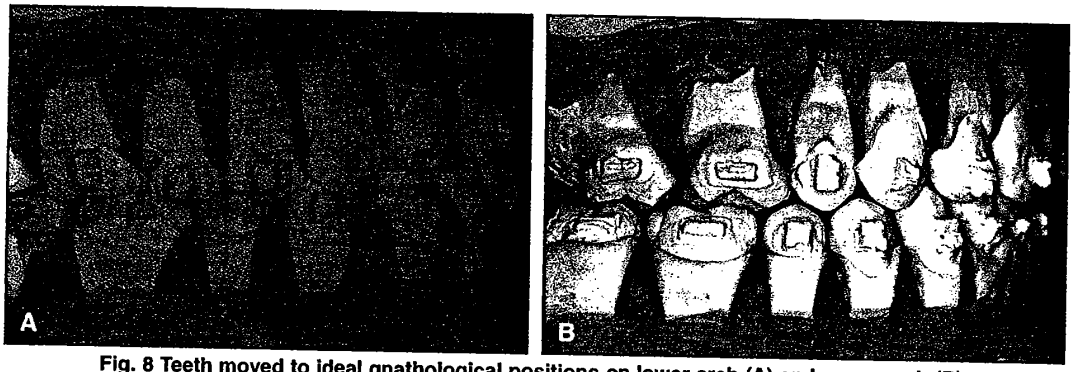


Fig. 8 Teeth moved to ideal gnathological positions on lower arch (A) and upper arch (B).

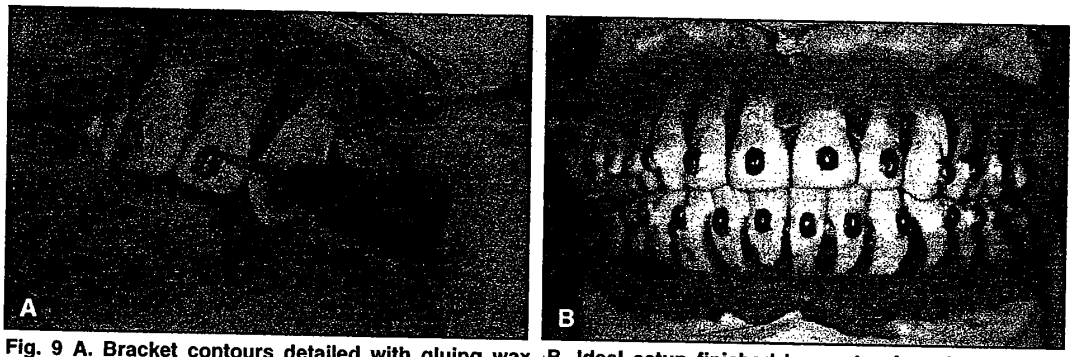


Fig. 9 A. Bracket contours detailed with gluing wax. B. Ideal setup finished by contouring gingivae and smoothing wax base.

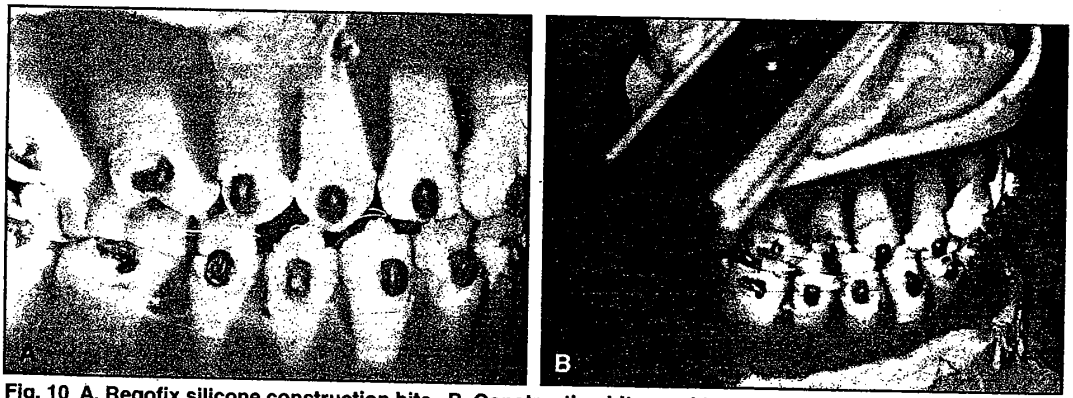


Fig. 10 A. Regofix silicone construction bite. B. Construction bite used to transfer ideal wax setups to splint-fixator.

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criteria,[11,12] first in the lower arch and then in the upper (Fig. 8). Considering the thickness and elasticity of the positioner material and the interbracket distances, individual tooth movements should generally be kept within 3mm.

7. Detail the fine slots and contours of the brackets on the setup models with gluing wax (Fig. 9). Smooth the wax bases, and contour the gingival areas.

8. Raise the incisal pin of the articulator 2.5mm. In Class II or deep-bite cases, a mandibular advancement of 1mm is reasonable. Overcorrection is not a concern, because the positioner will not be worn full-time. Take a construction bite using Regofix,* and transfer the ideal wax setups to a splint-fixator† (Fig. 10). Save the silicone construction bite for later use.

9. The two components of Odontosil come in separate cartridges and are vulcanized at room temperature by mixing them in a cannula in a 1:1 ratio. Separate the two ideal wax setups, then inject the Odontosil onto the occlusal surfaces, first of the lower arch and then of the upper (Fig. 11). Remount the setups on the fixator, and complete the positioner by applying the labial and lingual sections of Odontosil.

10. Carefully mold and smooth the silicone with a finger soaked in soapy water. Trim the contours with a wax knife. The better the modeling, the less finishing will be required after polymerization. To eliminate air bubbles, place the fixator in a pressure pot for about 30 minutes, at room temperature and at least two bars of pressure. The final set takes about two hours.

11. Carefully peel the lingual portions of the positioner away from the setup models with the fingers, then remove the rest with an instrument. Trim the positioner with sharp scissors, and grind it to final form, using removable, pear-shaped grinding caps in rough and fine gradations (Fig. 12).

*Dreve-Dentamid, Max-Planck-Strasse 31, 59423 Unna, Germany.

†Scheu-Dental GmbH, Postfach 7562, 58613 Iserlohn, Germany.



Fig. 11 Odontosil injected onto occlusal surfaces of lower (A) and upper (B) arches, then on labial (C) and lingual surfaces of mounted setups.



Fig. 12 A. Removal of Speed Positioner from wax setup. B. Trimming with sharp scissor. C. Grinding with pear-shaped cap.

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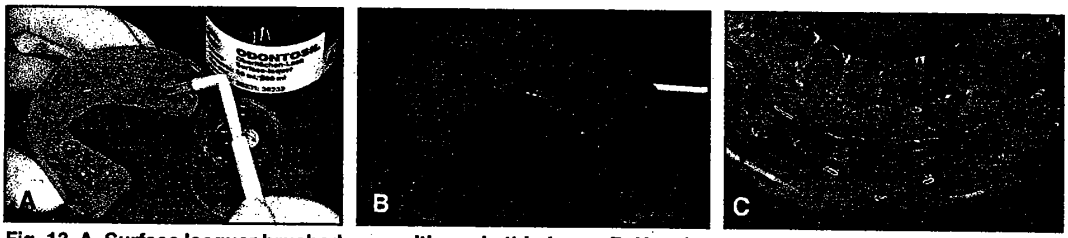


Fig. 13 A. Surface lacquer brushed on positioner in thin layer. B. Heat lamp accelerates polymerization of lacquer with silicone elastomer. C. Finished surface is transparent and shiny.

12. Apply the Odontosil surface lacquer* in a thin layer with a brush (Fig. 13). This lacquer bonds chemically with the silicone elastomer and leaves the surface transparent, shiny, and durable.

Appliance Delivery

The archwires must be removed before the Speed Positioner can be inserted. Have the patient place the positioner over the miniaturized brackets on the upper arch with a dry thumb and forefinger. The patient then closes the mandible until a click indicates proper seating of the positioner (Fig. 14).

At first, the patient should check the fit by biting down while supporting the appliance with the fingers. Less malpositioned teeth will move quickly into their ideal positions, and the other teeth will follow soon thereafter. Once the ideal intercuspation is reached with the mandible in centric relation, the positioner becomes a passive retention appliance.

Educate the patient thoroughly in how the Speed Positioner works. Demonstrate how mobile the teeth are after removal of the archwires, and emphasize the importance of wearing the positioner as prescribed in the first few days. The ideal setups and photographic records make effective visual aids. Give the patient a one-minute cleaning foam‡ to keep the positioner clean and fresh-tasting. Schedule the next few appointments at short intervals to maintain the patient's motivation.

Intermittent muscle activity will enhance the continuous force exerted by the positioner, and the brackets will keep it in place during sleep. Neither biting exercises nor night-time "stabilizers" are needed. Most patients should wear the Speed Positioner four hours per day and eight hours per night for about four weeks, then at night only for another four weeks. At this point, the gnathologic functional occlusion will usually have been achieved (Fig. 15), and the brackets can be removed.

*Dreve-Dentamid, Max-Planck-Strasse 31, 59423 Unna, Germany.
‡Block Drug Company, Inc., 257 Cornelison Ave., Jersey City, NJ 07302.

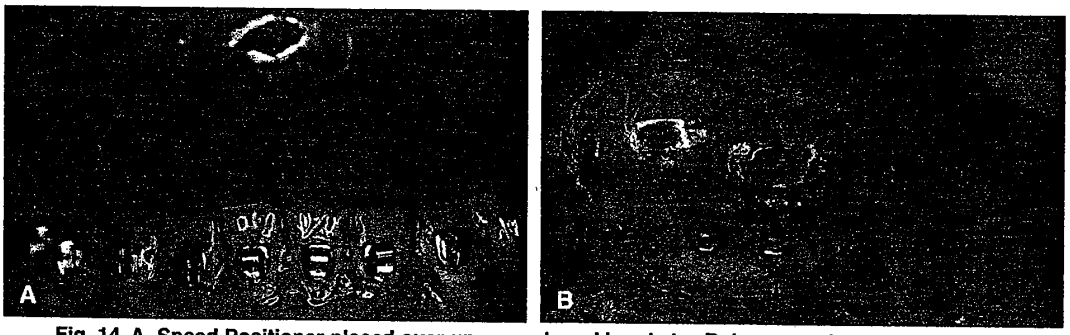


Fig. 14 A. Speed Positioner placed over upper arch and brackets. B. Lower arch clicks into place.

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Fig. 15 A. Case with missing upper lateral incisors after space closure, showing cusp-to-cusp relationship on both sides, misaligned individual teeth, and severe midline deviation. B. After one week of wearing Speed Positioner 12 hours per day. C. After five more weeks of wearing Speed Positioner 12 hours per day. D. After two weeks of wearing Speed Retention Positioner eight hours per day. Minor tooth-size discrepancy shown by small diastema between upper central incisors. E. After cosmetic recontouring and composite build-up.

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Speed Retention Positioner

Although conventional retainers can be used, we and most of our patients prefer to retain the ideal occlusion with a Speed Retention Positioner. This is made on the original wax setup models, mounted on the splint-fixator with the original construction bite. The brackets should be carefully ground away from the plaster teeth before pouring the Odontosil.

The Speed Retention Positioner will fit snugly because of its lack of bracket recesses and its close adaptation to the ideally positioned teeth. Since there is little strain on the elastomeric material, this retainer can be worn long-term.

If necessary, a substitute or follow-up Speed Positioner can also be made quickly from the original wax setups and construction bite.

Discussion

The Speed Positioner ensures precise control of final gnathological tooth positions in three planes of space. In growing patients, it can also help correct skeletal discrepancies.

The mounted setup allows the orthodontist to study the functional occlusion from different perspectives. Misalignments of individual teeth and tooth-size discrepancies will be revealed, and the plaster teeth can be moved until an ideal occlusion is reached.

Individual tooth movements of more than 3mm should be accomplished with fixed appliances. If the Speed Positioner is uncomfortable or does not fit properly at first, it can be saved until further detailing has been carried out.

REFERENCES

1. Kesling, H.D.: The philosophy of the tooth positioning appliance, Am. J. Orthod. Oral Surg. 31:297-304, 1945.
2. Kesling, H.D.: Coordinating the predetermined pattern and tooth positioner with conventional treatment, Am. J. Orthod. Oral Surg. 32:285-293, 1946.
3. Nishiyama, M.; Kamada, K.; and Horiuchi, S.: A new construction of tooth positioners with LTV vinyl silicone rubber, J. Nihon Univ. Sch. Dent. 19:93-102, 1977.
4. Yoshii, O.: New orthodontic device—dynamic positioner (DP), Nippon Dent. Rev. 452:61-74, 454:107-130, 457:146-164, 458:112-129, 1980.
5. Kamada, K. and Nishiyama, M.: Construction of tooth positioners with LTV vinyl silicone rubber and some case reports, J. Nihon Univ. Sch. Dent. 24:1-27, 1982.
6. Williamson, E.H.; Fisher, J.C.; and Stroop, J.R.: The influence of three types of positioners on mandibular condyle relationships, J. Clin. Orthod. 18:335-341, 1984.
7. Warunek, S.P.; Sorensen, S.E.; Cunat, J.J.; and Green, L.J.: Physical and mechanical properties of elastomers in orthodontic positioners, Am. J. Orthod. 95:388-400, 1989.
8. Warunek, S.P.; Strychalski, I.D.; and Cunat, J.J.: Clinical use of silicone elastomer appliances, J. Clin. Orthod. 23:694-700, 1989.
9. Rost, D.; Schwarze, C.W.; and Hilgers, R.D.: Materialeigenschaften der Werkstoffe für Positioner—eine in-vitro-Untersuchung, Fortschr. Kieferorthop. 54:71-75, 1993.
10. Rost, D.; Schwarze, C.W.; and Hilgers, R.D.: Die Kraftabgabe von Positionern bei unterschiedlicher Schneidezahnprotrusion, Fortschr. Kieferorthop. 56:104-109, 1995.
11. Roth, R.H. and Gordon, W.W.: Functional occlusion for the orthodontist, Part IV: The gnathological tooth positioner, J. Clin. Orthod. 15:246-265, 1981.
12. Chiappone, C.: Constructing the gnathologic set-up and positioner, J. Clin. Orthod. 14:121-133, 1980.

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Interpolating Splines with Local Tension, Continuity, and Bias Control

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Abstract

This paper presents a new method for using cubic interpolating splines in a key frame animation system. Three control parameters allow the animator to change the tension, continuity, and bias of the splines. Each of these three parameters can be used for either local or global control. Our technique produces a very general class of interpolating cubic splines which includes the cardinal splines as a proper subset.

CR Categories and Subject Descriptors: G.1.1 [Numerical Analysis]: Interpolation – *spline and piecewise polynomial interpolation*; I.3.5 [Computer Graphics]: Computational Geometry and Object Modeling – *curve, surface, solid and object representations*; I.3.7 [Computer Graphics]: Three-Dimensional Graphics and Realism – *animation*.

General Terms: algorithms

Additional Key Words and Phrases: key frames, inbetweening, bias, continuity, tension

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1. Introduction

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 [5]. This same principle is frequently used in computer assisted 3-D animation where camera and object positions are defined only at key points in the animation, leaving the calculation of intermediate positions to the computer. The straightforward *linear interpolation* algorithm used in many systems produces some undesirable side effects which give the animation a mechanical look, often referred to as the "computer signature." The most objectionable characteristic of this type of animation is the 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 1).

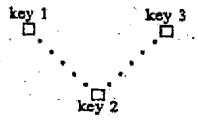


Figure 1. Discontinuity in direction with linear interpolation

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 2).

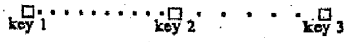


Figure 2. Discontinuity in speed with linear interpolation

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A third common problem is distortion, which may occur whenever the movement has a rotational component (Figure 3).

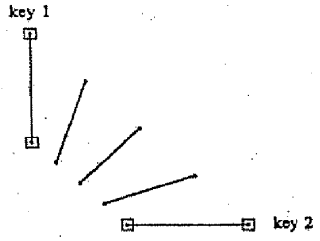


Figure 3. Distortion in length when rotation is simulated linearly.

In view of these serious drawbacks of linear interpolation, a number of different methods which produce smoother motion have been published. These techniques include *P-curves* [1], *skeletons* [6], *action overlap* [11], and *moving point constraints* [9]. All of these techniques require the animator to specify additional information other than just the key frames. A completely automatic system which uses only the key positions supplied by the animator was implemented by one of the authors [8]. The approach used there was based on fitting a set of interpolating splines through the key positions, resulting in much smoother animation than can be produced with linear interpolation

2. Interpolating Splines

We assume that each of the objects in the ith key frame in a sequence can be described by a collection of *points*. (As an example, the two designated endpoints of the line segment in key 1 shown in Figure 3 completely define the segment.) We assume that to each point in one key frame there will be a corresponding point in all other key frames of a motion sequence. (For example, the same two endpoints reappear in key 2 of Figure 3 to specify a later position of the line segment.) These assumptions are not as restrictive as they may appear to be. Even quite complicated curved objects can be expressed in terms of small numbers of *control points* using the techniques described in, for example, [7]. For the purposes of the discussion, we will fix our attention on one such point, designated P_i and referred to as the *key position*, in the ith key frame:

$$P_i = (x_i, y_i, z_i)$$

(We will carry on the discussion in terms of 3-D animation.) Given a sequence of corresponding key positions,

$$\cdots, P_{i-1}, P_i, P_{i+1}, \cdots$$

we want to interpolate them using a simple smooth curve. For sufficient generality to handle the multi-valued case, all curves will be treated parametrically as

$$P(s) = (x(s), y(s), z(s))$$

where s varies from 0 to 1 between each two key frames. Thus, we want to find smooth functions $x(s)$, $y(s)$, and $z(s)$ so that, for example,

$$P(0) = (x(0), y(0), z(0)) = (x_i, y_i, z_i) = P_i$$

and

$$P(1) = (x(1), y(1), z(1)) = (x_{i+1}, y_{i+1}, z_{i+1}) = P_{i+1}$$

on the interval between the ith and $i+1^{st}$ key frames. The positions of the inbetween frames which will correspond to the key position in question, then, will be $P(s)$ for $s = \Delta, 2\cdot\Delta, \cdots 1-\Delta$ for

$$\Delta = \frac{1}{N_i + 1}$$

where N_i is the number of inbetweens to be generated between the key frame containing P_i and the key frame containing P_{i+1}. Polynomials are a natural choice for the smooth functions because of their simplicity, but using a single interpolating polynomial of high degree for the entire sequence could result in motion which oscillates about the path we expect the animation to follow. A more "natural" fit of the key positions can be obtained by interpolating them with a cubic spline, a curve consisting of a succession of different cubic polynomial segments which are joined together with certain continuity constraints.

Each cubic polynomial extends between two key positions and is uniquely defined by four coefficients which we can determine from four independent constraints. Two constraints are given directly by the interpolation conditions: the spline segment must pass through the key positions at the start and the end of the interval. This leaves two free constraints which we can choose. The choice which defines the most commonly used form of cubic spline imposes first and second derivative continuity at the keys, but this approach is computationally expensive and quite inflexible. Instead, we choose to specify tangent vectors at the two adjacent keys to define each spline segment. In our notation the tangent vector to the curve we wish to construct through key position P_i is given by

$$D_i = \left(\frac{dx}{ds}, \frac{dy}{ds}, \frac{dz}{ds}\right)$$

No conditions will be imposed on second derivatives.

By default, we determine appropriate tangent vectors from the geometry of the surrounding keys. This approach can be generalized to produce a very flexible class of cubic splines by the introduction of control parameters which modify the length and direction of the tangent vectors.

Any cubic polynomial can be expressed as a scaled sum of four basis functions. Frequently these functions are taken to be the monomials s^3, s^2, s, 1, however, for our purposes the *Hermite interpolation basis functions* shown in Figure 4 are more useful.

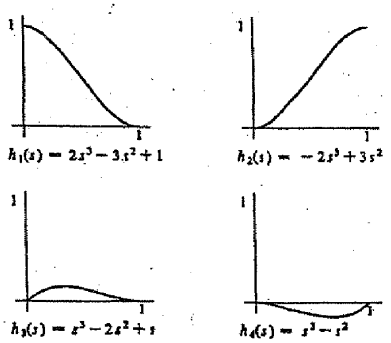


Figure 4. Basis functions for Hermite interpolation

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These functions have the following convenient properties:

	h_1	h_2	h_3	h_4
function value at $s=0$	1	0	0	0
function value at $s=1$	0	1	0	0
derivative at $s=0$	0	0	1	0
derivative at $s=1$	0	0	0	1

Note that h_1 alone determines the function value of the composite cubic at the start of the interval. Therefore, h_1 can be scaled with a coefficient of P_i to obtain the desired point P_i at $s=0$. Similarly, h_2 can be scaled with P_{i+1}. The derivative of the composite cubic is determined by h_3 at the start and by h_4 at the end of the interval, therefore D_i and D_{i+1}, the desired derivatives at the interval ends, can be used as scaling factors for h_3 and h_4. These observations lead to a triplet of cubic polynomials given by

$$\begin{aligned} P(s) &= (x(s), y(s), z(s)) \\ &= P_i h_1(s) + P_{i+1} h_2(s) + D_i h_3(s) + D_{i+1} h_4(s) \end{aligned}$$

Equation 1. Parametric cubic curve using the h basis.

In matrix form this expression reduces to

$$\begin{aligned} P(s) &= \mathbf{s} \cdot \mathbf{h} \cdot \mathbf{C} \\ &= \begin{bmatrix} s^3 & s^2 & s & 1 \end{bmatrix} \begin{bmatrix} 2 & -2 & 1 & 1 \\ -3 & 3 & -2 & -1 \\ 0 & 0 & 1 & 0 \\ 1 & 0 & 0 & 0 \end{bmatrix} \begin{bmatrix} P_i \\ P_{i+1} \\ D_i \\ D_{i+1} \end{bmatrix} \end{aligned}$$

Equation 2. Matrix format for parametric cubics using the h basis

Note that the vector $\mathbf{s}$ only changes from one frame in the animation to the next. Within a given frame it applies to the x, y, and z components of all key positions which are being interpolated. The matrix $\mathbf{h}$ contains the coefficients of the Hermite interpolation basis functions and is therefore constant for all frames and all key positions. In practice, $\mathbf{s} \cdot \mathbf{h}$ is calculated only once per frame. By contrast, each $\mathbf{C}$, which is a 4×3 matrix, corresponds to a single key position and is independent of the $\mathbf{C}$ associated with any of the other key positions being interpolated. It does not change from one frame to another (except at a key frame), and the independence implies that all key positions can be interpolated "in parallel".

3. A General Class of Interpolating Cubic Splines

Using this formulation as a framework, the remaining open question is how to find "appropriate" values for the components of D_i and D_{i+1}, the tangent vectors at the key positions, needed to fully specify $P(s)$. [10] describes the approach used for a class of cubic splines which are commonly called *cardinal splines*. Even though cardinal splines are not usually formulated in terms of the Hermite interpolation basis functions, the tangent vectors at the key positions are used to constrain the cubic segments. The tangent vector at P_i is calculated as $D_i = a(P_{i+1} - P_{i-1})$, where a is a constant which affects the tightness of the curve. A particular example of this class of splines is the Catmull-Rom spline for which $a = \frac{1}{2}$. Thus the tangent vector for the Catmull-Rom spline is

$$D_i = \frac{1}{2}(P_{i+1} - P_{i-1}) = \frac{1}{2}\left((P_{i+1} - P_i) + (P_i - P_{i-1})\right)$$

Equation 3. The Catmull-Rom spline

which is simply the average of the *source chord* $P_i - P_{i-1}$ and the *destination chord* $P_{i+1} - P_i$. The technique presented in this paper uses this average of adjacent chords as the default tangent vector. Thus our default spline, even though formulated differently, is exactly the Catmull-Rom spline (Figure 5).

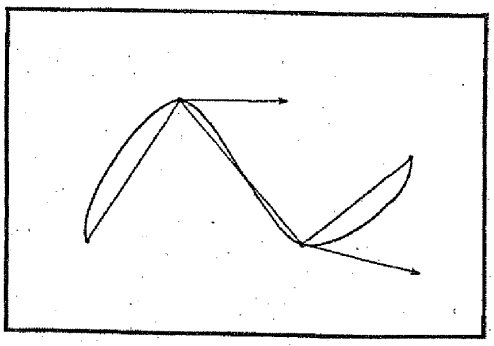


Figure 5. The Catmull-Rom spline

At the beginning of a motion sequence some arbitrary choice for the source chord (e.g. (0,0,0)) must be made. Similarly, the destination chord must be specified arbitrarily at the end of the sequence. Alternatively a specification of the tangent beginning and ending vectors can be made without regard to any chords. Setting $D = (0,0,0)$ was tried with some success in [8].

A "standard" smooth motion through a given set of keys does not always produce the effect desired by the animator. In certain cases he may want the motion to follow a wider, more exaggerated curve, while in other cases he may want the motion path to be much tighter, maybe almost linear. Even continuity in the direction and speed of motion is not necessarily desirable at all times. Animating a bouncing ball, for example, actually requires the introduction of a discontinuity in the motion at the point of impact.

The research described in this paper replaces the standard interpolating spline used in [8] by a highly flexible class of cubic splines which interpolate the same key positions but vary in several control parameters. These three parameters, *tension*, *continuity* and *bias*, allow the animator to fine-tune the animated sequence by changing certain characteristics of the "standard" interpolating spline either locally (applying only in the vicinity of a specific key frame), or globally (applying to the entire motion sequence). The introduction of these three control parameters produces a highly flexible class of interpolating cubic splines which include the cardinal splines as a proper subset.

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The concepts of tension and bias have been introduced before in connection with *approximating splines* in [2], [3], [4]. Our use of the term "bias" is similar to the concept being used by the authors of these references. The concept of "tension" which we are using is different, however. Their use of the word "tension" refers to an effect produced by adjusting the match between the second derivatives of adjoining polynomial segments, and we are exercising control only over first derivatives. We are able to produce visually similar effects, however, and so have chosen to borrow the use of their term. An excellent introduction to the theory of interpolating and approximating splines for computer animation can be found in [10].

The three control parameters tension, continuity, and bias are introduced by the convention of separating each tangent at the ith key position into an *incoming* and an *outgoing* part, respectively the *source derivative* DS_i and the *destination derivative* DD_i as indicated in Figure 6.

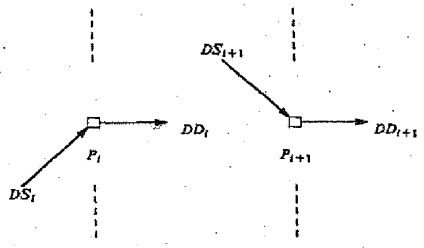


Figure 6. Incoming and outgoing tangents of two key positions.

These replace the single derivative D of the Catmull–Rom spline (Equation 3). Furthermore, the average $a = \frac{1}{2}$ of Equation 3 is relaxed in favor of a more selective average of the source and destination chord.

In the following three sections we will treat each of these three parameters independently of the other two. Then the three will be tied together in a fourth section.

3.1. Tension

The tension parameter t controls how sharply the curve bends at a key position (Figure 7).

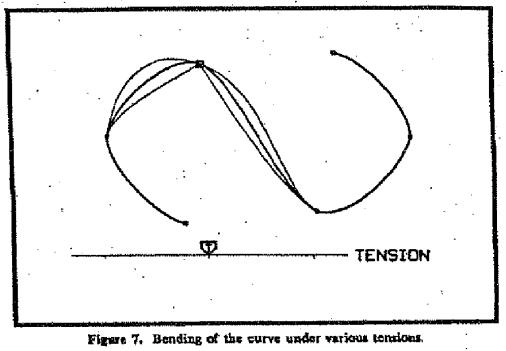


Figure 7. Bending of the curve under various tensions.

Tension is implemented as a scale factor which changes the length of both the incoming and outgoing parts of the tangent vector equally at a key position:

$$DS_i = DD_i = (1-t)\,\frac{1}{2}\cdot\left((P_{i+1}-P_i)+(P_i-P_{i-1})\right)$$

Equation 4. Tension equation.

For the default curve $t=0$, and the tangent vector is the average of the two adjacent chords (Figure 8).

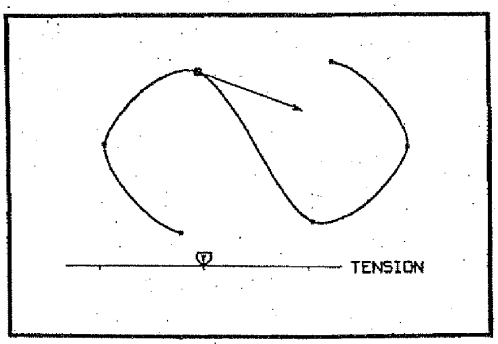


Figure 8. Default tension

Increasing the tension to $t=1$ reduces the length of the tangent vector to zero and thus tightens the curve (Figure 9).

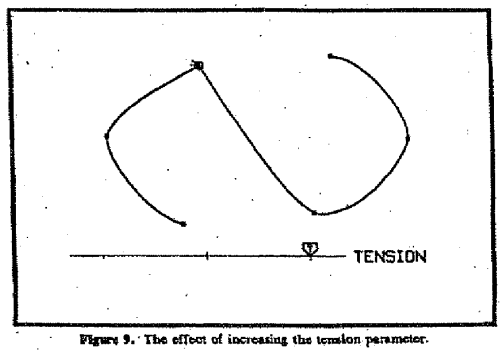


Figure 9. The effect of increasing the tension parameter.

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Reducing the tension to $t=-1$ increases the tangent vector to twice its default length and produces more slack in the curve (Figure 10).

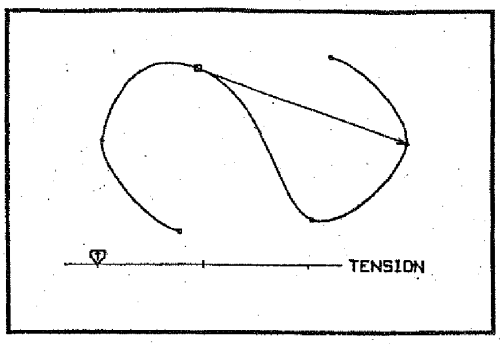


Figure 10. The effect of reducing the tension parameter.

If the same value of t is applied to all key positions in the sequence, varying t generates the entire class of cardinal splines with $a=\frac{1-t}{2}$ (Figure 11).

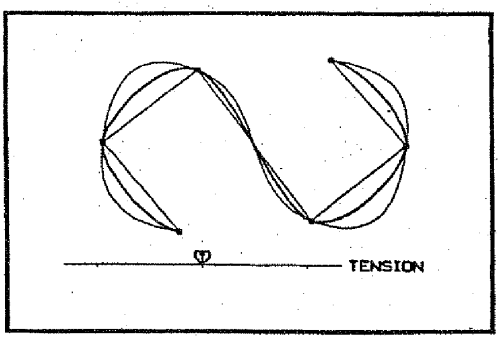


Figure 11. Several tension values applied uniformly to all keys.

The default case ($t=0$) is equivalent to the Catmull-Rom spline, where $a=\frac{1}{2}$.

3.2. Continuity

The principal reason for using splines in key frame animation is to avoid discontinuities in the direction and speed of motion which are produced by linear interpolation. However, in animation discontinuities are sometimes necessary to create realistic effects such as punching, bouncing, etc. A common technique to introduce such a discontinuity into an otherwise continuous spline is to repeat a key position or to simply terminate the spline at a key and start an entirely independent spline to interpolate the next sequence of key frames.

Neither of these approaches is very satisfactory because the discontinuity cannot be controlled. While it is true that, mathematically speaking, a spline's derivative is either continuous or discontinuous, the artist's view is quite different. He would like to have more control over continuity than a simple on/off switch. In fact, from the animator's point of view two curve segments which have very different tangent vectors at their joint appear "more discontinuous" than two curve segments which have fairly similar tangent vectors. This concept is implemented in our system as a parameter which controls the continuity/discontinuity at a key position (Figure 12).

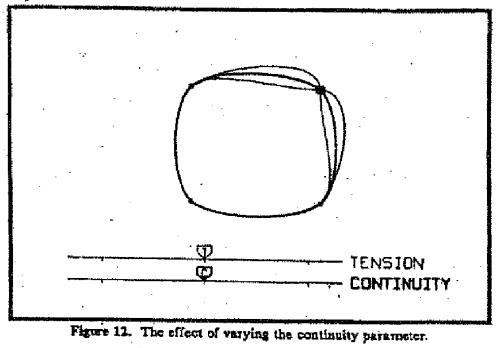


Figure 12. The effect of varying the continuity parameter.

Assuming default tension and using c to denote the continuity parameter, we allow the source and destination components of the tangent vector to differ from each other according to:

$$DS_i = \left(\frac{1-c}{2}(P_i-P_{i-1}) + \frac{1+c}{2}(P_{i+1}-P_i)\right)$$

Equation 5. The "incoming" continuity equation

$$DD_i = \left(\frac{1+c}{2}(P_i-P_{i-1}) + \frac{1-c}{2}(P_{i+1}-P_i)\right)$$

Equation 6. The "outgoing" continuity equation

Note that with $c=0$ (which we use as a default) we obtain $DS_i=DD_i$, which produces a spline with tangent vector continuity at the keys (Figure 13).

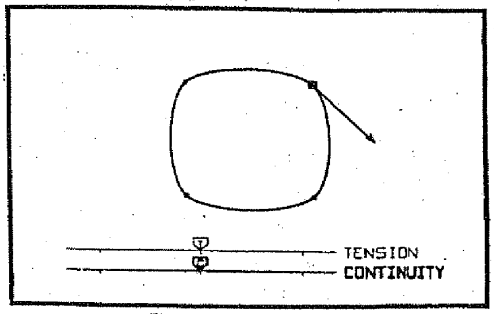


Figure 13. Default continuity.

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As $|c|$ increases, the two tangent vectors become increasingly distinct. When $c=-1$, the source tangent vector DS_i reduces to the source chord, and the destination tangent vector DD_i is the destination chord, producing a pronounced corner in the curve (Figure 14).

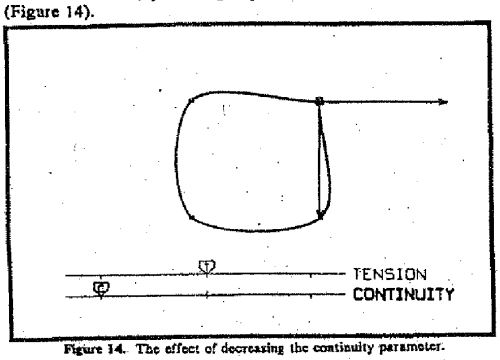


Figure 14. The effect of decreasing the continuity parameter.

Going in the opposite direction, at $c=1$, $DS_i = P_{i+1}-P_i$ and $DD_i = P_i-P_{i-1}$, produces a corner pointing in the opposite direction (Figure 15).

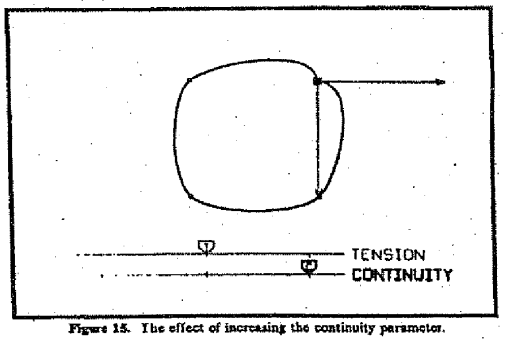


Figure 15. The effect of increasing the continuity parameter.

In Figure 16 some results of applying the same value of c to all key positions are depicted

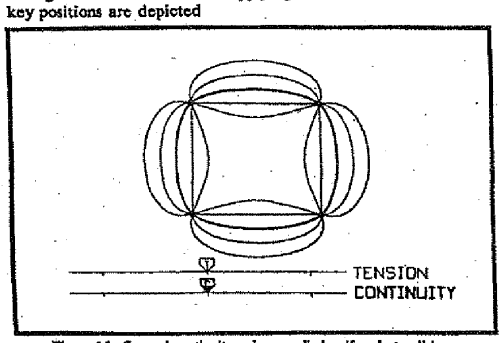


Figure 16. Several continuity values applied uniformly to all keys.

Looking only at the *path* of motion, the effects of increasing the tension or reducing the continuity seem to be rather similar (Figures 17 and 18).

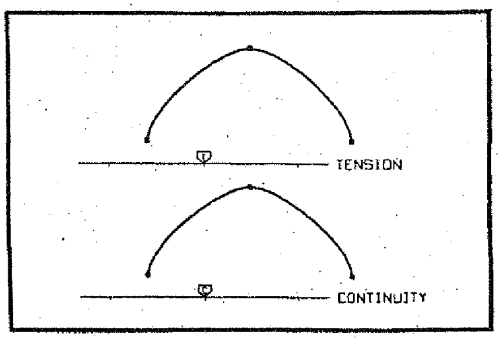


Figure 17. Default tension and continuity

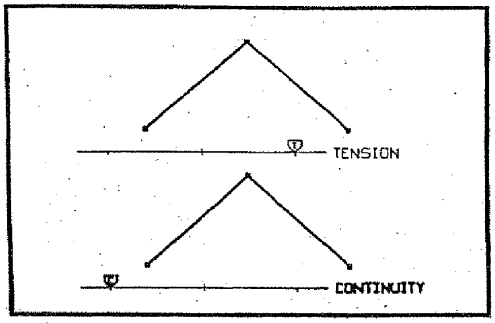


Figure 18. Increasing tension, reducing continuity

However, the *motion dynamics* are quite different (Figure 19).

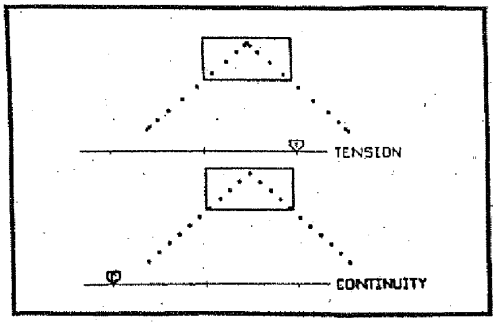


Figure 19. Differences in motion: tension vs. continuity.

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Increasing the tension does *not* introduce discontinuities in the velocity. Instead the length of the tangent vector, and therefore the speed, is eventually reduced to zero. By contrast, reducing the continuity produces an abrupt change in the direction of motion at the key position while the speed remains constant. This effect is often necessary to create realistic animation. For example, to make the movement of a ball careening off a tree look convincing, the animator must introduce a sharp corner in the path as the ball hits the tree. Increasing the tension would produce a corner in the path, but the speed at this corner would be zero, resulting in a *deceleration* before the ball actually hits. Reducing the continuity would produce the desired abrupt change, with the ball altering its direction of motion at the point of impact without slowing down ahead of time.

Generating the appropriate motion dynamics is extremely important in animation. If we look only at the motion path, the use of maximum tension appears to generate a discontinuity. However, this effect is simply a *geometric* discontinuity. What is needed in the case of the ball's encounter with the tree is a *parametric* discontinuity, a sudden change in the magnitude and/or direction of the velocity. This effect cannot be achieved by changing the tension because the tangent vector will always remain continuous under such a change, thus guaranteeing parametric continuity

3.3. Bias

The bias parameter b controls the direction of the path as it passes through a key position (Figure 20).

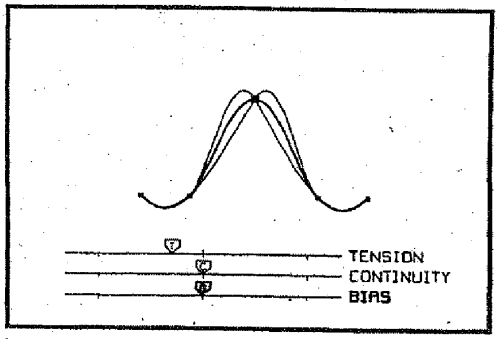


Figure 20. The behaviour of a curve under changing bias

Both incoming and outgoing parts of the tangent are formed as an average of the incoming and outgoing chords, but the bias assigns different weights to the two chords when forming the average. Assuming default tension and continuity ($t=c=0$), the tangent vector is given by:

$$DS_i = DD_i = \frac{1+b}{2}(P_i - P_{i-1}) + \frac{1-b}{2}(P_{i+1} - P_i)$$

Equation 7. The bias equation.

Note that with $b=0$ the two chords are weighted equally, and we obtain the default spline shown in Figure 21. When $b=-1$, the tangent vector is completely determined by the destination chord (Figure 22),

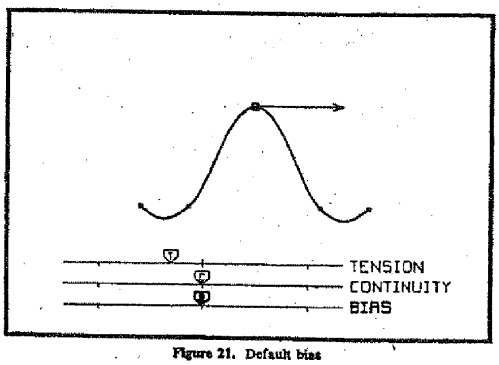


Figure 21. Default bias

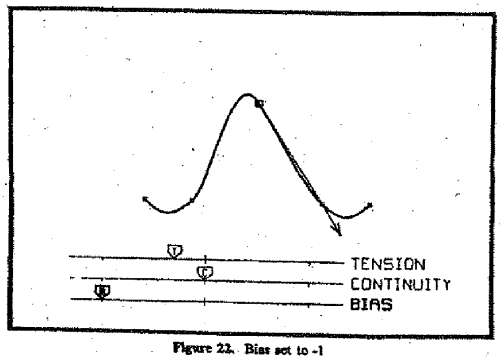


Figure 22. Bias set to -1

whereas with $b=1$ it is completely determined by the source chord (Figure 23).

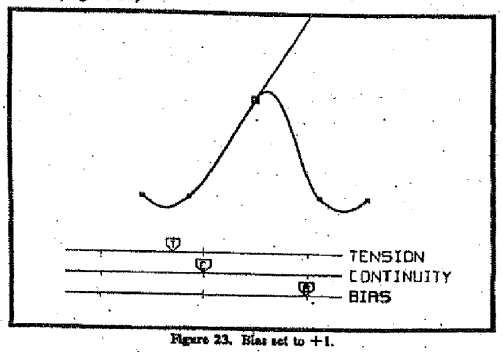


Figure 23. Bias set to +1.

The bias parameter easily simulates the traditional animation effect of following through after an action by "overshooting" the key position ($b=1$), or exaggerating a movement by "undershooting" a key position ($b=-1$).

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3.4. Composite Control

Combining the tension, continuity, and bias control parameters we obtain the following general equations for the source and destination tangent vectors at the key position P_i:

$$DS_i = \frac{(1-t)(1-c)(1+b)}{2}\cdot(P_i-P_{i-1}) + \frac{(1-t)(1+c)(1-b)}{2}\cdot(P_{i+1}-P_i)$$

Equation 8. The "incoming" composite equation

$$DD_i = \frac{(1-t)(1+c)(1+b)}{2}\cdot(P_i-P_{i-1}) + \frac{(1-t)(1-c)(1-b)}{2}\cdot(P_{i+1}-P_i)$$

Equation 9. The "outgoing" composite equation.

The spline segment between P_i and P_{i+1} can now be defined in terms of P_i, P_{i+1}, DD_i, and DS_{i+1}. All inbetween positions within this interval can then be generated by using Equation 2, varying the interpolation parameter s from 0 to 1 over the interval.

4. Adjustments for Parameter Step Size

If we assume default continuity ($c = 0$) at key P_i, the spline segment between P_i and P_{i+1} should join smoothly with the segment used between P_{i-1} and P_i. While this is true when looking only at the path of the motion, it may not necessarily be true for the speed of motion. The formulas given in Equation 8 and Equation 9 assume an equal time spacing of key frames, implying an equal number of inbetweens within each key interval. A problem can exist if the animator requests a different number of inbetweens for adjacent intervals. Consider the case where 10 inbetweens are supposed to be generated in the interval from P_{i-1} to P_i, but only 5 inbetweens between P_i and P_{i+1} as was shown in Figure 2. In the first interval, the step size for the interpolation parameter s will be $\Delta_1 = \frac{1}{11}$ whereas for the second interval the step size will be $\Delta_2 = \frac{1}{6}$. If the same parametric derivative is used for both splines at P_i, these different step sizes will cause a discontinuity in the speed of motion. What is required, if this discontinuity is not intentional, is a means of making a local adjustment to the interval separating successive frames before and after the key frame so that the speed of entry matches the speed of exit. This can be accomplished by adjusting the specification of the tangent vector at the key frame based on the number of inbetweens in the adjacent intervals. In practice this turns out to be very simple, because we have already made provisions for two distinct tangent vectors at each key position in order to accommodate the continuity control parameter. Once the tangent vectors have been found for an equal number of inbetweens in the adjacent intervals, the adjustment required for different numbers of inbetweens (N_{i-1} frames between P_{i-1} and P_i followed by N_i frames between P_i and P_{i+1}) can be made by weighting the tangent vectors appropriately:

$$\text{adjusted } DD_i = DD_i \cdot \frac{2 \cdot N_{i-1}}{N_{i-1}+N_i}$$

$$\text{adjusted } DS_i = DS_i \cdot \frac{2 \cdot N_i}{N_{i-1}+N_i}$$

Equation 10. Adjustment for parameter stepsize.

5. Current Experience and Future Developments

The tension, continuity, and bias parameters were designed to correspond closely to traditional animation effects. These ideas were tested and refined using a simple interactive spline display package. In one test we asked the animators to interactively modify the three control parameters until a spline passing through a set of key positions looked "natural" to them. We found that most animators left the continuity and bias at their defaults ($c=0$, $b=0$) but reduced the tension parameter. The tension values which animators considered to produce a "natural" looking curve for a given set of keys ranged from -0.1 to -0.4. It was interesting to note that while there was some disagreement between animators about the "best" tension value, each animator was surprisingly consistent in his choice.

These individual preferences are most likely related to differences in personal style. For example, some animators tend to animate movements more tightly (larger tension value) than others. This indicates that the tension is especially useful as a global default parameter which the animator can define according to his style preference. The continuity and bias parameters are mostly used in a local context, i.e. to achieve a particular effect at a specific key position. In practice, a small number of parameter combinations will probably be sufficient for most sequences. Several animators noted that the system should include but not be limited to a small set of predefined effects (e.g. "overshoot": $t=-0.3$, $c=0$, $b=1$). They still wanted to have the full power and flexibility of the three independent parameters available for more advanced users.

The algorithm described in this paper is currently being implemented at the National Film Board of Canada (free-form drawn 2-D and 2 1/2-D multiplane key frames) and the University of Waterloo (3-D key positions with skeleton control). These implementations will be used to test various user interface strategies for both inexperienced and advanced users.

6. Summary

The introduction of tension, continuity, and bias control produces a very general class of interpolating cubic splines. The flexibility which these parameters provide is especially useful in key frame animation, because it allows the animator to adjust the movement of objects without having to adjust or redraw the key frames (Figure 24).

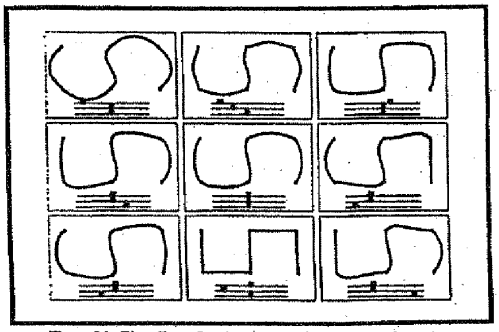


Figure 24. The effect of various parameter settings used together.

We have provided these control parameters by a simple technique of separating the tangent vector at each key frame

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into an incoming and an outgoing part and specifying these parts as a weighted average of the chords defined by the nearest neighbor key frames. Our system has the additional benefit that it can make adjustments to overcome speed discontinuities when the number of inbetweens is changed between key frames.

7. Acknowledgements

Feedback from animators is particularly important in a project such as this. We would especially like to thank Robert Forget, Rene Jodoin, Daniel Langlois, and Marc Aubry from the French Animation Studio of the National Film Board of Canada who as "test users" made many valuable suggestions which helped to clarify and refine our ideas.

Most of the illustrations in this paper are frames from the film "Interpolating Splines with Variable Tension, Continuity, and Bias" (National Film Board of Canada, 1984). We gratefully acknowledge the assistance of the Defence and Civil Institute of Environmental Medicine, Toronto, in the filming of this production.

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8. Bibliography

[1] R. Baecker, "Interactive Computer-Mediated Animation", PhD Thesis, MIT, Project MAC Technical Report MAC-TR-61, 1969.

[2] B. Barsky, "The Beta-spline: A Local Representation Based on Shape Parameters and Fundamental Geometric Measures", Ph. D. dissertation, Department of Computer Science, University of Utah, December, 1981.

[3] B. Barsky and J. Beatty, "Local Control of Bias and Tension in Beta-Splines", *Computer Graphics (SIGGRAPH '83)*, 17 (3), pp. 193-218, July, 1983.

[4] R. Bartels, J. Beatty, and B. Barsky, "An Introduction to the Use of Splines in Computer Graphics", Department of Computer Science, University of Waterloo, TR CS-83-09, August 1983.

[5] N. Burtnyk and M. Wein, "Computer Generated Key Frame Animation", *Journal of the SMPTE 80*, pp. 149-153, March, 1971.

[6] N. Burtnyk and M. Wein, "Interactive Skeleton Techniques for Enhancing Motion Dynamics in Key Frame Animation", Communications of the ACM 19 (10) pp. 564-569, October, 1976.

[7] D. Greenberg, S. Wu, and J Abel, "An Interactive Computer Graphics Approach to Surface Representation", Communications of the ACM 20 (10) pp. 703-712, October, 1977.

[8] D. Kochanek, "A Computer System for Smooth Keyframe Animation", MMath Thesis, Department of Computer Science, University of Waterloo, Technical Report CS-82-42, December, 1982.

[9] W. Reeves, "Inbetweening for Computer Animation Utilizing Moving Point Constraints", *Computer Graphics (SIGGRAPH '81)*, 15 (3), pp. 263-269, August, 1981.

[10] A. Smith, "Spline Tutorial Notes – Technical Memo No. 77", *SIGGRAPH '83 Tutorial Notes: Introduction to Computer Animation*, pp. 64-75, July, 1983.

[11] M. Tuori, "Tools and Techniques for Computer-aided Animation", MSc Thesis, Department of Computer Science, University of Toronto, 1977.

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Articulation simulation for an Intelligent Dental Care System

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CAD/CAM techniques are used increasingly in dentistry for design and fabrication of teeth restorations. An important issue is preserving occlusal contacts of teeth after restoration. Traditional techniques based on the use of casts with mechanical articulators require manual adjustment of the occlusal surface, which becomes impractical when hard restoration materials like porcelain are used; they are also time- and labour-consuming. Most existing computer systems ignore completely such an articulation check, or perform the check at the level of a tooth and its immediate neighbours. We present a new mathematical model and a related user interface for global articulation simulation, developed for the Intelligent Dental Care System project. The aim of the simulation is elimination of the use of mechanical articulators and manual adjustment in the process of designing dental restorations and articulation diagnostics. The mathematical model is based upon differential topological modelling of the jaws considered as a mechanical system. The user interface exploits metaphors that are familiar to dentists from everyday practice. A new input device designed specifically for use with articulation simulation is proposed.

Keywords: articulation, occlusion, dental systems

The Intelligent Dental Care System (IDCS) is an ongoing research project focused on computer-aided production of ceramic dental restorations, diagnosis for occlusal therapy and treatment and protocoling with the use of a database. An important feature of the system is use of articulation simulation for check of restoration design. The restorations created by the system should fit as well as possible the existing articulation of the patient; in usual dental practice this is achieved by manual adjustment of the restoration.

Most tooth restoration work in dental clinics is done by dentists and technicians using traditional methods. In the case of high-quality and long-life restoration materials such as porcelain or metal, the process of production of an inlay, onlay or crown (all of which we will refer to as *restorations*) requires significant resources, both in terms of time and human energy. Usually a mould of the tooth is taken and used by a technician to prepare a cast restoration, which in most cases must be adjusted by the dentist to have proper occlusal contacts with opposing teeth[1]. The cast is used with an adjustable mechanical articulator for manual simulation of the articulation. At least two visits by the patient to the clinic are required to prepare even a simple restoration using this technology. However, manual adjustment is quite difficult in the case of the use of hard materials (such as porcelain) for dental restoration. A computer articulation simulation checks the designed preparation before manufacturing a physical example of it, following fast automatic adjustment of the preparation. Another goal is articulation problem diagnosis, even if no particular tooth is under treatment. The idea is to detect articulation problems in more detail than is possible using traditional approaches, such as use of mechanical articulators. The computer articulation simulation is also used for planning treatment, evaluating automatically the results of various versions of virtual treatment. Thus, our objectives are speedup of restoration design and manufacturing (ideally a single visit to the clinic should be sufficient to complete treatment of a single tooth) and reduction of human labour (possibly eliminating the dental technician completely). These goals are achieved by:

- automation of manufacturing of restorations, including occlusal surface design, following gnathological rules (related to teeth and temporomandibular joint);
- simplification of articulation simulation by avoiding creation of mechanical models;
- elimination of manual adjustment of the inlay/onlay/crown after its manufacture;

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- development of an intuitive, easy-to-master, user interface using metaphors familiar to a dentist.

Within the last decade at least four CAD/CAM systems addressing the aforementioned problems have been developed: Sopha Bioconcept (France)[3] (also known as Duret system), Denticad (USA)[4], Cicero (Netherlands)[5] and CEREC (Switzerland)[1]. The CEREC system performs no articulation adjustment. Other systems simulate articulation at various levels; details on functionality and mathematical models employed are not available. A general impression, however, is that the articulation simulation is performed at the level of a tooth and neighbouring teeth; using this approach, many articulation problems cannot be detected.

This paper presents a geometric model used for articulation simulation and the related user interface of IDCS.

FUNCTIONALITY OF IDCS ARTICULATION SIMULATION

The process of creation of a restoration starts with measurement of the surface of the tooth under treatment, measurement of the surfaces of the jaws and measurement of the positions of the jaws. These last two measurements will be used for articulation simulation.

The next step is initial design of the shape of the restoration. The shape is partially constrained by the shape of the preparation, which will be reconstructed from measurements. The free (remaining) surfaces are taken from a library of shapes and/or a database, with a further adjustment according to the individual characteristics of the patient.

The ensuing shape is checked for articulation problems by the articulation simulator. The articulation simulation will detect basic articulation problems associated with the generated shape of the restoration. The following problems must be detected[6]: instability of occlusion; interference problems; bad position of the tooth with respect to the Spee curve; and change of habitual contact points in other teeth.

The information obtained will be fed to the shape generation software to change the shape so as to avoid the problems. We thus get an iterative process of design/check of the occlusal surface. Basic geometric features of the occlusal surface of the tooth (such as cusps, ridges and fossae) will be preserved where the properties of the restoration material allow their efficient reconstruction.

The final shape will thus be based on measurement data, library/database information about basic features of a tooth, general gnathological rules, and results of articulation optimization. The features unrelated to occlusion will therefore be based on previously stored data, and individual features of the patient. The user interface will give the dentist the possibility of interacting at any phase and perform manual adjustment of the shape, using the database and articulation simulation software.

Interactive shape design

Manual adjustment of the shape and the automatic shape design software are based on operations on topographical features. The automatic design and the interaction are inspired by the wax-up technique (Payne/Lundeen, Thomas)[6] used by the dental technician. It is important to extract essential topographical features of irregular shapes, to construct a higher level data structure that allows visualization using the traditional colour code of Lundeen and to perform operations on objects that are familiar and essential for the dentist (cusps, fossae, etc.). A huge number of control points is then reduced to higher level objects. The interactive shape design borrows a metaphor from the same wax technique. Wax is modelled layer by layer. The warm wax is transparent and easy to modify. As it cools (e.g. accelerated by blowing), it loses its transparency and becomes hard. The previous shape is visible during editing. With advances in computer graphics, it is not a very difficult problem to simulate and use such a method in the computer, switching between modes for adding, reducing and free manipulations. The articulation simulation can run in the background to produce warning messages and design hints immediately. These warnings are given in the form of textual messages and exposition of problem areas along with pseudocolouring the areas that produce the error. The problem zone need not have its causes in the immediate neighbourhood.

The designed shape is passed to a milling device, which manufactures a restoration.

MODEL FOR ARTICULATION SIMULATION

We present here a mathematical model for articulation simulation. The motivation of the model is described below.

The pair of human jaws is considered as a mechanical system, formed by two rigid bodies, the upper jaw and the lower jaw. Constraints imposed on the system include the position of the jaw joints (two-sided constraint) and the positions of the teeth (one-sided constraint). Given a position of the jaws and forces applied by the jaw muscles, we may calculate the pressures and torques experienced by each tooth. The parameters thus calculated may be exposed to the dentist, providing information about the correctness of the patient's articulation. The system may be used for indirect calculation using some geometric and kinematic characteristics that correspond to pressures and torques.

The system primarily simulates the behaviour of teeth near the grinding position, because the parameters of the articulation due to the joint constraints (the maximal opening angle, etc.) are easy to measure immediately. The following approaches may be used for evaluation of the articulation:

- Static approach;
- Dynamic approach;
- Averaged dynamic approach.

The above approaches may be used separately, or in combination; they are described in more detail below. The

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following basic assumptions are made:

1 Three-dimensional coordinates of enough points on the surfaces of the teeth are measured or may be easily found (say, from an appropriate surface representation); the coordinate systems are bound to the respective jaws.
2 The jaws (with the teeth) are rigid bodies.
3 The position of the upper jaw does not influence the pressures experienced by each tooth, only the position of the lower jaw in relation to the upper jaw (in particular, we neglect gravitational forces).
4 The lower jaw has three degrees of freedom if the upper jaw is fixed; in particular, the position of the lower jaw in relation to the upper jaw is completely determined by the position of one point in the lower jaw.

It should be noted that assumptions 2 and 4 are not considered absolute; a threshold error value is introduced for the account of minor deviations from these assumptions that obviously occur in the process of grinding.

The model involves three basic steps:

1 Geometric modelling: description of the configuration space.
2 Mechanical modelling: estimation of the pressures, torques and/or other characteristics for evaluation.
3 Analysis of the characteristics from Step 2 for diagnosis.

TOPOLOGY OF THE CONFIGURATION SPACE

Let us consider the configuration space Q of the mechanical system that we are interested in, that is, the pair of jaws. Recall that the configuration space is the set of all positions of the system endowed with the topology determined by our understanding of which positions are near; thus, each element (point) of Q corresponds to a particular position of the jaws. In most cases, the configuration space is a manifold, that is, admits a Euclidean coordinate system near each point.

In our case, at each position there are three degrees of freedom for possible motions of the lower jaw (though only in one direction at some positions), so Q must be three-dimensional.

Clearly, Q is bounded, because it is bounded in each coordinate. Furthermore, the boundary of Q is formed by two sets of positions of the jaw: D_j, the set of positions where the coordinates (the angle and the horizontal displacements) attain their extremal values allowed by the jaw joint; and D_t, the set of points where some teeth of the lower jaw are in contact with some teeth of the upper jaw.

The boundary $D = \partial Q = D_j \cup D_t$ is a two-dimensional manifold, not necessarily smooth. However, D_j and D_t may in principle be determined analytically in a form $f_j(x, y, z) = 0$ and $f_t(x, y, z) = 0$, where f_j is determined by the shape of the jaw joint, and f_t by the shape of the teeth.

Obviously, D_t is connected, because it is possible to move from any position in D_t to any other position in D_t remaining in D_t (that is, it is possible to move from any position in which teeth are in contact to any other positions in which some teeth touch each other so that the jaws are in touch all over the motion). The same applies to D_j and D. It follows that Q is homeomorphic to a domain in R^3 with a connected boundary. Furthermore, any loop in Q (that is, any motion of jaws that starts and ends at the same position) is homotopic to a constant mapping (that is, to the zero motion). Therefore Q is homeomorphic to a three-dimensional ball, and D_t to a two-dimensional disk.

Three coordinate systems are involved in calculations: the external coordinates u, v and w, the coordinates bound with the upper jaw x, y and z, and the coordinates bound with the lower jaw ξ, η and ζ.

To fix the coordinate systems (u, v, w) and (ξ, η, ζ), it is appropriate to measure the (external) coordinates of six points, three non-collinear points A_0, A_1 and A_2 on the lower jaw and three non-collinear points B_1, B_2 and B_3 on the upper jaw. It is important to find the coordinates of points of the jaw bones, not the surface of the skin, because deviations due to deformation of the skin over the bones are impossible to account for.

Given the external coordinates of the points, we may fix points A_0, B_0 as origins of the coordinate systems, and define the base vectors and coordinate transformation using standard formulas from linear algebra. The following points should be noted:

1 It is possible to eliminate two of the three coordinate systems, and carry out the calculations in one of them, recalculating the results if required (say, for visualization purposes) in any other. Note, however, that the transformation matrices depend on the position of the jaws; in particular, they are time dependent if we simulate motion of the jaws. It seems reasonable to choose as the working coordinate system (the one used for the calculations) the one bound to the upper jaw.
2 One important property of a coordinate system that can facilitate calculation of occlusions is that the configuration space should be *convex* with respect to one of the coordinates. In effect, in our case this means that every straight line in the direction of the coordinate should meet the surfaces of the teeth in the upper jaw and the lower jaw at most at one point (at least, in the positions of the jaws with the teeth clenched). The choice as above satisfies this condition if the points A_0, A_1 and A_2 lie in a 'horizontal' plane (that is, a plane that meets the jaw at a small angle; the term 'horizontal' is put in quotation marks because its actual position in the external frame of reference depends on a particular position of the patient).
3 Under the above assumptions, measuring six points is redundant, because as soon as the position of the upper jaw is fixed, position of a single point in the lower jaw determines the position of the lower jaw completely. However, restoration of the position of the lower jaw from one point requires additional information; this is discussed in the next subsection.

As we assumed, the position of the lower jaw is completely determined by the coordinates of a single point in the lower jaw. However, we need to be able to restore the position of the lower jaw from the coordinates of this single point.

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In principle, this requires knowledge of the structure of the jaw joint, and it is not easy to measure.

Another solution would be to measure the positions of the lower jaw that correspond to some of the positions of the point, and then interpolate.

In what follows, the position of the lower jaw means the position in relation to the upper jaw; in particular, the 'external' coordinates are the ones in a coordinate system bound to the upper jaw.

In principle, the lower jaw has six degrees of freedom, so its position is determined by the position of a point P fixed in the lower jaw and an orthogonal frame. Thus, to restore the position of the jaw from a position P, we need to find the mapping $\phi : R^3 \to SO(3)$ that assigns to each position of P the (orthogonal) transformation matrix from some given orthonormal frame to the position of an orthogonal frame that is frozen in the lower jaw. Thus, we fix an orthogonal frame ϵ_i, $i = 1,2,3$ frozen in the lower jaw; let ϵ_i^0 be the base that corresponds to some position P_0 of P in relation to the upper jaw. Then to any position P_t of P corresponds the position ϵ_i^t of the base. The transformation from ϵ_i^0 to ϵ_i^t is $\phi(P_t)$.

It is natural to expect that the position of the lower jaw is completely (up to some error value) determined by the positions of the surfaces of the jaw joint, and that the constraints are of the form 'a surface in the lower jaw is tangent to a surface in the upper jaw' (of course, the surfaces in question need not be the actual surfaces of the jaw bones). It is easy to see, however, that the condition 'the rigid body is tangent to a fixed surface at two points' only fixes two degrees of freedom, so we need to fix one more degree of freedom for the lower jaw. Therefore, we need to make an additional assumption about the possible position of the lower jaw. The simplest assumption of this kind is

Assumption: There are vectors $\mathbf{p}$ and $\mathbf{q}$ such that

$$\phi(P_t)\mathbf{p} \perp \mathbf{q}$$

for all positions P_t of the point P.

The geometric sense of the vectors $\mathbf{p}$ and $\mathbf{q}$ may be explained as follows. Suppose the upper and the lower jaws have planes of symmetry. Then the assumption is that the direction of the line where the two planes intersect remains constant (we do not assume that the *line* is constant, only that it remains parallel to a fixed direction as we move the jaws). Now $\mathbf{q}$ is the directing vector of this line, and $\mathbf{p}$ is the normal to the plane of symmetry of the lower jaw. In reality, the jaws may not be symmetrical, but we still assume the existence of the two vectors (although their geometric sense is not so obvious). Roughly, the vector $\mathbf{q}$ is the 'vertical' direction in relation to the upper jaw.

The vectors $\mathbf{p}$ and $\mathbf{q}$ may be found from measurement of several positions of the jaw (both P_t and $\phi(P_t)$ are measured; this is equivalent to measurement of six points). It is possible, in principle, to find the vectors $\mathbf{p}$ and $\mathbf{q}$ from three measurements, though finding it from many measurements by minimizing an appropriate deviation functional seems much more reliable.

It should be noted that the vectors $\mathbf{p}$ and $\mathbf{q}$ are not uniquely defined (which can be seen from simple geometric considerations); if we wish to select the solution so that $\mathbf{q}$ had the sense of the 'vertical' and $\mathbf{p}$ 'the normal to the symmetry plain of the lower jaw', we should select the solution in which the vector $\mathbf{q}$ is nearest to the 'vertical' vector $\mathbf{e}_3$.

As soon as we know the vectors $\mathbf{p}$ and $\mathbf{q}$, we may write the matrices of the operators $\phi(P_t)$ in the form $\phi(P_t) = C^t A(\alpha_1, \alpha_2) C$ where

$$A(\alpha_1, \alpha_2) = \begin{pmatrix} \cos\alpha_2 & -\sin\alpha_1 \sin\alpha_2 & -\cos\alpha_1 \sin\alpha_2 \\ 0 & \cos\alpha_1 & -\sin\alpha_1 \\ \sin\alpha_2 & \sin\alpha_1 \cos\alpha_2 & \cos\alpha_1 \cos\alpha_2 \end{pmatrix}$$

α_1 and α_2 may be interpreted as the angles of rotations of the lower jaw about the axes $\mathbf{q}$ and $\mathbf{p}$ (but we do not use this interpretation).

In the simplest statement, restoration of the mapping ϕ requires initial measurement of several positions of three points in the lower jaw (and three points in the upper jaw, to count into the coordinates bound to the upper jaw). To interpolate, we may use spline techniques, which, however, will give us piecewise interpolation. Another possible approach is to use the orthogonalization technique, where orthogonalization on the set of measured positions is applied to a set of basic functions.

An important issue in the application of this method is the choice of the base functions. We may use the following idea: choose some initial approximation derived from our general information about the shape of the jaw joint, and use, say, polynomials for improving the approximation. The initial approximation will obviously depend on several unknown parameters; some measured positions may be used for finding these parameters, and the rest for further approximation. Thus, we will search for $\phi(P_t) = (\alpha_1(x, y, z), \alpha_2(x, y, z))$ in the form

$$\alpha_i(x, y, z) = g_i(a_1, \ldots, a_k, x, y, z) + c_{i0} + c_{i1x}x + c_{i1y}y + \ldots$$

where $a_1, \ldots, a_k$ are parameters, found from the first $k/2$ measured points, and $g_i(a_1, \ldots, a_k, x, y, z)$ is the initial approximation; the error will be measured as $\|f - f_0\|$ where $\|\cdot\|$ is defined as the mean quadratic deviation from zero over the set of measured positions, and f_0 is the difference between the measured value and g_i.

Let us assume as the initial approximation the model in which the set of positions of the lower jaw is determined by the conditions that some surfaces associated with the joints are always tangential, and that the surfaces are of the second order (we do not assume that the surfaces are actual surfaces of the jaw joints, just some surfaces associated with the joints). The assumption leads to the system of equations

$$\begin{cases} (A^L x^L, x^L) + 2(B^L, x^L) + 1 = 0; \\ (Ca^L C^t(x^L - x), x^L - x) + 2(Cb^L, x^L - x) + 1 = 0; \\ A^L x^L + B^L = \lambda(Ca^L C^t(x^L - x) + Cb^L); \\ (A^R x^R, x^R) + 2(B^R, x^R) + 1 = 0; \\ (Ca^L C^t(x^R - x), x^R - x) + 2(Cb^R, x^R - x) + 1 = 0; \\ A^R x^R + B^R = \mu(Ca^R C^t(x^R - x) + Cb^R); \end{cases}$$

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where x^L and x^R are the points where the surfaces are tangents in the left and the right joint, λ and μ are the Lagrange coefficients, x is the position of the point P, $C = \phi(x)$ is the unknown matrix, A^L, A^R, a^L and a^R are constant 3×3 symmetrical matrices (quadratic parts of the equations of the surfaces in the coordinates bound with the respective jaw; the superscripts L and R stand for the left and the right joint), and B^L, B^R, b^L and b^R are constant vectors (linear parts of the equations of the surfaces). The system depends on 36 parameters if we do not assume symmetry of the jaws, and on 21 parameters if we do.

Once the jaw joint model is established, collision detection algorithms are used to find points of the set D_t. As the set D_t is known, we may represent grinding positions of the jaws as points of D_t, and motions of the jaws as curves in Q; the parts of the curves that lie in D_t correspond to the parts of the motion where actual grinding (or biting) takes place.

It should be noted that there are reasons to consider points of Q that do not belong to D_t, but lie near it. The reasons are:

- The representation of the surfaces of teeth is never exact;
- The practical purpose of the articulation correction is to correct the process of chewing food, and particles of foods have finite size;
- It is obvious that teeth normally meet at many points, and even regions; in the 'exact' approach, events like that are highly unusual (not in a general position). Therefore, it makes sense to account for non-rigidity of teeth and tooth mobility, and the possibility of minor rotations of the lower jaw about the back-to-front axis.

Therefore, it is appropriate to consider as the 'working area' the set $D_t^\delta = \{q \in Q$: the distance between the upper and the lower jaws does not exceed $\delta\}$ where δ is a small distance. Note that introduction of the set D_t^δ allows, in particular, smoothing out of the singularities of the surface and measurement errors due to the roughness of the surfaces of teeth.

It seems reasonable to choose the values of δ ranging from 0.3 mm (for soft food) to $\geqslant 1.0$ mm (for hard food). Moreover, it is possible to calculate the data for various values of δ, thus obtaining the characteristics relevant to various grinding regimes.

CALCULATION OF THE CHARACTERISTICS AND EVALUATION

Calculation of the characteristics and further evaluation of the articulation cannot be considered separately, because before calculation we need to fix what exactly we are going to calculate. Three major models for evaluation are considered, called here dynamic model, averaged model and averaged dynamic model.

Dynamic model

In this model, we assume that the motion of the lower jaw is given, that is, that we know the position of the lower jaw as a function of time. This function may be found from measurement with interpolation, with the orthogonalization method, or some other method. It is now possible to find the accelerations of the teeth near contact points. This information may be used to calculate pressures experienced by the teeth, provided that we know the characteristics of the additional forces applied by the jaw muscles at the positions when the teeth are in contact. The possibility of successful implementation of this approach depends on the variability of the grinding regimes used by different persons, or by the same person at different times.

One problem here is that the pressures found for each contact point are to be distributed over the contact area that arises due to the introduction of the error level δ above. A reasonable solution is to assume that the pressure on a particular point of the tooth is proportional to the cosine of the angle between the normal at the contact point and the point in question; thus, the distribution of the pressures is described by

$$p = \frac{F \cos \alpha}{S}$$

where F is the normal force applied to the contact point and S is the volume of the contact area.

A simpler and more reliable approach is to evaluate simpler characteristics than pressures, such as

- The points of teeth that are in contact at the position;
- The 'grinding contact areas' for each pair;
- The cosines of the angles between the axes of contacting teeth.

The characteristics thus calculated may be displayed on the screen for evaluation (see below about possible interface).

Static (averaged) approach

The idea of this approach is to use averaged characteristics rather than dynamically varying characteristics as in the previous model. Formally, we may define a 'characterizing function' f defined on the surface of the teeth with a parameter in D_t, and calculate the mean value of the characteristic over all possible positions of the lower jaw in D_t. The simplest choices of the function f are

$$f = \begin{cases} 1 & \text{if the point is in contact with some other point} \\ 0 & \text{otherwise} \end{cases}$$

The ensuing averaged characteristic tells the average involvement of the tooth in the grinding process, or

$$f = \begin{cases} \cos \alpha & \text{if the point is in contact} \\ 0 & \text{otherwise} \end{cases}$$

where α is the angle between the normal at the contact point and the axis of the tooth (which, of course, should be defined; it could be the direction of the fibres that form the tooth). The averaged characteristic may be considered as an estimate for the average effective loading on the tooth.

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It seems reasonable to introduce weight functions for the averaging, to take into account the following considerations:

- Some positions of jaws are very common in the grinding process, and some are quite unusual.
- Some (parts of) teeth are able to tolerate greater pressures than others.

Combined (averaged dynamic) approach

Finally, if we are able to extract some standard motions of the lower jaw in the grinding process, we may act as in the averaged model, restricting the integration to a neighbourhood of the curve in D_t that represents the motion. Thus, we obtain averaged characteristics for the given motion rather than for all positions of the jaws. It should be noted that at least three basic regimes should be distinguished, 'cutting' (incisors), 'biting' (canine teeth) and 'grinding' (molars).

VISUALIZATION: REPRESENTATION OF DATA FOR THE DENTIST

As in other disciplines, time is an important resource for a dentist, so the diagnosis must be fast and accurate; this implies the requirements of fast visualization, to present the result of the simulation in an easily understandable way. The dentist is trained to work and see in three-dimensional space, and this impression should be conveyed as much as possible when results of articulation simulation are presented. 3D computer graphics techniques offered by graphical workstations are an indispensable tool for analysis of complex motions of the mandible. Computer animation of the motion of the jaw reveals to the dentist information that cannot be assessed using traditional methods.

An important issue is the speed of image display. The image quality and realism can be offtraded for reduction in delay of visual response to the user request. Level of details of the teeth model should be automatically adjusted to the capabilities of the display in order to avoid latency in interaction with the dentist. For the purpose of aesthetic evaluation, more accurate rendering should be provided with a time penalty in proportion to the required image quality.

Since the jaw articulation is complex, visualization abstractions and metaphors that are familiar to the dentist are desirable. An issue of primary importance is display of the border of mandibular movement (the so-called Posselt figure), especially in the proximity of the occlusal contact area. Suzuki[7] introduced the notion of kinematic condylar points which simplifies analysis of the condylar movement path. Visualization of the axis passing through the left and right kinematic condylar points is very useful in clinical diagnosis and treatment of stomatognathic dysfunctions. The 'tapping test'[2], in which the dentist marks tooth contact points by coloured paper, is a useful metaphor of everyday clinical practice when simulated by the computer. Display of the colours (e.g. red is used to show contact point in centric occlusion) which exactly correspond to the colours of the paper used refers directly to the habits of dentists.

The functionality of the user interface is quite standard for visualization applications. An arbitrary view of teeth or jaws is feasible. By default, systems of most useful projections are provided. Final adjustment of viewing parameters can be done interactively through user interface facilities. Multiple windows can be opened at the same time, exhibiting different views (projections) of the same object. Selective rendering is possible, i.e. visualization of the single tooth in isolation, the group of selected teeth, the whole jaw. When particular teeth are outside the scope of the present interest of the dentist, they can be hidden (removed from display), while still considered by the articulation simulator. The visualization can be done in two colour modes: realistic colour mode, and pseudocolour mode to visualize any physical quantities (in this case 3D distribution of pressure and/or other characteristics).

Another important topic for design of the user interface is to provide the dentist with the possibility of controlling the system easily using only one hand. To that end we developed a user interface and interaction methods based on direct manipulation of objects[8].

With the output of the simulation module, the visualization module can display the following entities:

- Contact points in centric occlusion (habitual intercuspidation) in 2D. This will help the dentist to find supporting points.
- Animation for specific grinding paths, such as those corresponding to biting, grinding, motion from centric occlusion to lateral working position, etc.
- Average positions of contact points for one specific grinding path.
- Areas with no contact in a specific grinding path.
- A selected instance of a grinding configuration for the dentist to examine chewing in an interactive way.
- An averaged view of contact points.
- Differences of an averaged view to other simulations (i.e. before treatment, with other patients, etc.); this allows comparison of various versions of treatment for better choice.
- Biting in front view (see *Figure 1*).

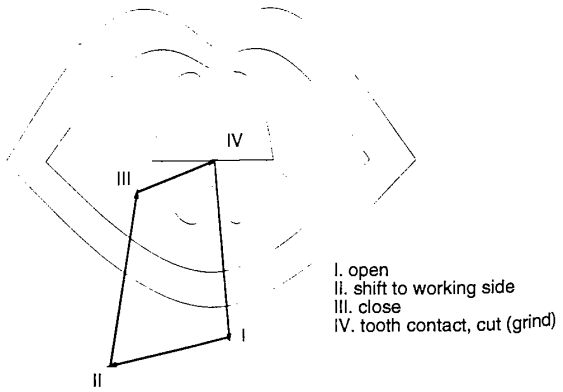


Figure 1 Biting in front view

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- Areas within contact distance (settable).
- Distribution of characteristics calculated in articulation simulation.

USER INTERFACE

In order to control dynamic processes, two-dimensional input devices such as a mouse or trackball have been used. In 3D simulation, these devices are not adequate, and their use implies obvious inconveniences. We propose a new input device (see *Figure 2*) which is an abstract mechanical model of a jaw including teeth, which can be moved in any direction. We have little intuition for 3D manipulation with a normal mouse and trackball. The special input device allows us to reduce the cognitive distance. The metaphor is based on the traditional approach using mechanical articulators. It should be stressed, however, that the device in question is used only for data input, not for the simulation itself.

The Articulation Simulation Controller must provide the following data to the simulation process:

- Relative position of upper and lower jaws;
- View direction angles x and y;
- Zoom factor z.

In addition, a feeling of friction and the control of boundaries need to be made available for the dentist's observation. Also, settings of the device must be stable; that is, if the dentist releases the Articulation Simulation Controller, the device parameters (see *Figure 3*) must not change. All relevant movements must be easy to perform. This can be achieved by building a light device, using balanced mechanics or servocontrolled mechanics. For hygienic reasons, all mechanical parts should be sterile and easy to clean. The time for dismantling the device should be minimal, so that a change of task can be performed smoothly.

Within the proposed approach, the dentist has a more realistic control with the Articulation Simulation Controller, which has a familiar shape. It brings back the control of a system to the user without immersing him into an expensive virtual world, which still lacks realism.

OTHER POSSIBLE APPROACHES TO DATA INTAKE

HMD and glove with force feedback

Using advanced techniques, such as head-mounted displays and gloves with force feedback, would allow one to manipulate and feel the measured model. In our approach, the dentist feels a generic model and has to look at the screen. The user is not immersed. On the other hand, such an approach in virtual reality would nowadays bring the installation costs to a prohibitively high level. Also, starting the system would consume much time. The dentist will have to wear a special glove and a helmet. Fast switching of tasks during work is difficult.

Camera-observed hand movements

Nowadays, cameras connected to computers are becoming less expensive and may be a standard device in future. This will open the door to new input methods to overcome the disadvantages of the traditional keyboard and mouse. The dentist may also use a pen with optically defined top and endpoints. This can help to distinguish the direction of movement. With a foot paddle (switch) the dentist can also virtually connect the pen to the image of the upper or the lower jaw on the screen. Connection to the lower jaw may be used for changing the exposed relative position of the jaws, and connection to the upper jaw for setting a new viewpoint.

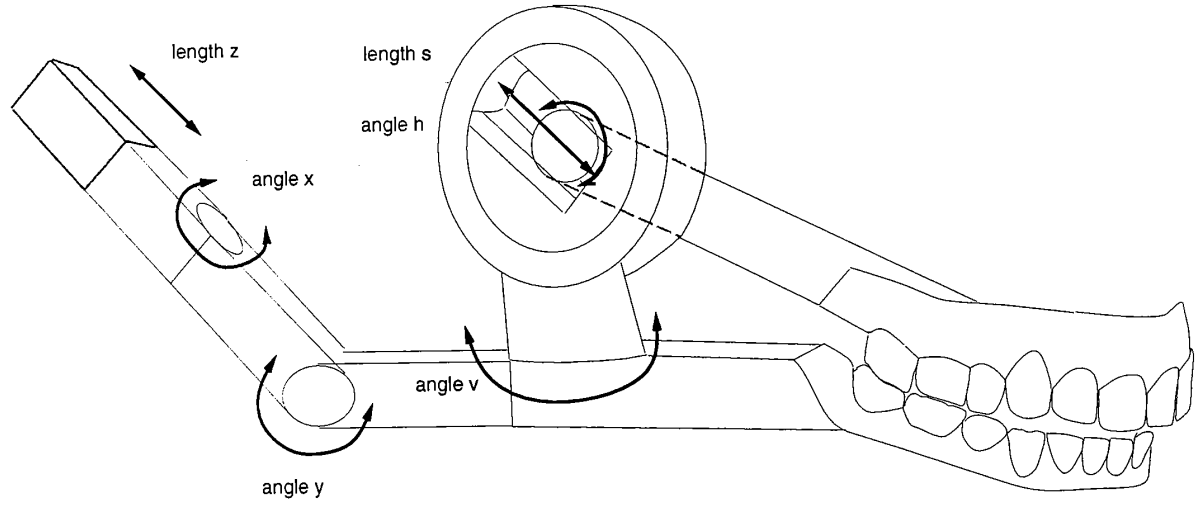


Figure 2 Principal mechanics of Articulation Simulation Controller

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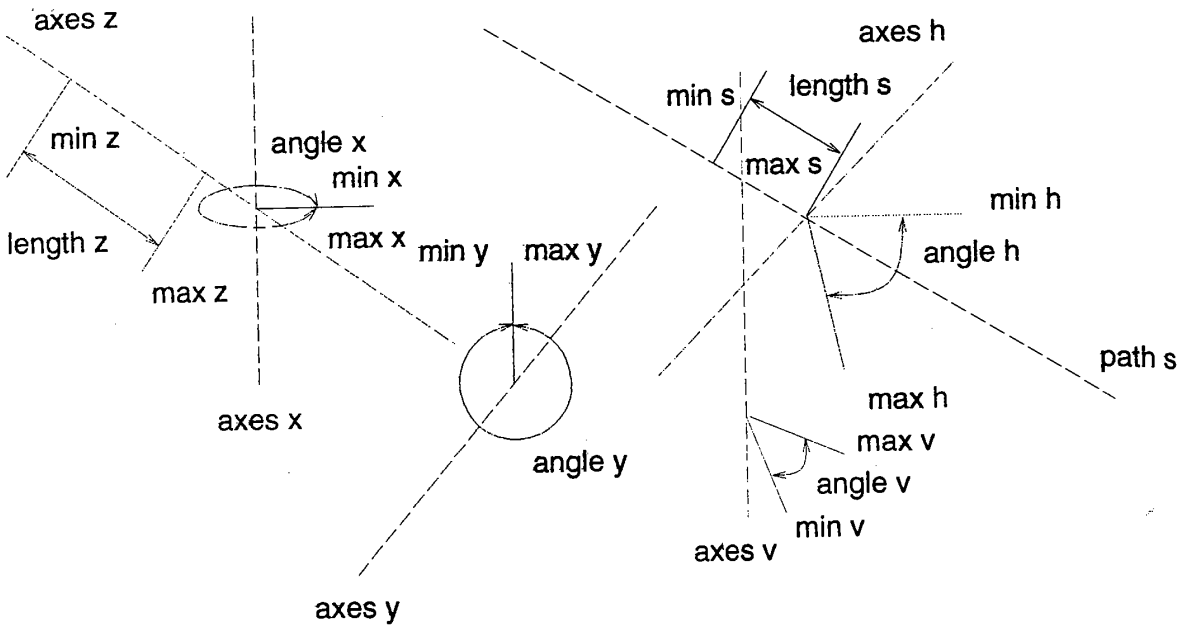


Figure 3 Parameters *z*, *x*, *y*, *s*, *v*, *h*

CONCLUSIONS

The project is not yet close to completion, and many details require validation and refinement. This progress report is addressed to those involved in development of computer-aided dental systems.

The basic concept of the Intelligent Dental Care System project is integration of restoration shape design, articulation simulation, database facilities and user interface in an easy-to-use system. Articulation simulation is used both in conjunction with a shape-modelling module, for evaluation of the shape design, and as a separate option, as a tool to facilitate specific treatment aimed at articulation correction. The system can hardly take into account all aspects of articulation treatment, such as, say, the neurological status of the patient; even so, it will be useful in dealing with specific problems related to the anatomy of the teeth. Of course, a system of this kind is useless unless it includes a relevant user interface. It should be noted that computer-aided dental systems are a relatively new idea, so it is difficult to expect computer expertise from the user. We tried therefore to arrange the interface in such a way that its use should resemble the functionality of the tools commonly used in dental practice.

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REFERENCES

1 Hofmann, N 'Fabricating and fitting computer-machined porcelain inlays'. *Das Deutsche Zahnärzteblatt–Zahnärztliche Welt* 1990, **7**, 530–537
2 Rateitschak, K H E M, Wolf, H F and Hassell, T M *Color Atlas of Dental Medicine 1, Periodontology*, Vol. 1, Georg Thieme, Stuttgart, 2nd edn, 1989
3 Duret, F, Blouin, J L and Duret, B 'CAD/CAM in dentistry'. *J. Am. Dent. Assoc.* 1988, **117**, 715–720
4 Rekow, D E 'CAD/CAM in dentistry: Critical analysis of systems'. In: *Computers in Clinical Dentistry* (ed J D Preston), Quintessence Publishing, Chicago, 1991, pp 172–185
5 van der Zel, J M 'Ceramic-fused-to-metal restorations with a new CAD/CAM system'. *Quintessence Int.* 1993, **24**(11), 769–778
6 Okeson, J P *Management of Temporomandibular Disorders and Occlusion*, C. V. Mosby, St Louis, 2nd edn, 1989
7 Suzuki, A 'A study on mandibular movement in six degrees-of-freedom with a newly developed jaw movement analyser'. *J. Jpn. Prosthodont. Soc.* 1987, **31**, 712–715
8 Conner, D B, Snibbe, S S, Herndon, K P, Robbins, D C, Zeleznik, R C and van Dam, A 'Three-dimensional widgets'. *Comp. Graphics* 1992, **25**, 183–188

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Three-dimensional dental cast analyzing system using laser scanning

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The purpose of this article is to introduce the outline of our newly developed three-dimensional dental cast analyzing system with laser scanning, and its preliminary clinical applications. The system is composed of a measuring device with a slit-ray laser projector and two sets of coupled charged devised video cameras, an image processing unit, a 16-bit personal computer as a controller, and an engineering workstation as a post processor. The dental cast is projected and scanned with a slit-ray laser beam. The raster coordinates of the target are determined with an image processor. Triangulation is applied to determine the location of each point. Generation of three-dimensional graphics of the dental cast takes approximately 40 minutes. About 90,000 sets of X,Y,Z coordinates are stored in the main memory of the microcomputer. The measurement error is less than 0.05 mm. Besides the conventional linear and angular measurements of the dental cast, we are also able to demonstrate the size of the palatal surface area and the volume of the oral cavity. The advantage of this system is that it facilitates the otherwise complicated and time-consuming mock surgery necessary for treatment planning in orthognathic surgery.
(Am J Orthod Dentofac Orthop 1996;110:365-9.)

In orthodontic treatment the information obtained from the dental cast is invaluable not only for the diagnosis, but also for treatment planning. However, it has been difficult to obtain quantitative information regarding probable changes in the volume of the oral cavity after treatment. Furthermore, it is imperative to set the treatment goal before commencing active treatment (VTO). For this purpose, we have used handmade set-up models to determine what the treatment goal would be. However, that is extremely time consuming and makes comparing multiple alternative treatment plans in an individual case a long and laborious process. Hence, the development of a computer-aided designing system for the orthodontic field has long been an important goal.

The purpose of this article is to introduce the outline of our newly developed three-dimensional analyzing system with laser scanning, together with some initial clinical results that indicate clinical feasibility.

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MATERIAL AND METHOD

The system is composed of a measuring unit (3D-VMS250R UNISN, Inc., Osaka, Japan), a 16-bit personal computer (PC-9821Ap, NEC, Inc., Tokyo, Japan) as the controller, and an engineering work station (Titan Vistra 800X Kubota Computer, Inc., Tokyo, Japan) as the post processor. All units are linked on the network.

Data Acquisition

The measuring device consists of a slit-ray laser projector, two CCD video cameras to capture reflected images, X-Y object tables, an R-table to measure the circumference of the object, an image processor, and a personal computer used as a data controller.

The dental cast is projected and scanned with a slit-ray laser beam of a 670 mm wavelength at 3 mW output, through a revolving polygon mirror (Fig. 1). This slit beam is projected in the X-Y plane that crosses the x-axis at right angles, and the reflected laser beams are simultaneously received with two CCD video cameras. The drive mechanism of the measuring device is driven by a stepping motor with a measuring pitch of 0.01 mm × N ($N\ max$ = 500). The object to be measured is fixed on the rotary table, and the X-table is moved in the slit-ray plane. In the case of a large object, y-axis measurements are made by dividing the y-axis plane into two

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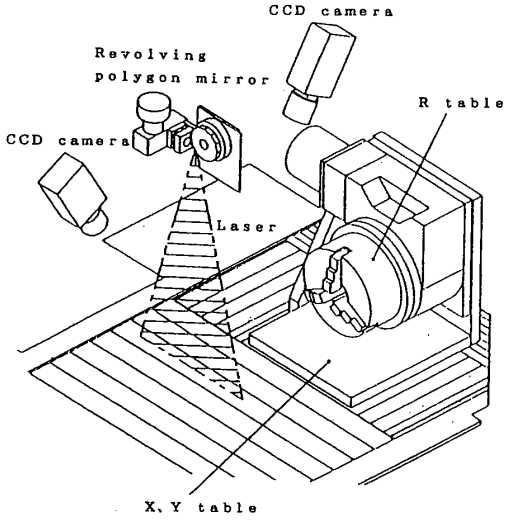


Fig. 1. Measuring device composed of slit-ray laser projector, two CCD video cameras to capture reflected images, X-Y object tables, and R-table to measure circumference of object.

parts. The R-table provides an automatic full circle sampling with a minimum blind sector by dividing 360° into six sectors. The z-axis measurements are calculated by using the principle of triangulation (Fig. 2). Triangulation requires only one CCD camera, but two cameras are used to ensure adequate sampling of recessed areas, which might not be sufficiently accessible with a single camera.

The image processor converts raster coordinates and brightness data of analog video signals input from the CCD cameras into digital data, which is then sent to the personal computer on real time. The personal computer imports the data from the image processor and, after moving the target to the next measurement position, converts the picture coordinates to three-dimensional spatial coordinates. Approximately 90,000 sets of X,Y,Z coordinates are stored in the main memory of the personal computer. The measurement error is less than 0.05 mm.

Generation of Three-Dimensional Graphics

The three-dimensional dot map data is relayed from the personal computer into the engineering workstation on the network, and the curved surface is automatically generated by root mean squaring the measurement data. Generation of a three-dimensional graphic of the dental cast takes approximately 40 minutes. A solid wax model can also be generated from the measurement data, with a numerical control milling machine (Comms PNC-2400G Corp., Hamamatsu, Japan Roland Digital Group).

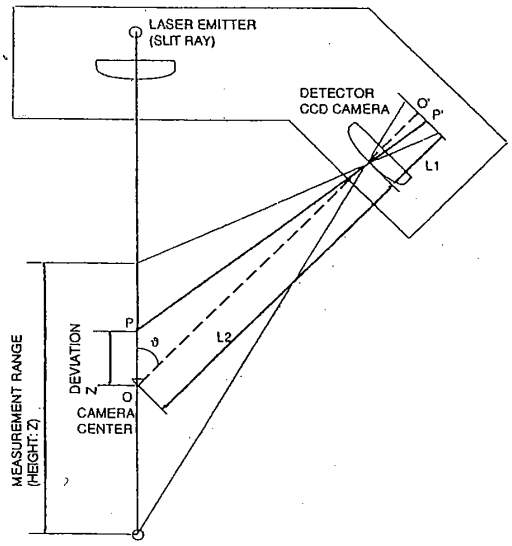


Fig. 2. Principle of triangulation. In this figure, laser emitter is positioned so that its light axis crosses at angle of 0. As point *P* shifts from camera center *O*, image point *P'* of CCD camera changes accordingly. By reading position of P', deviation of *Z* from camera center can be calculated.

RESULTS OF CLINICAL APPLICATION

To show the clinical use of our system, some experimental results are shown. Fig. 3 shows oral photographs of a patient in our orthodontic clinic with severe mandibular prognathism, and Fig. 4 shows a computed graphic of the corresponding dental cast.

Three-Dimensional Measurement Function

Fig. 5 shows the palatal surface area, and Fig. 6 the lateral view of the oral cavity. We can calculate automatically the size of the palatal surface area and the volume of the oral cavity with a computer program.

Three-Dimensional Computer Simulation

In the computer simulation of the set-up model, two upper premolars and four third molars were removed. Lower anterior teeth were moved labially about 4 mm from their original position, and all teeth were aligned on the basal arch with the oval line as the guideline of the arch shape (Figs. 7 and 8). Consequently, the simulation (Fig. 9) suggested that the mandible should be surgically moved 8.5 mm backward and rotated 4.4° to achieve proper overjet (2 mm) and overbite (2 mm).

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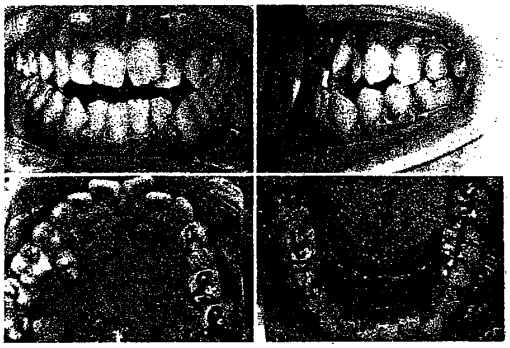


Fig. 3. Oral photographs of patient with severe mandibular prognatism.

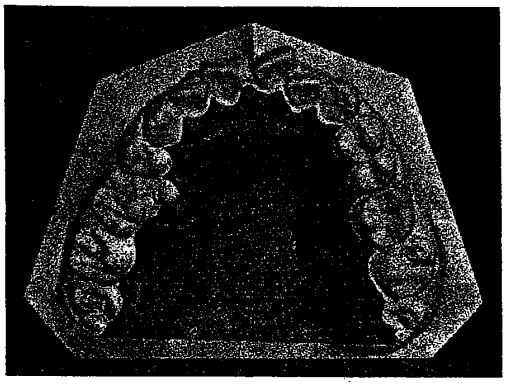


Fig. 5. Palatal surface area (3021.6 mm²).

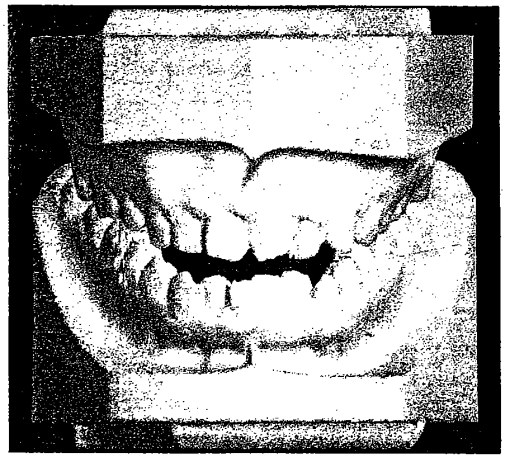


Fig. 4. Computer graphication of dental cast.



Fig. 6. Lateral view of oral cavity (61153.S mm³).

DISCUSSION

Since Simon[1] reported the analysis of the gnathostatic model in 1922, many research reports have been published regarding analysis of the dental cast, not only for evaluation of malocclusion but also for determining the treatment plan. Mooreees et al.[2,3] reported the averages of tooth size, and Howes[4,5] reported the relation of tooth size to the dental arch form. However, because conventional dental cast analysis was based on contact manual two-dimensional measurement, the problems regarding reproductive accuracy of the dental cast, measurement errors, and long data acquisition time were inherent in such an analysis. It was also difficult to obtain three-dimensional information, such as the size of the palatal surface area and the volume of the oral cavity.

Recently, coupled with the remarkable development of computer graphics, various noncontact three-dimensional analyzing systems that use Moire topography,[6] stereophotogrammetry,[7] and laser scanning techniques[8] have been developed in the field of dentistry. The laser scanning technique, particularly, has been applied not only in the orthodontic field but also in the prosthodontic field, to obtain various kinds of three-dimensional information from the dental cast.[9]

The features of our laser beam scanning system are as follows:

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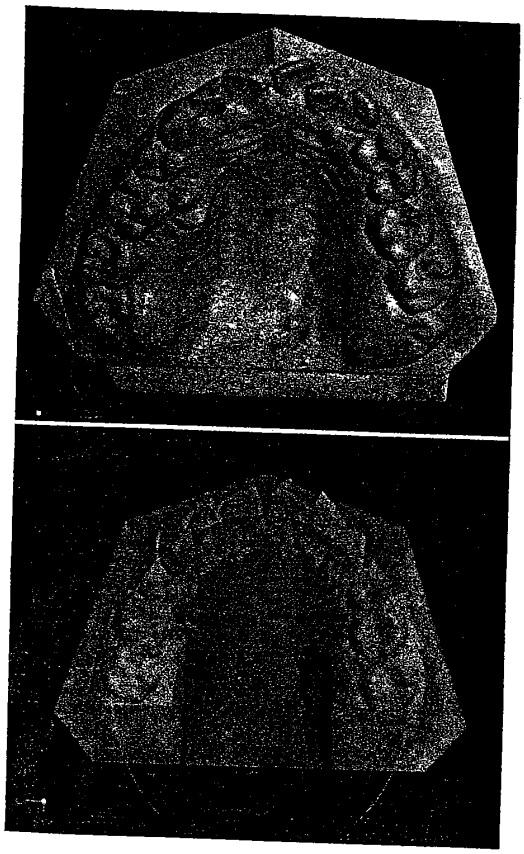


Fig. 7. Computed upper teeth alignment.

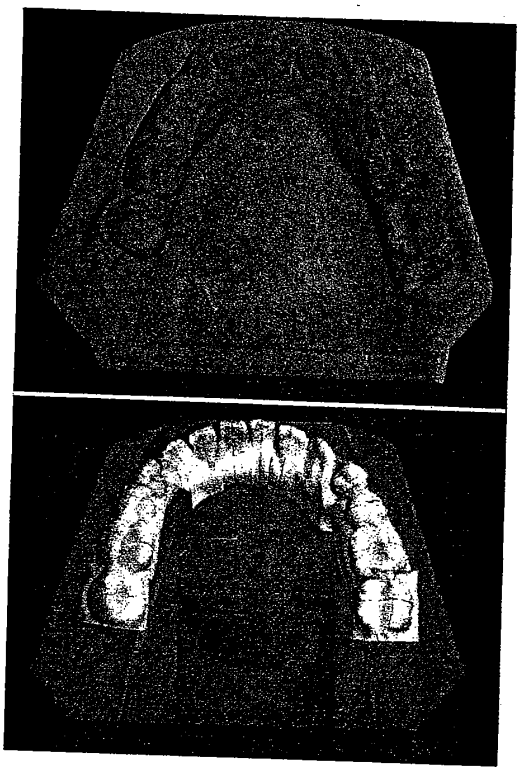


Fig. 8. Computed lower teeth alignment.

1. *High-speed measuring and processing*. Unlike the spot laser measuring method, this system produces 254-point data with a single slit scanning ray, thus greatly reducing processing time. In addition, several tens of thousands of sampled data obtained by image scanning can be speedily and accurately converted into three-dimensional coordinates for a graphic display by using a look-up table.[10] This table is created by calibrating 40 sections in the vertical plane at 25 points on a slit-ray axis of known coordinates. The table includes parameters of camera position and lens parallax.
2. *High accuracy*. Usually, the resolution of the slit-ray projection is dependent on the pixel alignment of the CCD camera. To enhance the resolution, a one-dimensional camera with a large pixel count may be used, but this is time consuming because it involves spot measurement. This system uses a slit-ray projection for high-speed measurement, and the slit video image is then analog-to-digital converted with an 8-bit analog-to-digital converter in the image processor. The personal computer calculated the location of the brightest data in the pixel with its neighboring bright data of the slit image, thus improving the accuracy of the generated pictures.

However, a disadvantage of the slit-ray projection is the impossibility of sampling beneath overhangs. It should also be noted that a parallax angle between the laser emitter and receiver causes a blind region around deep grooves, with an overhang.

Accordingly, more study on the specifications and geometric alignment of the slit-ray emitter and the CCD cameras, with respect to the target, is necessary to minimize blind sectors. Trial clinical applications suggest that the use of this system is feasible not only for clinical evaluation of maloc-

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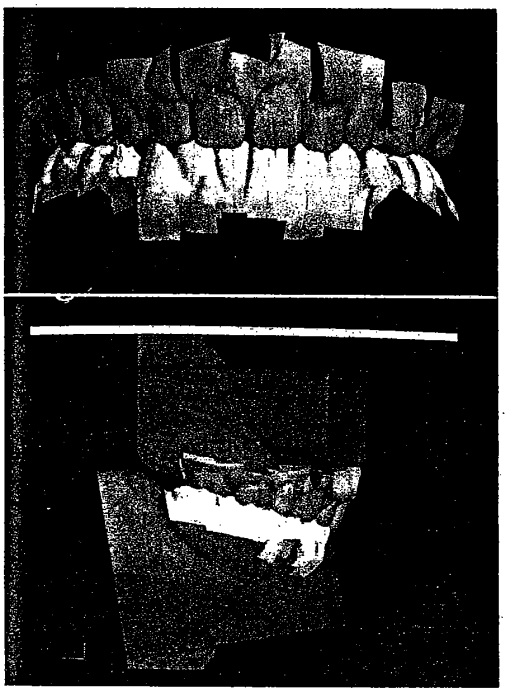


Fig. 9. Computed surgery.

clusion and treatment results but also for saving time necessary for treatment planning and diagnosis through the use of computed simulation of tooth movement.

We express our great appreciation to Mr. Muramoto and Mr. Fujisato of UNISN INC., for their kind assistance in designing clinical applications of this system.

REFERENCES

1. Simon PW. Grundzuge einer systematichen diagnostic der gebissanomalien. Berlin: Herman Meusser, 1922.
2. Moorrees CFA, Reed RB. Biometrics of crowding and spacing of the teeth in the mandible. Am J Phys Anthropol 1954;12:77-88.
3. Moorrees CFA, Thomsen SO, Jensen E, Kai-Jen Yen P. Mesiodistal crown diameters of the deciduous and permanent teeth in individuals. J Dent Res 1957;36:39-47.
4. Howes AE. A polygon portrayal of coronal and basal arch dimensions in the horizontal plane. Am J Orthod 1954;40:811-31.
5. Howes AE. Arch width in the premolar region — still the major problem in orthodontics. Am J Orthod 1957;43:5-31.
6. Kuroda T, Motohashi N, Kato Y. Prediction system of facial change. J Stomatol Soc Jpn 1960;57:441-5.
7. Chaya H, Ishikawa H, Imai T, Nakamura S. A three-dimensional analyzing system of face using stereophotogrammetry and computer graphics. J Jpn Orthod Soc 1988;47:560-78.
8. Soma K, Hisano M, Kuroki T, Ishida T, Kuroda T. High accuracy measuring device for dental cast — using device with flat laser beam. J Stomatol Soc Jpn 1992;59:259-64.
9. Maeda Y, Minoura M, Okada M, et al. A CAD/CAM system for removable dentures: part I, a system for complete denture fabrication. J Jpn Prosthod Soc 1993;37:800-5.
10. Ishimatsu T, Taguchi N, Ochiai T, Oohata T. Fast 3-dimensional measuring technique using a look-up table (measurement of a human head). Trans Jpn Soc Mech Eng 1991;57:1969-73.

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A Computer-Vision Technique for the Acquisition and Processing of 3-D Profiles of Dental Imprints: An Application in Orthodontics

Denis Laurendeau, *Member, IEEE*, Louis Guimond, and Denis Poussart

Abstract—This paper presents a computer vision technique for the acquisition and processing of three-dimensional images of the profile of wax dental imprints in the automation of diagnosis in orthodontics. The contribution of the paper is part of a diagnosis system that is designed to replace manual measurement methods, which use costly plaster models, by computer measurement methods using cheap wax dental wafers. This procedure will reduce the cost and acquisition time of orthodontic data, and facilitate the conduct of epidemiological studies.

The acquisition of the 3-D images is based on the absorption of light by a dispersive medium and uses standard CCD (charge coupled device) cameras. The profiles of both sides of the imprint are acquired simultaneously.

The 3-D image of each side of the imprint is segmented by nonlinear filtering of the 3-D data, and the interstices between the teeth are detected. Two operators are presented: one for the detection of the interstices between the teeth for incisors, canines and premolars, and one for those between molars. A method for deciding the optimal neighborhood of application of each operator is also presented. Experimental results show that the two operators are very effective at detecting the interstices. The computer vision technique uses little *a priori* knowledge and avoids the use of a large number of absolute thresholds.

I. Introduction

ORTHODONTICS is the branch of dentistry that is concerned with the study of growth of the craniofacial complex [20]. The detection and correction of development of malocclusions and other dental abnormalities is one of the most important and critical phases of orthodontic diagnosis.

Presently, orthodontists base their diagnosis on the craniofacial information provided by X-rays and by plaster models like the one shown in Fig. 1(a). The gathering of information required to lay down the diagnosis is a time consuming and costly operation. When taken too frequently, recordings of X-rays may become harmful to the patient, while obtaining a plaster model of the jaws is a complex operation for the orthodontist, and is a very unpleasant experience for the patient. A mold of the inside of the mouth must be obtained from which the plaster model is built. Furthermore, the plaster model must be manually improved in order to remove imperfections.

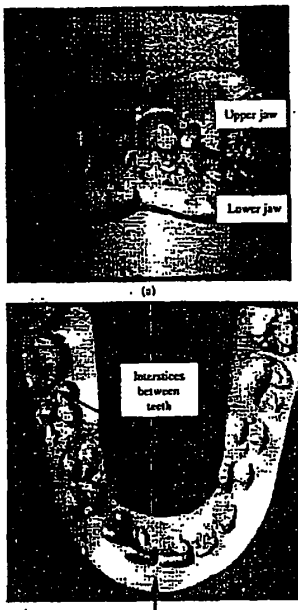


Fig. 1. Orthodontic parameters are actually measured on costly plaster models (a). The proposed system will obtain the parameters from dental imprints recorded on cheap wax bite wafers (b). (a) Plaster model currently in use for orthodontic diagnosis. (b) An imprint recorded on a wax bite wafer.

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In past years, efforts have been devoted to computerize diagnosis in orthodontics by the development of expert systems [3]. However, the cephalometric measurements that are fed to the expert system are still acquired manually from the analysis of X-rays and plaster models. This paper presents part of a system for the acquisition of orthodontic data from cheap dental wafers.

A. Description of the Orthodontics Project

The proposed approach to the problem of automatic diagnosis in orthodontics is to design a computer assisted system for the classification of skeletal and dental malocclusions from a limited number of measurements (orthodontic parameters). It is intended to perform these measurements by computer on a cheap wax dental bite wafer like the one shown in Fig. 1(b). The recording of the dental imprint does not require complicated equipment and does not hinder the patient. The automatic measurement of the parameters should require limited human intervention and should reduce processing time.

The measured parameters will be fed to an expert system [3] which will classify the severity of the malocclusions in three broad categories: 1) orthodontic treatment required, 2) elective orthodontic treatment, and 3) no orthodontic treatment required. The general structure of the system is shown in Fig. 2. The system is not intended to deal with extremely severe cases but is rather aimed at less severe cases that are more likely to be encountered in epidemiological studies.

A set of ten parameters has been defined (see Table I) [11]. These parameters have to be measured in the horizontal, frontal and vertical (sagittal) planes. Fig. 3 defines the different planes and the associated terminology. It is required to obtain a 3-D representation of the profile in order to measure the parameters in 3-D. A range finding acquisition module must be designed and interfaced to the computer. The range finder must extract the 3-D profile of both sides of the wax dental imprint recorded on the bite wafer. This information on the profiles has to be analyzed by a computer vision algorithm to extract the parameters.

Prior to the measurement of the orthodontic parameters, the position of the teeth on the imprint must be detected. This paper describes a computer vision technique for the acquisition of the 3-D profiles of dental imprints recorded on a wax dental bite wafer, and an algorithm for the detection of the interstices between the teeth (see shaded part of Fig. 2). The proposed technique uses 3-D range images of the wafer acquired from a special range finding method based on differential light absorption. It performs local processing of the images and does not require human intervention during or prior to the analysis of the 3-D profile of the imprints.

B. Structure of the Paper

The paper is divided as follows. First, Section II presents the part of the system that is responsible for the acquisition of the 3-D images of the imprints. Section II-A presents an overview of three-dimensional data acquisition techniques. Section II-B presents the basic principles of the range finding technique that has been designed for the orthodontic application, and describes the actual implementation of the acquisition system for the measurement of imprints on both sides of the bite wafer. Section III describes the 3-D image processing algorithm for the detection of the interstices between the teeth. Section III-A details the preprocessing steps of the algorithm, and Section III-B describes the steps for the detection of the interstices. System implementation is discussed in Section IV. Section V concludes on future developments.

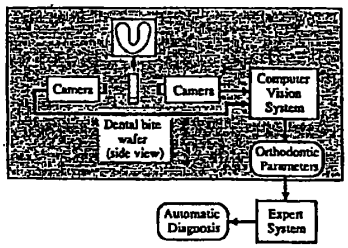


Fig. 2. Overall structure of the automatic system for orthodontic diagnosis.

TABLE I
LIST OF THE DEFINED ORTHODONTIC PARAMETERS

Parameter	Symbol
Sagital canine relation	RS_C
Sagital molar relation	RS_M
Horizontal incisor relation	RH_I
Vertical incisor relation	RV_I
Dento-maxillary relation	RD_M
Expansion of the Spee-curve	D_Spee
Depth of the Spee-curve	P_Spee
Frontal molar relation	RF_M
Depth of Wilson's curve	P_Wil
Frontal relation of mid-dental arch	RF_Ma

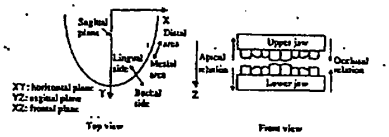


Fig. 3. Definition of the horizontal, frontal, and sagittal planes. Occlusal relations are also defined.

II. Three-Dimensional Data Acquisition System

The measurement of the orthodontic parameters listed in Table I requires 3-D information on the profile of the dental imprints. There are several techniques for the ac-

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quisition of 3-D information. The next section describes briefly some of the most wide-spread techniques, and explains why they are not suitable for the application in orthodontics.

A. An Overview of Three-Dimensional Data Acquisition Techniques

Three-dimensional data acquisition techniques are divided in two broad categories: passive and active. Passive techniques do not require a special lighting system to recover three-dimensional information. They use ambient lighting and one or more intensity images to compute the range map. The most well known passive techniques are photometric stereo [9], shape-from-shading [10] and stereovision [5]. However, these techniques work properly only if restrictions are imposed on the reflectance map of the surface of the objects. Furthermore, the shape-from-shading approach cannot deal easily with changes in surface convexity [10], while stereovision is faced with the correspondence problem [16].

Active ranging techniques use a special light source, usually a laser, to obtain three-dimensional information. The most popular techniques for range acquisition are striped lighting [21], time-of-flight [1], active triangulation [15], and synchronized triangulation [19]. These techniques all share the same principle: a laser pattern is projected on the surface of the objects, and a camera detects the position of the image of the pattern. The coordinates of the image and the geometric arrangement of the source-camera setup are used to compute the three-dimensional coordinates of surface points [18].

In the present application, it would be desirable to avoid the use of a laser source for safety reasons. A special range finding apparatus using harmless incandescent light projectors has thus been designed.

B. Three-Dimensional Range from Differential Light Absorption

The attenuation that accompanies light propagation through a dispersive medium is a common physical phenomenon. Using photometric principles [22], it is possible to show that the illuminance E perceived by an observer is a function of the position of the source x_S, the position of the observer x_O, the position of the observed point x_P, the orientation of the surface of the object relative to the source θ_{iS} and relative to the observer θ_{iO}, the vector of physical properties p_M of the dispersive medium, and the reflectance properties R at the surface of the object.

Equation (1) below sums up the dependence of the illuminance recorded by the observer as a function of the various geometric and photometric parameters

$$E = f(x_P, x_S, x_O, \theta_{iS}, \theta_{iO}, p_M, R). \tag{1}$$

By a judicious choice of dispersive medium and image acquisition geometry, it is possible to recover the depth of points at the surface of the objects and thus the 3-D

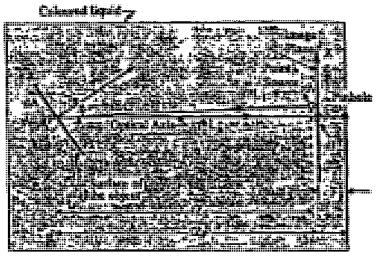


Fig. 4. Basic geometry for the computation of illuminance on the image plane of the pinhole camera.

profile of the surface. Let us consider the geometry of Fig. 4 where an object is immersed in a colored liquid of known coefficient of absorption α. The light source is a point source and the observer is modelled by a noninverting pinhole camera. Let us assume that the source is close to the optical axis and that the object is small relative to its distance from the image plane. The trajectory of a ray travelling from the light source to P, a surface element of area dA on the object, and travelling back to the image plane (where the area of the image of dA is dI) is almost parallel to the optical axis as shown in Fig. 4. If the incident ray has luminance L_i, the differential illuminance dE_P at the surface of the object is given by

$$dE_P = \frac{\cos(\phi)}{Z_S^2}\, dA L_i e^{-\alpha Z_P} \tag{2}$$

where Z_S is the distance between the source and point P, and Z_P is the depth of point P in the liquid.

The exponential term in (2) originates from the differential absorption of the incident ray [22]. If the surface of the object is lambertian with albedo ρ, the reflected luminance L_R is given by

$$L_R = \frac{\rho}{\pi}\, dE_P. \tag{3}$$

The illuminance dE_I of the image dI of surface element dA is given by the fundamental equation of image formation [9] with an additional exponential factor

$$dE_I = \left[\frac{\rho}{4}\right]\left[\frac{L_i}{Z_S^2}\right]\left[\frac{\delta}{F}\right]^2 \cos(\phi) e^{-2\alpha Z_P}. \tag{4}$$

Parameter δ is the diameter of the lens; F is the focal length of the pinhole. Equation (4) is composed of terms originating from the surface properties of the object $(\rho/4)$, geometric and photometric properties of the source (L_i/Z_S^2), camera characteristics (δ/F), orientation of the normal to the surface of the object relative to the optical axis of the camera $(\cos(\phi))$, and depth of the surface point $(e^{-2\alpha Z_P})$. The first three terms in (4) remain constant regardless of the point considered if the surface of the object shows uniform reflective characteristics. Setting

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$$K = \frac{\rho}{4}\frac{L_i}{Z_s^2}\frac{\delta}{F}.$$

Equation (4) becomes

$$dE_i = K\cos(\phi)\, e^{-2\alpha Z_P}. \tag{5}$$

Let us assume that the liquid has a strong absorption peak at wavelength λ_1 (e.g., $\alpha \neq 0$) but is transparent to all other wavelengths and, more specifically, at wavelength λ_2 (e.g., $\alpha \approx 0$). According to (5), the image of a point on the object taken at wavelength λ_1 will have illuminance $dE_{i,\lambda 1}$

$$dE_{i,\lambda 1} = K\cos(\phi)\, e^{-2\alpha Z_P} \tag{6}$$

while an image taken at wavelength λ_2 will have illuminance $dE_{i,\lambda 2}$:

$$dE_{i,\lambda 2} = K\cos(\phi) \tag{7}$$

since $\alpha \approx 0$ at λ_2. Taking the ratio between (6) and (7) and solving for Z_P yields

$$Z_P = \frac{1}{2\alpha}\ln\left[\frac{dE_{i,\lambda 2}}{dE_{i,\lambda 1}}\right]. \tag{8}$$

Equation (8) shows that it is possible to recover range from differential light absorption. It reflects the behavior of the range finding technique for a point source and an object close to the optical axis of the camera. The lateral coordinates of a point (e.g., the X_P and Y_P) are computed from the image coordinates of the point and the parameters of the camera. It is not possible to build a perfect point source. Consequently, a distributed source must be used [e.g., (2) becomes an integral relation]. Furthermore, all object points are not close to the optical axis of the camera. These specific aspects of the problem as well as those related to the calibration of the range finder have been studied and modeled. The basic aspects of the range-from-absorption method presented above are still valid in the case of a distributed source even though the governing equations are more complicated [13].

The range-from-absorption technique is used to acquire the 3-D profile of a dental imprint. For both sides of the imprint, a gray-level image is first acquired at wavelength λ_1 ($\alpha \neq 0$). Then, a second image is acquired at wavelength λ_2 ($\alpha \approx 0$). The depth of the surface is obtained with (8) [or with a calibration curve or look-up table].

Two aspects of the range-from-absorption technique are worth remark.

1) The range images of both sides of the imprint are in perfect registration.

2) The gray-level image of each side is in perfect registration with the 3-D image of this side.

The 3-D acquisition system is based on two important assumptions. First, it is assumed that the colored solution verifies Beer's law which states that the absorption property of the solution is proportional to the concentration of the dye in the solvent. In the present system, a blue organic dye is dissolved in distilled water. Experiments have shown that this type of solution verifies Beer's law over the useful range of absorption coefficients required for the application [13]. The second assumption is that the surface of the dental bite wafer shows Lambertian properties. Ideal Lambertian behavior is not mandatory but a smooth bidirectional reflectance distribution function (BRDF) [9] is highly desirable. For this reason, the bite wafers are covered with a thin coat of white matt paint before the 3-D range acquisition is performed.

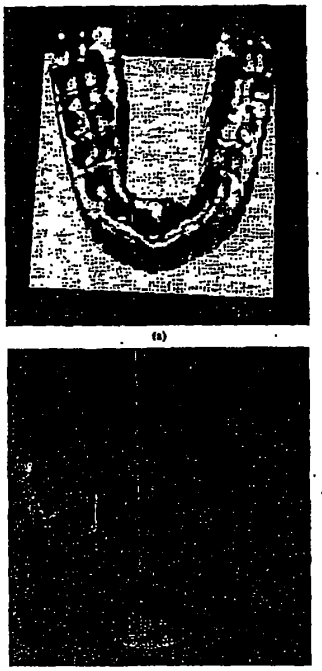


Fig. 5. Result of the acquisition of the 3-D profile of one side of a dental imprint. (a) Shaded representation of the 3-D image of the imprint. (b) Gray-level encoding of range (dark areas = large range values), upper jaw. Image size: 256 × 256.

Observation of (6)–(8) reveals that the accuracy on range values decreases as depth increases. The choice of the concentration of the solution is of paramount importance if a specific resolution has to be attained at maximum depth. It is possible to compute analytically the optimal concentration to attain a given resolution at maximum depth [14]. The acquisition of the profile of one side of a dental imprint is shown in Fig. 5(a) with a shaded represention of depth for a 256 × 256 image. Fig. 5(b)

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shows the same profile where increasing depth is encoded as decreasing gray-level.

The step following the computation of the 3-D profile of the dental imprint is to analyze the profile in order to find the interstices between the teeth. In the following, the 3-D range image will be referred as the *R*-image while the illuminance image (taken at λ_2, $\alpha \approx 0$) will be referred as the *I*-image.

III. Image Analysis

The computation of the orthodontic parameters listed in Table I requires a prior knowledge of the position of each tooth on the dental imprint. Although it may seem simple for a human observer to recognize this position, it is a rather complicated task for a computer vision algorithm. In the following sections, both the *I*- and *R*-images are used to find the position of the interstices between the teeth on the imprint.

A. Preprocessing of the Dental Imprint Image

The first step is to separate the wafer from the background. The approach is based on the fact that pixels on the imprint are brighter than pixels on the background. The *I*-image is thresholded, and only those pixels exceeding the threshold are considered for further processing. An expansion operation is performed on the thresholded image to make sure that small holes in the region belonging to the imprint are eliminated. The expanded image is then eroded 3 pixels more than the previous expansion to eliminate pixels lying on the background. This also eliminates pixels located on the border of the wafer that are associated to the side of the wafer. The pixels remaining after the erosion are considered as wafer pixels and form what is called the *WI*-image. The range pixels in the *R*-image corresponding to pixels in the *WI*-image are stored in the WR-image. An edge preserving filter is then applied to the *WR*-image to reduce noise without affecting sharp discontinuities near the teeth [12].

B. Detection of the Interstices Between the Teeth from the Preprocessed Dental Imprint Image

The next step is to find the interstices between the teeth using the *WR*-Image. Careful observation of the *WR*-image of the imprint [Fig. 5(b)] reveals the following.

1) The teeth correspond to regions of the *WR*-image with large Z_p values in (8).

2) The areas with small range values are associated with the lingual and buccal regions of the imprint that were not bitten, or with the interstices between adjacent teeth.

3) The shape of each tooth is different. This difference could be used to locate the position of the teeth. However, at this stage in the process, it is not required to know the type of tooth and it would be desirable to delay the identification until more information is available on the number of teeth and the number of gaps (e.g., missing teeth).

A possible approach to find the position of the teeth is to look for the position of the interstices between adjacent teeth in the *WR*-image. It might be argued that more *a priori* knowledge about the standard position of the teeth on the maxillaries could be used to guide the segmentation. For example, a technique similar to the one proposed by Harlow *et al.* for the segmentation of chest radiographic images [8] could be adapted to the orthodontic application. Harlow uses a symbolic representation of the normal structure of the human chest to find the position of the lungs, heart, etc. However, in the present application, there is no such thing as a "standard dentition" aside from the orderly disposition of the different teeth on each maxillary. The size, number, and position of the teeth may vary according to the age and size of the patient. It is thus difficult to base the segmentation on very specific structural characteristics of each type of tooth. The presented segmentation approach uses little *a priori* knowledge for the first segmentation stage.

The first segmentation step is to compute the coordinates of the center point of the top horizontal line of the *WR*-image. The bounding rectangle circumscribing the imprint is detected and the position of the point in the middle of the top edge of the rectangle is computed (see Fig. 6). Rays are drawn from this point until they intersect the lingual and buccal side of the imprint, and the midpoint between the intersections is computed as shown in Fig. 6. The location of 19 midpoints along the imprint are interpolated by a *B*-spline curve which is considered as the curved axis of the imprint.

The curved axis is used to detect the position of the interstices between adjacent teeth. The detection is performed as depicted in Fig. 7(a). A rectangular inspection window is moved by a parametric distance s along the axis, starting at the upper left end (parametric distance s_0). The following parameters are computed for each value of s, $s \in [0, 1, \cdots, N]$:

$$\mu_I(s, \theta_i) = \frac{1}{m \cdot n} \sum_{t=1}^{m} \sum_{r=1}^{n} z_p(t, r) \tag{9}$$

$$u_j(\theta_i) = \text{Max } [z_{t,r}]_{t \in [1..m],\, r \in [h_j, h_j + l]} \tag{10a}$$

$$c_I(s, \theta_i) = \text{Min } [u_j(\theta_i)]_{j \in [1..k]} \tag{10b}$$

with

$$\theta_i = \theta_n + i \cdot \frac{\pi}{18}, \qquad i = -3, -2, -1, 0, 1, 2, 3 \tag{11}$$

Each $\mu_I(s, \theta_i)$ in (9) is the average range value in the $m \times n$ inspection window at parametric distance s from the origin, and for a particular orientation θ_i of the window relative to the normal θ_n to the curved axis [see Fig. 7(b)]. Each $u_j(\theta_i)$ in (10a) is the maximum range value in the jth $h \times m$ subwindow of the $m \times n$ rotating window at angle θ_i. Finally, $c_I(s, \theta_i)$ in (10b) is the minimum range value among the k subwindows in the $m \times n$ rotating window for each value of θ_i.

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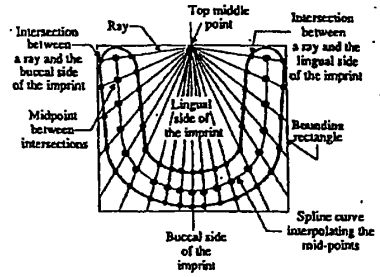


Fig. 6. Detection of the midpoints on the imprint starting from the top middle point of the bounding rectangle circumscribing the imprint in the image.

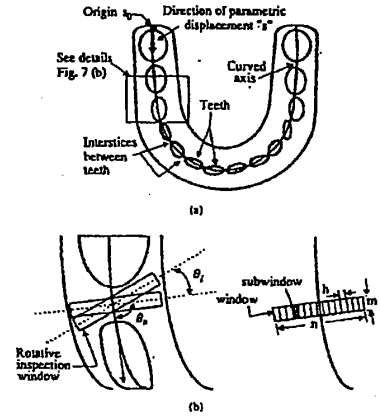


Fig. 7. Detection of the interstices between the teeth. (a) Rectangular window displaced along the curved axis of the imprint. (b) Detail of part of Fig. 7(a) showing the various parameters of the rotating window.

Two curves are plotted with the parameters computed from (9)–(11):

$$f_1(s) = \text{Max}\ [\mu_i(s, \theta_i)]_{i=-3,-2,\cdots,2,3} \quad (12)$$

and

$$f_2(s) = \text{Max}\ [c_i(s, \theta_i)]_{i=-3,-2,\cdots,2,3} \quad (13)$$

The plots of $f_1(s)$ and $f_2(s)$ consist of peaks, valleys, and plateaus as shown in Fig. 8. Peaks of large amplitude mostly correspond to the interstices between the teeth, small narrow peaks are caused by local range variations in the bottom part of molars. Valleys correspond to teeth, and plateaus correspond to missing teeth or wide interstices between the teeth. Careful observation of Fig. 8 reveals that $f_1(s)$ is more efficient for the detection of the interstices between molars for the following reasons.

1) Molars are larger than incisors and cover an important percentage of the width of the imprint.

2) Molars show rather deep fossae (distal, central fossae) separated by cusps (e.g., disto-buccal cusp) [17]. The alternation of fossae and cusps causes peaks to appear in $f_2(s)$ which may be erroneously taken as interstices between the teeth. Function $f_1(s)$ is less sensitive to fossae and cusps because of its average effect on the range data.

3) The interstice between two molars is curvilinear. This means that it is impossible to perfectly align the rectangular window with the direction of the interstice. Averaging reduces the effects of misalignment.

Premolars, canines, and incisors do not show pronounced alternation of fossae and cusps. Function $f_2(s)$ is thus more effective for the detection of the interstices between these teeth since it does not smooth the variations of the profile along the curved axis.

The detection of the interstices between the teeth is reduced to a task of peak detection on functions $f_1(s)$ and $f_2(s)$. It is also required to define the domain of application of each profile curve [$f_1(s)$ for molars, and $f_2(s)$ for premolars canines and incisors].

Ideally, large peaks corresponding to the interstices must be detected, and small narrow peaks caused by local variations must be ignored. This task may be accomplished by the use of nonlinear peak-passing filters [6] [7] combined with local curve smoothing. Functions $f_1(s)$ and $f_2(s)$ are first smoothed with cubic B-splines [2] in order to remove small variations caused by noise and local irregularities. The smoothed curves $f_1^l(s)$ and $f_2^l(s)$ are shown in Fig. 9(a).

Peak detection on the smoothed functions $f_1^l(s)$ and $f_2^l(s)$ is performed as follows. A window of width $\Delta s_l + \Delta s_r$ and centered at s_w, is moved along the profile curve $f_i^l(s)$ ($i = 1, 2$). For each s_w, the value of the function $g(s_w)$ in (14) is computed:

$$g_i(s_w) = f_i^l(s_w) - \text{Min}\ [\mu_{\Delta s_l}, \mu_{\Delta s_r}] \quad i = 1, 2 \quad (14)$$

where $\mu_{\Delta s_l}$ and $\mu_{\Delta s_r}$ are the average values of $f_i^l(s)$ on the left (Δs_l) and right (Δs_r) sides of the window. The operation in (14) detects peaks $\Delta s_l + \Delta s_r$ in width and filters out narrower peaks. Fig. 9(b) and (d) show the filtered output $g_1(s)$ and $g_2(s)$ of the profiles $f_1^l(s)$ and $f_2^l(s)$ in Fig. 9(a). Fig. 9(c) and (e) show the position of the peaks in Fig. 9(b) and (d) along the curved axis. If the distance between two peaks is smaller than a threshold value, they are considered as a single peak.

We must now check that the peaks that have been detected correspond to the interstices between the teeth. Peaks detected in Fig. 9(c) and (e) have been superposed on the image of the imprint of Fig. 5(a). The results are shown in Fig. 10(a) for ($f_1^l(s)$, $g_1(s)$), and in Fig. 10(b) for ($f_2^l(s)$, $g_2(s)$). The combination ($f_1^l(s)$, $g_1(s)$) is very effective for the detection of the interstices between molars but misses one interstice on the left side of the incisor group [see Fig. 10(a)]. The performance of the operator

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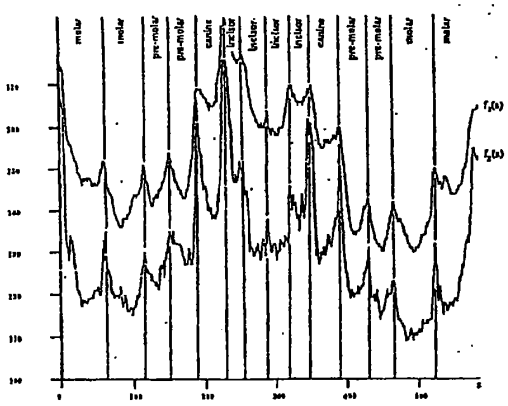


Fig. 8. Parametric curves $f_1(s)$ and $f_2(s)$ computed from the application of (12)–(13) to the 3-D data along the curved axis of the dental imprint in Fig. 5(a). The curves show peaks, valleys and plateaus.

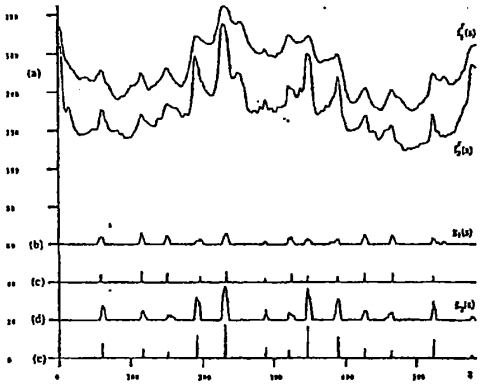


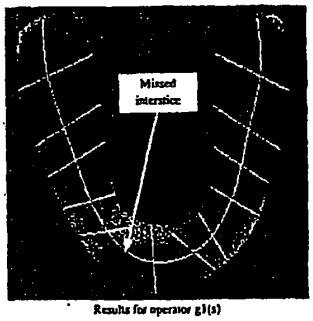
Fig. 9. Peak detection on the two curved axis operators $f_1(s)$ and $f_2(s)$. (a) Results $f_1^s(s)$ and $f_2^s(s)$ of filtering $f_1(s)$ and $f_2(s)$ with B-splines. (b) Result $g_1(s)$ of peak detection on $f_1^s(s)$. (c) Position of the detected peaks on $g_1(s)$. (d) Result $g_2(s)$ of peak detection on $f_2^s(s)$. (e) Position of the detected peaks on $g_2(s)$.

is still satisfactory for the detection of the interstices of the premolar group and the canines. However, the combination $(f_2^s(s), g_2(s))$ is much better at finding the interstices of the incisor group and those between the canines and the premolar group. Its performance over the molar group is reduced since it detects a false interstice on the molar in the upper right side of the imprint [see Fig. 10(b)].

The selection of the area of the imprint where the two operators are the most effective relies on *a priori* knowledge on the position of the incisors. Fig. 11 illustrates the principle behind the selection technique. First, the ap-

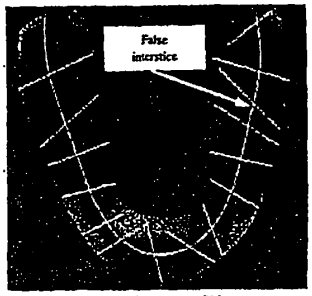
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Results for operator g1(s)

(a)



Results for operator g2(s)

(b)

Fig. 10. Position of the interstices between the teeth on the imprint of Fig. 5(a). (a) Position of the peaks for the operator ($f_1'(s)$, $g_1(s)$). (b) Position of the peaks for the operator ($f_2'(s)$, $g_2(s)$).

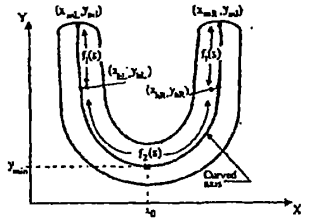


Fig. 11. Estimation of the optimal area of application of the operators for peak detection.

proximate coordinates (x_0, y_{min}) of the lowest point on the curved axis are computed from the B-spline equation of the axis. This point is located in the area of the imprint associated with the frontal incisors. Second, the coordinates (x_{mL}, y_{mL}) and (x_{mR}, y_{mR}) of the start and end points of the parametric curve of the axis are computed. These points are in the molar area of the imprint. The left (x_{hL}, y_{hL}) (with $y_{hl} = (y_{mm} + y_{mL})/2$) and right (x_{hR}, y_{hR}) (with $y_{hR} = (y_{mm} + y_{mR})$) midpoints on the axis are computed. Operator $f_1(s)$ is applied between (x_{mL}, y_{mL}) and (x_{hL}, y_{hL}) on the left side of the imprint, and between (x_{mR}, y_{mR}) and (x_{hR}, y_{hR}) on its right side. Operator $f_2(s)$ is applied on section $(x_{hL}, y_{hL}) \leftrightarrow (x_0, y_{min}) \leftrightarrow (x_{hR}, y_{hR})$ of the axis. Since both operators perform equally well in the mid-point areas, an accurate localization of (x_{hL}, y_{hL}) and (x_{hR}, y_{hR}) is not critical.

IV. Implementation Details and Discussion

The thickness of the basin filled with colored liquid is 15 mm. The maximum depth variation that is allowed on each side of the wafer is thus 7.5 mm since the same basin is used for both sides of the imprint. Refraction of the light rays at the liquid-air interface has been neglected. The colored liquid is obtained by mixing blue organic dye with distilled water. It shows an absorption peak at 625 nm, and is transparent to infrared radiation. For the experiments presented in this paper, the concentration of the solution was 0.01%. The filters used for the acquisition of the two images have the following characteristics: filter 1 has a transmission peak at $\lambda_1 = 600$ nm with a bandwidth of 80 nm, filter 2 has a transmission peak at $\lambda_2 = 750$ nm with a bandwidth of 40 nm. The distributed light source is made of four 75 W incandescent projectors placed behind a diffusing surface made of frosted Plexiglass. The (charge coupled device) CCD camera is a Panasonic WV CD52 with good sensitivity in both the infrared (λ_2) and visible (λ_1-orange) parts of the electromagnetic spectrum. The camera comes with an infrared rejection filter that is installed in front of the CCD sensor. This filter has been removed for the experiments. The image digitizer (a Digimax board from Datacube) has an 8 b A/D converter. A calibration curve representing (8), is used to compute range values from the two images acquired at λ_1 and λ_2.

The window for the computation of curves $f_1(s)$ and $f_2(s)$ is a 3 × 25 pixels rectangle. Five subwindows are used inside this window. The parameters of the nonlinear filter for peak detection using (14) are $\Delta s_1 = \Delta s_2 = 15$ pixels.

The technique for the acquisition of the 3-D profile of dental imprints and for the detection of the interstices between the teeth has been tested on a large number of imprints. The population from which the imprints were obtained is representative of the actual operating conditions considered for the system: no severe cases but cases with orthodontic malocclusions and possibly missing teeth. The accuracy in range is 0.2 mm at a depth of 7 mm and improves as depth decreases. This figure represents a considerable improvement over the 1 mm accuracy of the measurements performed on plaster models. Orthodontists consider that an accuracy of 0.2 mm is satisfactory for the present application. The accuracy of the range finding technique was estimated by measuring calibrated objects of known dimensions: a staircase pattern (7 steps,

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1 mm between steps), and a wedge. No variation of the accuracy with the lateral position of the point at the surface of the object was observed during the experiments. The accuracy could be affected by local changes in the surface properties. However, since the objects are painted with white matte paint, varying albedo effects are significantly reduced. During the experiments on the calibration patterns, no significant change in accuracy was observed over different areas of the painted surface. The dye that is used to prepare the solution has been chosen such that it does not chemically alter the surface characteristics of the painted objects.

The detection of the interstices between the teeth has proved to be very reliable, specially with the combination of operators $(f'_1(s), g_1(s))$ and $(f'_2(s), g_2(s))$. Since both operators show good performances in the canine and premolar regions, the estimation of the optimal area of application is not very critical as long as the incisor and molar areas are correctly discriminated. The technique fails to detect the interstices on poorly recorded imprints and on very severe orthodontic malformations where the teeth significantly deviate from the curved axis of the imprint. To prevent poor imprint recordings, the teeth must not go beyond the limits of the wax wafer, and the bite on the wafer must be deep enough. We are currently implementing an heuristic that will interpret the set of interstices obtained from the combination of the two peak detection operators. The result of the interpretation will be used to deal with missing teeth (or with false interstices).

V. Conclusion and Future Work

This paper has presented a method for the acquisition 3-D images of dental imprints and for the detection of the interstices between the teeth. The proposed technique is part of a system that is under development for automatic orthodontic diagnosis. The acquisition of the 3-D profile of dental imprints is based on differential absorption of light by a dispersive medium. The acquisition system is simple and requires off-the-shelf cameras and lighting systems. The detection of the interstices between the teeth on the dental imprints is based on nonlinear peak filtering of 3-D curves of the dental imprint.

The next step in the development of the automatic diagnosis system will be to identify the type of teeth and measure the orthodontic parameters. The information on the position of the interstices between the teeth found with the technique described in Section III will be combined to heuristic search algorithms in order to find missing teeth. Then, orthodontic parameters will be measured.

We intend to improve the acquisition system by using a better resolution image sampler. The effects of multiple reflections at the surface of the imprint on the accuracy of the range finding method is actually under study. Curved windows of adjustable size for the computation of functions $f_1(s)$ and $f_2(s)$ that are used for the detection of the interstices between the teeth will be tested on the imprints. Finally, special wafers with good reflective characteristics will be designed to eliminate the need for painting the wafers prior to data acquisition.

Acknowledgment

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References

[1] M. E. Bair, R. Sampson, and R. Zuk, "Three-dimensional imaging and applications," in *Proc. SPIE 1986 Cambridge Symp. Opt. Optoelectron. Advances Intell. Syst.*, vol. 726, Cambridge, MA, Oct. 28–31, 1986, pp. 264–274.

[2] R. H. Bartels, J. C. Beatty, and B. A. Barsky, *An Introduction to Splines for Use in Computer Graphics & Geometric Modelling*. Los Altos, CA: 1987.

[3] C. Bernard, J. M. Brodeur, A. Fournier, D. Poussart, D. Laurendeau, R. Goay, M. Olivier, and P. Retrouvey, "Computerized diagnosis in orthodontics for epidemiological studies: A progress report," in *Proc. 66th Gen. Session Int. Assoc. Dental Res.*, Montréal, P.Q., Canada, Mar. 9–13, 1988, 169 pp.

[5] R. O. Duda and P. E. Hart, *Pattern Classification and Scene Analysis*. New York: Wiley, 1973.

[6] R. O. Duda, D. Nitzan, and P. Barrett, "Use of range and reflectance data to find planar surface regions," *IEEE Trans. Pattern Anal. Machine Intell.*, vol. PAMI-1, pp. 259–271, July 1979.

[7] J. O. Eklundh and A. Rosenfeld, "Peak detection using difference operators," *IEEE Trans. Pattern Anal. Machine Intell.*, vol. PAMI-1, pp. 317–325, July 1979.

[8] C. A. Harlow and S. A. Eisenbeis, "The analysis of radiographic images," *IEEE Trans. Comput.*, vol. C-22, pp. 678–689, July 1973.

[9] B. K. P. Horn, *Robot Vision*. Cambridge, MA: M.I.T. Press, 1986, ch. 10.

[10] ——, "Obtaining shape from shading information," *The Psychology of Computer Vision*, P. H. Winston, Ed. New York: McGraw-Hill, ch. 4, pp. 115–155.

[11] R. Houde and L. Guimond, "Ortho Mesure—Manuel de l'utilisateur," Internal Rep. VSN-001-H89, Comput. Vision Digital Syst. Lab., Laval Univ., P.Q., Canada, May 1989 (in French).

[12] Joint System Development Corp., *SPIDER User's Manual*. Tokyo, Japan, 1983.

[13] D. Laurendeau and J.-D. Xu, "3D acquisition through differential absorption of light," Internal Rep. VN-1, Comput. Vision Digital Syst. Lab., Laval Univ., Aug. 1988 (in French).

[14] D. Laurendeau and L. Guimond, "Calcul du coefficient d'absorption optimal pour l'obtention d'une précision donnée sur la profondeur dans un système de mesure de profondeur basé sur l'absorption différentielle de la lumière dans un milieu dispersif," Annu. Rep., Comput. Vision Digital Syst. Lab., Dep. Elec. Eng., Laval Univ., July 1989 (in French).

[15] X. Maldague, D. Poussart, D. Laurendeau, and R. April, "Tridimensional form acquisition apparatus," in *Proc. SPIE Int. Symp. Opt. Optoelectron. Appl. Sci. Eng.*, vol. 665, P.Q., Canada, June 4–6, 1986, pp. 200–208.

[16] D. Marr, *Vision: A Computational Investigation into the Human Representation and Processing of Visual Information*. San Francisco, CA: W. H. Freeman, 1982.

[17] R. E. Moyers, *Handbook of Orthodontics*. Yearbook Medical Publishers, 1973, 778 pp.

[18] D. Poussart and D. Laurendeau, "3D sensing for industrial computer vision," in *Advances in Machine Vision*. New York: Springer-Verlag, 1989, ch. 3.

[19] M. Rioux, "Laser range finder based on synchronized scanners," *Appl. Opt.*, vol. 23, pp. 3837–3844, Nov. 1984.

[20] J. H. Scott and N. B. B. Symons, Introduction to Dental Anatomy. New York: Churchil Livingstone, 1982, 9th ed.

[21] Y. Shirai, "Recognition of polyhedrons using a range finder," *Pattern Recogn.*, vol. 4, pp. 243–250, 1972.

[22] J. W. T. Walsh, *Photometry*. London, England: Constable, 1958, 3rd ed.

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ARTICLES

A number of computer-aided design and computer-aided manufacturing (CAD-CAM) systems are being generated for electronically designing and milling dental restorations. Such systems eliminate the need for impressions, temporary prostheses, and laboratory assistance. Furthermore, the entire procedure can be completed in one appointment. Although the dental literature described some of these developments in moderate detail, little or no information is available regarding one of the newest systems. Already available in Europe, this new CAD-CAM device is capable of fabricating a ceramic restoration in less than 20 minutes. This paper describes the operation procedures of this new system as it relates to clinical practice.

A new method for generating ceramic restorations: a CAD-CAM system

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Milton E. Essig, DMD

As reported in the literature,[1] computer-aided design and computer-aided manufacturing (CAD-CAM) is now applicable to the clinical practice of dentistry. Recently, a great deal of attention has been given to a new method designed for generating dental restorations. Based on computerized processing, the technique reflects a major breakthrough in restorative dentistry. By means of CAD-CAM, it is currently possible to construct various types of ceramic restorations during a single appointment. Furthermore, such procedures can be completed without taking impressions or fabricating temporary prostheses. In fact, the restoration can be completed entirely without laboratory assistance.

Although a number of systems have been described in the literature,[2-6] one of them has received only limited attention. Identified as CEREC (ceramic reconstruction) CAD-CAM system and manufactured in West Germany, this system already is commercially available in West Germany and should be available in the United States in late 1989. This article describes this new system as it relates to clinical practice.

The system designs the restoration electronically, and then mills it from a block of porcelain. The entire fabrication process may be performed by the clinician or in conjunction with the dental auxiliary immediately after the cavity preparation has been generated. Currently being used by the dental profession in Europe, the system can fabricate porcelain inlays, onlays, or veneers of varying complexity. It can, for example, fabricate multisurface restorations including occlusal cusp replacement.

The entire unit is relatively small. In fact, the computer and milling components are about the size of a tabletop personal computer. Front and rear views are illustrated in Figures 1 and 2.

Procedure

The optical impression

After the cavity preparation has been generated, the image is transferred to the screen of the small computer. This stage commonly is referred to as the optical impression. The procedure is performed by placing a small handheld video camera with a 1-cm wide lens over the occlusal surface.

The scanner, when positioned over the prepared tooth, emits an infrared light through the lens. The light rays pass through an internal grid containing a series of parallel lines. The pattern of light and dark stripes which fall on the surface of the prepared tooth is then reflected back to the scanning head and onto a photoreceptor. The intensity of the reflected light is recorded as voltage which is, in turn, converted to digital form. This information is then transmitted to the computer.

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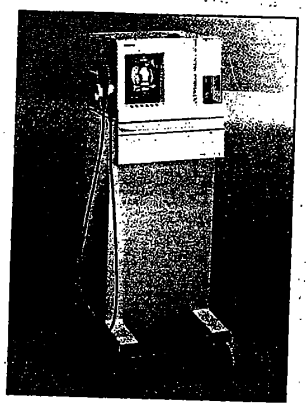


Fig 1 ■ Front view of ceramic reconstruction unit illustrating occlusal view of prepared tooth on the computer terminal screen.



Fig 2 ■ Rear view of ceramic reconstruction unit showing location of water supply.

Commonly, the surfaces of the prepared teeth lack sufficient reflectivity to generate a suitable image onto the computer screen. Consequently, it is necessary to coat the preparation and the surrounding tooth structure with an appropriate light reflecting agent. A typical situation is illustrated in Figure 3. Since the light reflecting agent coats the preparation evenly and is only several μm thick, it does not affect the fit of the restoration.

Procedurally, the handheld camera is positioned over the prepared tooth as shown in Figure 4; an image of the preparation is then simultaneously projected onto the screen. The camera is adjusted until the image is clear, and all aspects of the cavity preparation are in complete focus. The camera should also be angulated so that all of the prepared walls can be seen from an occlusal view. Once the appropriate optical orientation is generated, the operator can "freeze frame" the preparation on the screen. From this optical impression, the three-dimensional inlay or onlay pattern can be developed. A typical image of a prepared cavity on the unit is illustrated in Figure 5.

Designing the restoration

The proposed restoration is designed from the fixed image of the cavity preparation, which is projected onto the screen. A cursor is used to define the limits or the boundaries of the designed ceramic restoration. Movement of the cursor is controlled by the reverse "mouse" located on the top of the unit.

The first position of the cursor is fixed at the edge of the gingival margin against the buccal or the lingual wall. The
is moved along the internal line
at intermediate positions as sho
Figure 6. On command, the com
draws a continuous line throug
placed points (Figure 7). Interesti
the computer demonstrates the loc
of the gingival floors, axial walls,
pulpal floor as viewed through
buccolingual cusp. A typical exa
is also shown in Figure 7. This i
is located to the left of the lingual cu

Next, the gingival margins are e
lished using the same aforementi
procedures. At this point, the cavosu
margin, as well as the buccal and lin
walls, are established. This whole pro
is computed automatically by the sys
and can be monitored on the comp
screen. The procedure can be stop
at any time allowing the operato
carefully examine or edit the electr
ically generated margins or walls of
preparation. Then, if necessary,
program permits the operator to mod
the pattern. Such a step may be neces
to develop an optimal adaptation o
restoration to the walls of the preparati
A typical signal midway through
procedure is illustrated in Figure 8.
electronic signal indicates both the sha
of the wall, as well as the location
the cavosurface angle. After completi
of this step, the proximal contour
contact are established, as well as
location of the marginal ridges.

At this point, the proposed restorat
has been designed electronically. Th
on command, the monitor develop
three-dimensional model of the
or onlay to be constructed (Fig 9).
electronically designed restoration
stored automatically on the progr
disk (floppy). The instrument is
ready to cut the restoration from a bl
of porcelain. An experienced opera
can complete the imaging of the prepa



Fig 3 ■ Occlusal view of prepared tooth after application of light-reflecting agent.



Fig 4 ■ Clinical view of handheld camera positioned over prepared tooth.

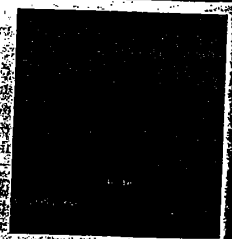


Fig 5 ■ Image of prepared tooth on computer terminal screen.

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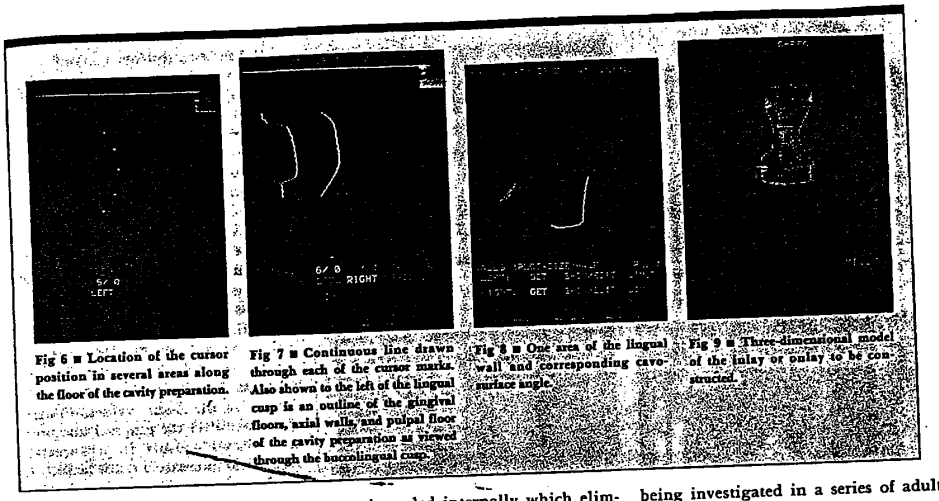


Fig 6 ■ Location of the cursor position in several areas along the floor of the cavity preparation.

Fig 7 ■ Continuous line drawn through each of the cursor marks. Also shown to the left of the lingual cusp is an outline of the gingival floors, axial walls, and pulpal floor of the cavity preparation as viewed through the buccolingual cusp.

Fig 8 ■ One area of the lingual wall and corresponding cavosurface angle.

Fig 9 ■ Three-dimensional model of the inlay or onlay to be constructed.

tooth and the electronic designing of the restoration in approximately 2 to 8 minutes.

Milling of the ceramic restoration

The appropriate ceramic block is selected from a series consisting of different sizes and shades. A typical standard block of porcelain is shown in Figure 10. The porcelain is mounted on a metal stub which then allows it to be inserted into the milling unit. After insertion of the ceramic block into the milling device, the small door is closed and the grinding operation is initiated (Fig 11, 12). The entire milling operation generally takes 4 to 6 minutes.

Generation of the ceramic restoration is performed by means of a diamond-covered disk (Fig 13) in conjunction with a high-velocity water spray. As the porcelain block rotates on its axis, the diamond wheel not only rotates but also translates up and down over the porcelain being cut. Such an arrangement permits the generation of the appropriate angles necessary for excellent adaptation to the walls of the cavity preparation. A series of steps (actually 200-400 steps or cuts) associated with the milling of a restoration from a block of porcelain is illustrated in Figure 14. After completion of the milling operation, the restoration falls to the bottom of the chamber where it is readily retrieved in preparation for insertion.

The motion of the diamond wheel is driven directly by a hydraulic drive. The water is cycled internally which eliminates the need for external water supply and drainage. The pump system and water reservoir are located in the mobile stand or pedestal of the unit. The water reservoir system even contains a microporous filter that traps any of the loosened diamond particles separated from the wheel for future retrieval.

The computer program associated with the cutting process has a number of interesting features. Before the milling process, the screen displays the dimensions of the restoration from one proximal surface to the other in 1/100th of a millimeter. Furthermore, during the cutting operation the screen continuously informs the operator of the percentage of completion. Finally, a continuous readout is displayed concerning the cutting efficiency of the diamond wheel, thereby indicating the probable need for replacement.

At this point, the ceramic restoration is bonded directly to the walls of the cavity preparations. After final occlusal contouring and adjustment of the occlusion, the surface is polished. Figure 15 shows the completed restoration.

Clinical evaluation

The CEREC system is currently being evaluated at the University of Alabama School of Dentistry, department of biomaterials. In addition to evaluating the system, a number of different porcelains and luting agents are being investigated. A total of 150 restorations are being investigated in a series of adult patients.

After a clinician has sufficient experience, the entire procedure starting with the initiation of the cavity preparation to completion of the restoration averages 1 to 1½ hours. Proficiency, however, requires a training period of at least 2-3 days, and the fabrication of several restorations.

Several rules are related to the cavity preparation. First, the axial walls of the cavity preparation must be slightly divergent. Next, they must be straight; localized undercuts in the dentin are permissible, as the electronic beam usually cannot detect these from an occlusal view. These defective areas are filled automatically during the cementation process. Finally, the proximal box should have a flat gingival plane with a well-defined cavosurface margin that is not beveled. In all other aspects, the principles of the inlay and onlay preparation are essentially the same as those used in conjunction with alloys or heat-cured composite resin systems.

After fabrication of the ceramic restoration, its internal aspect is etched with a buffered hydrofluoric acid gel and then a silane coupling agent is applied. The restoration is bonded to the etched enamel surfaces by means of a dual-cured composite resin luting agent. After photocuring, the occlusal surface is contoured to normal anatomic form and occlusion.

The ceramic reconstruction system generates all internal and external aspects

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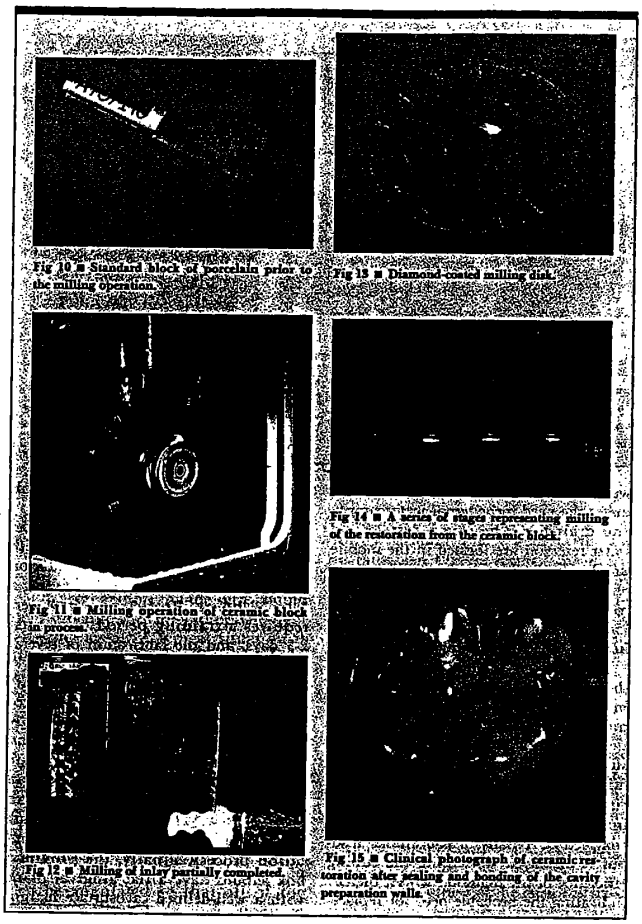


Fig 10 ■ Standard block of porcelain prior to the milling operation.

Fig 13 ■ Diamond-coated milling disk.

Fig 11 ■ Milling operation of ceramic block in process.

Fig 14 ■ A series of images representing milling of the restoration from the ceramic block.

Fig 12 ■ Milling of inlay partially completed.

Fig 15 ■ Clinical photograph of ceramic restoration after sealing and bonding of the cavity preparation walls.

of the restoration up to and including the contact area and marginal ridges. It is necessary, however, for the clinician to develop the occlusal incline planes, grooves, and fossas. This procedure is usually performed using a flame-shaped, fine-particle diamond instrument. Conventional porcelain polishing procedures are used to finalize the restoration.

Interfacial gap

The margin or the space between the restoration and the tooth structure is quite critical. As a general rule, the interfacial gap should not exceed 100 μm, particularly on the occlusal surface. Margins greater than this commonly result in extensive wear of the luting agent. Under such conditions, this interfacial material takes on the same type of wear characteristics commonly associated with posterior composite resins. Subsequently, interfacial staining, microleakage, secondary caries and marginal fracture can be expected. The CAD-CAM system described in this study is fully capable of generating marginal gaps of 50 μm. To maximize adaptation, the instrument can be instructed to increase or decrease the radial dimensio of the restoration by a given numb of microns. This procedure can be carr out simply by keying in the calculat amount on the keyboard located belo the screen.

One of the unique aspects of the syst is the control for determining the corre location of the margins for the resto ration. The first of these is a readou of the X, Y, Z coordinates on the scre in microns (a three-dimensional locatio of the cursor). Consequently, it is possib to precisely locate the gingival margi proximal wall-gingival margin, or an other line angles associated with th cavity preparation. Movement mesiall of the cursor across the gingival floo for example, will generate relatively litt change in the Z-axis values. Continua movement over the gingival margin wi immediately result in a significan numerical increase in this value. As result, it is possible to control locatio of the restoration margins within 1 pix (the dimension of a pixel is 55 μm).

The next feature designed to increa dimensional accuracy is a graphic displa of the Z-axis position at any XY locatio Designed as a bar graph or histogram it permits rapid imaging for faste determinations. The final feature is a enlarged image of the cross-shaped curso a portion of which changes from ligh to dark (white to black) as a margin traversed.

Restorative materials

Two main types of ceramic materia are considered here. The first of thes is a conventional porcelain containin quartz embedded in a feldspathic po celain in which examples include Vit (Vita Zahn Fabrik) and Ceramco (Johnso & Johnson). The second option contain no quartz particles (Dicor, L. D. Caulk and normally is fabricated in conjunctio with the lost-wax technique.

The advantage to the latter is that it has the same hardness as enamel. Also because it contains no particles of quart it offers less potential for abrading th antagonist cusp.

Summary

The CAD-CAM CEREC system is a smal complex unit developed for electronicall designing and milling ceramic resto rations. The system makes it possibl to generate a restoration without takin impressions, developing temporary pros

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theses, and without laboratory assistance. The entire restorative procedure is performed in one appointment. Basic features include the following:

—the cavity preparation is scanned stereo-photogrammetrically, using a three-dimensional miniature video camera;

—the small microprocessor unit stores the three-dimensional pattern depicted on the screen;

—the video display serves as a format for the necessary manual construction via an electrical signal;

—the microprocessor develops the final three-dimensional restoration from the two-dimensional construction;

—the processing unit automatically deletes data beyond the margins of the preparation;

—the electronic information is transferred numerically to the miniature three-axis milling device;

—driven by a water turbine unit, the milling device generates a precision-fitting restoration from a standard ceramic block;

—the entire process of electronic designing and subsequent milling of a ceramic restoration requires approximately 10 to 15 minutes.

JADA

The CAD-CAM system described in this article is CEREC, manufactured by Siemens AG in West Germany.

Information about the manufacturers of the products mentioned in this article is available from the authors. Publication of the names of the products or manufacturers does not imply endorsement by the American Dental Association. Neither the authors nor the American Dental Association has any commercial interest in the products mentioned. Because of the German origin of the system described in this paper, not all products may be available in the United States.

Dr. Leinfelder is alumni/Volker professor of clinical dentistry, and director, biomaterials clinical research; Dr. Isenberg is professor, department of restorative dentistry; and Dr. Essig is associate professor, department of restorative dentistry. Address requests for reprints to Dr. Leinfelder, department of biomaterials and restorative dentistry, School of Dentistry, University of Alabama at Birmingham, Birmingham, AL 35294.

1. Duret F, Blouin J-L, Duret B. CAD-CAM in dentistry. JADA 1988;117:715-20.

2. Heitlinger P, Rodder F. Verfahren zur Herstellung von Zahnersaltz und Vorrichtung zer Durchfuhrung des Verfahrens. De Patent no. 25911, 1979.

3. Mormann WH, Brandestini M. Verfahren zur Herstellung medizinischer und zahntechnischer alloplastischer, endo und exoprothetisher Passkorper. European patent no. 0 0054 785, 1985.

4. Williams AG. The Switzerland and Minnesota developments in CAD/CAM. J Dent Pract Adm 1987;4:50-4.

5. Rekow D. Computer-aided design and manufacturing in dentistry: a review of the state of the art. J Prosthet Dent 1987;58:512-6.

6. Moermann W, Jans H, Brandestini M, Ferru A, Lutz F. Computer machine adhesive porcelain inlays: margin adaptation after fatigue stress [Abstract]. J Dent Res 1986;65:762.

7. Brandestini M, Moermann W, Lutz F, Krejci I. Computer machined ceramic inlays: in vitro marginal adaptation [Abstract]. J Dent Res 1985;64:208.

8. Rekow ED, Speidel TM, Erdman AG. Computer-aided system to automate production of posterior dental restorations [Abstract]. J Dent Res 1986;65:317.

Self-Assessment Questions

1. The CAD-CAM system described in this paper
   a) requires the use of conventional impressions
   b) is based on the use of a laser beam
   c) is capable of milling a porcelain onlay in several minutes
   d) was developed at the University of Georgia

2. Which of the following statements is most correct?
   a) the CAD-CAM system described in this paper requires laboratory
   b) the milling operation is performed using a diamond
   c) the restoration is completely finished on the laboratory bench
   d) the entire procedure of fabricating and placing the restoration can be finished in one appointment

3. Which of the following best describes the type of preparation to be described with the CAD-CAM system described in this paper
   a) full crown
   b) 3/4 crown
   c) onlay and inlay
   d) all the above

4. The final restoration is produced from a

5. In general, the distance between the edge of the restoration and the wall of the cavity preparation should be

   a) polycarboxylate cement
   b) composite resin
   c) zinc phosphate cement
   d) glass ionomer

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Article Summary

Title: Computer-aided Cefalometry and New Mechanics in Orthodontics
Authors : V. Manetti, F. Segu et al. (Milan)

The authors describe a computer-aided cephalometric system for obtaining correct dental diagnosis. The measurement results are entered using the computer keyboard, based on the cephalometric point coordinates made available through a digitizer. This process is conducted for three tele-radiographic projections. Computer-analyzed data are delivered to a plotter (see Fig. 3). These results are used for graphical representation of skeletal and dental problems for help in surgical and orthodontic procedures.

In particular, these cephalometric results are used in a semi-automatic device for preparation of braces and loops (see Figs. 8 – 10) from orthodontic wires designed for correction of teeth displacement. This way, individually fit braces can be made quickly at a single bent, so that chemical and mechanical properties of the material are not modified. Fig. 12 illustrates a brace forming apparatus having precalibrated bending points positioned in the same plane.

Kephalometrie mit Computer und neue Mechanik in der Orthodontie

V. Manetti, F. Segù, S. Segù, B. Zanini, Mailand

Die elektronischen und mechanischen Geräte, die in unserem orthodontischen Zentrum als Hilfsinstrumente angewendet werden, sollen die Arbeitsleistung sowohl vom qualitativen als auch vom ergonomischen Standpunkt aus verbessern.

Die erste Errungenschaft ist ein Minicomputer, der ein höchst wissenschaftliches, originelles System kephalometrischer Analyse ausarbeitet und eine korrekte orthodontische Diagnose und Kontrolle der Therapie ermöglicht (Abb. 1).

Der Realisierung des Soft, als Fluß-Diagramm dargestellt, die den elektronischen Instrumenten die Möglichkeit gibt, die meisten orthodontischen Probleme zu lösen, haben wir langjährige Forschungen, Programmierungen, Überprüfungen gewidmet; dies geschah an Hand von etwa 3000 Fällen, die wir in Mailand analysiert und gespeichert haben.

Um die Wachstumsabweichung wissenschaftlich zu untersuchen und die Dysgnathie zu veranschaulichen, haben wir als nötig erachtet, die kephalometrische Untersuchung zu verbessern, indem wir die Analyse der Schädel-Kieferbeziehungen in Projektion L.L. mit jener der gleichen Strukturen in Projektion P.A. und A.S.S. vervollständigen, abschließend die wichtigsten Angaben einander gegenüberstellen und so eine korrekte orthodontische Diagnose erhalten (Abb. 2).

Das Input beginnt, wie bekannt, mit der Übertragung der Identifizierungsdaten des Patienten, den allgemeinen klinischen Angaben, dem Ausmaß der Kieferbögen und mit dem mesiodistalen Durchmesser der einzelnen Zähne. Die ermittelten Daten werden notiert und auf Tastenschaltern dem Computer übertragen. Das Input wird durch die Einführung der Koordinaten der kephalometrischen Punkte vervollständigt, die dank eines Digitizers ermittelt werden. Dieser Vorgang wird für die drei teleradiographischen Projektionen durchgeführt. Infolge der Leistungsfähigkeit der

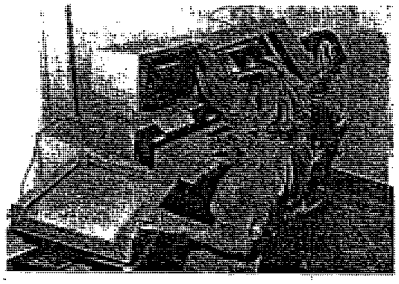


Abb. 1. Minicomputer.

Fortschr. Kieferorthop. 44 (1983), 370—376 (Nr. 5

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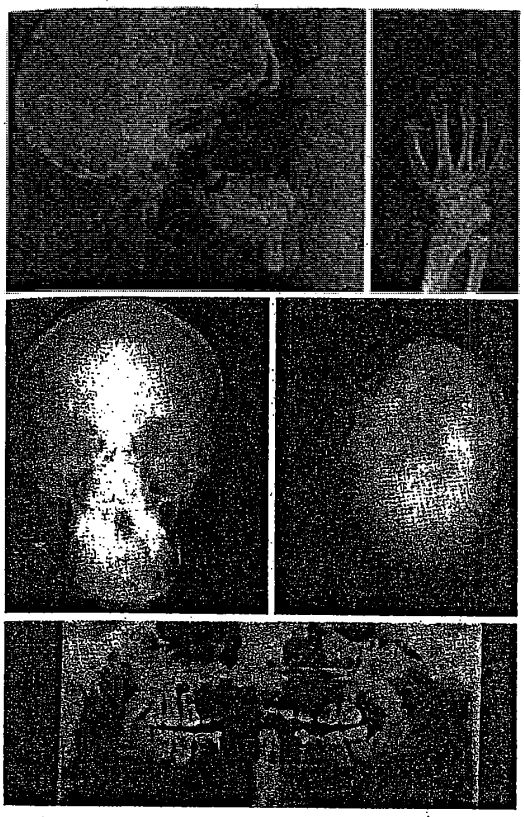


Abb. 2. Analyse der Schädel-Kieferbeziehungen, Projektion L.L. verglichen mit P.A. und A.S.S.

elektronischen Instrumentierung und dank des Softsystems kann der Computer die Daten rasch und fehlerlos sowohl auf Bild als auch in Druck und Plotter liefern (Abb. 3). So ist es in unserem Zentrum möglich, die Messungen der skelettalen und dentalen Beziehungen auf sagittaler und vertikaler Ebene zu veranschaulichen (ANB, open), den Sitz der Disharmonie sowie die Schätzung des Kieferwachstums

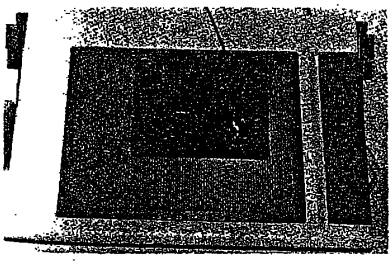


Abb. 3. Koordinaten-Digitizer, der die kephalometrischen Punkte in 3facher teleradiographischer Projektion vermittelt.

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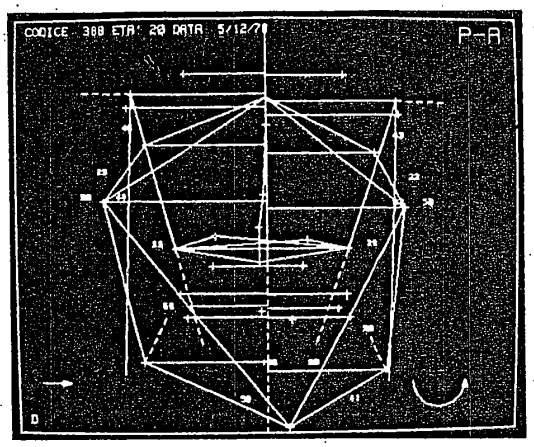


Abb. 4. Darstellung skelettaler und dentaler Messungsergebnisse auf sagittaler und vertikaler Ebene.

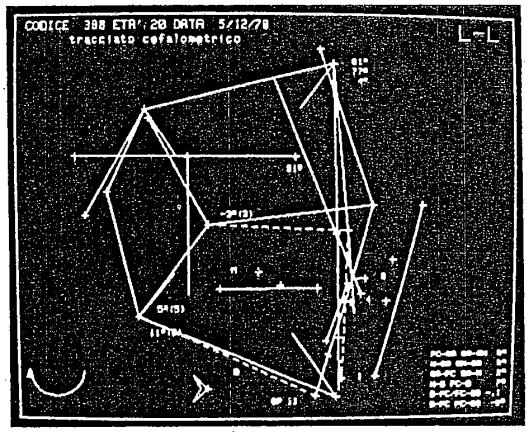


Abb. 5. Dargestellte Unterscheidung zwischen endoalveolären Verschiebungen und Endognathie sowie lateralen Verschiebungen und Laterognathie.

zu erkennen und somit die richtige Anwendung orthopädischer, orthodontischer und chirurgischer Methoden zu gewährleisten (Abb. 4).

Die graphische Darlegung der Daten in P. A. untersucht die Dysgnathie wissenschaftlich in den transversalen, sagittalen und vertikalen Dimensionen, quantifiziert das Niveau und den Grad der Ataxie, der Schädel-Kiefer-Assymmetrie und erlaubt, die Verschiebungen endoalveolärer Natur von Endognathie und seitliche Verschiebungen positioneller Art von Laterognathie zu unterscheiden (Abb. 5).

Die kephalometrische Analyse wird durch die Überprüfung der Teleradiographie in axialer Projektion vervollständigt. Die symmetrische Achse dieser Projektion geht von den gleichen radiographisch-anatomischen Punkten der P. A.-Projektion aus und ermöglicht die Gegenüberstellung von Daten und kephalometrischen Befunden hinsichtlich der Kiefer, der T. M.-Gelenke sowie der vorderen und mittleren

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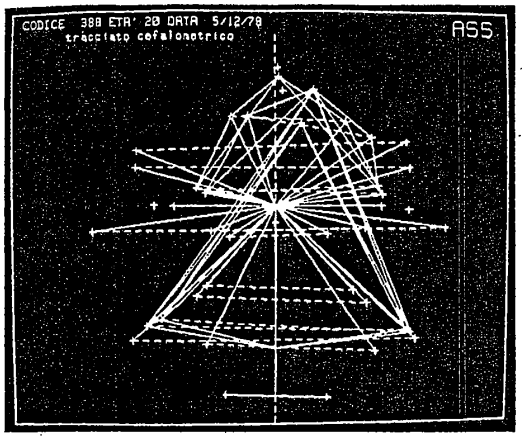


Abb. 6. Kephalometrische Analyse, vervollständigt durch Teleradiographie in axialer Projektion.

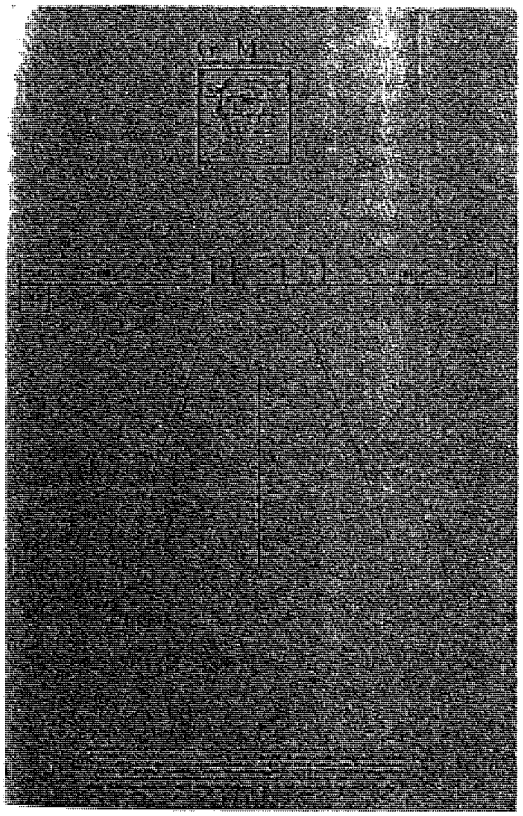


Abb. 7 Therapiebestimmung durch den Computer.

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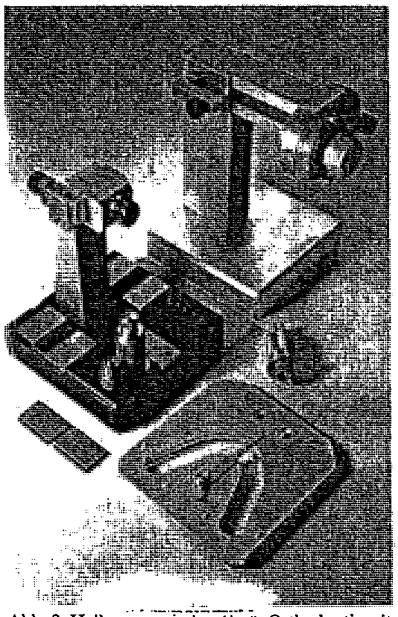


Abb. 8. Halbautomatisches Gerät Orthodontic mit Zubehör zur Anfertigung von Bögen und Loops.

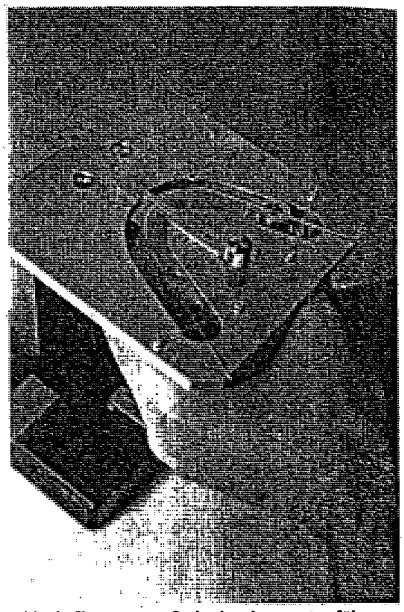


Abb. 9. Zusatzgerät Orthodontic, zur Ausführung der vorgesehenen Loops bereits am Draht.

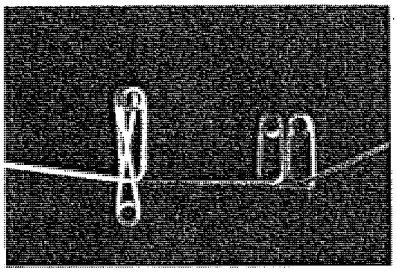


Abb. 10. Platte Orthodontic 809-0 zur Durchführung der Biegungen „Ist order".

Schädelbasisstruktur. Neu ist die Tatsache, daß der Korrelation diagnostische Befunde zugrunde liegen und nicht Messungen oder geometrische Konstruktionen (Abb. 6).

Der Computer ist schließlich in der Lage, die kephalometrischen Angaben mit der dentalen Messungen in Beziehung zu bringen, den dentalen Einteilungsgrad im Hinblick auf die Regulierung der Skelettklasse zu errechnen und somit die Therapie vorzubestimmen (Abb. 7).

Als weitere Hilfe schlagen wir die Verwendung eines halbautomatischen Geräte zur Anfertigung von Bögen und Loops, dem jeweiligen Fall angepaßt, vor. Da Hauptproblem jeder Bandmethode ist die Anfertigung von Loops auf dem ortho

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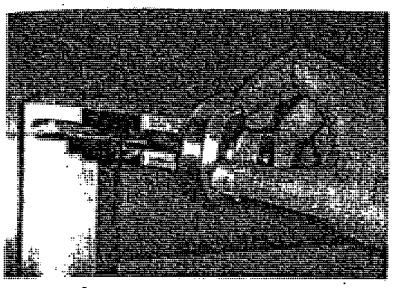


Abb. 11. Instrument zur Durchführung der Biegungen „3rd order".

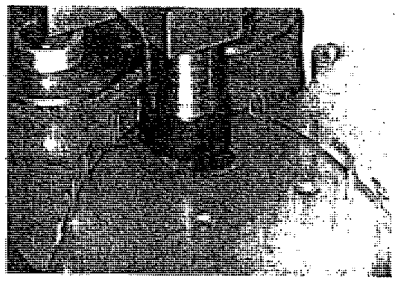


Abb. 12. Bogenformer mit vorgraduierten Cammes.

dontischen Draht, um korrekte Zahnverschiebungen zu erzielen. Die Anwendung des Orthodontic mit Zubehör erlaubt es, alle Biegungen „1st, 2nd, 3rd order" leicht durchzuführen. Diese Biegungen verschiedenen Ausmaßes werden mit Präzision angefertigt, ohne die chemisch-physischen Merkmale der Drähte zu verändern. Bedeutend und einzigartig ist die Möglichkeit, Individualbögen herzustellen, deren Loops genau an den gewünschten Stellen angebracht werden können (Abb. 8).

Das zusätzliche Instrument Orthodontic erlaubt, Ideal- und Individualbögen aus geradem Draht herzustellen wie mit den üblichen Bogenformern, nur wurden auf dem Draht die verschiedenen von der Behandlung vorgesehenen Loops bereits ausgeführt. Die Anfertigung der Bögen wird extrem einfach und präzise (Abb. 9).

Mit der Platte Orthodontic 809-0 werden die Biegungen „1st order" durchgeführt. Man arbeitet am verankerten Draht. Indem die Cammes auf gleicher Ebene rotiert werden, vermeidet man eventuelle Höhenunterschiede oder unbeabsichtigte Torques (Abb. 10).

Um auf dem Draht Biegungen „3rd order" einzufügen und ihren genauen Winkel zu überprüfen, bedienen wir uns einer ebenfalls einzigartigen Instrumentierung, die das Einsetzen des anhaltenden Torque und des zunehmenden Torque am erwünschten Platz ermöglicht (Abb. 11).

Merkmal des Gerätes ist, daß man den Torque ohne Höhenunterschiede erhält; der Draht kann im erwünschten Bereich gedreht werden und danach folgt die Bearbeitung des individuellen Bogens; da unser Bogenformer über vorgraduierte Cammes verfügt, verändert er nicht den Winkel des eingesetzten Torque (Abb. 12).

Unsere Instrumente werden durch weitere Zubehörteile vervollständigt. Sie ermöglichen die Herstellung der Sektionsbögen sowie auch besondere Biegungen, um alle Probleme, die mit der Zahnregulierung verbunden sind, zu lösen. Somit stehen sie auf der Höhe der verschiedenen orthodontischen Arbeitsmethoden.

Zusammenfassung

Die kephalometrische Analyse, mit Hilfe des Computers in den drei Raumprojektionen ermittelt, läßt uns Ursache und Sitz der Abweichung des normalen Wachstumsvorganges im Kieferbereich feststellen. Der Behandler wird somit in der Wahl und der Anwendung der orthopädischen und orthodontischen Apparate gelenkt, um das Phänomen des harmonischen Wachstums wiederherzustellen; sie sind in der The-

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rapie die Hauptfaktoren der morphologischen individuellen und funktionellen Regulierung. Die Anw
dung des Ortodontics und seiner Zubehörteile erlaubt es, alle Biegungen „1st, 2nd, 3rd order" leicht u
mit großer Genauigkeit durchzuführen.

Summary

Cephalometric analysis with the help of a computer allows one to assess the changes in all the th
projections of space, the facio-maxillary complex. In this way the orthodontist can more readily cho
the best type of appliance to re-establish more favourable lines of growth in the individual.

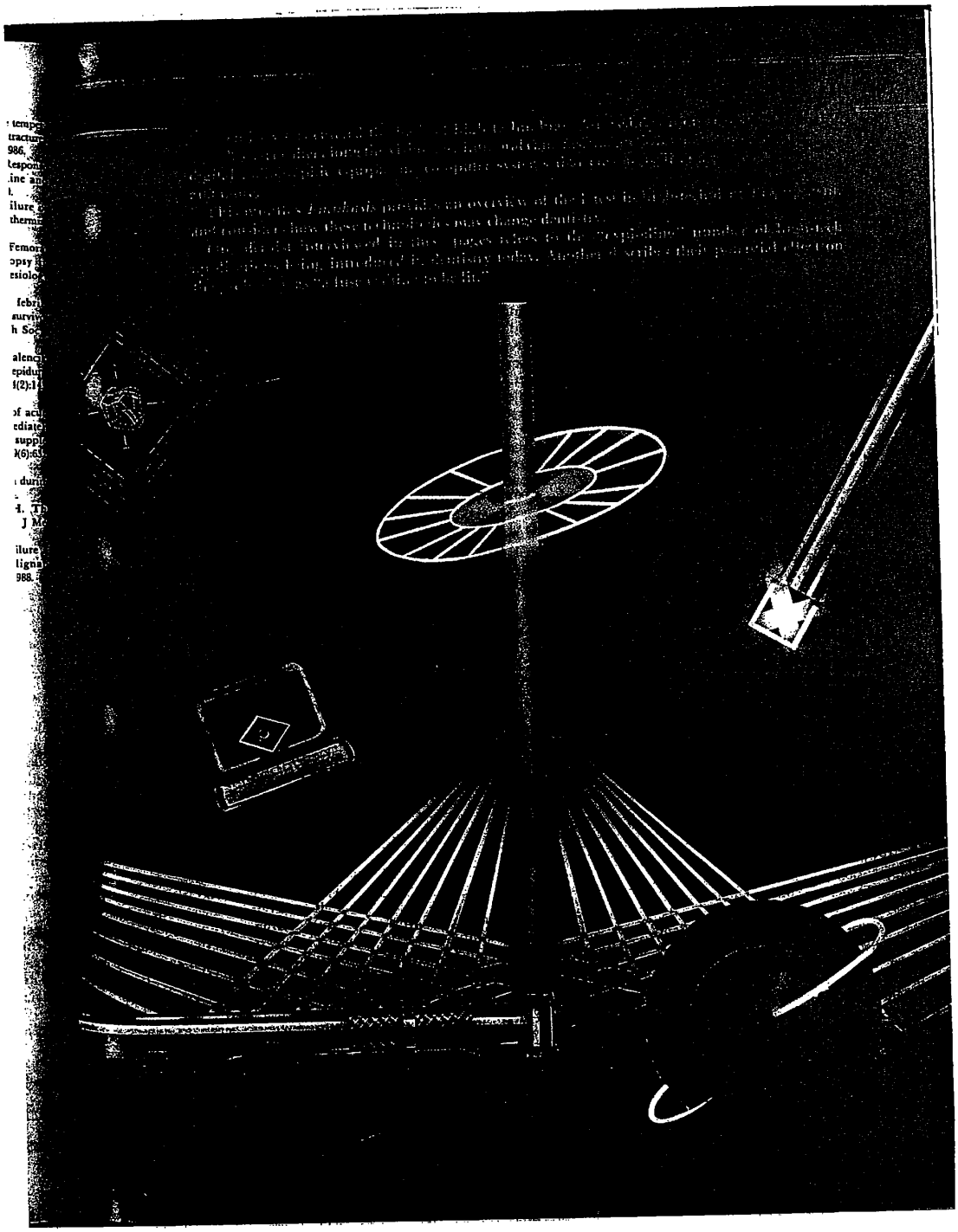
Résumé

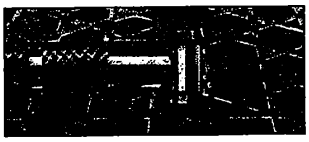
L'analyse céphalométrique réalisée dans les trois dimensions de l'espace à l'aide d'un ordinateur,
met de mieux déceler les causes et le siège de la modification de la croissance normale dans le dom
stomatognathique. L'orthodontiste est ainsi guidé dans le choix et l'application des appareillages or
pédiques et orthodontiques pour rétablir une croissance harmonieuse: ils demeurent en thérapeutiqu
facteurs fondamentaux de la correction morphologique individuelle et fonctionnelle. L'emploi de l'O
dontic et de ses accessoires permet de réaliser facilement et avec grande précision, tous les plis des 1e
et 3e degré.

Anschr. d. Verff.: Dr. *Sandro Segù,* Via Cappuccini 8, I-20122 Milano.

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History has it that in 1790, with his invention of the dental foot engine—something of a modified spinning wheel—John Greenwood freed fellow practitioners from the arduous and clumsy chore of cranking, turning, and twisting needed to work the rudimentary manual drills common at the time.

The hand-operated devices, with a top capability of 100 revolutions per minute, quickly moved aside for increasingly sophisticated, speedier, and in time, quieter handpieces. Dentistry had entered the industrial era.

Since then, the pace of technological advances has quickened with each step. And it appears that today, with the recent introduction of such new technology as lasers, dentistry may be at the threshold of another new age.

"Laser surgery," said Dr. Robert M. Pick, assistant professor of periodontics, Northwestern University dental school, "with all its advantages appears to be an incredible alternative to conventional surgery. The laser works much better than a scalpel in many areas of the mouth. As an example, it is much easier to negotiate a laser in and around mucobuccal folds than it is a scalpel."

Moreover, continued Dr. Pick, the laser can coagulate [blood vessels 0.5 mm and smaller], vaporize, and cut. "And patients show remarkable progress a short time after surgery."

Lasers (light amplification by stimulated emission of radiation) are photons of electromagnetic radiation created from the collision of photons and energized atoms. The released beam of light—linear, continuous, and intense— ranges from the visible to infrared regions of the light spectrum.

Laser surgery most commonly involves "lasing mediums" of crystal and gas atoms, energized by an electric current. In dentistry, the carbon dioxide and, increasingly, the neodymium/Yttrium Aluminum Garnet (or YAG) lasers, have found numerous applications. "The carbon dioxide laser was developed in the United States back in 1964," said Dr. Pick, adding that it found its first uses in plastic surgery, dermatology, and ear, nose, and throat operations.

Dr. Pick and colleague, D. Bernard C. Pecaro, professor and chairman of oral and maxillofacial surgery at Northwestern University dental school, started to research carbon dioxide lasers and look for possible clinical applications in dentistry back in 1988. "The carbon dioxide laser is the laser of choice for working with soft tissue," said Dr. Pick. So far Drs. Pick and Pecaro have used their Coherent Medical Group's Ambulase carbon dioxide lasers for frenectomies, incisional and excisional biopsies, removing phenytoin (Dilantin) hyperplasia, and benign growths and lesions. In addition, oral surgeons have used the laser to excise malignant lesions.

"With the laser," Dr. Pick pointed out, "you get a bloodless surgery—both at the time of the operation and, for the most part, postsurgically. You get instant sterilization of the wound because of its high heat; you get very little swelling and scarring; and from the patient's point of view, in about 90% of the cases, postsurgical pain is just about eliminated."



Dr. Pick

That last advantage, reducing pain, may well prove to overhaul negative perceptions of dentistry. Since Dr. Martin Kraidin, a periodontist in Miami, purchased a carbon dioxide laser in January 1988, he's seen his patients' attitudes toward oral surgery improve dramatically.

"One of the most difficult things we dentists fight is the fear of pain," said Dr. Kraidin. "Anything dentistry can do to eliminate or decrease the fear of pain from dental practice is a big advantage for patients and dentistry alike. And laser surgery is easier for the patients: it's faster, it means gentler treatment of the so tissue, it involves no bleeding, and it hel decrease pain.

"It's been a new experience for me see patients come in and ask, 'I want know if I'm a candidate for laser surger The field of lasers is a fuse waiting to lit; I think it will revolutionize de tistry."

As for future applications of the carbo dioxide laser, Dr. Pick anticipates wide u in the removal of malignant tumor because it's so effective in sealing bloo vessels and lymphatics, and thereb helping to prevent "seeding," or the sprea of tumor cells.

"One area that I'm really excited abou which we're conducting research in, is th application of carbon dioxide lasers to p and fissure sealing," continued Dr. Pick "Because the laser does have the abili to melt enamel, it may prove to be th best pit and fissure sealant we've ever had If we can lase along pits and fissures o molars and reseal them, well, that's grea because it's actually the enamel that's don it."

Also, studies in Europe have shown tha lased enamel is more resistant to decay A possible explanation, said Dr. Pick, i that recrystallization of the enamel make it more resistant to caries.

In the 5 years that Dr. Pick has bee working with carbon dioxide lasers, he given every prospective surgical patient a the Northwestern University dental schoo clinic the opportunity to choose betwee conventional and laser surgery. Each o his patients, "numbering in the hundreds," said Dr. Pick, opted for the laser because of its ability to sterilize the wound instantly, mimimize swelling and scarring, prevent bleeding, and reduce pain. "I'm still like a little child about this laser surgery," said Dr. Pick. "It's that exciting."

The other form of laser, the YAG laser has also generated excitement in dentistry recently. Although long used in op thalmological surgery, its applications to dentistry have come under study only in the past 5 years. In 1983, Dr. Terry D Myers, a general practitioner in Walled Lake, MI, and his brother, William, an ophthalmologist, began to experiment with the YAG laser's potential for dental uses.

"The idea to apply the YAG laser to dental procedures came from a marriage of disciplines, if you will," said Dr. Myers "I was helping my brother on an eye project and he asked me where the use of lasers stood in dentistry. At the time,

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didn't really know. So he suggested that I bring some extracted teeth down to his office for tests."

During their experiments, they found that stains and organic debris in the teeth were vaporized with each pulse of the YAG laser. "We could see miniature explosions under the microscope," said Dr. Terry Myers.

Buoyed by the results of their informal tests, the brothers undertook a thorough search of the dental literature to determine current applications of lasers in dentistry. They then set about modifying the YAG laser for dental uses.

"This particular YAG system we developed, called the American Dental Laser dLASE 300 [currently under review by the Food and Drug Administration (FDA), with a decision expected later this spring], is the first of its kind," said Dr. Myers. "In order to adapt it to dentistry we had to rework some of its internal operations. For example, we had to modify the pulse rate—how fast it pulses per second and for how long all had to be thought of specifically for dentistry."

Unlike the continuous beam of the carbon dioxide laser, the pulsating YAG laser works in short microsecond bursts. "As such," continued Dr. Myers, "we can take advantage of the thermal energy but apply it so quickly to the target area that we minimize the thermal effect." (As with the carbon dioxide laser, though, anesthesia is needed when using the YAG for surgery.)

Dr. Myers' laser also integrates fiber-optic technology. "And with the fiber-optic system, we can deliver the laser energy either through a handpiece with a conventional look or through a miniaturized plastic finger grip with a little optic fiber protruding."

Dr. Myers reports a growing number of uses for his laser. Thus far, the dLASE 300 has been used for such soft tissue applications as gingivectomies, frenectomies, and gingival curettage. By switching the fiber-optic system from a contact to a noncontact tip, it also can be used for such hard tissue procedures as vaporizing caries, cutting dentin, sterilizing tooth surfaces, etching enamel, removing extrinsic stains, and preparing pits and fissures for sealants. "The other hard tissue procedures that we're beginning to look into are root canal therapy applications," said Dr. Myers.

While acknowledging the YAG laser's advantages, Dr. Wayne Wozniak, assistant secretary, ADA Council on Dental Materials, Instruments, and Equipment, cited the need for further research. "The laser is certainly an interesting development," he said. "I know much research has been done with it in the surgery area, but I think its application for decay removal needs more study. We know that the YAG laser works only on decay. But when you're preparing a tooth for a filling, sometimes you have to remove some of the intact portion of the tooth structure to ensure retention of the restorative material."

"There's also the question of heat buildup," said Dr. Wozniak. "Until successful clinical tests prove its safety, I'd be concerned about the heat when removing decay close to the pulp."

Meanwhile, testing of the YAG laser continues. And for Dr. Myers, it's only a matter of time before the new technology becomes an indispensable tool in the dental office. "I think that ultimately, whether it's a YAG or another type of laser that has not yet been dreamt of, within 5 or 6 years we should be able to throw away our handpieces," he said.



Dr. Myers

"At that time, we should be able to have a laser system able to vaporize enamel, do all restorative procedures, crown preps, and inlaid preps. That would be the ultimate."

If that day should come, though, it's a good wager that other technologically advanced equipment will come along to fill the space vacated by discarded handpieces. Take, for example, the recently introduced intraoral cameras.

One of the main concerns for product development staff at Dentsply/Equipment Division, when their intraoral camera was on the drawing boards, was to make it as simple to operate as possible. "The big challenge during the development of this camera was melding the technology to the easiest use in the dental environment," said Keith Peithman, product manager. "We didn't want to burden dental professionals with a piece of complicated equipment. And I think we have achieved making a camera that is easy to run. It takes just 1 or 2 hours to learn to operate."

After about a year in development, company engineers emerged with their DentalVision system. The color video camera, less than one-third of an inch in diameter, rests atop a 6½-inch-long handpiece. Also included are a monitor, a video processor, a keyboard for controlling illumination and entering patient data, and a footswitch to freeze the image.

At the outset, company officials expected the bulk of their market to be dental schools and clinics. "But it immediately attracted the attention of solo and small practices," said Mr. Peithman. "It's a very good communication tool for the dentist. It makes extremely clear to patients what their condition is and the alternative remedies. The patients enjoy seeing their dental condition and being made a part of the treatment planning process."

With the ability to store images on video floppy disks, dentists can show patients the progress of treatments. They can also, by compiling a library, illustrate the outcome of suggested procedures, calling up instances of past patients who had similar dental treatment.

"We also find that dentists benefit from the camera," added Mr. Peithman. "It makes their job easier when they can graphically explain different treatment modalities to patients in a manner that the patients easily understand."

As with DentalVision, Fuji Optical System's DentaCam intraoral camera, introduced in 1987, has found a receptive market among general practitioners. "Our camera is at the end of a hand-held instrument that looks a lot like a dental mirror," said David Cooper, Fuji Optical president. "Basically, what the dentist does is provide a video walk through the patient's mouth.

"Then when he comes across a problem, he freezes the image on the monitor and discusses the problem with the patient. There's a real two-way communication. And the result of this is, by the end of the examination, the patient totally

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understands the nature of the problem. Consequently, as a result of the video examination, as far as we've been able to determine there's been nearly 100% acceptance of the recommended treatment plan."

Dr. Randolph K. Shoup, a general practitioner in Indianapolis, purchased a DentaCam system in March 1988. "My whole practice," he said, "is geared toward patient education and elevating my patients to a higher level of understanding of proper dental care. I do this so that they will want a greater amount of excellence in their dental work." And DentaCam, Dr. Shoup continued, has made the task of patient education "light-years easier."

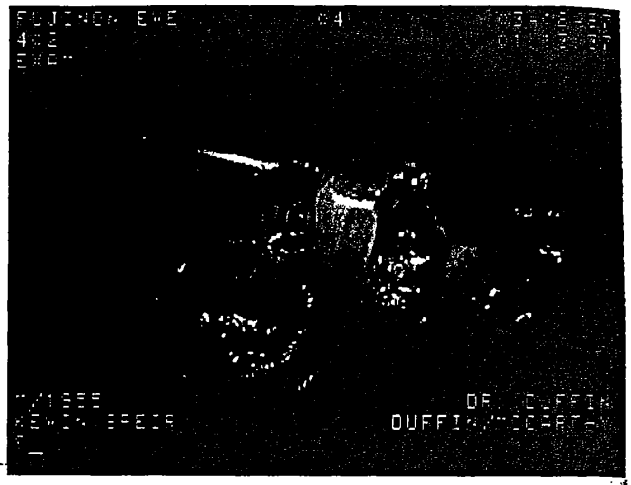
"When a patient comes in the office, I might say, for example, 'you have several old alloy restorations, and you have a number of options: you can either replace these alloys with others or you can look to have something nicer with onlays or inlays, whether porcelain or gold.' "

Dr. Shoup uses the camera to show patients the problem, and then asks them to look at before-and-after photographs of various alternative treatments taken in past cases.

"Rather than having to pitch or sell what I feel is in the patients' best interest, I simply let them view it and choose. And almost to the patient, they will opt for a greater degree of excellence in their care than I think they probably would have without the camera."

Another recent technological advance designed to enhance dental care involves digital radiography, a development that offers a wide field of advantages over conventional radiography, explained Dr. Jack D. Preston, director of advanced education in prosthodontics and the Harrington professor of esthetic dentistry at the University of Southern California, Los Angeles.

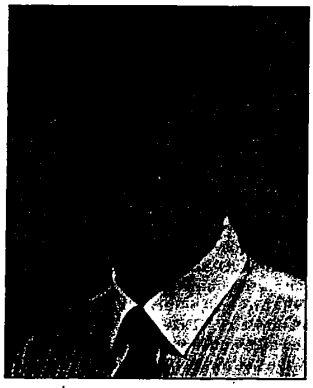
"Digital radiography," he said, "is capturing the radiographic image using nonfilm media and displaying that image in real time on a video monitor or a CRT, rather than using hard copy; and then storing the image on a computer disk, for example. In this process, X rays will stimulate a diode array, and that diode



The DentaCam intraoral camera helps patients decide on treatment plans.

array is either processed or it may give you a direct image readout. In other words, as the exposure is being made, the image is being formed on the monitor. And this is done with less radiation than film techniques."

Dr. Preston added that the French company Trophy introduced such a device last year. Named RVG (Radio/Visio/Graphy), the unit includes an intraoral device that transmits the image to a monitor and prints out a hard copy.



Dr. Shoup

"Digital radiography will mean less radiographic exposure to the patient," said Dr. Preston. "Also, it means the potential for making fewer films and doing more with them. With a digital device, you can mark a block within that radiograph and focus or zoom in to it. You can then obtain information by computer analysis, such as relative radiodensity and even plot histograms [bar graphs] of radiodensity, which allows a more objective method of diagnosis than current methods."

The ultimate goal, though, Dr. Preston said, is to design a machine capable of providing three-dimensional X-ray pictures. "With a three-dimensional radiograph, you would be able to see the morphology of periodontal disease and many other conditions," he said. "Also, a lot of the diagnostic data would be there in exponents and you could do annual evaluations of carious lesions by radiodensity, for example."

Three-dimensional digital radiographs would also allow dentists to chart the progress of diseases, said Dr. Preston. By using subtractive radiography, dentists would be able to overlay two images taken at different times, subtract one from the other, and compute the difference.

"Three-dimensional radiography," said Dr. Preston, will offer dentists a much more direct way of viewing their patients. "And although the general dentist seems

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somewhat reluctant to advance into electronic mediums in the clinic, I think that the digital radiograph will be the first major entry of the computer into the treatment facility. It offers so much."

In the past, when trying to get a glimpse of a temporomandibular (TM) disorder or look for tumors in soft tissue, the dentist had to rely on invasive surgery or inconclusive radiographs.

But with the advent of magnetic resonance (MR) imaging, he or she can peer inside soft tissue without arthography or radiation exposure.

An MR image is created when radio frequency energy is transmitted to and sent back from the patient's body under a strong magnetic field. An MR system consists of a large cylindrical magnet, weighing up to several tons; gradient coils and their power supply; radio frequency transmission and receiving coils and their power supply; shim coils to correct magnetic forces in the environment; and computers.

MR imaging is based on the principle that nuclei of hydrogen atoms in the body, with odd numbers of protons and neutrons, have "nuclear spin," characteristics of movement similar to a spinning toy top. Normally nuclear spin is random, but when a patient is placed inside a magnet, his or her nuclear magnetic movements align with the external magnetic field, temporarily producing a "net magnetic moment" in the patient.

Magnetized atoms within the tissues absorb and remit energy of a set radio frequency applied at 90° and 180° angles to the external magnetic field, emitting a signal detected by the MR system and converted into images by computer. The gradient system of coils constructs positional information for the images, and the resulting image is printed on film and can be stored on disk or magnetic tape.

MR images are a form of computed tomography (CT), a high-resolution imaging method that often is used to examine bone. Since MR detects hydrogen atoms, it is most useful in examining soft tissue or fat. Often, a dentist can use both imaging methods to produce a multiple diagnostic picture, since the elements each detect are in complement.

"For evaluation of TM disk position and for soft tissue tumor diagnosis, MR imaging is frequently the best method because it can depict soft tissue and it's not invasive," said Dr. Charles Schoenfeld, assistant secretary of the ADA Council on Dental Materials, Instruments, and Equipment. "Although it isn't suitable for conventional hard tissue analysis because of limitations in spatial resolution, it lets you evaluate soft tissue without injection of a radiopaque medium or radioisotopes."

"Most major metropolitan areas and academic centers have MR centers," said Richard W. Katzberg, MD, director of radiological research and MR imaging at the University of Rochester (NY) School of Medicine and Dentistry. "There are about 800 centers across the United States today, and the numbers are growing. If a clinician suspects internal derangement of the TM joint, it can help him or her verify that there is such a problem as well as the specific nature of the problem."

MR allows the dentist to zero in on a TM disorder, said Dr. Katzberg, and ordering an MR procedure for a patient can be as easy as finding a center experienced in the procedure and filling out a consultation form.

"It's more widely available than arthrography was in the past, since there were fewer skilled arthrographers than there are MR centers," Dr. Katzberg said. "It's done a lot for TM disorder diagnosis because it's easy, it's accurate, it's painless, and it's safe for the patient."

Use of MR for diagnosis in dentistry will grow in the future as the number of MR centers continues to grow, Dr. Katzberg

Imaging a management tool

A computer imaging system is a wonderful educational tool in terms of marketing to patients who may not be familiar with the treatments and materials available today," said Dr. Jacqueline Dzierzak, a Chicago general dentist.

Incorporating an imaging system into a dental practice results in positive reinforcement of therapies, as well as a boost for the practice, for the dentist, and for the patient, said Dr. Dzierzak.

"A lot of people don't realize what they do to disguise defects in their mouths," she said. "They may put their hands over their faces, tighten their lips, or smile very guardedly. When you use the camera to record them, you can capture all those unconscious habits and say, 'If this bothers you, we can find a treatment to take care of the problem.'"

Marketing the benefits of the system to patients is easy, according to Dr. Dzierzak, because the "high-tech" equipment lets patients know that they can receive "high-tech" treatment. "It gives you the image and identity of being on the cutting edge of dentistry when you can offer the newest and best materials and techniques available."

Presenting a new computer imaging system to patients can be done through a "practice newsletter," informational materials placed in the waiting room, or by imaging every suitable patient who comes into the office, she added. "It does take time to computer image, about 15 or 20 minutes a patient, realistically. It comes down to evaluating who is an appropriate candidate."

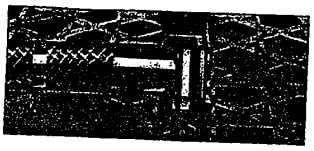
The dentist can image a patient, and present him or her with a Polaroid photo of the predicted results, or with both "before" and "after" images. The Polaroid film package adds a disclaimer to each photo which states that the image shows the predicted outcome of treatment. This way, the patient has tangible evidence of how the proposed treatment can turn out, and can even take it home for further consideration.

The options that allow the dentist to make slide shows and videos for "outreach marketing" presentations to groups outside the office also help educate people about new technologies, techniques, and materials, she added. "The system is pretty portable and you can even take the camera with you and image people in the group."

Dentists should be able to learn the basic imaging functions in about 2 hours, she said, and the more complicated features in 3 or 4 days. With practice, imaging becomes easier and faster, just like any other clinical technique.

"It's really easy when a patient has a space between two front teeth to computer image it and close it," she said. "It's not so difficult to change the vertical length, straighten edges, or reshape teeth. It's a little more difficult to image a more complex case, but it can be done. And you can give the patient a pretty realistic idea of how he or she will look facially."

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predicts. "Although some third-party payers have balked at the cost of a procedure, a lot of the battle is won and MR is becoming more widely recognized as a valuable diagnostic tool."

More cautiously optimistic about MR technology in dentistry is Dr. Carol Bibb, a professor at University of California at the Los Angeles dental school. Dr. Bibb, a specialist in TM joint anatomy, is concerned that the technology is too new and underexplored for wide general use.

"I'm excited about its potential because in TM diagnosis there is a real need for a method to image soft tissue, but I have reservations about it because I feel that more time should be spent taking care of preliminary studies."

Dr. Bibb cautions dentists not to "jump on the bandwagon with MR until it can be studied more extensively. Wide use right now may be considered premature," she said.

As dentists in increasing numbers trade pencil and paper for a keyboard and monitor, the sophistication and applications of computers in dentistry continue to grow rapidly. In the dental office, computerized recordkeeping may not be considered high-tech any longer—dentists are focusing on the emerging roles the computer can play in diagnosis and treatment of patients.

"With the emergence of optical disks for recording patient records, radiographs, visual documentation, and dentist-patient communication, everything will eventually be recorded optically, replacing hard copy altogether," predicts Dr. Preston. "That is where the profession is going."

Dr. Preston, also a part-time practicing prosthodontist, noted that the average general dentist might be a little fearful of incorporating computer technologies into clinical practice, "but they will soon realize the tremendous potential these technologies provide. Dentists in the future will also have more access to artificial intelligence and robotics."

Artificial intelligence systems don't do the thinking for the dentist, said Dr. Preston, but rather they draw from a knowledge base to apply relevant knowledge in problem-solving situations. Such systems are incorporated into CAD-CAM (computer aided design-computer aided manufacture) systems that allow custom milling and placement of restorations with a precision level that can equal that obtained through the "lost wax method."

Developing technology in CAD-CAM is "revolutionizing restorative dentistry," said Dr. Karl F. Leinfelder, Volker professor of clinical dentistry and director of biomaterials clinical research at the University of Alabama at Birmingham (UAB) dental school. "CAD-CAM systems are opening up the door for new technologies in the dental office, and I think the trend will be heading more and more toward electronic design."

The UAB dental school has initiated a controlled clinical study using a CAD-CAM system developed at the University of Zurich in Switzerland. Currently available in Europe and in use by several West German dentists, the system awaits FDA approval for distribution in the United States. The fully enclosed system, about 1 cubic foot in size, consists of a computer system, camera, mouse, and a milling machine.

After cavity preparation, the operator holds a 1-inch square camera over the prepared tooth and the image is projected on the monitor. The operator moves the computer's cursor with a mouse to define the limits of the preparation. Then the artificial intelligence program electronically designs an inlay or onlay. After the restoration is designed, the operator can command the system to mill the restoration from a small block of porcelain.

"Dentists are going to love this system," said Dr. Leinfelder. "What it means for them is that a patient can have a restoration placed in one appointn without temporaries, without i sions."

Another CAD-CAM system, dev by French dentist and dental rese Francois Duret, can produce co crowns, inlays, onlays, and thre fixed partial dentures. (The syst profiled in the November 1988 is *JADA*.)

Dr. Duret's system consists of components: a laser source and cam record the cavity image throu combination of holography and Moir CAD system of hardware and softwar creates a prosthesis design on the mo which can be modified to the der specifications; and the CAM system automatically mills the prosthesis fr variety of dental materials.



Drs. Duret (left) and Preston

Dr. Duret's system can all be integrat into one dental operatory, or more tha one optical probe can be linked to a sing computer system. A dental office can lin its system to another office or to a denta laboratory with a milling machine b using a telephone modem.

Computers also are changing esthetic dentistry as dentists use computer imaging to show patients how their smiles would look after proposed treatment.

Most systems include a computer and monitor with imaging hardware and software, a video camera, tripod, special lighting, and an electronic pen and graphics board.

Systems also can include a Polaroid camera to "freeze" before and after images on one photograph for patients to take with them, laser disk storage, 35 mm slide-producing capability, an intraoral camera, or a video recorder. The system can be integrated with data base, word process-

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ing, or office management capabilities. It can be used to perform orthognathic analysis or even to make title slides or image labels for use in video presentations.

"There's a lot of imaging in consumer markets now—from hairstyling to landscaping," said R. Michael Null, president of McGhan InstruMed Corp in Carpinteria, CA. "As the general consumer becomes more aware, he or she will begin to demand it of dentists, too."

McGhan, which has worked in computer imaging for 3 years, develops software designed especially for distinct markets, such as dentistry, said Mr. Null. The company's first such program, geared toward plastic surgery, was modified and placed in the office of Dr. Arlen D. Lackey, a private dentist in Pacific Grove, CA. Dr. Lackey was one of two practitioners who used the system for about a year, making suggestions and modifications that streamlined the program into a simple but effective clinical tool.

"I incorporated imaging into new patient examinations," said Dr. Lackey, who also is on the faculty at the University of California and the University of the Pacific dental schools and is a practice management consultant. "Although every patient is not a candidate for imaging, about one of every two does have a cosmetic problem that we can discuss."

After patients complete a "smile analysis" form that indicates the features of their smiles they'd like to improve, Dr. Lackey has one of his dental team members take the "before" computer images using two views—full face and a close-up of the smile. Treatment plans with "after" images are done following the appointment to save time.

"It only takes about 5 minutes to image a patient, but depending on their treatment needs, it can take anywhere from 15 to 45 minutes to come up with a treatment plan," Dr. Lackey said. "We do the proposed treatment plan after the patient has been dismissed. When the patient comes back to the office we can show them the proposed image in a short time."

Patient response, said Dr. Lackey is "phenomenal. Most of the time they are delighted with the image—that's the beauty of it. If there is something they don't like, we can correct it while they're there."

Dr. Lackey also is finding a good response rate with established patients who return to the office for periodic cleanings and scalings. "In particular, older patients who have experienced normal wear and tear on their teeth may be interested in treatments to brighten or restore their smiles," he said. "These patients represent a powerful market for response to imaging. We can show them how bleaching, bonding, or porcelain veneers can help them achieve a better smile."

The two biggest assets of computer imaging are elimination of miscommunication between the patient and the dentist and a much higher rate of patient acceptance in cosmetic treatments, said Dr. Lackey. "In my practice the cosmetic treatment market has moved markedly upward."



Dr. Lackey

Imaging system manufacturers have begun to integrate their systems with intraoral cameras, enabling dentists to document complete intraoral and extraoral visual records for patients. However, Dr. Lackey hopes that the computer industry does not put all its eggs in one basket with regard to dentistry. From a practice management standpoint, he says, the dentist can benefit more from having more than one system in the office.

"In the future I see dental offices having two to three computer systems that are specific in function," he said. "Although hardware costs are initially higher, the price of PCs [personal computers] is dropping, and there is a danger in having one huge system and having that system break down. The dentist has to modify computer technology to get the best productivity in his practice.

"Dentists are a conservative group," Dr. Lackey added. "But all aspects of dentistry are changing. It seems overwhelming, but [the new technology] is wonderful."

Dr. Jacqueline Dzierzak of Chicago has used a computer imaging system in her practice for more than 6 months. "It's a fun tool to use, and you can learn the basic functions of the system in a couple of hours," she said.

Dr. Dzierzak adds that dentists don't need to be "computer literate" to use an imaging system. "It's very simple. You take an image of a patient, freeze it, and duplicate it to have two identical images on the screen. Then you can make modifications on one by using the graphics features while the patient watches."

When the system is installed, the dentist is given a short but intense training session that covers every function, but stresses the basics. This way, the dentist can begin imaging patients right away—after just a few hours.

"The main advantage," said Dr. Dzierzak, "is that it takes away that gray area where you may be saying one thing and the patient is saying another and you're not sure if you know exactly what the patient wants in the end. You don't know if you can satisfy their desires in terms of treatment."

In the past, said Dr. Dzierzak, the dentist had to discuss treatment plans with a patient through use of models or radiographs, which are difficult for the patient to relate to their own looks. "Treatment was dependent on whether they had faith and trust in their dentist, without knowing what their clinical capabilities were."

With imaging, the dentist can show the patient what the possible results will be. "It takes away the insecurity. It takes away the anxiety patients feel when they're putting their money, their trust, their looks in your hands," she said.

Imaging proposed treatments also can help in communicating with the dental laboratory, said Dr. Dzierzak. "You can send them a color guide, as well as measurements and angle specifications taken with the software program."

Now that intraoral cameras can be integrated into some systems, Dr. Dzierzak hopes to see development of an office system that combines imaging, intraoral camera input, electronic periodontal probe charting, computerized occlusal analysis, CAD-CAM restorations, and word processing capabilities to create total visual records for patients in one office documentation center.

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"Technology is moving in that direction," Dr. Dzierzak said. "We won't be living without computers much longer."

Dr. Delwin McCarthy, a general dentist in Hemet, CA, is working to incorporate an intraoral camera and computer system with a laser and a CAD-CAM system to fabricate restorations. Such an all-inclusive system will make it possible to record the tremendous amount of information obtained in a dental examination, said Dr. McCarthy.

"Things are really exploding with regard to dentistry," he said. "Technology has evolved so much in the last 5 to 6 years that we are on the brink of new technologies as revolutionary as development of anesthesia or the high-speed handpiece were in their day. Soon every dental office will be able to take care of its own [laboratory] work."



Dr. Dzierzak uses a computer to project results for patient treatment.

The opinions expressed or implied in this article are strictly those of the interview participants and do not necessarily reflect the opinions, official policy, or position of the American Dental Association.

This article was written by Daniel McCann and Stacie Fisch, senior editors, *ADA News*.

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Invisible Retainers

JAMES A. MCNAMARA, DDS, PHD, KAREN L. KRAMER, CDA, JAMES P. JUENKER

The invisible retainer of Ponitz[1] can be used either at the end of orthodontic treatment or as a transitional retainer between certain stages of treatment. For example, a phase of fixed appliance therapy to align the dentition and eliminate dental compensations often precedes an orthopedic phase of treatment (e.g., Frankel appliance, Herbst appliance) or an orthognathic surgery procedure. If a functional appliance is to be used, the teeth must be held in their new positions during appliance fabrication so it will fit at the time of delivery. A quick and inexpensive temporary retainer is desirable during this interim period.

The invisible retainer is simple to construct, easy to deliver, and inexpensive. In addition, when the invisible retainer is used as a finishing appliance, minor changes in tooth position can be made on the work model prior to appliance fabrication. When the appliance is used as a transitional retainer, the model is not altered prior to appliance fabrication.

Appliance Construction

Alginate impressions are taken of the upper and lower dental arches, using standard aluminum trays, and a wax bite registration is taken to articulate the models. After the models are poured and trimmed (Fig. 1), they are occluded with the wax bite in place, and the backs are trimmed flush. The wax bite is then removed, and the models are occluded and checked for any rotations or other dental irregularities (Fig. 2).

To reset the irregular teeth, interproximal cuts approximating the long axis of the tooth are made in the maxillary work model with a laboratory saw (Fig. 3A), and gentle finger pressure is used to fracture the remaining plaster and free the tooth from the model (Fig. 3B). A laboratory knife is then used to trim the area of the model in which the tooth is to be repositioned. Stone must be removed from the sides of the tooth— to permit rotation correction— and from the base (Fig. 3C). Medium-hard pink wax is melted and placed into the area where the tooth has been removed (Fig. 3D), and the tooth is temporarily repositioned in the wax (Fig. 3E).

The same procedure is carried out in the lower arch (Fig. 4), in this case using a laboratory knife to apply pressure (Fig. 4B). The models are then occluded, and the teeth to be reset are repositioned as ideally as possible (Fig. 5) and waxed in place. The wax contours are smoothed (Fig. 6).

The clinician is usually limited to resetting only one tooth per quadrant. In the case illustrated, the upper and lower second premolars on the left side were also repositioned. We have had good success in repositioning premolars, canines, and incisors, but only limited success in repositioning the upper and lower permanent molars.

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A Biostar positive pressure thermal forming machine (Great Lakes Orthodontic Products) is used to fabricate the invisible retainer. The work model is placed into the large (125mm) model holder. Lead pellets are placed around the model to a point 1mm below the desired margin of the appliance (Fig. 7A,B).

The holding frame is placed on the pressure chamber with the gasket and the four holding pins facing upward. A piece of 1mm splint Biocryl is placed inside the four pins of the holding frame (Fig. 7C). The Biocryl is secured in position by placing the clamping frame over the holding frame, making certain that the material remains properly aligned within the four pins. The handle of the clamping frame is turned to the left and secured with light pressure to lock it in place (Fig. 7D).

The heating element is moved into position over the pressure chamber (Fig. 7E) and left in place for approximately 30 seconds to soften the splint Biocryl. The heating element is removed, the pressure chamber is rotated over the model holder (Fig. 7F), and the pressure chamber handle is engaged. Air pressure, rather than partial vacuum pressure as advocated by Ponitz, is used to push the softened Biocryl onto the work model.

After two minutes, the pressure chamber handle is unlocked and the pressure chamber is rotated out of position (Fig. 7G). The clamping frame is removed and the Biocryl with the embedded work model is taken off the Biostar (Fig. 7H). Excess Biocryl is removed from the work model with a sturdy pair of scissors (Fig. 7I), and the general contours of the invisible retainer are established with a carborundum disc (Fig. 7J,K). A pair of scissors is used for the final finishing of the appliance (Fig. 7L). No further polishing or trimming is usually necessary, although a light sanding, pumicing, and polishing of the edges of the appliance may be required.

It is important to always cover at least part of the last molar in each arch to prevent extrusion of these teeth with full-time appliance wear. The maxillary invisible retainer is usually trimmed to include full palatal coverage (Fig. 8A). The facial surface of the appliance is trimmed to follow the approximate contour of the gingival margin (Fig. 8B-D).

The mandibular invisible retainer is trimmed in a horseshoe shape, again covering the last molar (Fig. 9A). The facial and lingual surfaces are trimmed to approximate the gingival margins (Fig. 9B-D). Invisible retainers require virtually no adjustment at the time of delivery, except for the trimming with scissors in the area of tissue impingement. Often invisible retainers can be mailed to the patient with instructions to trim the acrylic at any point where it causes irritation.

If teeth have been reset in the invisible retainer, the patient should be told that the appliance will take a few hours to a few days to seat in place. If too much tooth movement has been carried out on the work model or more than one tooth per quadrant has been reset substantially,

the appliance may never fit and will have to be remade.

Retention Sequence

Invisible retainers are only one part of routine retention procedures, which in the senior author's practice include the following sequence:

1. Two to three months before appliance removal, the need for a supracrestal fiberotomy[2,3] or other periodontal surgical procedure is evaluated and the procedure is performed if needed. Such procedures enhance the stability of teeth that have been rotated during alignment.

2. One month before debanding and debonding, the upper and lower archwires are removed, and alginate impressions are taken over the fixed appliances. These models are used to fabricate a positioner to be delivered at the time of appliance removal.

3. One week before appliance-removal, the upper and lower archwires are removed, and the teeth are ligated together in serpentine fashion from second premolar to second premolar, using standard ligature wire.[4] This procedure allows for settling of the occlusion without the opening of any interdental spacing. The patient is instructed to chew gum as much as possible during the following week.

4. At the time of appliance removal, the bands, bonds, and serpentine ligature wire are removed. After the appropriate hygienic procedures have been performed, the patient is given the positioner and told to wear it full-time for the next 24 hours except during meals, as much as possible for the next five days, and then four hours a day plus nighttime wear for six weeks.

5. Two weeks later, a lateral headfilm and panoramic radiograph are taken and the fit of the positioner is checked.

6. Four weeks later, the patient is recalled; if the positioner wear has been satisfactory and acceptable occlusal results have been achieved, upper and lower impressions are taken for the fabrication of invisible retainers as described. Impressions are taken every six to eight weeks, and new invisible retainers are fabricated until ideal tooth position is achieved. Usually only one or two sets of retainers are necessary to obtain a satisfactory occlusal result if the retainers are worn as directed.

7. Long-term retention is usually accomplished with removable Hawley or Ricketts retainers and occasionally a fixed lingual retainer in the lower arch. Invisible retainers can be used on a long-term basis, but they are generally not as durable as wire-and-acrylic retainers.

Conclusion

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Invisible retainers have had a high level of patient acceptance because they are inconspicuous. They can be used effectively either as retention appliances that allow some finishing occlusal adjustments or as transitional retainers to hold teeth in position until appropriate functional appliances are available.

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1. Ponitz, R.J.: Invisible retainers, Am. J. Orthod. 59:266, 1971.

2. Edwards, J.G.: A study of the periodontium during orthodontic rotation of the teeth, Am. J. Orthod. 54:441-459, 1968.

3. Edwards, J.G.: A surgical procedure to eliminate rotation relapse, Am. J. Orthod. 57:35-46, 1970.

4. Schaal, D.M.: Personal communication, 1976.

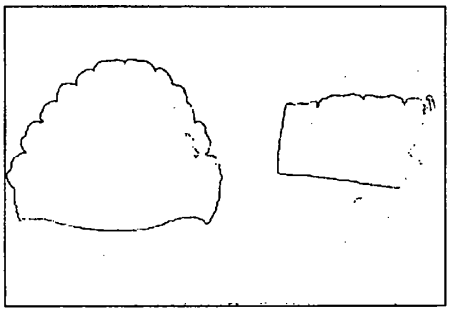


Fig. 1 Trimmed maxillary and mandibular work models.

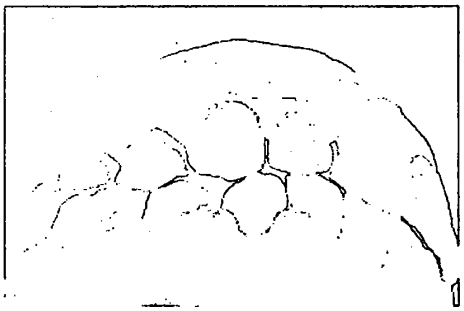


Fig. 2 Dental casts in centric occlusion. Note the in regularities in position of upper canine and lower second premolar.

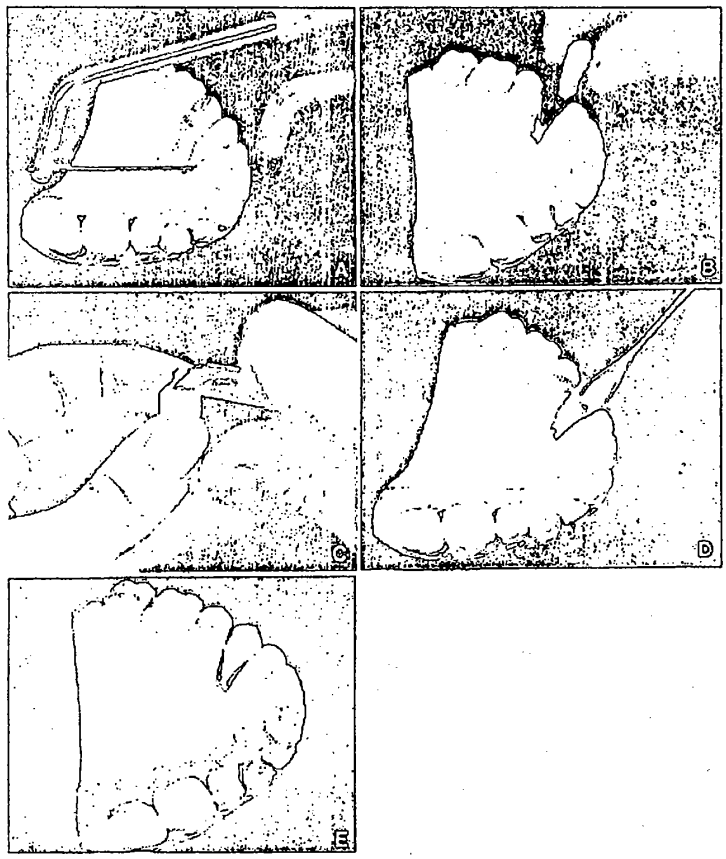


Fig. 3 Repositioning of the upper right canine. A. Tapered cuts made with laboratory saw. B. Tooth treed from model. C. Tooth trimmed. D. Melted wax placed in tooth space. E. Tooth temporarily placed in corrected position.

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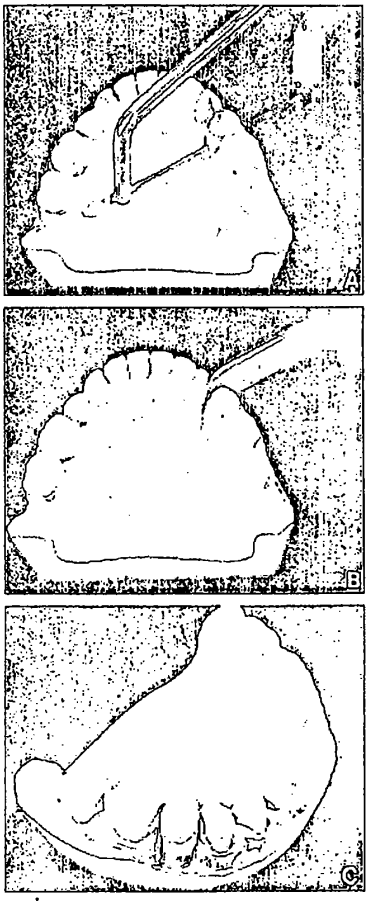


Fig. 4 Repositioning of the lower second premolar. A. Interproximal cuts made. B. Tooth treed from model. C. Tooth secured In preliminary corrected position.

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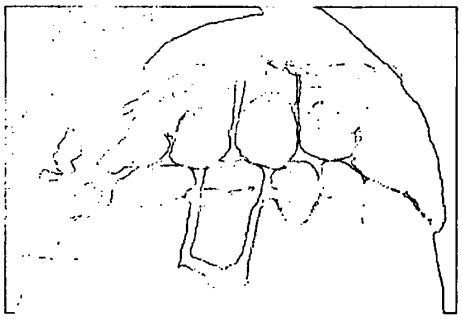


Fig 5 Upper canine and lower second premolar repositioned as ideally as possible.

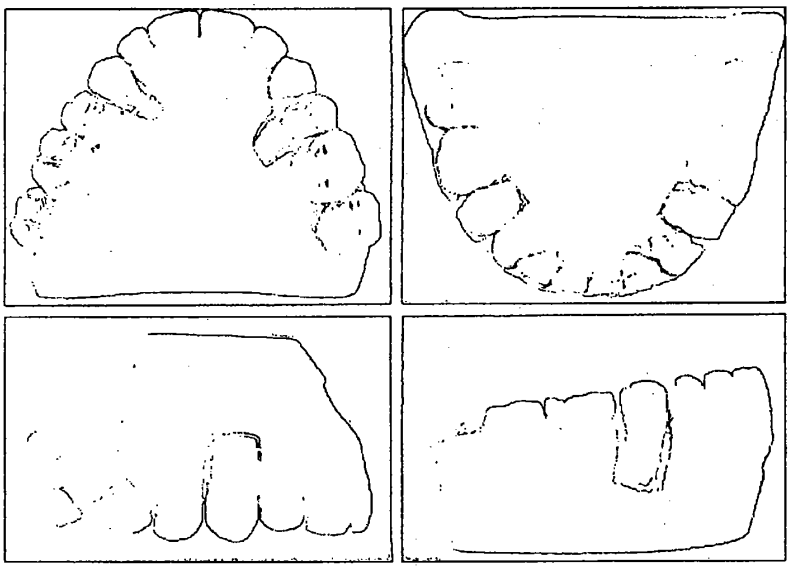


Fig 6 Final waxing of the dental cast after final repositioning of teeth.

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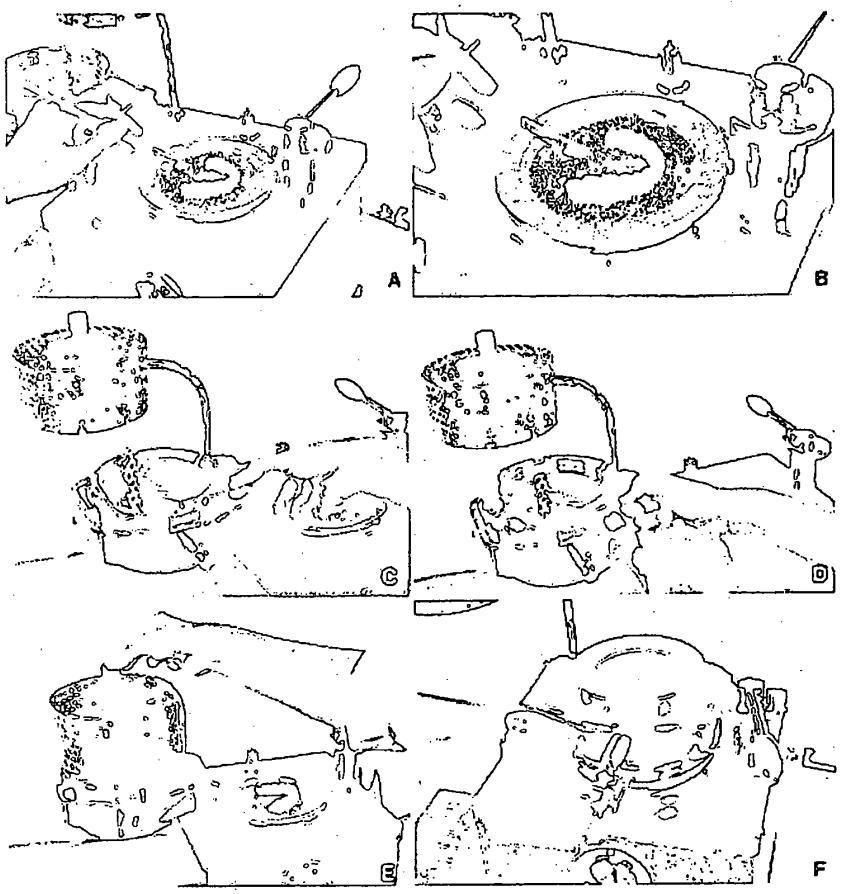


Fig. 7 Fabrication of the invisible retainer using a Biostar. A,B. Placing dental cast In model chamber with lead pellets covering the areas the acrylic will not touch. C. Placing 1 mm splint Biocryl In pressure chamber. D. securing clamping frame over the Biocryl. E. Placing heating element over pressure chamber. F. Placing and securing pressure chamber over model carrier.

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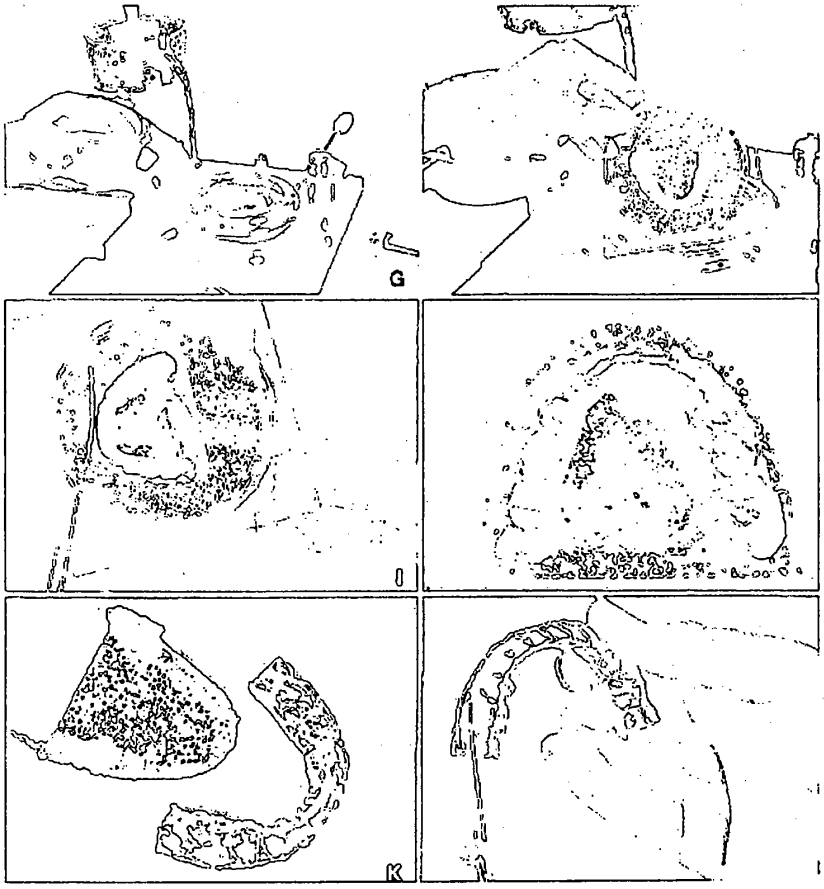


Fig. 7 (cont.) G. Removing pressure chamber from model carrier after two minutes. H. Lower model embedded in Biocryl. I. Preliminary trimming with scissors. J. Occlusal view of cuts made in Biocryl by carborundum disc. Only the cuts In the area of lower second molar are obvious. K. Appearance following cuts. L. Final trimming.

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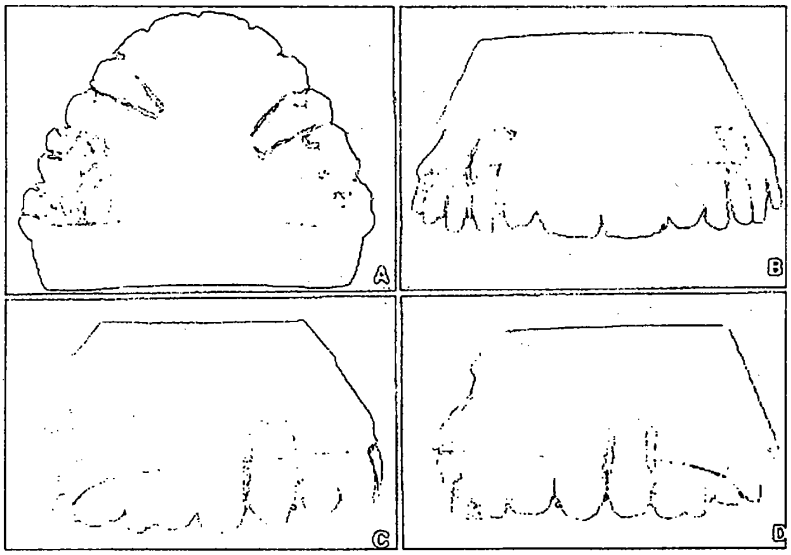


Fig. 8 Finished maxillary Invisible retainer.

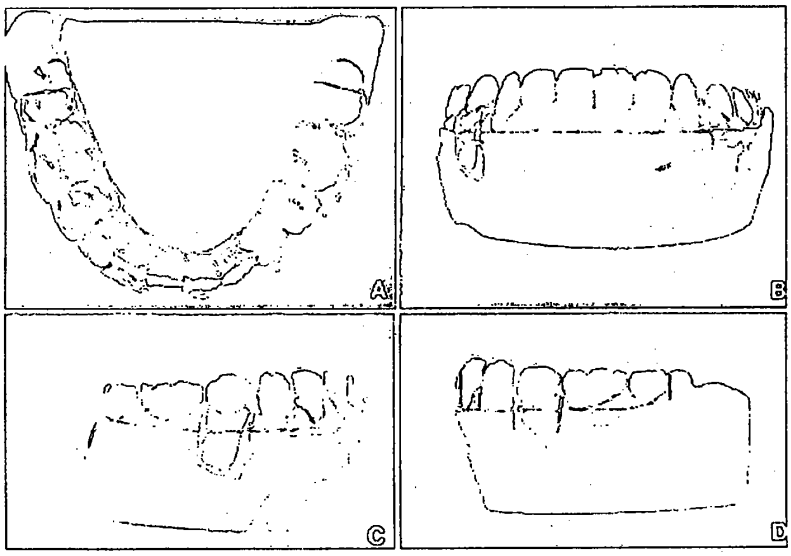


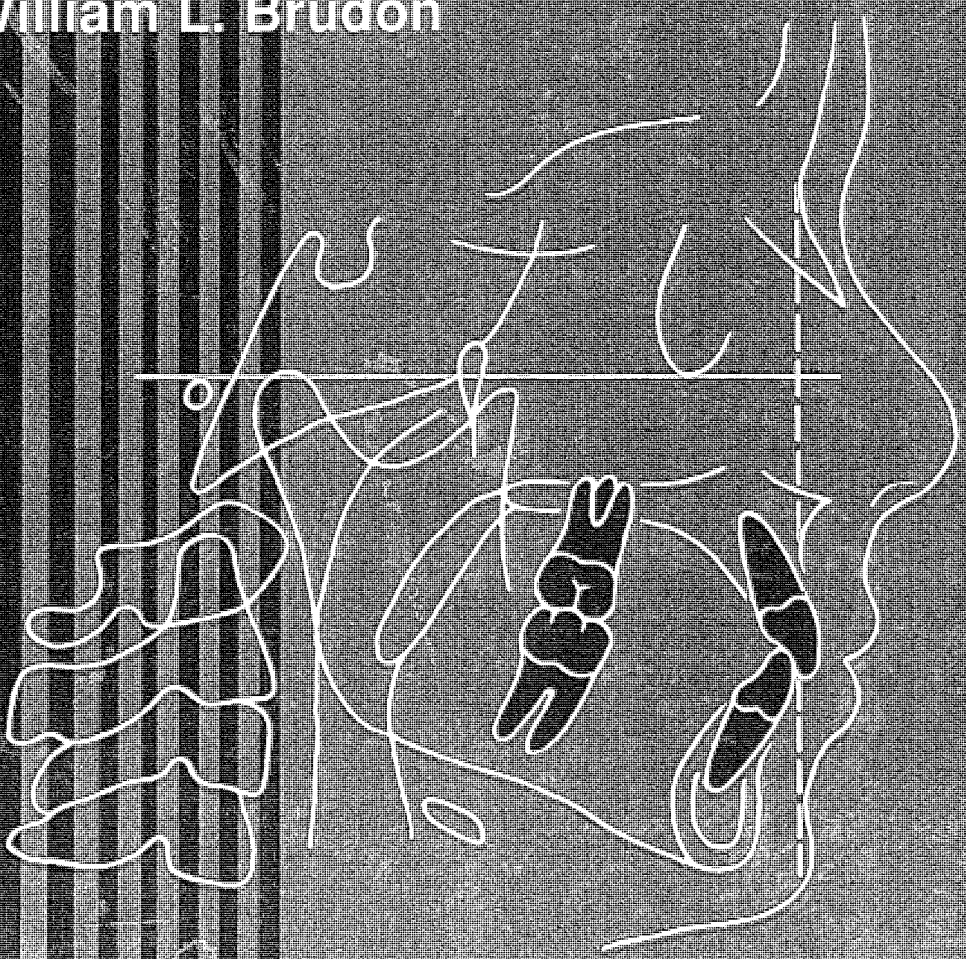
Fig. 9 Finished mandibular Invisible retainer.

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Orthodontic and Orthopedic Treatment in the Mixed Dentition

James A. McNamara, Jr.
William L. Brudon



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Orthodontic and Orthopedic Treatment in the Mixed Dentition

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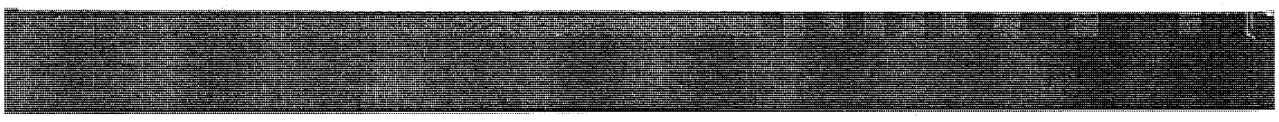
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Chapter 19

INVISIBLE RETAINERS

The invisible retainer (Fig. 1), developed by Robert Ponitz of Ann Arbor, Michigan (Ponitz, 1971), is formed from a sheet of thin Biocryl™ that is heated and forced by pressure on to a work model of the dentition (McNamara *et al.*, 1985).

FUNCTIONS OF INVISIBLE RETAINERS

The invisible retainer can be used for three purposes: minor tooth movement, long-term retention, and as a transitional retainer.

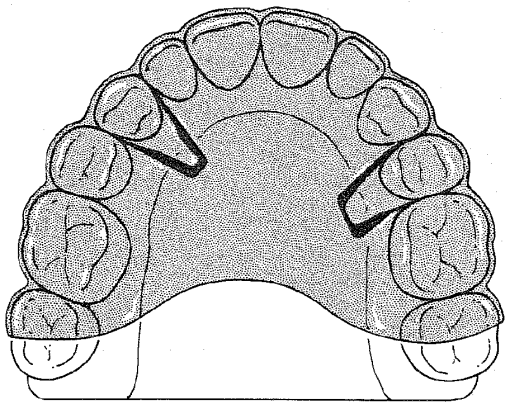


Figure 1. Maxillary invisible retainer. Note that the posterior extension is contoured to prevent evoking the patient's gag reflex.

Minor Tooth Movement

The most common time during which invisible retainers are used is immediately after debonding or after positioner wear is concluded. Even though the vast majority of dental irregularities have been eliminated, small inter-arch and intra-arch discrepancies often remain at the end of treatment. By using a series of invisible retainers, the fine detailing of the occlusion can be accomplished by resetting up to one tooth per quadrant in the work model prior to retainer fabrication.

Small adjustments can be achieved most easily in incisor and premolar tooth position due to their shapes. Taking advantage of the shapes of these teeth, minor changes in tooth position can be accomplished. For example, if a lower incisor is reset into an ideal relationship before fabricating the appliance, the elasticity of the acrylic used in the fabrication of the retainer can help force the rotated tooth into a new position of alignment.

The canine teeth often are difficult to reposition using an invisible retainer. Simple tipping movements are accomplished easily as is minor tooth intrusion. However, the correction of rotations is made more difficult with these conical-shaped teeth. As with all teeth, extrusive movements are difficult to produce.

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Only very minor changes in the position of the molars should be attempted. Occasionally, a remaining band space can be closed by repositioning the molar more anteriorly. However, gross changes in the position of the molar usually are not possible because the invisible retainer will not fit the molar in its new position.

Usually a set of invisible retainers is worn for one or two months before a new set of retainers is made. The number of sets of retainers necessary, is, of course, dependent upon the quality of the orthodontic result at the time of debonding. If multiple teeth have to be reset in a quadrant, multiple sets of invisibles will be necessary.

Long-term Retention

The second function of the invisible retainer is to stabilize the dentition in its current position. Of course, invisible retainers are used as a long-term retention appliance after minor tooth movements have been achieved. These acrylic retainers usually will last for six to twelve months, depending on the parafunctional activities of the patient. Some patients use these retainers indefinitely, while the invisible retainers of others show a high degree of wear and/or breakage. In the latter case, wire and acrylic retainers (e.g., Hawley, circumferential retainers) can be used effectively.

Many clinicians are concerned about using any retainer that provides occlusal coverage. It has been our experience that, in general, the occlusal coverage provided by the invisible retainer does not appear to pose many clinical problems. The patient usually "self-equilibrates" the upper and lower appliances within a few days, and symptoms of temporomandibular joint disorders are rare. As with any removable appliance, patients are instructed to discontinue invisible retainer wear if any problems with their temporomandibular joints are encountered.

One of the major advantages of the invisible retainer is that it provides a positive positioning of the teeth, thus aiding in the prevention of relapse. This is particularly true with the position of the incisors, specifically the lower four incisors and the upper lateral incisors. Using many types of conventional wire retainers, minor changes in tooth position often are observed; this is not the case when invisible retainers are worn as directed.

If patients have interproximal spacing at the end of treatment, the use of invisible retainers is contraindicated, as no space closure is possible. Prior finishing with a positioner is advisable. If a positioner is not used, a retainer such as a circumferential retainer is recommended.

Use as a Transitional Appliance

As mentioned earlier, the invisible retainer also can be used as a transitional appliance between phases of orthodontic treatment. If, for example, incisor intrusion and protrusion have been accomplished successfully prior to the fabrication of a functional appliance, the invisible retainer is used as a transitional retainer until full-time functional appliance wear has been achieved.

Generally, the transitional retainer should be used without the resetting of any of the teeth. Even though minor irregularities may remain, changing the position of certain teeth while a functional appliance is being fabricated may lead to problems with the fit of the functional appliance. This is particularly true if an acrylic splint Herbst appliance is used because of the precise reproduction of the anatomy of the teeth in this type of appliance.

FABRICATION OF INVISIBLE RETAINERS

The precise steps in appliance fabrication have been described previously by McNamara and co-workers (1985). This article will be summarized and updated below. In this summary, the possibilities of making minor changes in tooth position with invisible retainers will be stressed.

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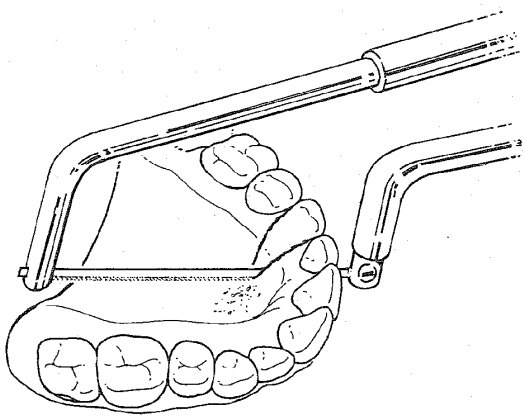


Figure 2. A laboratory saw is used to remove the canine from the model. Note the tapered cuts.

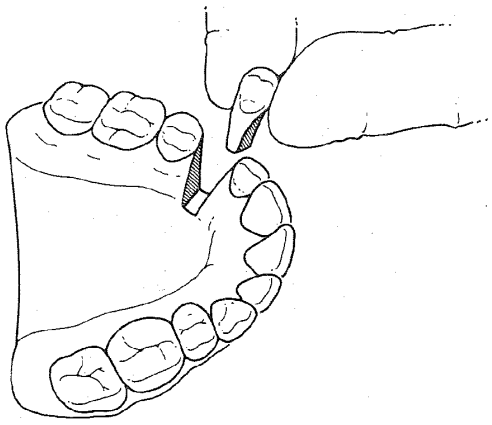


Figure 3. Finger pressure or a laboratory knife is used to break the remaining plaster, freeing the tooth. The cut in the stone is trimmed so that the tooth can be repositioned, allowing enough space for wax.

Preparation of the Work Models

Upper and lower alginate impressions are made using standard aluminum trays, and a wax bite registration is obtained in centric occlusion to articulate the models. The impressions then are poured and trimmed as standard work models with minimal base (Fig. 2). The models are trimmed with the wax bite in place so that the backs of the work models are trimmed flush.

The wax bite is removed and the models are placed together in order to evaluate whether any changes in tooth position are indicated. In this example, the repositioning of a canine will be shown (Figs. 2 & 3).

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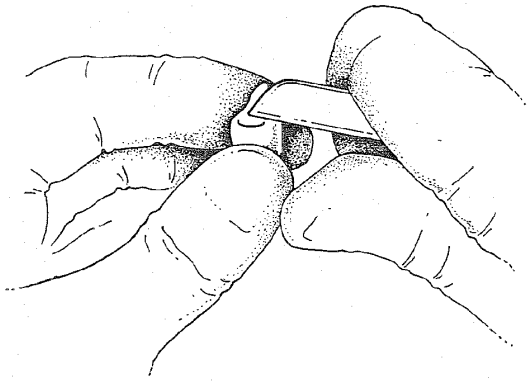


Figure 4. Tooth trimmed with laboratory knife.

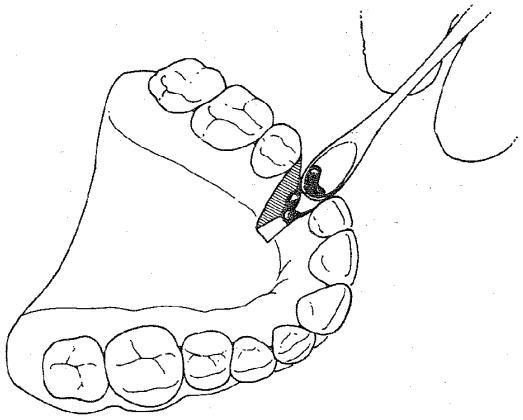


Figure 5. Melted wax placed in tooth space.

Minor Tooth Repositioning on Work Models

As mentioned earlier, one of the limitations of using an invisible retainer as a tooth-moving device is that in order to insure appliance fit, usually only one tooth per quadrant can be reset in each retainer. In the four premolar extraction case used in this example (Fig. 2), it is necessary to reposition the upper right canine. Interproximal cuts that approximate the long axis of the tooth are made on the maxillary work model with a laboratory saw, and gentle finger pressure is used to fracture the remaining plaster and free the tooth from the model (Fig. 3).

A laboratory knife is used to trim the area of the model in which the tooth is to be repositioned. Stone also must be removed from the sides of the "extracted" tooth (Fig. 4) to permit rotation correction. Medium-hard wax is melted and placed into the area where the tooth has been removed (Fig. 5), and the tooth is repositioned temporarily in the wax (Fig. 6).

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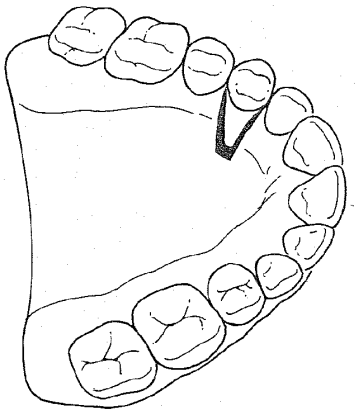


Figure 6. Tooth secured in preliminary corrected position.

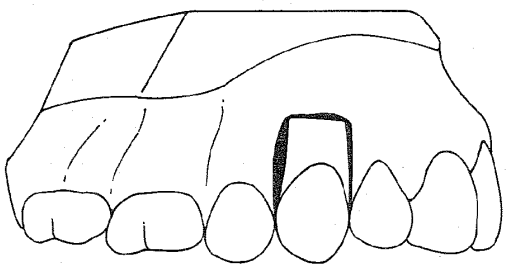


Figure 7. After the occlusion has been checked and the tooth is properly positioned, the wax is smoothed to a final contour.

The same procedure is carried out in the lower arch in which the remaining premolar is to be repositioned. The upper and lower dental casts are occluded, and the final changes in tooth position are achieved. The wax contours are smoothed (Fig. 7) and the models are ready for fabrication of the invisible retainer (Fig. 7).

Application of Acrylic

The invisible retainers are formed from 1mm thick splint Biocryl™ using a Biostar™ positive pressure thermal forming machine (Great Lakes Orthodontic Products, Tonawanda, NY). The work model is placed into the large (125 mm) model holder of the Biostar™. Lead pellets are placed around the model to a point 1mm below the desired margin of the appliance . The holding frame is placed on the pressure chamber, with the gasket and the four holding pins facing upwards. A piece of 1 mm splint Biocryl™ is placed inside the four pins of the holding frame, and acrylic is secured in position by placing the clamping frame over the holding frame. The handle of the clamping frame is turned to the left and secured with light pressure to lock it in place.

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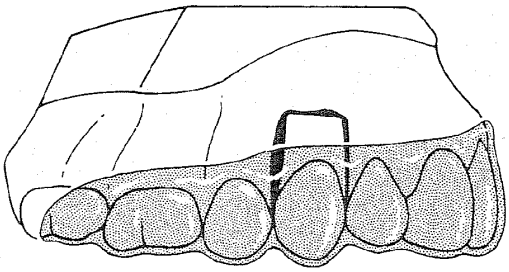


Figure 8. Finished trim of the maxillary invisible retainer. Care should be taken not to encroach on the gingival margin.

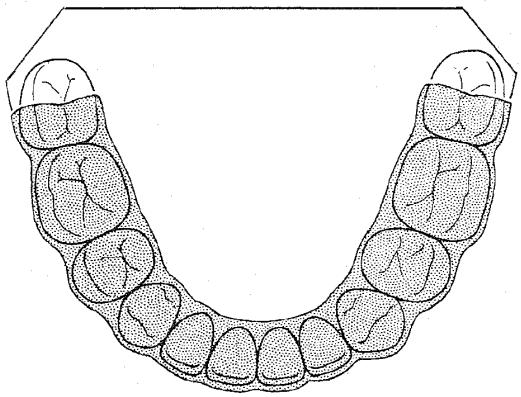


Figure 9. Finished contour of mandibular invisible retainer. Note that at least part of the last tooth is incorporated into the retainer bilaterally.

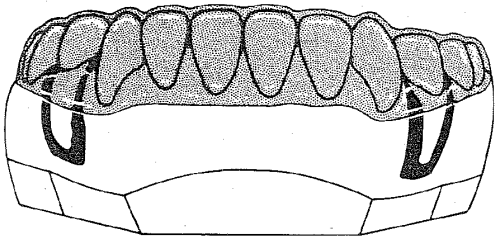


Figure 10. Final contour of the mandibular retainer.

The heating element is moved into position over the pressure chamber and left in place for approximately 30 seconds to soften the acrylic. The heating element is removed, the pressure chamber is rotated over the model holder and the pressure chamber handle is engaged. Air pressure,

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rather than partial vacuum pressure as originally advocated by Ponitz (1971), is used to push the softened Biocryl™ onto the work model at about five atmospheres of pressure.

Trimming of Acrylic

After two minutes, the pressure chamber handle is unlocked and the pressure chamber is rotated out of position. The clamping frame is removed and the acrylic with the embedded work model is taken off the Biostar™. Excess acrylic is removed from the work model with a sturdy pair of scissors, and the general contour of the invisible retainer is established with a carborundum disk. Then, the occlusal portion of the acrylic is gently pried from the cast, breaking many of the teeth of the cast. The plaster remnants then are removed from the retainer.

A pair of scissors are used for the final trimming and finishing of the appliance. No further polishing or trimming usually is necessary, although a light sanding, pumicing, and polishing of the edges of the appliance may be required in some instances.

It is extremely important always to cover at least part of the last molar in each arch to prevent extrusion of these teeth with full-time appliance wear. The invisible retainer usually is trimmed to include full palatal coverage (Fig. 1). The facial surface is trimmed to follow the approximate contour of the gingival margin (Fig. 8).

The mandibular invisible retainer is trimmed in a horseshoe shape, again covering part of the last molar (Fig. 9). The facial and lingual surfaces are trimmed to approximate the gingival margins (Fig. 10). Invisible retainers require virtually no adjustment at the time of delivery, except for trimming with scissors in areas of soft tissue impingement. Often invisible retainers can be mailed to the patient with instructions to trim the acrylic at any point at which it causes irritation.

If teeth have been reset in the invisible retainer, the patient should be told that the appliance will take a few hours to a few days to seat completely. If too much tooth movement has been carried out on the work model or more than one tooth per quadrant has been reset substantially, the appliance will not fit and will have to be remade.

FINAL REMARKS

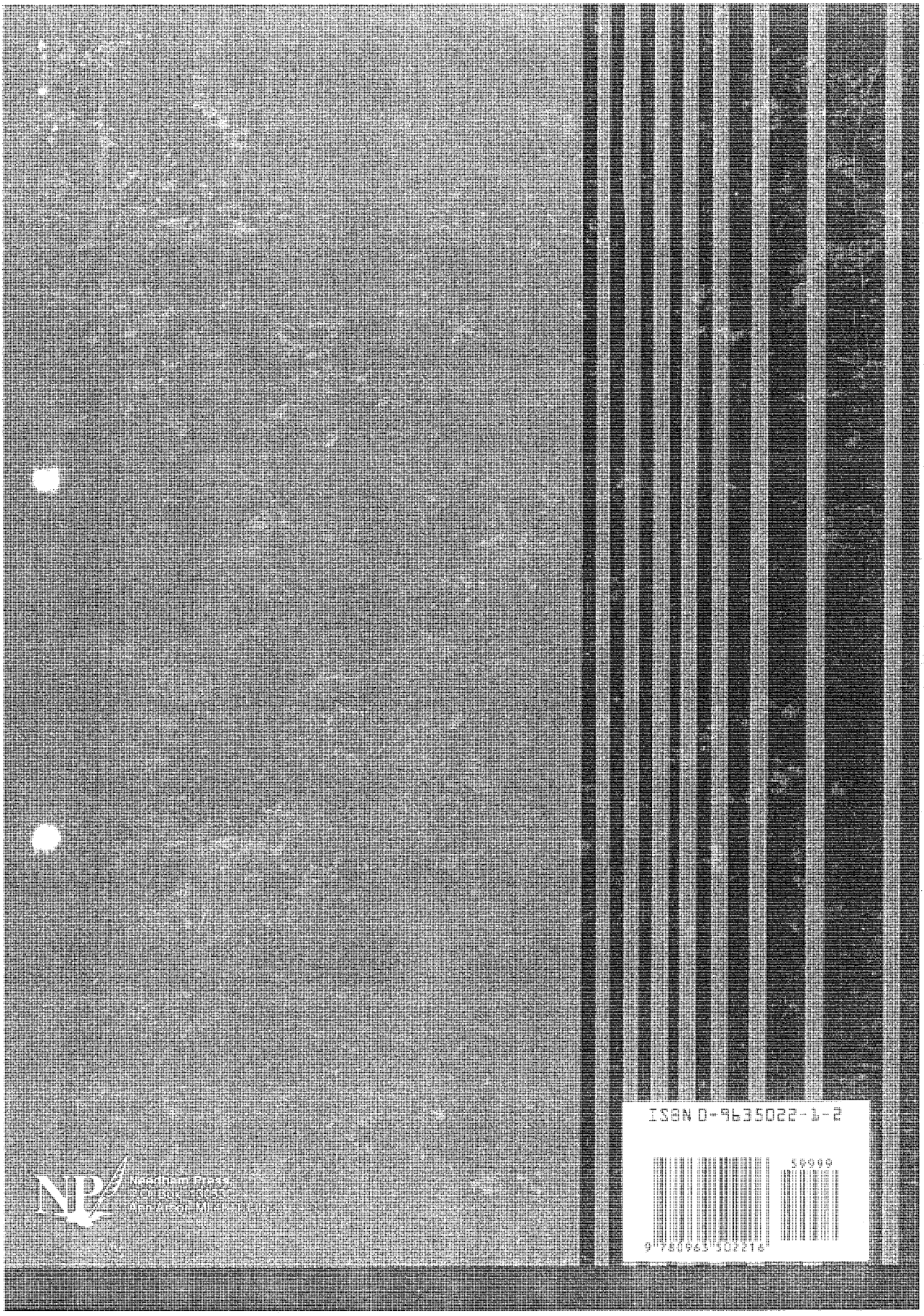
Invisible retainers have had a high level of patient acceptance because they are inconspicuous. The invisible retainer is simple to construct, easy to deliver, and inexpensive. In addition, when the invisible retainer is used as a finishing appliance, minor changes in tooth position also can be obtained. These appliances are not as durable as wire-acrylic retainers, but they do provide control over tooth position when worn over the long term.

REFERENCES CITED

McNamara, J.A. Jr., K.L. Kramer and J.P. Juenker. Invisible retainers. J. Clin. Orthod. *19*:570-578, 1985.

Ponitz, R.J. Invisible retainers. Am. J. Orthod. *59*:266, 1971.

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ISBN 0-9635022-1-2

333 Immunocytochemical localisation of extracellular matrix and intra-cellular components during murine palate development. M.W.J. Ferguson* & D. Pyle, Dept. Basic Dental Sciences, University of Manchester, England.

Mammalian palatal shelves, initially develop vertically but later reorientate to become horizontal. The shelf medial edge epithelia meet, fuse to form a seam and degenerate. Epithelial differentiation (medial-cell death, oral-keratinisation and nasal-pseudostratified ciliated columnar cells) is specified by the mesenchyme. We investigated regional differences in intermediate filaments, extracellular matrix and basement membrane components in day 11-14 embryonic mouse palates. Affinity purified polyclonal antibodies against cytokeratins, desmoplakins, fibronectin, various collagen types (principally I, III and IV), laminin and bullous pemphigoid antigen were used immunocytochemically in frontal and crystal sections of mouse heads. All palatal epithelia stained for cytokeratins and mesenchyme cells for vimentin. Fibronectin and collagen types I and III were widely distributed. Type III was dense in the lingual bases of the vertical shelves and may be implicated in shelf elevation. Collagen types I, III, IV and VI were located in and close to basement membranes. These components were lost when shelves were separated into epithelia and mesenchyme by trypsin but preserved on the mesenchyme if EDTA separation was employed. In both cases, adjacent mesenchymal extracellular matrix was retained. Desmoplakins localised on the apical and basal surfaces of medial edge epithelia during seam formation. Seam degeneration was preceded by a disappearance of laminin from the basement membranes of the fusion zone. Medial edge epithelial cells, disperse into the mesenchyme with fragments of type IV collagen from their basement membranes attached. This epithelia to mesenchyme cell conversion is an important additional (to cell death) mechanism in the breakdown of the palatal epithelial seam. This work is supported by grants from the MRC and the Wellcome Trust.

334 Method for the Evaluation of Stresses in Metal-Ceramic Systems. P. DORSCH. Ivoclar AG, Schaan, Fürstentum Liechtenstein

In the production of metal-ceramic restorations the mismatch of the thermal expansion coefficients (TEC) of dental alloys and ceramic materials results in stresses in the restorations which can lead to fractures in the porcelain. The objective of this investigation was to calculate, on the basis of deformation measurements of metal-ceramic compounds, the stresses in the ceramic layer caused by firing.

Metal strips of dimensions 3.0 mm x 20.0 mm and thicknesses of 1.0 mm and 1.5 mm were prepared from a Ni-Cr-alloy and coated on one surface with dental ceramic layers of 0.2 mm, 0.4 mm, 0.6 mm and 0.8 mm thickness. With a heating rate of 5 K / min the deformation changes depending on the temperature were determined by using an electronic dilatometer with a slightly modified specimen support. The measured deformations were compared with the stresses in the ceramic material calculated by the individual TEC, E-Moduli and thickness of the metal and porcelain layers.

The results show: (1) The thicker the ceramic layers, the larger the deformations. (2) The thicker the metal substrata, the smaller the deformations. (3) The larger the differences in the TEC, the higher the deformations. (4) There is no proportional relation between the value of deformation and the stresses in the ceramic material. (5) From a certain thickness ratio of ceramic material to metal tensile stresses in the surface of the ceramic occur even at a higher TEC of the alloy.

Conclusion: Stresses in a metal-ceramic system are not only determined by the TEC but also by the thickness of the layers. To estimate the stress situation, the measurement of the deformation of specimens is not sufficient. It is also necessary to regard the problem mathematically, whereby the method described will give precise data.

335 A Viscoelastic Analysis of the Porcelainized Semicircular Arch. P.H. DeHoff* and K.J. Anusavice, University of North Carolina at Charlotte and University of Florida Gainesville, Florida

The semicircular arch with gapped diametral segment has been shown to be a sensitive indicator of alloy-porcelain thermal contraction differences. This device can be used to estimate residual and transient stresses as well as the setting temperature at which incompatibility stresses first develop during a cooling cycle. However, these quantities depend on cooling rate, geometry and thermal contraction mismatch. In the absence of a valid theoretical model, data collected under one set of conditions cannot be extrapolated to a different set. The objective of this study was to develop an analytical procedure for calculating setting temperature, transient stress and residual stress for the porcelainized semicircular arch. All calculations were made for a Ni-Cr alloy in combination with a commercial opaque porcelain product. Calculated setting temperature as a function of cooling rate followed the Moynihan equation while the setting temperature increased nonlinearly with porcelain/metal thickness ratio. Variation in the porcelain/metal thickness ratio from 1:2 to 4:1 resulted in an increase of approximately 50°C in calculated value of setting temperature at a simulated cooling rate of 50°C/min. Calculated transient and residual stress values based on a viscoelastic analysis were somewhat lower than equivalent stresses calculated using an elastic analysis. The shape of the stress versus temperature curve during isothermal cooling was in qualitative agreement with published results for a split metal ring. This theoretical model shows promise as a means to evaluate alloy-porcelain incompatibility using porcelain viscosities and ΔL/L values measured in a dilatometer.

This study was supported by NIDR Grant DE 06672 and the UNCC Foundation.

336 Effects of Porcelain Fusion on Alloy/Oxide Interface Morphology, Composition G. BARAN*. Temple University School of Dentistry. Philadelphia, Pennsylvania.

Previous studies have shown that the composition and morphology of oxides formed on Ni-Cr alloys are highly dependent on alloy microstructure. The purpose of this study was to examine the effect of porcelain fusion on the formation of Ni-Cr alloy oxides.
Cast samples of five proprietary Ni-based alloys were prepared. Some were oxidized at temperatures similar to those recommended for preoxidation of the alloys; others were left unoxidized. The ceramic material was prepared as a 50:50 mixture of components 3 and 5 as described in the Weinstein patent. Solid buttons of the synthetic porcelain were polished on one side and applied to the alloy surface and fused. After cooling, the alloy was removed by dissolution in 10% Br-methanol solution. The area of porcelain in contact with the alloy was examined by SEM/EDAX.
Results show that the oxide formed on two alloys was highly porous. Wrinkled oxides formed on some alloys retained that morphology after porcelain fusion. Oxides that form on non-oxidized alloys that were covered with synthetic porcelain do so slowly, but their morphology seemed unaffected by the porcelain. Oxides are not completely dissolved by porcelains with compositions similar to proprietary dental porcelains under the time/temperature conditions used here.

Study supported by N.I.H. under DE 05519.

66(A) 333 IADR 589

337 Changes in the Fit of Castings During Various Processing Stages. L.A.J. VAN LOON*, H.L. BETCKE, F.R. BEURZE, C.L. DAVIDSON. Department of Clinical Materials Science, ACTA, University of Amsterdam, Louwesweg 1, Amsterdam.

The fit of dental castings is still a problem in dentistry. The aim of this study was to develop and test a device with which quickly and easily, the changes in fit caused by the various processing stages can be determined. Cylindrical rings with conical (1.43°) innerside were placed on a rod with identical connicalness. The rod is provided with markings. The location of the ring on the rod is taken as the momently fit of the sample. The fit of wax model is taken as the reference. The heat processing of the castings for porcelain baking is followed by registrating the new location on the bar. The shift in location is translated geometrically into change in inner diameter. As a control on these measurements, the dimensions of the ring, inside as well as outside, were determined with a measuring microscope. Three bake-on alloys were studied (Pors On, Bond On 4 and Degudent H).
In general the measurements on the bar showed a slight contraction of the castings, whilst the opposite effect was observed when the dimension were measured microscopically. All heat treatments after casting led to a decreasing inner diameter of the samples. A tentative explanation to both observations is that the surface irregularities from the investment and casting procedures are detected with the rod but not with the microscopical measurement. Also the formation of hard oxydes might contribute to the observed phenomenon. Therefore it might be concluded that the proposed measuring procedure is a sensitive instrument to study the various factors affecting the fit of dental castings.

338 Effect of Die Material on Marginal Fit of Dental Castings: A. AL-SHAAIR*, R.S. STEIN and D. NATHANSON Bosoton University Graduate School of Dentistry.
Marginal fit of cast dental restorations is of primary importance. Die materials and investing procedures can influence the accuracy of casting and their fit. The purpose of this study is to determine effect of die material and investing procedure on marginal fit of cast gold copings. A plastic molar model tooth was reduced with a diamond bur to create a full crown preparation with a deep chamfer and a mesial retention groove. This model was duplicated to produce a cast base metal master die. Elastomeric impressions (n=36) of the master die were made and devided into 3 groups according to the die materials used: Group A: Die stone (Die Keen, Columbia Dental); Group B: Refractory material (Divestment; Whip-Mix); Group C: Epoxy die material (Roc Model, Kuwata Pan Dent). Wax patterns were formed on all dies using a dipping wax (Dura Dip, Belle de St. Claire). In groups A and C the wax patterns were removed from their dies and invested (Cristobalite, Whip-Mix). In group B the wax patterns were invested with the refractory dies and additional refractory material (Divestment) to fill the casting rings. Copings were cast in a type III gold alloy (Firmilay, Jelenco), cleaned, seated on the master die and examined in a light microscope. Mean marginal discrepancies (u) were as follows: Group A: 30±4.5; Group B: 16±2.8; Group C:43±5.1. A one way ANOVA revealed a signif. diff. ($P<.001$) among the groups. A T-test showed a significant diff. between any two groups ($P<.001$). The refractory die material produced castings with signif.better fitting margins as compared to die stone or epoxy dies. Die stone was significantly better than epoxy.

339 Computer Machined Adhesive Porcelain Inlays: Margin Adaption After Fatigue Stress. W. MOERMANN, H. JANS, H. BRANDESTINI, A. FERRU & F. LUTZ. University of Zurich, Dental Institute, CAR/PER/PDM, Switzerland.

Under thermal stress computer machined adhesive porcelain inlays maintained an unprecedented high quality of marginal adaption and were significantly superior to comparable amalgam and gold restorations (J Dent Res 64, 208 Abstr.305, 1985). The purpose of this study was to evaluate gingival margin adaptation of machined porcelain inlays after thermocycling & occlusal fatigue stress.
48 MOD inlay cavities were prepared in extracted human molars with 90° and 135° cavo-surface angles(csa) respectively, at the gingival proximal margins. The cavity margins were etched and a simultaneously light- and chemically curing luting composite was used to insert the porcelain inlays. Bonding agent was applied to 12 cavities with 135°csa prior to seating the inlays (1). 12 cavities with 135°csa (2) and 24 cavities with 90°csa (3) received no bonding agent application. The micromorphology of the restoration/tooth interface of the gingival margins of all restorations was analyzed before and after a combined fatigue test (500'000 cycles, 22.5 N, 1.6 Hz) plus thermocycling (1250 cycles, 5°-60°C) using a replica technique and the SEM. The percentages of "Excellent Margin" after combined occlusal and thermal stress were 43%(3), 79%(2) and 95%(1). Two way ANOVA and linear contrast tests showed significant differences (1 vs.3:P<0.001; 1 vs.2:P<0.01; 2 vs.3:p<0.05) between the 3 groups.
A most durable and consistently high quality of marginal adaptation was achieved in the group using bonding agent application prior to the seating of the porcelain inlays with the aid of luting composite.

340 Strength and Performance of Improved Foil Crown Techniques.
A.J. SPANAUF*, H.H. RENGGLI, M.M.A. VRIJHOEF, Dental School, University of Nijmegen, the Netherlands.

Significant improvements are claimed as to new foil crown techniques. In this study two proprietary foil techniques (Flexobond, Elephant, The Netherlands; Plati Deck, Schöne, The Netherlands) have been evaluated in the laboratory. A conventional (casted) porcelain-fused-to-metal (PFM) crown was used as a reference. One system (Flexobond) has been clinically screened. In the laboratory part, uniform master dies were produced. Standardized crowns were made on these dies and cemented in place with a polycarboxylate cement (Ceramco, Johnson & Johnson, USA). All luted crowns were tested in compression. Failure was detected with both mechanic/audio and mechanic/electronic means. For the clinical part 21 crowns were placed in 11 patients. All the crowns were cemented with Ceramco cement. The general oral hygiene and periodontal condition of the patients were satisfactory. Overjet and overbite were normal. Follow-up time was up to 12 months. Comparative average compressive breaking loads (SEM between brackets) were as follows: Flexobond, 220 (3); Plati Deck, 146 (13); PFM, 292 (18) kgf. The compressive breaking load of the foil crowns increased significantly according as the porcelain thickness increased. The lower values related to the Plati Deck system might be traced back to a worse fit of the series of crowns tested. A better fit is expected to give better results: The clinical results are as follows: No adverse reactions were observed in relation to periodontium. No fractures were found. The marginal adaptation was good. No problems were detected as to the biocompatability in general. The esthetic results were satisfactory.

341 The Castability of Dicor Castable Ceramic Material Compared to Type II Casting Alloy. R.J. HOARD,* J.J. HOM, E.R. HEWLETT and J.F. WATSON, UCLA School of Dentistry, Section of Operative Dentistry.

The potential to cast thin sections of appropriate length can be related to capability of a material to produce accurate marginal fit. This study was designed to compare the property of castability of a castable ceramic (Dicor) to an A.D.A. certified Type II casting alloy.

A wax pattern was fabricated using wax forms supplied with the Dicor technique system. This pattern used the sprue former wax as a base to form a manifold type structure from which monofilament lines projected approximately 5-6 mm. The diameter of the nylon lines ranged from 132 um to 1270 um.

Each pattern was invested and cast according to manufacturer's specifications with the tailing edge marked for proper orientation in the casting machine. It was necessary to use two types of casting machines; both were centrifugal types. One was designed for Dicor by Dentsply and the other was designed by Kerr for precious metals.

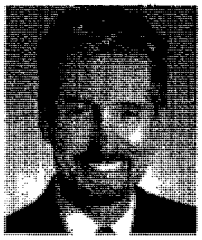
Each casting was divested and measured for length of casting of the monofilament, on a Gaerther measuring microscope.

It was found that both Dicor and type II gold were capable of producing a complete casting at 1270 um and 724 um diameter. But only type II gold was capable of producing a partial at the smallest 152 um and 132 um diameters. Dicor's inability to produce a consistent casting at the smallest levels bears further investigation.

AOA/Pro CORNER

Correcting Mild Malalignments – as Easy as One, Two, Three

Randall C. Moles, DDS, MS
Racine, Wisconsin



Dr. Randy Moles received his dental and orthodontic training from Marquette University, where he has served as associate professor of orthodontics and guest lecturer. He has been active in the research and development of new orthodontic products and has lectured and published in the areas of TMD and practice management. Dr. Moles is the author of *Ending Head and Neck Pain: The T.M.J. Connection*, a book directed to sufferers of chronic headache. He has patented a custom scuba mouthpiece (marketed under the name *Seacure*) that reduces the jaw pain and fatigue that divers commonly experience. Dr. Moles is engaged in the private practice of orthodontics in Racine, Wisconsin.

The good news is that we live in an era when aesthetics are extremely important, increasing and broadening the demand for our services. Orthodontic manufacturers have responded by providing aesthetic appliances such as clear and lingual brackets. The bad news is that this same preoccupation makes it even more difficult to choose treatment for some malalignments. One area that's currently gaining popularity is correcting mild tooth malalignments with retainers. While too minimal to justify the cost of full appliances, the choice of limited braces or an active spring-type appliance worn on a 24-7 basis, for many patients, is simply not an acceptable alternative.

The Red, White and Blue Invisible Active Retainer System offers a solution to those adults who are just outside the normal range of other tooth-aligning appliances, such as a Hawley or spring-type, or patients who want the most simple aesthetic system possible to correct minor to intermediate tooth malalignments. In addition to being aesthetically pleasing, these retainers won't effect the patient's speech and are very cost effective.

The Red, White and Blue System consists of a series of three invisible active retainers. The lab fabricates them by sectioning the teeth to be corrected from work models and resetting them in progressively corrected setups. The small, incremental changes in tooth position create forces that move the teeth. The idea of creating retainers from teeth reset on a model is very similar to the fabrication of positioners dating back to 1940 and spring retainers to 1970. Each Red, White and Blue retainer has a corresponding colored dot for easy identification and is worn in that sequence.

In-Office Procedures

1. Assess necessary tooth movement and space requirements.

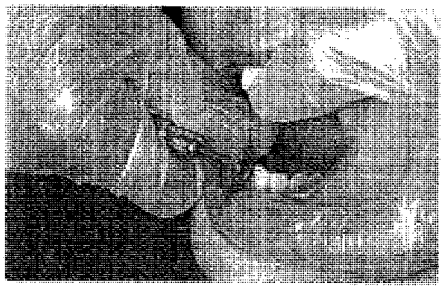


Figure 1. Enamel reduction creates interproximal space for tooth alignment.

2. Create interproximal space with slenderizing as needed.

Although you can perform enamel reduction at any time, I prefer to complete it before treatment, if tooth position permits (Figure 1). If not, you may find it necessary to do some enamel reduction during treatment.

3. Take accurate impressions.

Be careful of the second molar area because it's often difficult to capture and will affect the seating and retention of the retainers. In my practice, we pour our own models. When the stone is in liquid form, we're very careful to mix it until it's bubble free before pouring it into the impressions. A centric occlusion wax bite is helpful to the laboratory to establish proper overbite and overjet relationships.

4. Prepare the laboratory prescription. Indicate which teeth are to be repositioned and include instructions for enamel reduction.

The prescription is similar to a spring retainer primarily designed for anterior correction; however, it's possible to make small adjustments in cuspid or even bicuspid position with the Red, White and Blue System. Be careful not to overpower the appliance by

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trying to provide too much rotation and space closure at one time. If you have performed enamel reduction prior to treatment, be sure to schedule the patient back as soon as possible to avoid tooth movement and poorly seated retainers. If you schedule the patient out longer, be sure to make them a temporary retainer.

Patient Delivery

When the system arrives from the laboratory, deliver the retainers to the patient. The Red color-coded retainer is worn first. Look for good seating of all the teeth in the appliance. If the teeth don't seat, insert the retainers and have the patient bite down with cotton rolls between the teeth for five to ten minutes. Since the appliance will eventually seat, a slight discrepancy of .5 mm on an individual tooth is acceptable (Figure 2).

Patient Instructions

The appliance is worn a minimum of 22 hours a day for maximum tooth movement. While wearing the retainers, the patient should gently bite down, squeezing their teeth together to help seat them so the teeth will move faster. After two weeks the patient will change to the White retainer and two weeks later to the Blue one. Instruct them to call if they have any problems seating the retainers.

It's also important for the patient to check the tightness of contacts between teeth when flossing. If the floss is tight, they should call for an appointment for us to check the contact and possibly clear it with a diamond strip (Figure 3). This is important since the force of these retainers is limited. A tight contact could stop a tooth from moving. Sometimes a tooth position makes it impossible to perform enamel reduction needed for complete alignment. In this case, it may be necessary to see the patient more often to repeat this process. Occasionally, the patient may need to wear a retainer for more than two weeks if the next one won't seat properly.

The Red, White and Blue Invisible Active Retainer System is a valuable addition to our aesthetic treatment armamentarium. It offers an extremely comfortable, aesthetic, and minimally intrusive solution to patients with mild tooth alignment problems. When a patient has already had braces and now experiences minor relapse, it's especially gratifying to have the opportunity to offer this retainer as a simple, aesthetic alternative. As we all know, when patients are happy our practices grow!

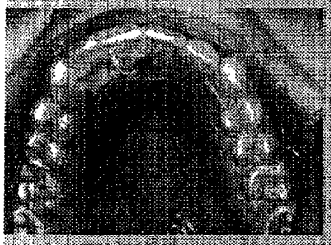


Figure 2. The appliance should seat completely on all teeth and in this case is positioned over a *flipper*.



Figure 3. Tight contacts between teeth are reduced with a diamond strip.

Mild Tooth Malalignment Case

PRETREATMENT

49-year-old female with post orthodontic relapse and mild shifting of lateral incisors. Patient didn't want to wear a metal spring-type retainer and requested an aesthetic appliance.



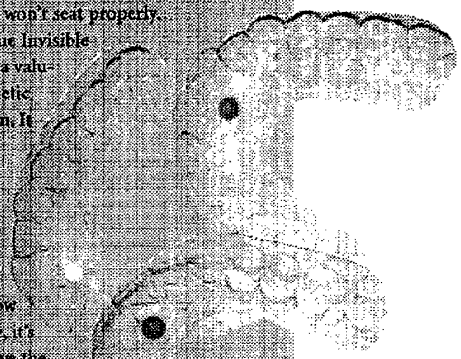


POSTTREATMENT

Patient wore upper and lower retainers for six weeks to correct crowding. She continues to wear the Blue retainer at night for retention.







See the Red, White and Blue System at the AOA/Pro Booth.

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Separatdruck aus: Schweiz. Mschr. Zahnmed. 95: 1118, 1985

12

Zahnärztliches Institut der Universität Zürich, Abteilung für Kariologie, Parodontologie und Präventivzahnmedizin (Vorsteher: Prof. Dr. F. Lutz)

Marginale Adaptation von adhäsiven Porzellaninlays in vitro

W. Mörmann / M. Brandestini* / A. Ferru* / F. Lutz / I. Krejci

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Die marginale Adaptation von adhäsiv eingesetzten MOD-Porzellaninlays und je 6 konventionellen Amalgam- und Goldgussfüllungen als Kontrollen wurde in vitro an extrahierten menschlichen Molaren untersucht. Die Porzellaninlays wurden mit Hilfe de Cerec®-Systems[1] hergestellt. Mit diesem von Brains[1] entwickelten Verfahren wurden die Kavitäten stereophotogrammetrisch abgetastet und Inlays anhand der räumlichen Daten in einem elektronisch kontrollierten Schleifprozess maschinell ausgearbeitet.

Die Porzellaninlays wurden kavitätenseitig geätzt und mit Hilfe eines Kompositmaterials nach Anwendung der Schmelz-Ätz-Technik eingesetzt. Die Mikromorphologie der approximalen Füllungsränder wurde im REM bei 400facher Vergrösserung mit Hilfe einer Replikatechnik vor und nach 2500 vollständigen Zyklen im thermischen Wechselbad (10° - 60° - 10 °C) untersucht. Die Randdichtigkeit im Bereich der zervikalen Stufen wurde nach der Temperaturwechselbelastung anhand eines Farbpenetrationstestes untersucht.

Der durchschnittliche Prozentsatz «perfekter Rand» pro Approximalrand war bei Porzellaninlays sowohl vor (98 ± 2%) als auch nach (88 ± 7%) der Temperaturwechselbelastung signifikant ($p < 0{,}001$) höher als bei Amalgam (64% bzw. 9%) und bei Gold (11% bzw. 3%). Farbpenetration trat bei Amalgam an 8, bei Gold an 10 und bei Porzellaninlays an 2 von je 12 zervikalen Stufen auf.

1. Einleitung

Die Realisation zahnfarbener Füllungen der Klasse II als dauerhafte, okklusionstragende Restorationen scheint prinzipiell auf drei Lösungswegen möglich zu sein, und zwar mit:

1. Kompositfüllungen
2. Kompositinlays
3. Porzellan- bzw. Keramikinlays in Verbindung mit dentaler Adhäsivtechnik

* Brains, Brandestini Instruments, CH-8702 Zollikon

[1] Cerec®-System, Brains, CH-8702 Zollikon

Nach Auffassung der American Dental Association gibt es bis heute keinen Werkstoff auf Kunststoffbasis, der uneingeschränkt anstelle metallischer Füllungswerkstoffe eingesetzt werden kann. (*Phillips* und *Lutz*, 1983; *Lutz* et al., 1985). Einer der wichtigsten Nachteile der direkt in der Kavität aushärtenden Seitenzahnkomposits ist die ungenügende marginale Adaptation (*Lutz*, 1980). Diese ist auf die den heutigen Kompositsystemen eigene Polymerisationsschrumpfung zwischen 1,5 und 3,0 Volumenprozent zurückzuführen (*Forster* et al., 1982; *Goldman*, 1983; *Masutani* et al., 1983).

Mit chemisch- und/oder lichthärtenden Zementierungs-Komposits eingesetzte vorpolymerisierte MOD-Komposit-Inlays wiesen in vitro einen hohen Prozentsatz (97%) perfekter marginaler Adaptation auf (*Mörmann* und *Lutz*, 1982; *Mörmann* et al., 1982a, b). Klinisch wurden mit Kompositinlays in bezug auf Form und Farbe ästhetisch in hohem Masse befriedigende Resultate erreicht (*Mörmann*, 1982; *James*, 1983). Eine REM-Analyse der marginalen Adaptation von MOD-Kompositinlays in vivo ergab aber eine kontinuierliche Qualitätsverschlechterung von anfangs 97% «perfektem Rand» auf 84% nach 12 Monaten und auf 55% nach 24 Monaten (*Mörmann* und *Ameye*, 1983; *Mörmann*, 1985). Eine 6 Monate dauernde In-vivo-Untersuchung der marginalen Adaptation von MOD-Kompositinlays aus vier verschiedenen Kompositkonstruktionen bestätigte diese Tendenz (*Marolf* et al., 1984). Die zeitabhängige viskoelastische Deformation bei hohen Belastungen besonders bei mikrogefüllten Komposits erklärt die beobachtete Abnahme der Randqualität zum Teil (*Cock* und *Watts*, 1985).

In einem Laborversuch verschlechterte sich die anfangs hohe Randqualität von MOD-Kompositinlays unter dem Einfluss von 1250 Temperaturzyklen zwischen 5 °C und 60 °C signifikant um 30%, was auf den hohen thermischen Expansionskoeffizienten des Komposits zurückgeführt wurde (*Roulet* et al., 1984).

Dentalporzellan und neue Keramikmaterialien liegen in ihren physikalischen Eigenschaften der Zahnhartsubstanz, besonders dem Zahnschmelz, wesentlich näher als Kompositmaterialien (*Craig*, 1985; *Phillips*, 1982; *Adair* und *Grossman*, 1984; *Jones*, 1982; *Kullmann* und *Pötters*, 1984; *McLean*, 1984; *Hobo* und *Iwata* 1985a, b). Geätztes Dentalporzellan kann mit hohen Retentionskräften klinisch dauerhaft adhäsiv mit Zahnschmelz verbunden werden (*Horn*, 1983; *Calamia* und *Simonsen*, 1984; *Calamia*, 1985). Die adhäsive Inkorporation von Porzellan- bzw. Keramikrestorationen wendet wie die Kompositinlay-Technik die Grundelemente der dentalen Adhäsivtechnologie an, nämlich die Schmelz-Ätz-Technik (*Buonocore*, 1955) und gefüllte Kunststoffe (*Bowen*, 1958) als Befestigungsmaterial.

Die Herstellung von Porzellan- bzw. Keramikinlays mit herkömmlichen Modell- und Brenn- bzw. Gussverfahren bedingt normalerweise zwei Patientensitzungen mit zwischenzeitlich provisorischer Versorgung der Kavität und einen vielstufigen technischen Herstellungsprozess (*Craig*, 1985; *Siebner*, 1983; *Adair* und *Grossman*, 1984; *Hobo* und *Iwata*, 1985a, b). Die Entwicklung des Cerec®-Systems[1] ermöglicht es, unmittelbar nach Präparation und Unterfüllung, Porzellan- bzw. Keramikrestorationen in einem Zuge stereophotogrammetrisch abzutasten, maschinell herzustellen und einzusetzen (*Brandestini* et al., 1985; *Mörmann*, 1985). Ziel der vorliegenden Studie war es, die marginale Adaptation von adhäsiv eingesetzten Cerec®-Inlays nach Belastung im thermischen Wechselbad im Vergleich zu Amalgam- und Goldgussfüllungen zu untersuchen.

2. Material und Methode

2.1 Zahnmaterial

Die in der vorliegenden Studie verwendeten Füllungs-, Unterfüllungs-, Ätz- und Adhäsivmaterialien sind in der Tabelle I aufgeführt. Extrahierte menschliche Molaren, die in einer 0,1%-Thymol-

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Tab. 1 Füllungs-, Unterfüllungs-, Befestigungs- und Zementierungsmaterialien, Ätzmittel und Versiegler.

Porzellan:	Vitadur 353 N[5]
Porzellanätzmittel:	Conex[6], 60 sec
Schmelzätzung:	Ätz-Gel[7] (H_3PO_4, 60 sec)
Versiegler:	Heliobond[7]
Befestigungskomposit:	Experimentell VP 307[8]
Unterfüllung:	Life[9], Dünnschicht 15–30 µm
Zement:	De Trey Zink Cement Improved[10], Type I: Fine Grain, Cl. II, normal härtend, Prod.-Nr. 810202/810407
Amalgam:	Dispersalloy[11], Regular Set Code 2896, Prod.-Nr. 041883A, 3D 828. Trituration 7 sec, 2 und 3 Portionen
Gold:	Aurofluid 3[12]

[5] Vita Zahnfabrik, Bad Säckingen, BRD
[6] Denticon Dental GmbH, Konstanz, BRD
[7] Espe GmbH, Seefeld, BRD
[8] Ivoclar AG, Schaan, FL
[9] Sybron Kerr, Basel, CH
[10] De Trey AG, Zürich, CH
[11] Johnson & Johnson Co., East Windsor, New Jersey, USA
[12] Métaux Précieux SA, Metalor, Zürich, CH

Lösung aufbewahrt blieben, wurden für die Kavitätenpräparation benutzt. Die Zähne wurden mit Handinstrumenten und der rotierenden Bürste unter Anwendung eines Bimsstein-Wassergemisches gereinigt.

2.2 Kavitätenpräparationen für Porzellaninlays

Sechs konventionelle kastenförmige MOD-Inlaykavitäten wurden zur Aufnahme von Porzellaninlays präpariert. Die Kavitätenpräparation entsprach der für Kompositinlays verwendeten Technik (*Mörmann*, 1982), jedoch ohne zirkuläre Randabschrägung. Der pulpale und pulpo-axiale Kavitätenboden wurde mit einem hartabbindenden $Ca(OH)_2$-Unterfüllungsmaterial in dünner Schicht (etwa 15–30 µm) bedeckt (*Mörmann* et al., 1983, 1985). Die Kavitäten wurden im Anschluss mit Wasser ausgesprayt und mit Pressluft getrocknet.

2.3 Das Cerec®-Rekonstruktionssystem[2]

Das stereophotogrammetrische Abtast- und Fabrikationssystem wurde bereits früher beschrieben (*Mörmann* und *Brandestini*, 1985) und darüber berichtet (*Brandestini* et al., 1985; *Mörmann*, 1985).

Das System erlaubt die Abtastung einer Kavität, die Rekonstruktion und die Fabrikation eines Inlays aus Porzellan bzw. Keramik in einem Zuge.

Ein Funktionsschema ist in Abbildung 1 dargestellt. Zum System gehört ein stereophotogrammetrischer Abtastkopf, der über den präparierten Zahn positioniert wird (Abb. 2). Über den Videoteil des Abtastkopfes kann die Kavität unter beliebigen Blickwinkeln auf einem Monitor bei achtfacher Vergrösserung kontrolliert werden (Abb. 3a). Sobald sich alle Kavitätenwände in einer der Präparations- bzw. Einschubachse des Inlays entsprechenden Betrachtungsrichtung darstellen, löst der Zahnarzt den stereophotogrammetrischen Vermessungsvorgang (Abb. 3b) aus. Die räumliche Erfassung einer Kavität dauert 0,2 Sekunden. Ein Graphiksystem erlaubt es, die registrierten Daten zu speichern und diese durch Konstruktionseingaben zu ergänzen (Abb. 3c). Die Konstruktion des Füllungskörpers (Abb. 3d) wird mit Hilfe eines Mikroprozessors durchgeführt. Dieser hat unmittelbaren Zugriff zu den Daten im Bildspeicher und steuert in der Bearbeitungsphase eine Miniaturschleifmaschine.

[2] Brains, Brandestini Instruments, CH-8702 Zollikon

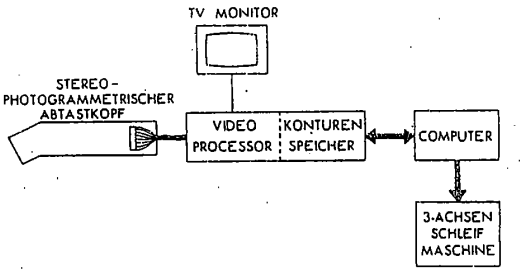


Abb. 1 Funktionsschema des Cerec®-Systems.

2.4 Porzellanprobekörper

Das maschinelle Ausschleifen eines Klasse-II-Inlays geht von einem vorfabrizierten Porzellankörper mit den Massen 9×9×13 mm aus. Für den vorliegenden Versuch wurden die Porzellanrohlinge mit Hilfe konventioneller Zahntechnik hergestellt. Vitadur-353-N-Frittenpulver wurde mit Aqua destillata gemischt und manuell in eine Stahlform mit den Massen von 10×10×15 mm kondensiert. Der kondensierte Frittenblock wurde unter Vakuum, mit einem Temperaturanstieg von 60 °C/min, bei 950 °C und mit einer Haltezeit von 1 Minute gebrannt. Die Porzellanblöckchen wurden mit einem Attachment verbunden, welches die Befestigung des Porzellanrohlings in der Ausarbeitungsmaschine erlaubte. Der Schleifprozess dauerte für ein Klasse-II-Porzellaninlay etwa 4 bis 8 Minuten (Abb. 4).



Abb. 2 Stereophotogrammetrischer Abtastkopf zur direkten Abtastung von Kavitäten in der Mundhöhle.

2.5 Adhäsivtechnik – Einsetzen der Porzellaninlays

Die inneren Oberflächen der Porzellaninlays wurden mit einem verdünnten Flusssäurepräparat 60 Sekunden lang geätzt. Danach wurden die Porzellaninlays gründlich mit Wasser gespült und mit Pressluft getrocknet. Die Schmelzränder der Kavität wurden vor dem Einsetzen der Inlays mit Hilfe eines flammenförmigen Finierdiamantinstrumentes[3] (15 µm Diamantkorn) leicht gebrochen. Der Schmelz wurde dann mit einem Ätz-Gel 60 Sekunden geätzt.

[3] Composhape-Set, Intensiv AG, Lugano, Schweiz

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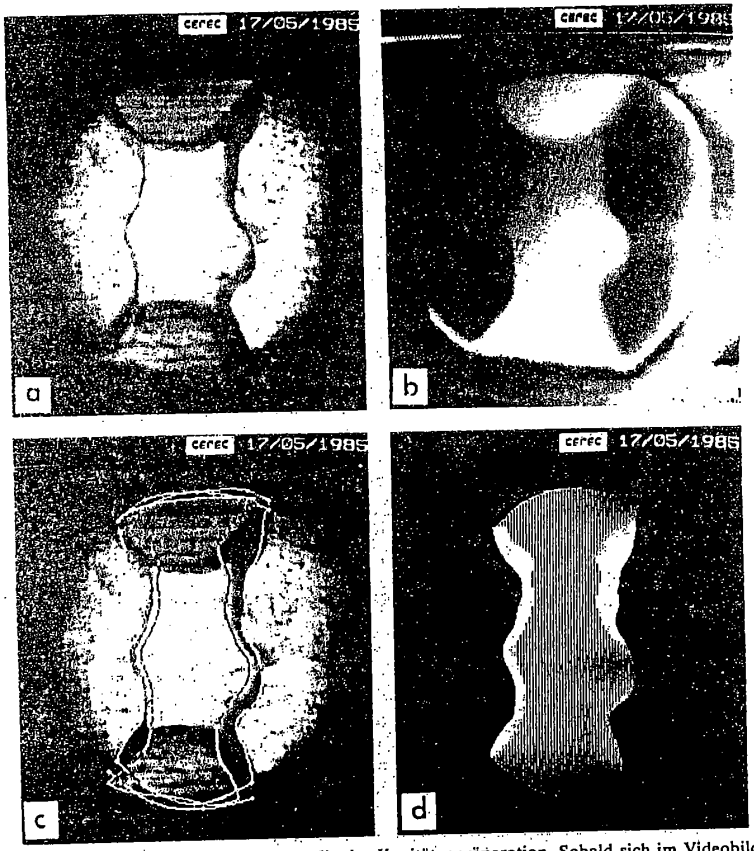


Abb. 3a Video-Suchbild zur Kontrolle der Kavitätenpräparation. Sobald sich im Videobild durch entsprechende Positionierung des Kamerakopfes alle Kavitätenwände in einer der Präparations- bzw. Einschubachse des Inlays entsprechenden Betrachtungsrichtung einsehen lassen, löst der Zahnarzt den stereophotogrammetrischen Vermessungsvorgang aus.
b) Helligkeitskodierte räumliche Abtastung einer MOD-Kavität.
c) Halbautomatische Inlaykonstruktion durch manuelle Markierung einzelner Eck- und Extrempunkte. Markierung der Kontaktbereiche und der Randleisten.
d) Datenreduktion auf die zur Inlayherstellung erforderlichen Daten. Approximal werden die Daten zwischen der Randleistenlinie, der Äquatorlinie und dem zervikalen Kavitätenrand automatisch ergänzt.

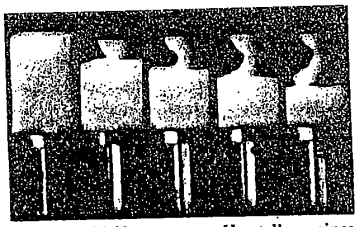


Abb. 4 Schleifvorgang zur Herstellung eines MOD-Inlays aus einem Porzellanrohkörper dargestellt in Abschnitten, die jeweils eine Minute auseinanderliegen.

Im Anschluss an einen Versieglervorstrich auf dem Inlay und in der Kavität wurde ein kombiniert licht- und chemisch härtendes mikrogefülltes Kompositmaterial angemischt (Zweipastensystem) und im Überschuss in die Kavität gefüllt. Das Porzellaninlay wurde dann in die Kavität eingesetzt und die an den Kavitätenrändern austretenden Materialüberschüsse des Befestigungskomposits mit einem feinen Spatel entfernt. Danach wurden die okklusalen und approximalen Füllungsbereiche je 60 Sekunden mit sichtbarem Licht gehärtet. Die Okklusalfläche wurde mit Konturier- und Finierdiamantinstrumenten[3] ausgearbeitet (*Lutz* et al., 1983; *Mörmann* et al., 1983). Die proximalen Flächen wurden mit flexiblen Disks[4] unter Wasserspray poliert (Abb. 6).

2.6 Amalgamfüllungen – Goldinlays

Sechs MOD-Goldinlays und sechs MOD-Amalgamfüllungen von ähnlicher Grösse wie die Porzellaninlays dienten als Kontrollfüllungen (Abb. 6). Für Gold und Amalgam wurden Unterfüllungen aus Zinkphosphatzement gelegt. Die Amalgamfüllungen wurden manuell kondensiert und geschnitzt. Eine Woche nach dem Legen der Füllungen erfolgte die Politur mit flexiblen Disks. Die Goldinlays wurden mit Zinkphosphatzement zementiert und die approximalen Füllungsränder vor dem Aushärten des Zinkphosphatzementes mit Arkansassteinchen brüniert.

2.7 REM-Analyse

Von den Approximalflächen aller Test- und Kontrollfüllungen (Abb. 7) wurden anschliessend an die Politur Replikas für die rasterelektronenmikroskopische Untersuchung genommen. Die Mikromorphologie der Grenzflächen Füllung/Zahnhartsubstanz bzw. Zementierungsmaterial/Zahnhartsubstanz wurde bei 400facher Vergrösserung beurteilt. Randbezirke, die frei von 1. Überschüssen, 2. Unterschüssen, 3. Randspalten, 4. Schmelzfrakturen im Bereich des Füllungsrandes oder 5. Frakturen des Füllungsmaterials im Bereich des Randes waren, wurden als «perfekter Rand» gewertet. Auf die Gesamtlänge jedes approximalen Füllungsrandes wurde der Prozentanteil mit der Bewertung «perfekter Rand» berechnet (*Lüscher* et al., 1977). Innerhalb jeder Untersuchungsgruppe (Amalgam, Gold und Porzellan, jeweils vor und nach dem Temperaturwechselbad) wurden jeweils 12 proximale Replikas beurteilt.

2.8 Statistische Auswertung

Die Varianzen der sechs Gruppen (Amalgam, Gold, Porzellan, je vor und nach Temperaturwechselbelastung) schienen sich stark zu unterscheiden. Deshalb wurden zunächst zwei Varianz-Homogenitätstests (*Cochran and Bartlett-Box-Test, Bock*, 1975) durchgeführt. Die Tests ergaben, dass die Varianzen signifikant verschieden waren. Eine Ar-

[4] Sof-Lex discs, 3M & Co., St. Paul, Minnesota, USA

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cussinus-Transformation löste das Homogenitätsproblem. Die transformierten und die nicht transformierten Daten wurden einer Varianzanalyse unterworfen. Allerdings ergaben sich zwischen den beiden Analysen keine substantiellen Unterschiede, deshalb wird im folgenden nur die Analyse der nicht transformierten Daten dargestellt. Um Unterschiede zwischen den einzelnen Füllungstypen festzustellen, wurden *Helmert-Kontrasttests* durchgeführt.

2.9 Farbpenetrationstest

Ausser den Randbezirken der proximalen Füllungsoberflächen wurden alle Zähne mit einer doppelten Schicht gefärbten Nagellackes abgedeckt und dann in ein Immersionsbad mit wässriger, 0,5% basischer Fuchsinlösung für 20 Stunden eingelegt. Die Molaren wurden dann mesio-distal mittig durch die MOD-Füllungen mit einer langsam rotierenden Trennscheibe unter Kühlung mit Kerosin durchtrennt. Das Fuchsin ist in Kerosin unlöslich und wird deshalb während des Schneidens nicht herausgelöst. Die Farbpenetration wurde auf der Basis einer Ja/Nein-Entscheidung anhand 4fach vergrösserter Farbdiapositive der Zahnschnitte beurteilt.
Ein Flussdiagramm der Untersuchung ist in Abbildung 5 dargestellt.

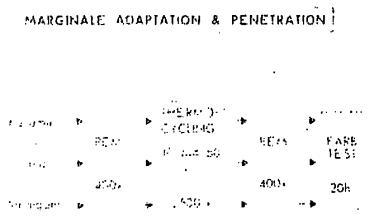


Abb. 5 Flussdiagramm der Untersuchung.

3. Resultate

Das Ergebnis der REM-Randanalyse ist in Abbildung 8 dargestellt. In der Varianzanalyse waren die Haupteffekte, nämlich die Werte der Füllungstypen und die Werte vor und nach Thermocycling, beide hochsignifikant ($p < 0{,}001$) voneinander verschieden. Die Interaktion zwischen diesen beiden Faktoren war ebenfalls hochsignifikant ($p < 0{,}001$).

vor/nach	
Thermocycling	$F(1/66) = 186{,}84$ $(p < 0{,}001)$
Füllungstyp	$F(2/66) = 825{,}05$ $(p < 0{,}001)$
Interaktion	$F(2/66) = 73{,}25$ $(p < 0{,}001)$

Im ersten Helmert-Kontrasttest waren die beiden Metallgruppen gegen die Porzellangruppe hochsignifikant ($p < 0{,}001$) verschieden. Amalgam und Gold unterschieden sich ebenfalls hochsignifikant. Das Ergebnis des Farbpenetrationstests an je 12 zervikalen Stufen pro Füllungstyp lautete: Gold = 10, Amalgam = 8 und Porzellan = 2 zervikale Stufen mit Farbpenetration.



Abb. 6 Typische Approximalflächen der untersuchten Amalgam- (a), Gold- (b) und Porzellanfüllungen (c).

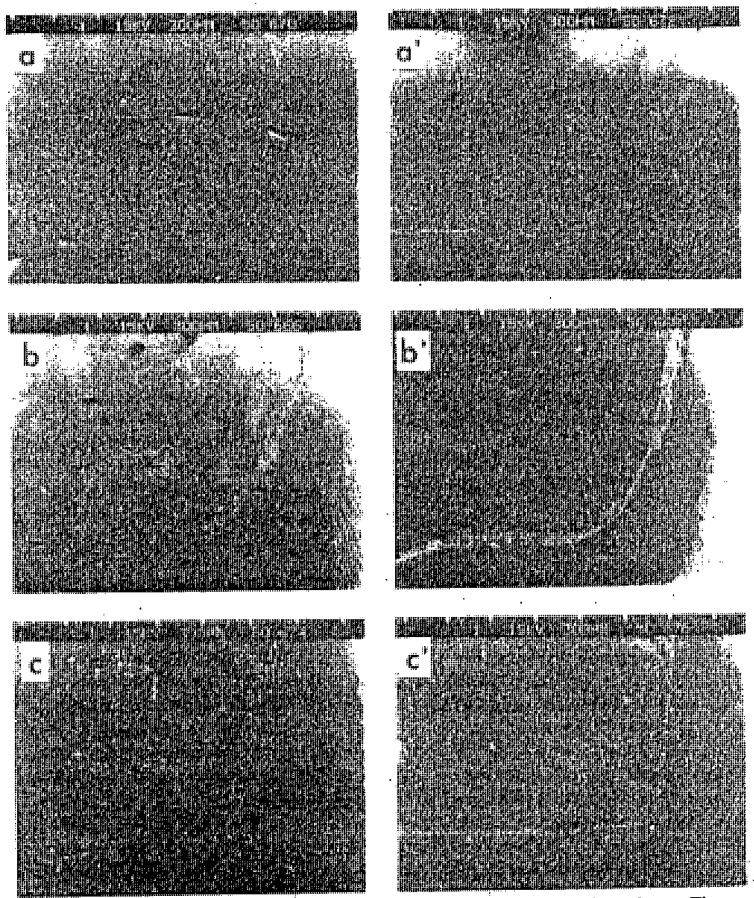


Abb. 7 REM-Bilder, 50fache Vergrösserung, jeweils vor (a, b, c) und nach (a', b', c') Thermocycling. Die Pfeile in c und c' bezeichnen die ungefähre Grenze des Adhäsivbereichs auf dem Schmelz.

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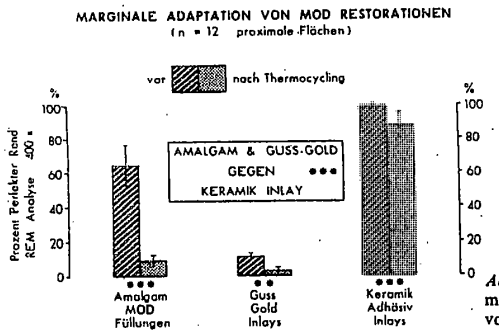


Abb. 8 Ergebnis der mikromorphologischen REM-Analyse vor und nach Thermocycling.

4. Diskussion

Die vorhandene Laboruntersuchung analysiert das Konzept, Klasse-II-MOD-Kavitäten mit zahnfarbenen Füllungskörpern unter Anwendung folgender Technik und Materialien wiederherzustellen:

1. stereophotogrammetrische Kavitätenabtastung
2. elektronisch kontrollierte, maschinelle Inlayherstellung
3. dentale Adhäsivtechnik
4. Porzellan- oder Keramikmaterialien

Dieses Konzept verspricht dauerhafte, okklusionstragende zahnfarbene Füllungskörper direkt nach der Kavitätenpräparation und Unterfüllung zur Verfügung zu stellen, die sofort adhäsiv eingesetzt werden können.

Die heute zur Verfügung stehenden Seitenzahnkomposits, welche zur Anfertigung zahnfarbener okklusionstragender Klasse-II-Füllungen propagiert werden, besitzen eine beschränkte Gebrauchsdauer (*Lutz* et al., 1985). Füllungen aus diesen Materialien müssen im allgemeinen nach einigen Jahren wegen okklusalem Substanzverlust oder wegen der sich zunehmend verschlechternden Randverhältnisse ausgetauscht werden (*Phillips* und *Lutz*, 1983; *Lutz* et al., 1985).

Eine Reihe von Untersuchungen zeigten, dass die Verarbeitung von Kompositmaterialien im Sinne der direkten oder indirekten Inlaytechnik initial zu einer starken Qualitätssteigerung gegenüber direkt in der Kavität ausgehärteten Komposits führte mit porenfreien, homogenen Füllungskörpern und einem hohen Prozentsatz an perfekter marginaler Adaptation (*Mörmann* und *Lutz*, 1982; *Mörmann* et al., 1982a, b). Der aber in vivo beobachtete, kontinuierliche Abbau der marginalen Adaptation von Inlays aus heisspolymerisierten, mikrogefüllten Kompositmaterialien unterschiedlicher Konstruktion lässt grundsätzliche Zweifel an der Eignung mikrogefüllter Komposits für okklusal belastete MOD-Restorationen berechtigt erscheinen (*Mörmann* und *Ameye*, 1983; *Marolf* et al., 1984). Auf der Basis dieser Untersuchungsergebnisse wurde für Kompositinlays der erwähnten Art eine voraussichtliche Gebrauchsdauer von 3–5 Jahren veranschlagt (*Marolf* et al., 1984).

Ergebnisse einer Laboruntersuchung der marginalen Adaptation von Kompositinlays nach 1250 thermischen Wechselzyklen legte die Erklärung nahe, dass der im Vergleich zur Zahnhartsubstanz 4- bis 6mal höhere thermische Expansionskoeffizient der mikrogefüllten Kompositmaterialien als wesentlicher Faktor beim Abbau der marginalen Adaptation der MOD-Inlays anzusehen ist (*Roulet* et al., 1984). In der vorliegenden Untersuchung ergab die Analyse der Randmikromorphologie der adhäsiv eingesetzten Porzellaninlays den hohen Prozentsatz von 98 ± 2% «perfekter Rand». Nach der hohen Temperaturwechselbelastung von 2500 Zyklen war die Randqualität zwar signifikant ($p < 0{,}01$), aber im Vergleich der Durchschnittswerte nur geringfügig auf 88 ± 7% gesunken. Dieses Ergebnis belegt, dass das adhäsive Verbundsystem «geätzter Schmelz - Befestigungskomposit - geätztes Porzellan» eine sehr hohe Qualität der marginalen Adaptation erreicht, die im Vergleich zu konventionellen Metallfüllungen und Inlays aus mikrogefüllten Komposits, durch thermische Einflüsse wenig gemindert wird. Die Hauptmassen in diesem adhäsiven Verbund, das Porzellan und die Zahnhartsubstanz, sind in ihren thermischen Eigenschaften sehr ähnlich (*Adair* und *Grossman*, 1984; *Craig*, 1985). Der hohe thermische Expansionskoeffizient des als Adhäsiv verwendeten mikrogefüllten Kompositmaterials wirkte sich offenbar nur in geringem Masse aus. Die im Vergleich zum Zahn und zum Prozellaninlay geringe Masse des Befestigungskomposits und dessen beidseitige mikromorphologische Verankerung dürften dafür ausschlaggebend sein.

Die Relevanz der hohen Randqualität des Adhäsivsystems wird durch den Vergleich mit dem Verhalten der marginalen Adaptation bei den Amalgam- und Goldfüllungen bestätigt. Die MOD-Amalgamfüllungen wiesen initial eine relativ hohe Randqualität von 64% «perfekter Rand» auf (Abb. 6 und 7). Nach dem Thermocycling war die marginale Adaptation auf 9% «perfekter Rand» gefallen. Der Effekt des Thermocyclings auf die marginale Adaptation des Amalgams war hochsignifikant ($p < 0{,}001$). Die marginale Adaptation der Goldinlays war schon anfänglich wegen des Zinkphosphat-Zementierungsspaltes sehr niedrig (11%) und wurde durch das Thermocycling nochmals signifikant ($p < 0{,}01$) auf 3% «perfekter Rand» vermindert. Verglichen mit Amalgam- und Goldrestorationen wiesen die adhäsiven Porzellaninlays sowohl vor als auch nach der thermischen Wechselbelastung eine hochsignifikant ($p < 0{,}001$) bessere marginale Adaptation auf. Die Ergebnisse der Farbpenetrationsuntersuchung bestätigten, dass die mikromorphologisch hohe Randqualität der adhäsiven Porzellaninlays mit einer hohen Randdichtigkeit gleichbedeutend war. Die mikromorphologisch schlecht abschneidenden Goldinlay-Ränder waren nur in zwei von zwölf Zervikalbereichen dicht.

Gesamthaft unterstützen die Ergebnisse dieser Untersuchung das Konzept, dass mit dem Cerec®-System hergestellte Porzellaninlays durch Anwendung der Adhäsivtechnik mit hoher und thermisch beständiger Randqualität eingesetzt werden können.

Verdankung

Herrn Prof. Dr. *P. Schärer* danken wir für die freundliche Bewilligung zur Herstellung von Probekörpern im Keramiklabor. Frau *H. Bolli-Besançon* und Herrn *P. Nötzli* sind wir für die Hilfe bei den Laborarbeiten zu Dank verpflichtet. Herrn *Seth Rubin* danken wir für die statistische Beratung.

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Résumé

Adaptation marginale in vitro d'inlays adhésifs en porcelaine

L'étude présente l'évaluation d'inlays esthétiques en porcelaine obtenus d'après le mode de fabrication Cerec®. Six cavités MOD préparées sur des molaires humaines extraites ont été échantillonnées par un procédé optique électronique en vue de la fabrication d'inlays correspondants à partir d'ébauches en porcelaine. Les bords de la cavité ont été mordancés et on a utilisé un composite pour sceller les inlays. Six inlays MOD en or et six obturations MOD en amalgame de taille similaire servirent de référence. On a examiné les bords approximaux de toutes les restaurations à l'aide d'un microscope électronique à balayage par méthode de réplication avant et après un traitement thermique de 2500 cycles (10° - 60° - 10 °C). On a testé le joint marginal par la pénétration d'un colorant après les cycles thermiques. Sur les trois groupes de douze bords approximaux, on a constaté une absence totale de pénétration pour deux restaurations en or, quatre en amalgame et dix en porcelaine.

Après analyse au microscope électronique à balayage (400×), le pourcentage «d'excellente adaptation» avant et après traitement thermique était de 11% et 3% pour les obturations en or, de 64% et de 9% pour les amalgames et de 98% et 88% pour les restaurations en porcelaine. En regard du joint marginal et de la micromorphologie de l'interface dent/restauration, l'étude a prouvé que les inlays adhésifs en porcelaine étaient significativement ($p < 0{,}001$) supérieurs aux restaurations en amalgame et en or.

Summary

In-vitro marginal adaptation of adhesive porcelain inlays

The purpose of this study was to evaluate esthetic inlays made of dental porcelain using the Cerec®-fabrication technique. Six MOD inlay cavities were prepared in extracted human molars. Porcelain inlays were made using an optical topographic scanning procedure and an electronically controlled machine which mills prefabricated blanks of dental porcelain 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 porcelain 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 cycles (10° - 60° - 10 °C) using a replica technique and the SEM; the marginal seal was evaluated by dye penetration performed after thermal cycling only.

Complete absence of dye penetration was found in 2 gold-, 4 amalgam-, and 10 porcelain-restored proximals out of 12 per group. In the SEM analysis (400×), the percentages of "Excellent Margin" before and after thermal cycling were 11 and 3 for gold, 64 and 9 for amalgam, and 98 and 88 for porcelain restorations. In regard to both marginal seal and micromorphology of the tooth/restoration interface, the study proved: adhesive porcelain inlays were significantly superior ($p < 0.001$) to comparable amalgam and gold restorations showing an unprecedented high quality of marginal adaptation.

Literatur

Adair, P.J. / Grossman, D.G.: The castable ceramic crown. Int. J. Periodont. Rest. Dent. *2:* 33–45, 1984. – *Bock, R.D.:* Multivariate statistical methods in behavioural research. Mc Graw-Hill, New York 1975. – *Bowen, R.L.:* Development of a silica-resin direct filling material. Report 6333. National Bureau of Standards, Washington 1958. – *Brandestini, M. / Mörmann, W. / Ferru, A. / Lutz, F. / Krejci, I.:* Computer machined Ceramic Inlays: In Vitro Marginal Adaptation. J. dent. Res. *64:* 208 (Abstr. No. 305), 1985. – *Buonocore, M.G.:* A simple method of increasing the adhesion of acrylic filling materials to enamel surfaces. J. dent. Res. *34:* 849–853, 1955. – *Calamia, J.R. / Simonsen, R.J.:* Effect of coupling agents on bond strength of etched porcelain. J. dent. Res. *63:* 162–362, 1984. – *Calamia, J.R.:* Etched porcelain veneers: the current state of the art. Quintessence Int. *16:* 5–12, 1985. – *Craig R.G.:* Restorative dental materials. Mosby, St. Louis 1985, p. 48. – *Forsten, L. / Kuusisto, E. / Ruokolainen, R. / Udd, B.:* Marginal leakage in vitro of composite fillings in posterior human teeth. Proc. Finn. dent. Soc. *78:* 155–158, 1982. – *Goldman, M.:* Polymerization shrinkage of resin-based restorative materials. Aust. dent. J. *28:* 156–161, 1983.

Hobo, S. / Iwata, T.: Castable apatite ceramics as a new biocompatible restorative material. I. Theoretical considerations. Quintess. Int. *16:* 135–141, 1985a. – *Hobo, S. / Iwata, T.:* Castable apatite ceramics as a new biocompatible restorative material. II. Fabrication of the restoration. Quintess. Int. *16:* 207–216, 1985b. – *Horn, H.R.:* Porcelain laminate veneers bonded to etched enamel. Dent. Clin. North. Amer. *27:* 671–684, 1983. – *James, D.F.:* An Esthetic Inlay Technique for Posterior Teeth. Quintessence Int. *14:* 1–7, 1983. – *Jones, D.W.:* Ceramics and glass as restorative materials. In: Biocompatibility of dental materials, Vol. 4. CRC Press, Boca Raton 1982, pp. 79–122. – *Kullmann, W. / Pötters, G.:* Vergleichende Untersuchungen zum thermischen Expansionskoeffizienten an 50 verschiedenen Kunststoff-Füllungsmaterialien. Dtsch. Zahnärztl. Z. *39:* 96–100, 1984. – *Lüscher, B. / Lutz, F. / Ochsenbein, H. / Mühlemann, H.R.:* Microleakage and marginal adaptation in conventional and adhesive Class II restorations. J. prosth. Dent. *37:* 300–309, 1977. – *Lutz, F.:* Beiträge zur Entwicklung von Seitenzahn-Komposits. Zahnärztl. Inst. KAR PAR PZM, Zürich 1980 (ISBN 3-85656-004-1). – *Lutz, F. / Mörmann, W. / Krejci, I.:* Seitenzahnkomposits – Ja, Nein oder Jein? Dtsch. Zahnärztl. Z. *40:* 892–896, 1985. – *Marolf, R. / Roulet, J.-F. / Mörmann, W. / Lutz, F.:* Kompositinlays – Randqualität und Verschleiss nach 6 Monaten. Schweiz. Mschr. Zahnmed. *94:* 1215–1224, 1984.

Masutani, S. / Lui, J.L. / Setcos, J.C. / Lutz, F. / Phillips, R.W.: SEM analysis of marginal adaptation of Class II resin restorations. IADR Progr. & Abstr. *62:* No. 138, 1983. – *McLean, J.W.:* Perspektiven der zahnärztlichen Keramik. In: Dentalkeramik, 1. Internationales Keramik-Symposium. Ed. McLean, J.W. Quintessenz, Berlin 1984. – *Mörmann, W.:* Komposit-Inlay: Forschungsmodell mit Praxispotential? Quintessenz *33:* 1891–1901, 1982. – *Mörmann, W. / Lutz, F.:* Composite-inlays: Marginal adaptation, seal and occlusal abrasion. (IADR Abstract No. 58). J. dent. Res. *61:* 571, 1982. – *Mörmann, W. / Lutz, F. / Ameye, C.:* Composit-inlays: Marginal adaptation, seal and occlusal abrasion. (IADR Astract 617). J. dent. Res. *61:* 247, 1982a. – *Mörmann, W. / Ameye, C. / Lutz, F.:* Komposit-Inlays: Marginale Adaptation, Randdichtigkeit, Porosität und okklusaler Verschleiss. Dtsch. Zahnärztl. Z. *37:* 438–441, 1982b. – *Mörmann, W. / Ameye, C.:* Unveröffentlichte Daten, 1983. – *Mörmann, W. / Lutz, F. / Curilovic, Z.:* Die Bearbeitung von Gold, Keramik und Amalgam mit Composhape®-Diamantschleifern und Proxoshape®-Interdentalfeilen. Quintessenz *34:* 1575–1583, 1983. – *Mörmann, W. / Schmid, U. / Mörmann-Buchmann, J.E. / Roulet, J.F.:* Die Dichtheit von Kalziumhydroxid-Unterfüllungsmaterialien in dünnen Schichten. Schweiz. Mschr. Zahnheilk. *93:* 609–626, 1983.

Mörmann, W.: Keramikinlay – die Seitenzahnfüllung der Zukunft. Vortrag am 30.3.1985, Karlsruhe, 25 Jahre Akademie für Zahnärztliche Fortbildung, Karlsruhe. 4. Internat. Quintessenz-Symposium, 3. Internat. Keramik-Symposium, 1985. – *Mörmann, W. / Brandestini, M.:* Verfahren zur Herstellung medizinischer und zahntechnischer, alloplastischer endo- und exoprothetischer Passkörper. Europ. Pat. Nr. 81 110 135.1, 1985. – *Mörmann, W. / Lutz, F. / Bolli-Besançon, H.:* Löslichkeitsbeständigkeit und Säureresistenz von Kalziumhydroxid-Unterfüllungsmaterialien. Schweiz. Mschr. Zahnmed. *95:* 14–30, 1985. – *Phillips, R.W.:* Skinner's science of dental materials, 8th ed. Saunders, Philadelphia 1982, p. 84 (ISBN 0-7216-7235-3). *Phillips, R.W. / Lutz, F.:* Status report on posterior composites. J. Amer. dent. Ass. *107:* 74–76, 1983. – *Roulet, J.F. / Jaeger, U. / Ameye, C / Mörmann, W.:* Quantitative SEM-analysis of composite inlay margins after fatigue stress. J. dent. Res. *63:* 175 (IADR Abstract 37), 1984. – *Siebner, H.:* Herstellung eines Keramikinlays. Quintess. Zahntech. *9:* 277–280, 1983.

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The vacuum formed dental contour appliance

by HENRY I. NAHOUM, D.D.S.*

► A novel way is presented for constructing dental appliances which are used to change or maintain contours. These appliances, which are made by vacuum forming thermoplastics, are particularly adaptable for various procedures in orthodontics, periodontics, restorative dentistry, and dental surgery as well as for other purposes met in dental practice.

Although the art of vacuum forming was developed during the Second World War, its use in dentistry is relatively new. The author has been using vacuum formed appliances since 1959† in association with Tronomatic Machine Manufacturing Co. In 1962 Godwin[1] reported on the construction of a vacuum formed vinyl mouth guard in which a vacuum cleaner was used as the means of evacuation. Later Godwin[2] reported on an improved method and also suggested a less efficient "impressed" method in which a sponge is used to adapt the vinyl. This paper will concern itself with vacuum formed appliances made with a commercial vacuum former using a wide variety of thermoplastics (Fig. 1).



Figure 1. A commercial vacuum former.

Methods and materials

The appliances are made of any thermoplastic which comes as calendered films or molded sheets. Acetate, Butyrate, polyethylene, styrene or vinyl molding compounds are used in clear, transluscent, opaque or colored films or sheets. The thickness varies from .010 to .040 inches (.040 = 1 mm). The characteristics of the material that is chosen depend on the length of time the appliance is to be used, the thickness and the purpose of the appliance. For night guards a hard material may be used, whereas for orthodontic purposes a highly elastic plastic is desired. In all cases, it is necessary for the material to be inert, non-toxic, odorless, tasteless, and unaffected by the chemicals of the body. It should have a minimum of water absorption and no warpage. In addition, the molding qualities must be good or excellent. After molding the appliance, it is washed in a mild alkaline solution or detergent to remove any surface impurities and excess plasticizer (on the surface).

The plastic film or sheet is molded to a cast or die by a vacuum forming machine using a drape or straight method. The process is as follows: The plastic is

* Associate clinical professor of dentistry, Columbia University School of Dental and Oral Surgery.

† The first series of appliances were registered through the U. S. Post Office on July 23, 1959.

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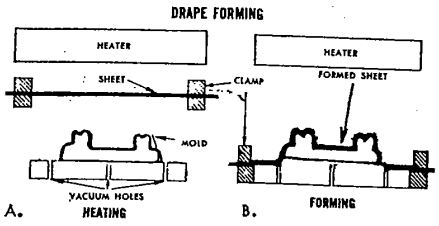


Figure 2. (after Butzko & Stratton). The vacuum forming process.

The appliance may also be fabricated to move teeth. Anterior spaces can be closed and minor rotations can be corrected. To do this a plaster cast is made. The teeth are sawed off the cast with a fine jeweler's saw or a fissure bur. The teeth are then repositioned on the model with wax (Fig. 3). The contour appliance is vacuum formed over the altered (waxed) model. The excess is cut away



A B

Figures 2A and 2B. Formed Appliance.

heated to the molding temperature, which varies with each plastic (Fig. 2A). It is draped over the model and the vacuum is turned on (Fig. 2B). The vacuum is from a tank which has been evacuated to 28 inches of mercury and from a vacuum pump which operates simultaneously. Atmospheric pressure, equivalent to approximately 14 pounds per square inch, molds the plastic to the model instantaneously.[3] Positive air pressure can also be used, as in pressure forming, but this was not necessary for the plastics used in our work.

My primary interest was with reference to the orthodontic applications of the appliance. It is readily apparent that this appliance may be used as a retainer to prevent teeth from moving, following orthodontic treatment. If the clear plastic is used, an acceptably cosmetic appliance results that may be worn all the time.



Figure 3. Clear plastic appliance made on a cast which has the maxillary incisors repositioned in wax. Note that a thin film of molten wax spreads around these teeth.

with a razor and the appliance is removed from the cast, cleaned and inserted into the mouth. Correction is attained as a result of the pressure exerted on the irregular teeth by the appliance which was made on a corrected model. The appliance, of elastic plastic,

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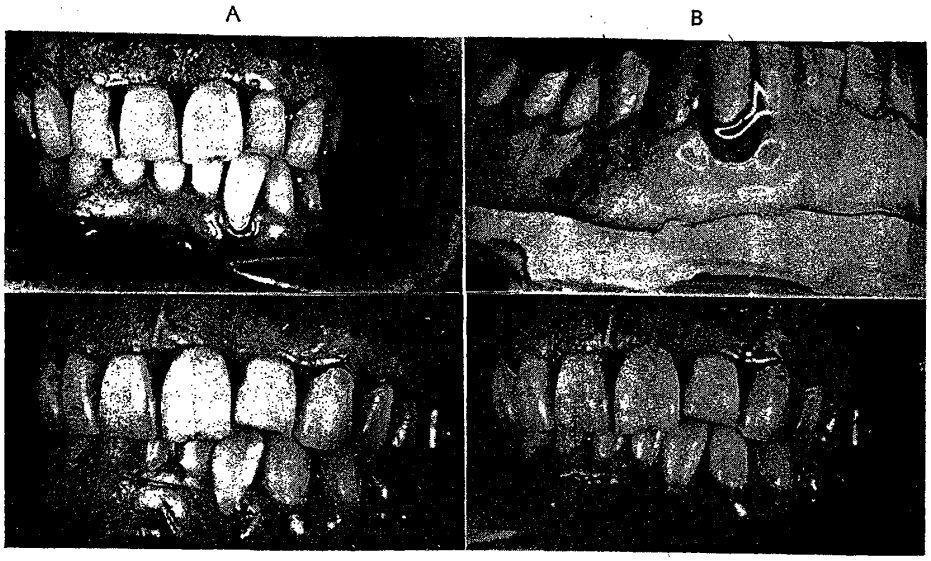


Figure 4A. Patient with lateral incisors in cross bite. The lower incisor has been disced on the mesial and distal.
Figure 4B. Lower tooth repositioned with wax and clear plastic appliance made on this altered model.
Figure 4C. Patient wearing the appliance after two months.
Figure 4D. Completed correction.

snaps over the teeth and the mucosa and exerts pressure until the teeth attain the desired positions. This type of appliance is effective for contraction but not for expansion.

Several appliances can be made on this waxed cast which is used over and over. A hole may be made in the base of the cast with a fine drill to assist in the vacuum forming. After the appliance is made and trimmed, compressed air directed into the hole assists in removing the appliance from the cast.

Fig. 4(A,B,C,D) shows the above procedure as applied to a patient with an anterior cross bite involving the maxillary and mandibular right lateral incisors. The lower incisor was disced on the mesial and distal to create space and a clear plastic appliance was used for the correction.

If the correction is too great to be done in one step, the adjustment may be done in two or more phases in which partial and progressive adjustments are made in each appliance. When the teeth are aligned, the final appliance is used as a retainer to maintain the teeth in their corrected positions. The corrections made by this appliance are usually limited to the six anterior teeth.

An appliance can be made for use as a habit breaker. It can be molded to the facial surfaces of the teeth while in occlusion and worn day or night as indicated to prevent nail biting, thumb or finger sucking or tongue thrusting and other perversions of normal swallowing, sucking or mouth breathing, etc. (Fig. 5). The appliance is molded to plaster casts by vacuum forming. It can also be molded directly on relieved alginate impressions of the mouth.

For mass movement of teeth with external force, a hook is welded or bonded to the appliance. This hook

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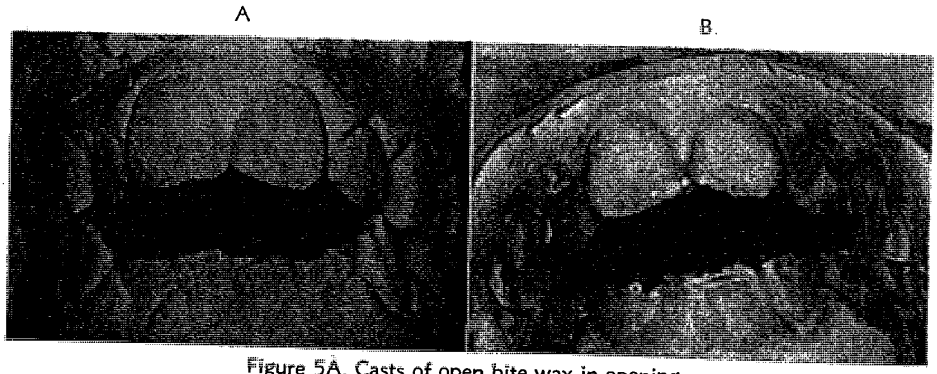


Figure 5A. Casts of open bite wax in opening.
Figure 5B. Open bite with plastic formed over upper and lower anterior teeth.



Figure 6. Two views of a plastic appliance made over a banded tooth. Note wire in buccal tube.

serves as an attachment for elastics from the opposing dental arch or to elastic pressure from some external source, such as a head cap.

Another variation is to make molar bands with buccal tubes for extra-oral force. A cast is made with the bands in position. Then a clear plastic appliance is constructed which covers the molar bands. A hole is made into the plastic so that the orifice of the buccal tube is uncovered. This permits a conventional face bow to be used with extra-oral force together with a plastic appliance for the mass movement of all the teeth simultaneously (Fig. 6).

Orthodontic appliances are made for either or both jaws and may be worn at all times. The patient is able to eat with the appliance in position. It can also be made in such a way that the upper and lower appliances are welded or bonded to each other in a fixed relation. In this case, the patient is unable to eat with the appliance in place. Clear plastic is used for cosmetic reasons.

In periodontics the appliance is used as a splint to limit the mobility of loose or periodontally involved teeth (Fig. 7). This is worn during the course of periodontal treatment until a fixed splint is made. As a night guard the contour appliance is worn in the same fashion as a splint. However, if it is not desirable for the patient to occlude the opposing dentition to the guard, self-curing clear acrylic can be processed over the appliance into the grooves and over the cusps to create a smooth plane. This also gives a hard rigid surface if it



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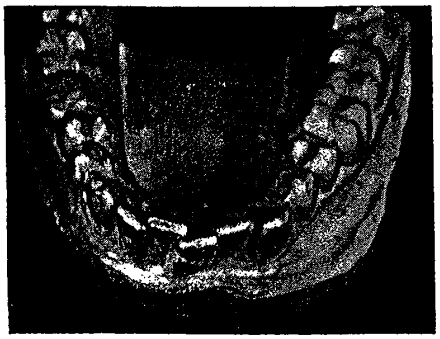


Figure 7. Night guard for lower teeth.

is desired. The guard can also be used to carry medicaments to the gums or to hold a surgical pack in place following periodontal or gingival surgery. It serves to make the pack less bulky and to arrest the hemorrhage.

In restorative dentistry it is used as a temporary bridge or for temporary crowns. An impression of the mouth is taken and plaster casts are made. Teeth that are missing are replaced with wax or artificial teeth on the casts (Fig. 8). Any teeth that require recontouring are corrected with wax. The occlusion is checked, then a full, clear appliance is made. The teeth that require preparations for crowns are now prepared (ground down) in the mouth. The temporary bridge, splint or crowns are made by pouring self curing acrylic of an appropriate shade into the bridge area of the contour appliance. The appliance is now inserted in the mouth and the excess acrylic carefully removed. The acrylic can be observed through the clear appliance so that color, contour, or voids (bubbles) may be corrected. The occulsion is established by closing the mouth onto the appliance. As soon as the acrylic sets it becomes hot (flash setting point) and it is removed. In former methods, it was not possible to observe the acrylic or to know when the acrylic in the mouth set, hence the patient often suffered burns. Now it is possible to feel the warmth through the thin clear plastic and remove the bridge immediately. It is allowed to complete the set out of the mouth. After the thermoplastic is removed, the bridge will require no polishing nor adjustment; it will be as smooth as glass. Acrylic does not adhere to acetate. Temporary crowns may be made in the same way or just a veneer may be made to be placed over the natural teeth and worn within an appliance. This can serve as a cosmetic appliance that is worn for photography, speeches, performances, etc.

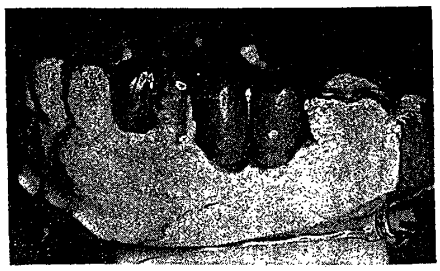


Figure 8. Plastic contour appliance made for a temporary bridge. Three teeth are waxed in place.

Discussion

It is our belief that an efficient and sophisticated vacuum former, similar to those used for commercial purposes is required to make consistently good appliances from a wide range of materials. A soft, low fusing plastic, such as vinyl, can be formed with home-made machines but these would be inefficient for acetates, oriented styrene and the more heat-resistant plastics.

The advantages of these appliances are:

1. That the appliance is made on a plaster cast which can be used repeatedly to make a large number of appliances without destroying the cast.
2. Adjustments may be made in wax. Teeth can be cut off the model and

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repositioned with wax to hold the teeth. The appliance is made on this altered model without having to duplicate the cast. Teeth can also be recontoured or reconstructed with wax.

3. The method is extremely rapid and inexpensive when the proper machinery is used.
4. The appliance is "invisible" when made of clear plastic.
5. The appliances may be worn at all times over the teeth and mucous membranes. It may be used to eat with and need only be removed to be cleaned like a denture. It is understood that the plastic does not have the efficiency of porcelain or enamel for mastication.
6. It eliminates a flasking process.

Summary and conclusions

A technique has been described for vacuum forming a versatile dental contour appliance. The appliance had a wide range of applicability in the various specialties of dentistry. For orthodontics it can be used as a means of regulating (moving) teeth; as a retainer when orthodontic treatment has been completed, or as a habit breaker. In restorative dentistry it can be used to make temporary bridges, to duplicate dentures, to duplicate or to make models for demonstration purposes, to make bases for art models, to adapt base plates to be used for bite blocks or to take impressions. In periodontics the appliance is used as a splint or night guard. It is also valuable as a vehicle for medicaments and as a cover following periodontal surgery. In dental surgery it is useful as a splint, stent, or vehicle for medicaments. For cosmetic purposes it adds lustre to the teeth by covering them with a clear film. It also serves as a protective mechanism to trauma from a blow, etc., and to protect the teeth from food debris.

Acknowledgments

The author is indebted to Mr. Joseph Swick, President of Tronomatic, Inc. for technical assistance and for the use of his equipment. In addition, special thanks to Dr. Joseph E. Fiasconaro for many valuable suggestions.

References

1. Godwin, W. C.: A Simplified Mouth Protector Technic, J. Michigan D. A. 44: 133 (April) 1962.
2. Godwin, W. C.: A Simplified Mouth Protector Technic II, J. Michigan D. A., 44: 227 (July–Aug.) 1962.
3. Butzko, R. L. and Stratton, E. B.: Thermoplastic Sheet Forming, Modern Plastics Encyclopedia, 35: 736 (Sept.) 1957.

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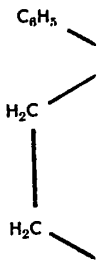
Were you among the missing?

The final figures for the 1963–64 ADA Relief Rund show that out of a membership of 12,113 in the Dental Society of the State of New York, only 2,602 contributed. It seems unbelievable that 9,511 members **did not** do their share to this worthy cause. Contributions to the 1964–65 fund should be made soon but will be acceptable up to June 30, 1965.

Testing of Alvo Ethanes followi

by JACOI JERRY

► Pain be severe quently more co pain can addictio of side e ziness, a search f analgesi non-toxi oped in ported t tively fr It is tive, e ino) pr availabl lowing i



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CEREC CAD/CAM Inlays:

Aesthetics and Durability in a Single Appointment

by Ross W. Nash, DDS

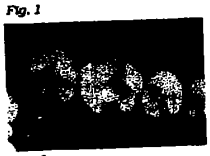
One of the newest innovations in cosmetic and restorative dentistry is the CEREC system by Siemens for fabricating ceramic restorations. This system provides the capability of delivering high quality inlays and onlays in a single appointment with the aid of a computerized milling machine. It is also possible to produce porcelain veneers with the system and research is currently progressing in this area. At the present time inlays with marginal gaps equal to most laboratory fabricated indirect porcelain equivalents are possible. The milling procedure produces contours which follow the general occlusal form of the tooth while final anatomy is completed by the operator using high speed burs after the restoration is bonded in place. The restorations are milled from very dense prefabricated Dicor MGC (machinable glass ceramic) blocks as compared to packed and oven fired porcelain or cast glass alternatives. The final restorations are durable and aesthetic as the following example illustrates.

Figure 1 shows a mandibular first molar containing an amalgam restoration. Recurrent decay has resulted in undermining of the mid facial cusp and the restoration needs replacing. The patient desires a tooth colored alternative and a CEREC inlay was chosen. For a CEREC inlay or onlay a rubber dam is a must. A number 245 carbide fissured bur is used to remove the amalgam and refine the preparation. All margins should end in enamel with no bevels. Box forms which go over the marginal ridges must not have more than one step. Occlusal margins can be undercut, thus preserving more tooth structure but walls of the box forms need a slight divergence. Figure 2 illustrates an occluso-facio-lingual preparation with a calcium hydroxide base in an excavated area.

With the preparation completed, the next step is to apply a wetting liquid and a light reflecting powder. Figure 3 shows the powdered preparation ready for an optical impression. A small camera is placed over the prepared tooth and the image is transferred to a computer and appears on a small screen on the face of the unit (Figs. 4). Through a series of steps using a foot switch, a track ball on top of the unit and some finger switches, the operator outlines the basic contours while the computer defines the walls and margins. Figure 5 shows the left wall designed and the right wall partially finished. Note the cursor points along the mesio-lingual wall. The overlayed line to the left is the occluso-gingival contour generated by the computer for the left wall. In Figure 6 the inlay design is

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Fig. 1


Fig. 2

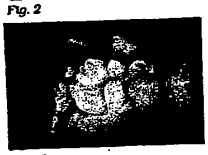

Fig. 3


Fig. 4


Fig. 5



Fig. 6

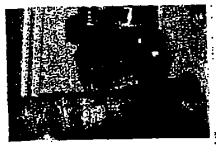

Fig. 7


Fig. 8


Fig. 9

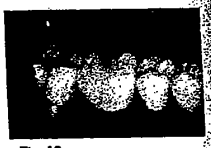
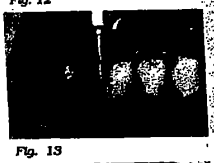
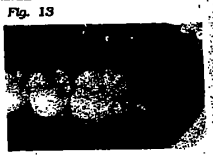

Fig. 10


Fig. 11


Fig. 12


Fig. 13


Fig. 14

Exclusive Interview:

Dr. Harald O. Heymann

Interviewed by Ross W. Nash, DDS

As a user of the CEREC CAD/CAM system in my private practice, I have found it a practical and efficient tool when the right clinical conditions exist. The preparation is all-important and must be mastered for good results. Mastering of the computer design techniques takes practice and patience, and dedication to the learning process is a must. My learning process began at the Carolina Institute for CAD/CAM Technology at the University of North Carolina. To get an academic perspective, I interviewed Dr. Harald O. Heymann, Chairman of the Department of Operatory Dentistry at the School of Dentistry and the head of the Institute.

Dr. Nash: Harald, tell me about the Institute and a little about where you are going with it.

Dr. Heymann: Ross, we established the Carolina Institute for CAD/CAM Technology as a formal institute to promote CE activities related to CAD/CAM (computer assisted design/computer assisted manufacturing) and to relate to the research we are conducting in this area. Our efforts are not entirely restricted to the CEREC system. We certainly have broader interests in CAD/CAM. Our any one particular system. Dr. Steve Bayne, who is the Section Head of Bio-materials and President of the American Academy of Dental Materials, has worked closely with Dr. Diane Rekow at the University of Maryland, who is also developing a CAD/CAM sys-

tem using stereo photography. Our efforts to date have centered around CEREC because it was the first commercially available CAD/CAM system. We were selected along with the University of Alabama Birmingham to be one of the two sites for clinical trials in the United States. Our success in clinical research resulting from the dedicated work

cont'd on pg. 30



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CEREC CAD/CAM Inlays

cont'd from pg. 22

mpleted and ready for milling. The inlay design may be viewed with the image of the tooth removed from the screen.

At this stage a ceramic block is placed in the milling unit (Fig. 7) and the milling process begins (See front cover, center right). The milling machine is run by a self contained water reservoir in the base of the unit which both drives and cools the system.

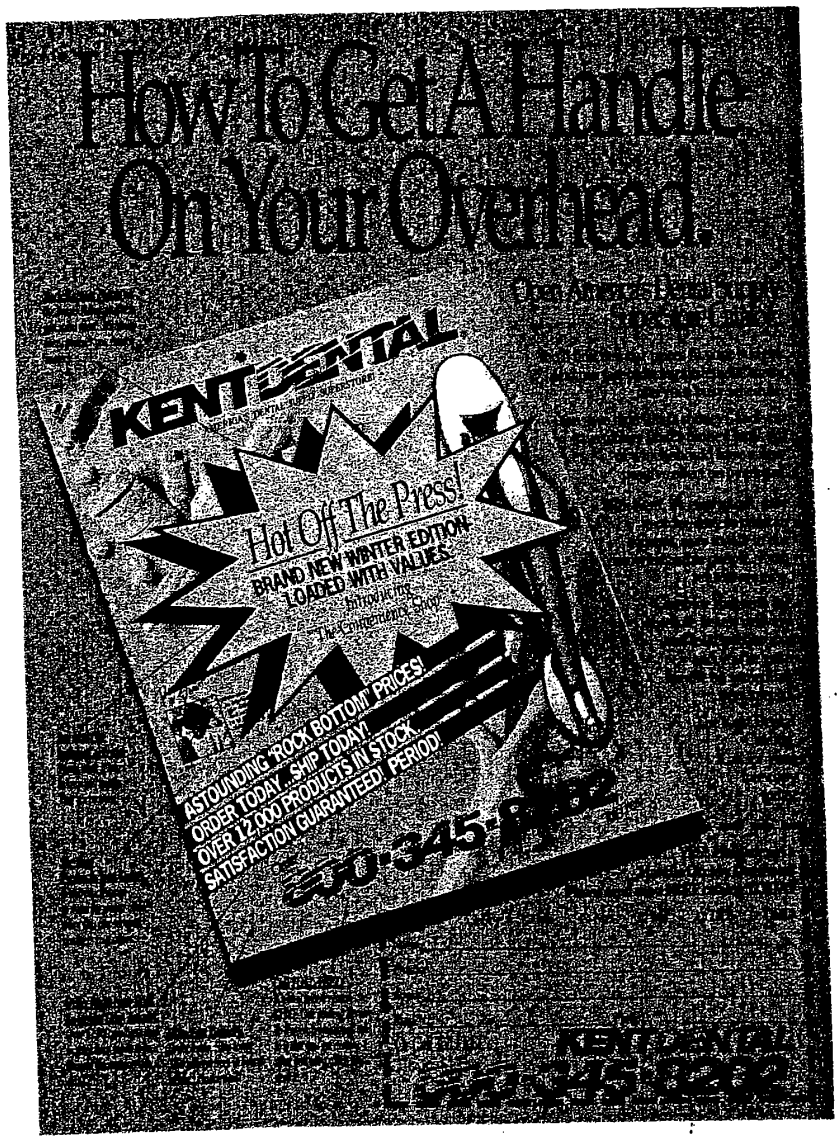
Internal line angles of the cerec inlay are lightly relieved with a fine diamond . The internal surface is treated with an etching gel to form micropores for mechanical retention (Fig. 8) and silane is applied to the etched surface followed by a thin layer of bonding resin which is then light cured.

The enamel of the prepared tooth is etched with enamel etching gel (Fig. 9), rinsed and dried. Dentin primer and bonding resin are applied to the tooth and a dual cured luting composite is used to bond the inlay to place (Fig. 10). Figure 11 illustrates initial contouring with a diamond bur. The rubber dam is removed and occlusion checked with articulating ribbon (Fig. 12). The occlusion is adjusted and final anatomy is placed with diamond burs. Polishing is accomplished with fine diamonds followed by thirty fluted finishing burs (Fig. 13) and diamond polishing paste. The result is a beautiful bonded ceramic restoration (Fig. 14).

CAD/CAM technology is providing us with the opportunity to produce high quality ceramic restorations in a single appointment and it is expected that the day is coming when these types of restorations will be routine in a modern dental practice.

Products Used:

1. 245 Carbide Fissured Bur
2. Dicor Porcelain Blocks - L. D. Caulk
3. Dicor etching gel - L. D. Caulk
4. 37 percent Phosphoric Acid gel
5. XR Dentin Primer - Kerr
6. XR Bond - Kerr
7. Dual Cement - Vivadent
8. Two Striper Diamonds - Premier
9. Thirty Fluted Finishing Burs - Kerr
10. Diamond Polishing Paste - Healthco



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Interview with Dr. Harald O. Heymann

cont'd from pg. 20

of Dr. Cliff Sturdevant and Dr. Karl Leinfelder beginning as far back as 1969, was probably the reason we were chosen. The School of Dentistry at the University of North Carolina had one of the first clinical research programs in the country. Since that time, we have developed a reputation for establishing a world-class data base with conservative aesthetic posterior restorations and it was a logical step that we pursue efforts in CAD/CAM research. Dr. Karl Leinfelder was instrumental in our selection and we work very closely with him at UAB.

The institute presently conducts several participation courses each year in the use, design and fabrication of computer generated ceramic inlays. Even though the system we use is the CEREC by Siemens, we have the academic freedom to design the course as we would like to teach it and we present pros and cons of the system to relate it to the developing clinical research as we see it.

Dr. Nash: What can you tell me about the CEREC system itself?

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Interview with Dr. Harald O. Heymann

cont'd from pg. 20

Dr. Heymann: I think it is a very promising system. It represents the first available system in an emerging technology, a new technology that I believe will become commonplace in the modern-day dental practice.

CEREC is an acronym for ceramic reconstruction. With this system, a conservative aesthetic restoration can be placed in one relatively short appointment without the need for a conventional impression or temporary. It involves making an optical impression of the cavity preparation. The information is then digitized through an analog-to-digital converter and stored in the memory of a computer. It is coupled with an on-screen design of the restoration which results in the computer directing a three-axis milling machine to fabricate an inlay.

As with most computer software, there is a learning curve. Dedication is required to learn the software, but once you become fairly proficient at the design data entry, a high quality inlay can be achieved. I have been pleased with the quality of restorations I have seen to date. I think the fit is comparable to that from most commercial laboratories. Obviously, the better the fit, the less important the cement, and the more experienced you are at using the system, the better the inlay will be.

The two most important aspects of the entire procedure are the quality of the preparation and the quality of the optical impression. Those are not unlike the factors that relate to clinical acceptability of a conventionally fabricated ceramic inlay. With a computer system like this, as the saying goes, "garbage in, garbage out." An inlay preparation with well-defined margins and an optical impression that records all of these margins accurately can result in an inlay that fits nicely.

I think the weak link in the procedure is the optical medium that must be applied to the preparation, this represents a thickness that cannot always be totally compensated for and sometimes results in a film thickness of cement that is greater than we would like to see especially with inexperienced operators. An experienced operator can compensate for this thickness by increasing the radial dimensions of the inlay on the machine. We're conducting clinical research to assess the correlation between film thickness of the cement and wear at the marginal interface with the tooth structure. Over a period of time, we will be able to see just how critical the fit really is and what type of wear we will see both in contact and contact-free areas.

Dr. Nash: Do you have a feeling right now as to the average fit and degree of clinical acceptability of a well designed and machined CEREC restoration for the general practice?

Dr. Heymann: We are running tests both *in vitro* and *in vivo* to determine the fit. *In vivo*, we are measuring marginal gap size through the generation of epoxy replicas and subsequent SEM (*Scanning Electron Microscope -ed.*) evaluations. *In vitro*, we are placing CEREC inlays in extracted teeth and sectioning them at specific locations both occlusally and proximally and measuring the resin cement thickness to quantify what the fit is. Dr. John Sturdevant and I will be presenting some of these results at the IADR meeting this year. My feeling is that the gaps probably range from 50 microns to locally as much as 200 microns.

When I first saw the CEREC system I thought that it would never work, but I was looking through the eyes of an operative dentist comparing it to the mar-

cont'd on pg. 54



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Interview With Dr. Heymann
cont'd

inal fit of gold inlays. The difference is that we are dealing with an adhesive system and the question is how much do the adhesive qualities of the cement adhering to the inlay and tooth overcome the deficiencies of the cement itself. In other words, how large of a gap can we tolerate? The larger the gap, the more important the cement. For that reason we feel that microfills are the best cementation materials because of their favorable history of wear resistance. It is still too early to tell for sure, but our one year results look quite good.

The clinical applicability of the CEREC system in private practice would depend on the aesthetic demands of the clientele that the dentist is serving.

Dr. Nash: Would you also say it would also relate to the dedication to learning the system well enough to produce the highest quality results?

Dr. Heymann: Absolutely, that is a given. You have to become proficient with any new technique or any new service you are trying to offer to your patients before actually providing it.

Given an experienced operator, I think these are going to be good aesthetic restorations. Certainly, if I were presently going to choose between a laboratory fabricated conventional feldspathic porcelain inlay and a CEREC inlay from a material such as MGC, there is no question that I would rather have the CEREC. The choice would largely be a function of the restorative material at this point. One significant advantage a CEREC inlay made from a material such as MGC is that the material itself is formed under significant pressure to inherently reduce porosity and improve the physical properties.

Dr. Nash: What is Dicor MGC?

Dr. Heymann: MGC is a Dicor material made by Dentsply which is intrinsically colored and has a "chameleon" quality in it that picks up the color of the surrounding tooth structure. It is easily contoured; this is an important property because, obviously we have to generate the final contours in the mouth with rotary instruments. It is highly polishable and produces an enamel-like luster. It is kind to opposing tooth structure and is fracture-resistant.

After one year with fifty restorations in one study in place, we have had zero incidence of cohesive fracture. Not so much as even a chip. I don't believe I could say that regarding conventional feldspathic porcelain inlays which have a much higher incidence of cohesive fracture.

Dr. Nash: What about biocompatibility?

Dr. Heymann: The smooth surface texture in contact with soft tissue should promote good gingival health. There have been several studies by Malament and others which show that Dicor appears to be less plaque retentive than other restorative materials as well as enamel itself. From the standpoint of wear and abrasion of opposing tooth structure, Dicor has been shown by Jacobi, Shillingburg and others to be very kind to opposing tooth structure when compared to feldspathic porcelain. Of course, with conventional Dicor, you had to put a feldspathic colorant on the surface to obtain the final coloration. With Dicor MGC, you don't have to do that because it is intrinsically colored. I'm very excited about the material and that it is an inherent part of this CAD/CAM system. The material was tailored to the milling system of the CEREC.

Dr. Nash: What about the future of the CEREC?

Dr. Heymann: I think it is very bright. I, for one, have come almost full circle on my opinion of the relevance and future importance of CAD/CAM technology. After seeing restorations done at the University of Zurich, training there with Dr. Moermann, and conducting clinical research and a number of participation courses here at UNC, I have seen enough of these restorations to know that this technology will definitely have a place in a modern-day dental practice.

Even though the CEREC may appear to be relatively unsophisticated compared to the Duret system, which is exceedingly more complex and has significantly higher resolution, it does provide a clinically acceptable restoration. One of the primary advantages is that the CEREC is a mobile unit and in one appointment a patient can come in and receive an aesthetic restoration which has beautiful contours and surface texture. It does not rely on a modem for transmission of information to a centralized receiving unit where the restoration is fabricated. It also does not rely on the generation of a model of the tooth. In fact, the information is obtained directly from the tooth.

I think we are witnessing the first step in an evolutionary process that is going to progress to more and more sophisticated levels. We will probably look back in ten to fifteen years at the CEREC system as being the "Model-T" of CAD/CAM, but every new emerging technology has to start somewhere and it has already entered the market place at an amazingly sophisticated level.■



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A New Construction of Tooth Positioner by LTV Vinyl Silicone Rubber

by

Minoru NISHIYAMA, Katsuyuki KAMADA** and Satoshi HORIUCHI****

Introduction

Tooth positioner, an orthodontic appliance with the elasticity of rubber materials applied, contrived by KESLING[1～3] as retainer to be used after active treatment, is presently used not only for closing the band space due to the band removal after active treatment, for the minute regulation of occlusal relation and for aftercare as retainer, but also for even active treatment as appliance to be used instead of multi-band appliances, as it is possible to regulate malocclusion, moving the teeth with rubber-like elasticity applied.

Since KESLING contrived the tooth positioner, various materials having rubber-like elasticity have been applied to it[4～12], but few materials have all the necessary properties [13,14]. That is, defects[13,14] have been pointed out such as 1) lack of mechanical properties, 2) sufficient effect of treatment cannot be obtained, a long-term use in the mouth causing the decrease of mechanical properties, and 3) feel uncomfortable when applied.

Polyurethane rubber, tasteless, odorless and superior in elasticity, has recently been developed to improve the above-mentioned defects, but its producing process is complicated, and not only that, large-scaled facilities are necessary, as it is produced under the pressure, 5 kg/cm² at 120°C, with methacrylate resin used as mould material, so it has not been widespread as yet. Therefore, the development of material whose manipulability is simple and having excellent physical properties is urgently desired.

The authors, from this point, noticing LTV vinyl silicone rubber, tasteless, odorless and easy in molding, as well as having extremely preferable elasticity, contrive the method to prepare tooth positioner with this material, clinically applicable, and here is the report on its physical properties and the preparing method of tooth positioner.

Material and Properties

LTV vinyl silicone (Toray Silicone Co., Ltd.'s CF 5005) is of double mix type, composed of base material and curing agent.

1. Composition and character

Base material is thixotropic paste of dimethylvinyl siloxy polydimethylsiloxane with chloroplatinic acid (catalyst) added, and curing agent is liquid composed of

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polyhydromethylsiloxane and dimethylvinylsilowy polydimethylsiloxane.

2. *Mix ratio and curing*

Standard mix ratio of the base material and the curing agent is 10:1 (weight percent), and the mixture has 24-hour pot life at room temperature (25°C). Curing finishes in a short time (100°C·20 minutes, 150°C·10 minutes), in case mould materials have good thermal conduction, but in the case of plaster mould in water bath, using the dental flask, the adequate curing time is 60–90 minutes at 100°C.

The curing mechanism is an addition polymerization as shown in Fig. 1, and no by-product is produced. But careful treatment is necessary, as its curing is liable to be incomplete in case it comes in contact with those containing sulfur, phosphorus, nitrogen compound, organometallic salt and flux.

3. *Toxicity*

The present material is considered having little toxicity, as it has passed the test, No. 434 notification issued by the Ministry of Health and Walfare in Japan.

4. *Physical properties of set product*

Tables 1 and 2 show the physical properties of set product.

It is proved as a result of examination on specimens steeped in 37°C water for 90 days that changes in mechanical properties are not recognized. So it is presumed that the present material would show preferable rubber-like elasticity even if it is used for a long term.

Preparing Method of Tooth Positioner

Tooth positioners made of the present material and hitherto clinically used show satisfactory results. Its preparing method is as follows:

1. *Making of set-up model*

Table 1. Physical properties of LTV vinyl silicone

Item	Physical Properties
Specific gravity	1.12
Hardness (Shore hardness)*	43
Tensile strength (kg·cm²)*	48.9
Elongation (%)*	380.3
Tear Strength (kg.cm)*	16.3
Young's modulus (kg·cm²)	16
Elastic strain (%)	3.60
Permanent deformation (%)	0.10
Water absorption (mg cm²)**	0.02

* Storage in 37°C water, 90 days
** Storage in 37°C water, 30 days

Table 2. Thermal deformation of LTV vinyl silicone

Temperature (°C)	Thermal deformation (%)
40	0.02
50	0.03
60	0.09
70	0.12
80	0.29



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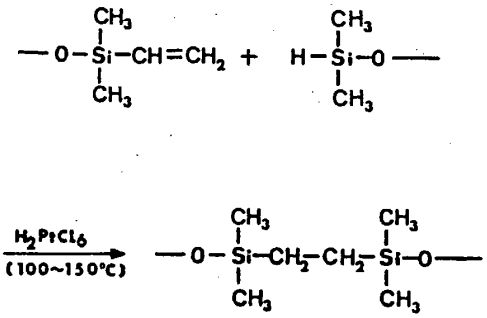


Fig. 1 Curing mechanism of LTV vinyl silicone

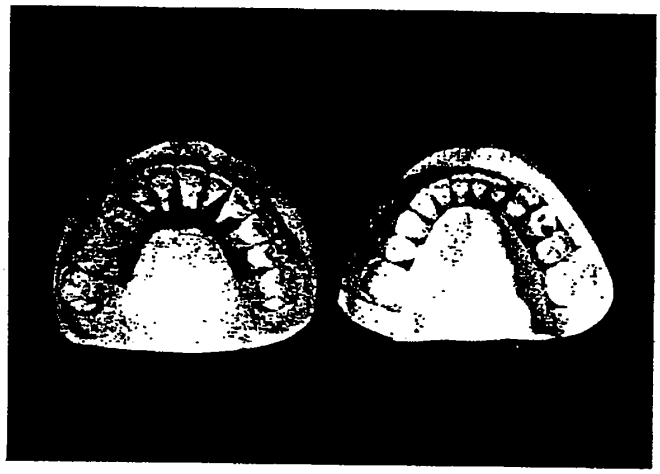


Fig. 2 Set-up model

Set-up model is prepared in accordance with the conventional method[1~3] with upper and lower teeth split and arranged in ideal positions (Fig. 2).

With the set-up model mounted on the articulator, bite raising, about 4 mm, is performed to take wax-bite.

The set-up model is duplicated with alginate impression material to prepare a working model (Fig. 3), and the upper and lower working model is fixed with the wax-bite to make wax model (Fig. 4).

2. *Making of plaster mould and filling of silicone mixture.*

Plaster mould (Fig. 5) is prepared according to the conventional method with a dental flask used, and alginate separater is applied to it.

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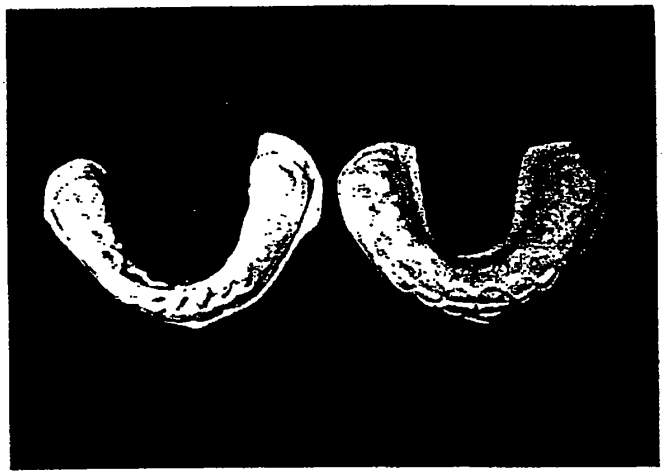


Fig. 3 Working model

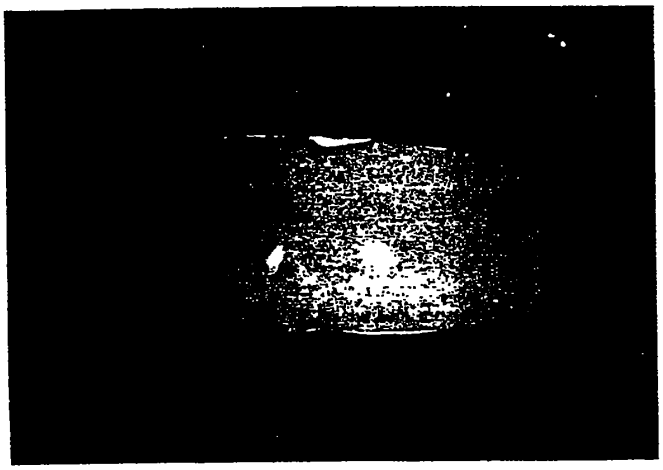


Fig. 4 Wax model of tooth positioner

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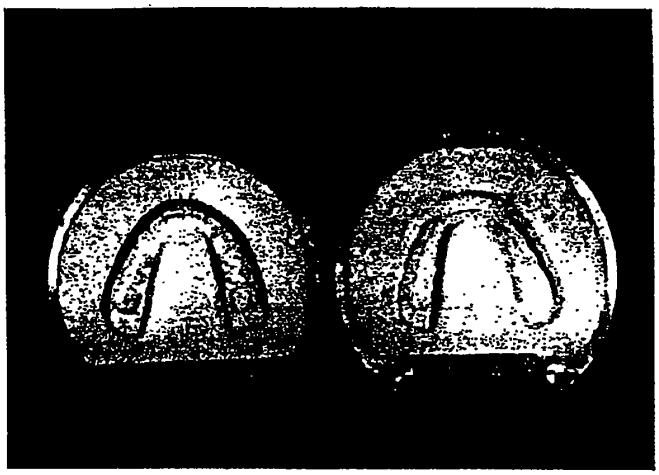


Fig. 5 Split plaster mould

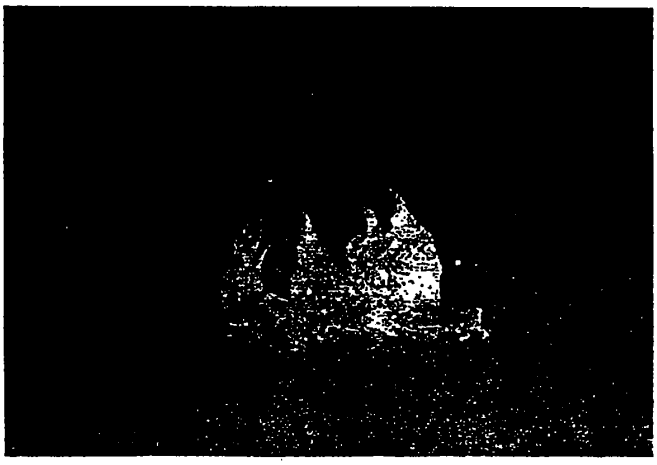


Fig. 6. LTV Silicone mixture

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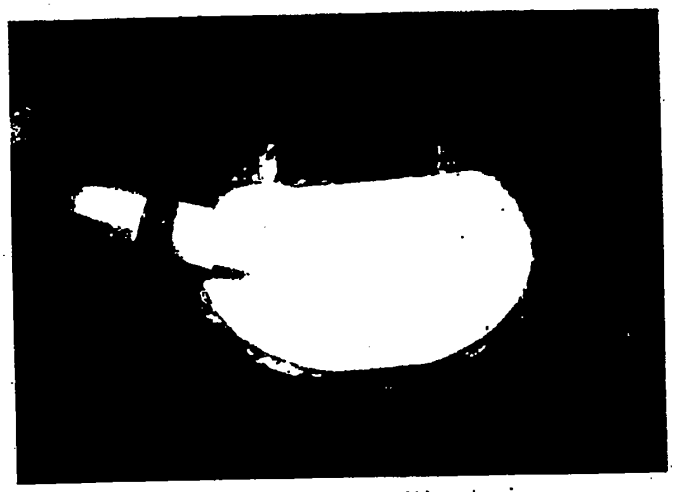


Fig. 7 Mixture is filled into mould by syringe

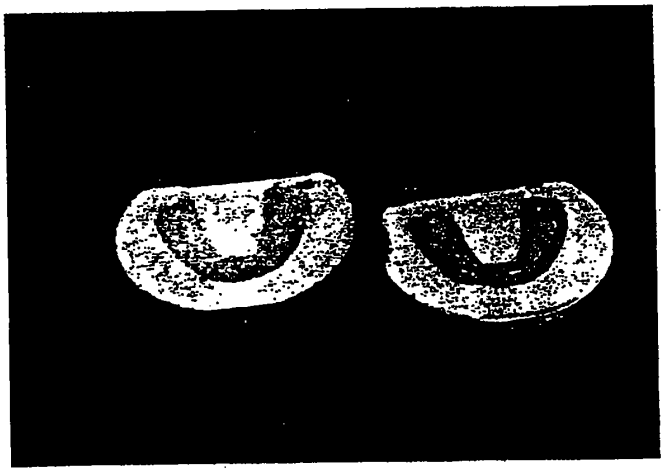


Fig. 8 Mixture is filled

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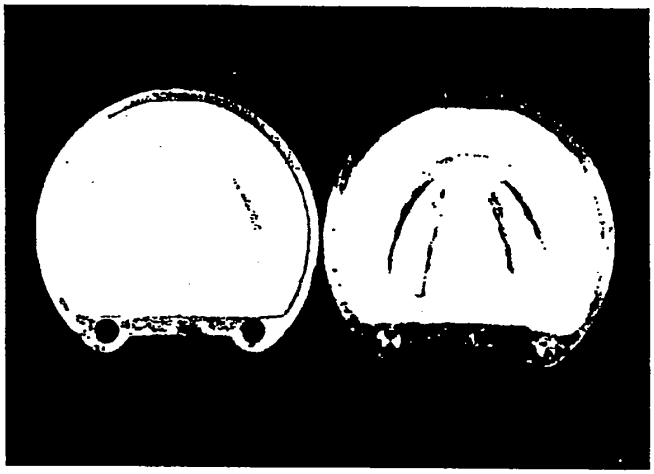


Fig. 9 After curing flasks are separated

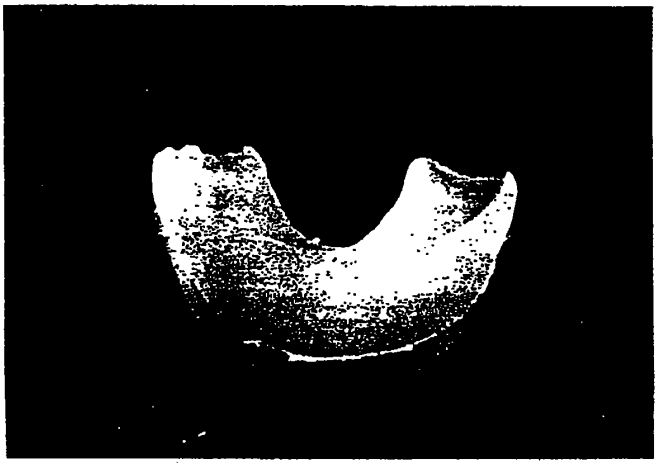


Fig. 10 Tooth positioner immediately after the takeout

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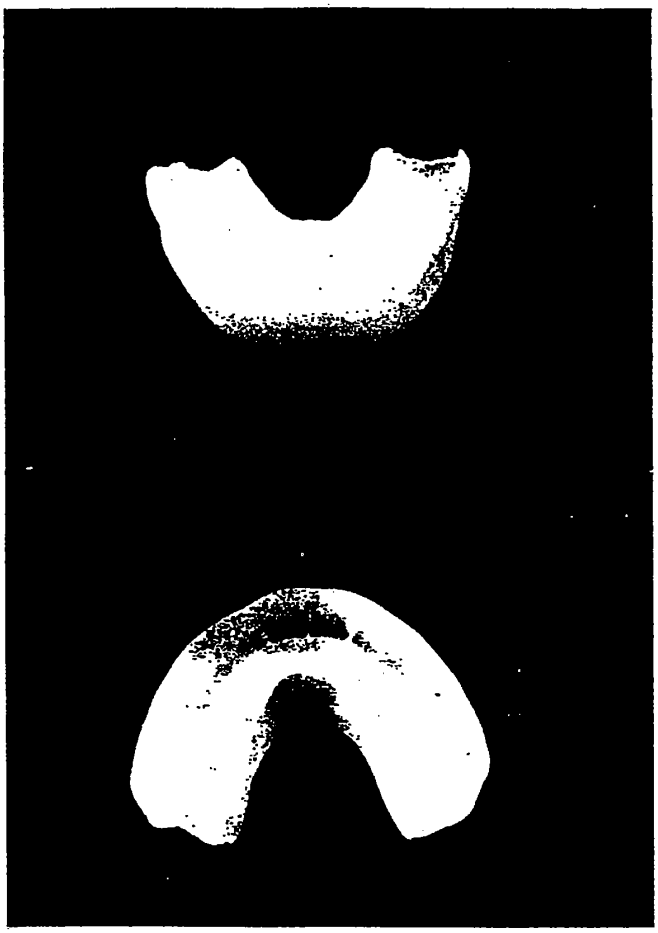


Fig. 11 Accomplished tooth positioner

Base material and curing agent are mixed in the ratio of 10:1, and the mixture (Fig. 6) is filled into the plaster mould with a syringe (Figs. 7 & 8).

The mixture is thixotropic, and is easily pushed out into the mould with a syringe. Again, it having 24-hour pot life, there is no hurry about mixing and filling.

3. Curing of silicone

The mixture filled in the plaster mould is pressed (approximately 50~60 kg/cm²) with the split mould on, and is heated in 100°C water bath (or by dry heat), held

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[7] HESTER, H. C.:
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with a cramp, for 60~90 minutes.

4. Takeout and polish

After being cured, the flask is taken out from the water bath to be left in the room temperature, still being cramped. The moulded product is then taken out after being cooled. Takeout is very easy; cured silicone, having preferable elasticity, can easily be taken out through the split between upper and lower flasks (Figs. 9 & 10).

Flash is very thin (30~50 μ) in the case of split moulding, and it is considered that there is little change in the height of bite.

Polish is almost unnecessary. Flashes are cut with scissors and the traces are restored with carborundum point and rubber point, and then tooth positioner is accomplish (Fig. 11).

Summary

The present material, having wide function area because of its excellent rubber-like elasticity, can afford to move teeth to a great degree, as compared with the conventional tooth positioner. Besides, its manipulability is preferable. So, wide application can be expected regarding the teeth movement.

The preparing method by use of this material has merits as follows:

1) Silicone mixture can easily be filled into mould by disposable syringe.
2) Manipulability is preferable, silicone mixture having 24-hour pot life at the room temperature.
3) Curing finishes in a comparatively short time at low temperature.
4) The set product is tasteless and odorless and shows preferable rubber-like elasticity.
5) Preferable moulding products can be obtained by use of plaster moulds, without any special mould materials.
6) Takeout of moulding products is easy, easily separated from the moulds.
7) The surface of products is very lubricous.
8) The products having very thin flash even in the split moulding case, have little effect on the height of bite.
9) Its clinical application proves the effect of treatment to be extremely preferable.

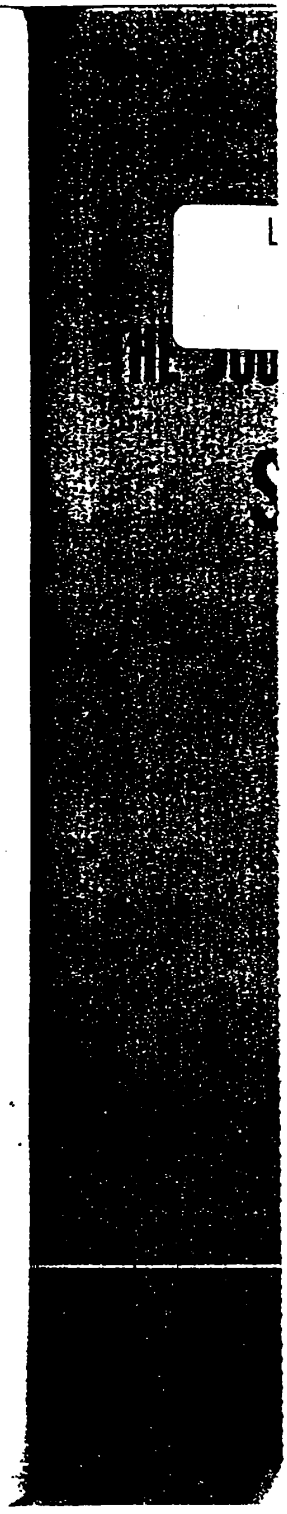
References

[1] KESLING, H. D.: The philosophy of the tooth positioning appliance; Amer. J. Orthodont., Vol. 31, 297~304, (1945).
[2] KESLING, H. D.: Coordinating the predetermind and tooth positioner with conventional treatment; Amer. J. Orthodont., Vo. 32, 285~293, (1946).
[3] KESLING, H. D.: The diagnostic set-up with consideration of the third dimention; Amer. J. Orthodont., Vol. 42, 740~784, (1956).
[4] SVED, A.: The problem of retention; Amer. J. Orthodont., Vol. 39, 659~682, (1952).
[5] JARABAK, J. R. and FIZZELL, J. A.: Technique and treatment with the light-wire appliance; C. V. Mosby Co., Saint Louis, p. 718~720, (1963).
[6] GOTTLIEB, E.L.: Success and failure with the positioner appliance; J. Practical Orthodont., Vol. 2, 506~522, (1968).
[7] HESTER, H. C.: Vacuum molded vestibular shield; J. Practical Orthodont., Vol. 2, 224~225, (1968).

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[8] DIMOND, H. D.: Rapid fabrication of plastic positioners; J. Practical Orthodont., Vol. 2, 235~238, (1968).
[9] PRESCOTT, M. A. and FERTMAN, A.: Construction of the silicone rubber tooth positioner in your own laboratory; J. Practical Orthodont., Vol. 2, 456~460, (1968).
[10] COTTINGHAM, L. L.: Gnathologic clear plastic positioner; Amer. J. Orthodont., Vol. 55, 23~31, (1969).
[11] KAMEGAI, T.: Construction of tooth positioner; J. Jap. Orthod. Soc., Vol. 28, 204~210, (1969).
[12] WELLS, N. E.: Application of the positioner appliance in orthodontic treatment; Amer. J. Orthodont., Vol. 58, 351~366, (1970).
[13] SUGIMURA, H. et al.: Materials for tooth positioner; J. Jap. Orthod. Soc., Vol. 25, 106~114, (1966).
[14] YOSHII, O.: Studies on the new orthodontic rubber materials (Part 1); JDAM, Vol. 12, 234~242, (1971).
[15] YOSHII, O.: Studies on the new orthodontic rubber materials (Part 2); J. Jap. Orthod. Soc., Vol. 31, 168~174, (1972).
[16] YOSHII, O.: Studies on the new orthodontic rubber materials (Part 3); J. Stomatol. Soc. Jpn., Vol. 40, 103~121, (1973).



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Digital documentation of individual human jaw and tooth forms forapplications in orthodontics, oral surgery and forensic medicine

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References Cited: 3
INSPEC Accession Number: 6135682
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Abstract
On account of the complex geometry of individual maxillary sinus and teeth, the classical approach for documentation in orthodontics is casting in plast There are millions of individual plaster forms taken from orthodontic patients, that need to be stored, sorted and accessed-depending on the local legislation-for periods up to decades. As an alternative to plaster casting archives we propose a digital solution for long-term archivation of the complex geometrical patient data in orthodontics and oral surgery. The paper includes the description of the used scanning methods and the hardware set-up. Further the applied algorithms for automatic 3D-modeling and visualization are described. The contribution describes the actual application, some representative results and offers some proposals for other application fields of digital documentation

Index Terms
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Controlled Indexing
data visualisation dentistry medical computing patient treatment surgery visual databases

Non-controlled Indexing
automatic 3D-modeling complex geometrical patient data archiving digital documentation forensic medicine hardware set-up human jaw forms human tooth forms individual maxillary sinus individual teeth oral surgery orthodontics plaster forms scanning methods visualization

Author Keywords
Not Available

References

No references available on IEEE Xplore.

Citing Documents

1 Robotic system approach for complete denture manufacturing, Yong-De Zhang; Zhan-Fang Zhao; Pei-Jun Lu; Yong Wang; Ru-Jie Song; Ji-Lian Lu
Mechatronics, IEEE/ASME Transactions on
On page(s): 392- 396, Volume: 7, Issue: 3, Sep 2002

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Digital Documentation of Individual Human Jaw and Tooth Forms for Applications in Orthodontics, Oral Surgery and Forensic Medicine

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Abstract - **On account of the complex geometry of individual maxillary sinus and teeth, the classical approach for documentation in orthodontics is casting in plaster. There are millions of individual plaster forms taken from orthodontic patients, that need to be stored, sorted and accessed - depending on the local legislation - for periods up to decades. As an alternative to plaster casting archives we propose a digital solution for long-term archivation of the complex geometrical patient data in orthodontics and oral surgery. The paper includes the description of the used scanning methods and the hardware set-up. Further the applied algorithms for automatical 3D-modelling and visualization are described. The contribution describes the actual application, some representive results and offers some proposals for other application fields of digital documentation.**

I. INTRODUCTION

Since 1993 our group worked on different applications of touchless and image based 3D data acquisition with typical object dimensions in the area from some cm up to 2 m. One of the working directions was a solution for digital documentation of small, unique, free-shaped and complex moulded specimen. The choice of this direction was determined by a market analysis and some special user requests that showed a certain interest for touchless 3D-measurement and documentation in non-technical application fields like culture, museums, archeology, palcontology, anthropology etc. Typical objects of interest for such applications are bones, teeth, fossils, pieces of pottery but also small designed models, plaster castings of bodyparts, internal organs etc. From here some specific requirements regarding robustness, simplicity of the user interface and a high degree of automatization in measurement, calibration and modelling procedures, the possibility of combined registration and processing of form and surface (texture) information were defined. From the start the team was confronted with limitations, resulting from the user request for solutions in the bottom to medium price range.

During the project period interesting application fields for equivalent solutions in orthodontics and oral surgery were investigated. As turned out, a circle of users in private established orthodontical practices as well as in orthodontic and oral surgery hospitals was urgently interested in a drastic reorganization of documentation and archivation of patient (form) data. This, of course, was discovered especially in Germany. The legislation rspctv. regulations in different European countries require different quality and accuracy levels regarding the archivation of orthodontic patient data. In some countries only certain picture views (photos) of the plaster castings of a patient should be stored, in others there is no archivation required at all. In Germany, the plaster castings of orthodontic patients are to be saved not only during the treatment period (usually 2-3 years), but also for a long time after. This regulation is determined by forensic aspects at the one hand and has a background in the attempt to have a body of evidence in all cases of lawsuits with patients or health insurance institutions at the other.

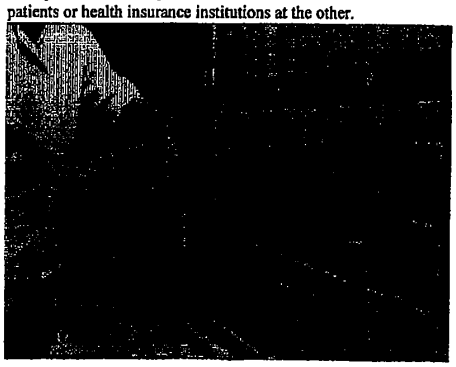


Fig. 1 Typical situation in conventional plaster archives

As far as a private orthodontist gets up to 100 - 150 new patients a year (i.e. aprox. 300 - 450 patients currently in treatment) and at least two pairs of plaster models (lower and upper jaw, before and after treatment) -in many cases three to five pairs- per patient appear, easily thousands of plaster models should be managed and stored in only one practice, where a great part of them is really archived and not more „touched" for medical needs. Usually the plaster models are put in hundreds of labeled paper boxes, which in their order occupy a number of shelves and increase the necessary area and the rent rspctv. price of the rooms (Fig. 1). The same problem -proportional to the number of patients treated- arises in large orthodontical hospitals.

Our solution - labelled 3DENT and including all steps from object digitalization up to basic virtual analysis tools - was presented at CeBIT '98 fair in Hannover.

II. 3D DATA ACQUISITION

The 3D-data acqusition part of the 3DENT device is based on active stereometric measurement. A number of light patterns is projected sequentially to the object of interest while an image-sensor takes images of the object. The projected light patterns are deformed in dependence on the object geometry and the defined angle between projector and camera axes. 3D-co-ordinates are then calculated by triangulation.

A. Setup of 3D measurement (hardware)

The 3D-measurement hardware consists of a stripe projector, CCD-camera, a two-axis positioning device, and construction elements, including adjustment correction.

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Optical axes of camera and projector as well as the main rotation axis of the positioning device are adjusted in one plane, the second rotation axis perpendicular to this plane. The points of intersection of positioning and sensor-projector system axes are identically (Fig. 2). Due to known dimensions and large degree of similarity of all objects (human jaw plaster casting models) it was possible to use a relatively simple positioning equipment even with constant (but programmable) position stops. The first realized transformation is a rotation of the object plate (0-360 degrees) around the vertical axis of the plate. The second moving axis (rotation, ±70 degrees) is located parallel to the baseplate and perpendicular to the plane formed by the optical axes of camera and projector, intersecting this plane in the point where this two axes meet. For positioning we use two DC driven, encoder controlled, zero-allowance transmissions with a final resolution of 0.12 arcsec. Image acquisition is performed by an analog b/w CCD-camera with pixel synchronisation and square pixel geometry. A PCI-framegrabber board is used to digitize and transfer the image data to the PC.

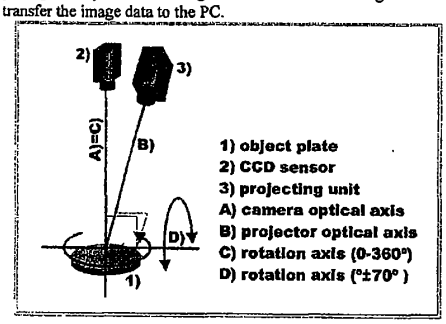


Fig. 2 Constructive arrangement of the measurement hardware

A special device (Breuckmann GmbH) is used as projector. Light patterns in this case are carried out on a glass carrier, wich is moved through the optical channel by a high precision, stepper driven transmission. The patterns used for projection are stripe shaped and the moving direction of the carrier is parallel to the stripes [2].

B. Measurement method:

Two kinds of patterns are used in the projection sequence: At the start six binary stripe patterns (Gray-code) with nearly rectangular intensity characteristics are projected to the object, where the stripe width in the following step is exactly the half width of the actual one. Then, four phase shift patterns with a sinusoidal intensity characteristic and equal period length (period length identical with the finest Gray-code stripe width) are projected with a phase shift of ¼ of period length.

By the help of the Gray-coded sequence it is possible to identify and seperate all stripes, even if they are interrupted or partially shifted in the image. The Gray-code images are binarized and then assembled into a code-image, where all pixels from one stripe get the same value, unambiguosly representing a certain stripe number [1].

The images resulting from the phase-shift projections are processed in a way that is known from interferometric calculations [1][2]. After this calculations we get a phase angle between 0 and 360 degrees for each pixel, defining its position inside the smallest projected stripe. Due to the integrated phase-shift calculation it is possible to reach a resolution about 5-20 times better than by a comparable laser light-cut method.

C. Calibration method:

The calibration of the system is performed by the help of a special high precision calibration solid with defined dimensionality and optical markers at the surface. This solid allows the registration of the absolute phase value as a function of the horizontal image co-ordinates in two height levels (located parallel to XY-plane with known distance). This calibration curves are used as the base of the later performed triangulation calculations.

The calibration procedure contains also automatical recognition of the optical marker array at the surface of the calibration solid. The marker positions in the calibration image are recognized with subpixel accuracy and further used for the definition of calibration distances. In this way, the calibration procedure is simple to perform and does not require special skills of the user. Extented calibration procedures, that should be performed only after assembly or constructive modifications of the setup, include the check of the module adjustment and use additional calibration equipment.

D. Implementation and system design:

All mechanical, optical and electronic modules of the system, including a complete PC with standard interfaces (LAN, parallel, SVGA, diskettes) were finally installed in a case, wich -among other advantages- guarantees a complete independence from environment light conditions. The device is shown in Fig. 3.

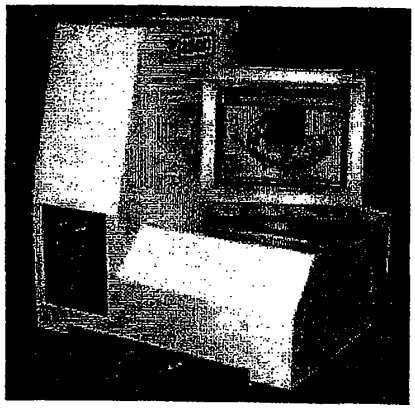


Fig. 3 : 3DENT solution for digital documentation in orthodontics

III. MODELLING PROCEDURE

The lower described sequence of algorithmic procedures was choosen from among several others by the criteria of

- robustness and 100 % automatical flow-off
- feasibility at PC-level and acceptable for users processing time
- resulting model quality.

The amount of data piling up from one object view is about 100.000 space co-ordinates in the standard case (using a 760x550 pixel matrix camera). Several (usually five) sets - or point clouds - from different, but defined positions are transferred to the modelling procedure.

In a first step the - separated yet - point clouds are submitted to a filtering procedure wich is based on parametric B-spline

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approximation in two directions. In this way eventually remaining noise is removed and the point distribution is already corrected into a partially (in the projection) regular grid. It would also be possible to fill up or to "mend" smaller holes in the actual data, but we don't do it, because surely we have the missing surface points in one of the other object views. We don't reduce the amount of data and do not increase it by approximating new co-ordinates at this point.

In the next step the position transformation of the separate point clouds is performed by the help of the given transformation angles and all point co-ordinates are read into a scalable octree structure, wich defines the common co-ordinate system. The octree data structure is used for the purpose of optimized data access. The depth of the octree is variable, but should be defined by user or initialization before data are read in. So, we achieve a possibility to define the complexity (and accuracy) level of the resulting model, wich, in its order, defines calculation time and model size and is proportional to the octree depth.

The average point of all 3D-co-ordinates related to one of the smallest cubes, defined by the deepest octree level is taken as the new valid point. Taking in account, that the inital point data from the different views are characterized by a multiple redundance over the most surface parts, it is evident, that even with a large octree depth a substrantial data reduction takes place during this procedure.

The modelling algorithm now generates a mesh of connected triangles from the resulting 3D point data. A start triangle is formed by connecting three space points in an octree neighborhood. From here, new triangles from occupied neighbor octrees are generated iterativly at the "free" edges of the mesh.

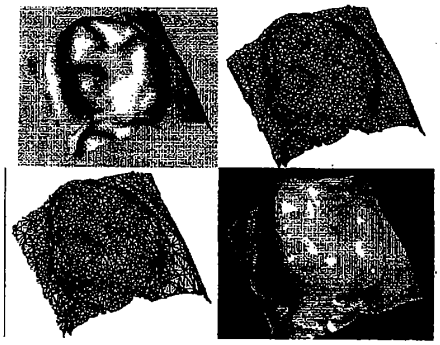


Fig. 4: Object detail result from the modelling procedure

So, the mesh is growing at its borders with every iteration until either there are no free edges (completely closed mesh) or there are no more neighbors available. In the last case, the algorithm checks for eventually remaining separate points or surface parts.

The program is able to optimize the generated mesh (number of triangles) by restructuring it with a given space curvature tolerance limit. Usually it is possible to reduce the mesh size to aproximatelly 60 % without a visible degradation or remarkable effects in accuracy.

In Fig. 4 one detail of a jaw model (first molar, upper jaw) was virtually cut out for demonstration. It contains the usual gouraud shaded visualization view, the triangle mesh laying behind it, the optimized mesh, calculated with a tolernace of 1.5 degrees between neighboring triangles and finally a raytraced view of the (optimized) mesh.

IV. MODEL VISUALIZATION AND STORAGE

The complete software library was written and implemented under WINDOWS-NT™, the graphic interface was programmed using the OPEN-GL graphic interface standard. The new calculated ore stored models are usually presented to the user as gouraud rendered objects, wich can easily been moved, rotated or zoomed by the help of the pointing device. Several other visualization modes (wireframe, depth-dependent colorization, point cloud) are available, too.

Actually we use a binary format for archivation of the surface models. In this case, all plaster models located today at a average orthodontical practice can be stored on 4 - 8 CD-ROM. Of course, it is also possible to keep and archive the original (eventually filtered) point data from the scanner. Other available output formats are raytracer interface, VRML and standard CAD (DXF, VDA) for 3D surface data and TGA format for free choosen objects views (images).

V. EXTENDED APPLICATION AREAS AND TOOLS - OUTLOOK

The new, digital documentation / archivation of patient data could bring a remarkable growth in comfort and effectivity for orthodontical practices, doctors, students and health insurance institutions. The arguments for this are savings in logistic and storage expenses, quick and comfortable access to the virtual models, information exchange with colleagues or other institutions, possibility of easy centralization and „outsourcing" of patient archive management.

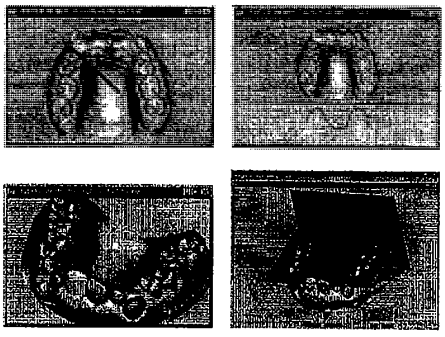


Fig. 5: Examples from interactive analysis tools

At the other hand, digital archives open up more possibilities for a new quality level in diagnostics and treatment analysis, as well as for forensic aims. So, we actually are implementing a special toolbox for orthodontists, allowing to perform the basic quantitative evaluation of the patients jaw symmetry and occlusion pathology using the virtual models (special interactive measurement tools like a virtual calipers, implementation and visualization of Occlusion-, Tuber- and Paphe-Median planes, correlated positioning of upper and lower jaw model, special object cuts etc. - Fig. 5). In the future, volume difference models from different treatment periods can be calculated for a graphical and objective comparision and evaluation of the treatment progress. Finally, the complete patient and treatment documentation could be united, if desired - paperless, and easy accessable from a structured data bank. In forensics,

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identification jobs could be performed much faster by effective matching procedures with data banks via remote access.

People from other potential application fields like archaeology, museum, biology, plastic surgery as well as dental technicians expressed their interest for the introduced here solution.

VI. ACKNOWLEDGEMENT

The reported work was supported by the Ministry of Economics (BMWi) in the frame of the development programme „Marktvorbereitende Industrieforschung und wirtschaftlicher Strukturwandel" (grant No.725/97). The authors feel also obliged to express their thanks to Mrs. Dr. med. Furkert for her consultations and professional support regarding orthodontical theory and praxis.

VII. REFERENCES

[1] W. Riechmann „Kombination von Photogrammetrie, codiertem Lichtansatz und Phase-Shifting-Verfahren zur hochauflösenden Oberflächenvermessung," in GMA-Bericht 23 *Optisches Messen von Länge und Gestalt*, 1994, p. 211

[2] B. Breuckmann, *Bildverarbeitung und optische Meßtechnik in der industriellen Praxis*, Franzis-Verlag, München: 1993

[3] G.-H. Schumacher, *Odontographie*, 5. Auflage, Hüthig, Heidelberg: 1995

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DENTIST

JANUARY/FEBRUARY 1989

The ... of implants —pages 37-42

Computers

'Foolish' concept propels technology

Computers design, mill restorations

By Jim Pinkham
Managing Editor

Eighteen years ago, Dr. Francois Duret lost his position on the University of Marseilles dental faculty because he was foolish enough to think that computers could help dentists design and make restorations.

Since then, Dr. Duret's ideas have found a foothold.

"You have to be around this man awhile to see how broad he is," said Dr. Jack Preston, a prosthodontics expert and restorative dentistry professor at the University of Southern California. "He's a true genius, and I don't use that term very loosely."



Siemen's Cerec system promises to accurately design porcelain inlays, onlays and veneers.

The dental imagination is now broad enough to envision systems that will make impressions and temporaries obsolete. In the not too distant future, a patient may require a crown, an inlay, an onlay or a bridge and leave the office with it an hour later.

Dr. Duret's system was scheduled for sale in France in late 1988 and is one of five that could reach the American market

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Computers design, mill restorations

continued from page 1

within the next two years.

Optical Probe

All of the systems involve an optical probe that captures an image of the tooth, measures boundaries of existing tooth structure and relays the information to a computer.

With varying degrees of user intervention, the computer then calculates the dimensions of the restoration.

The computer then sends that data to a milling machine linked to the system. The mill cuts and fashions the final product using conventional materials such as porcelains, ceramics, and semi-precious metals and alloys.

Dr. Preston said the Duret system can design and mill crowns in three dimensions with proper anatomical design and proximal and occlusal contacts.

Hennson International of Vienne, France, is marketing the Duret system in the United States, setting up offices in Los Angeles. Jean Claude Haas, chief executive for Hennson's U.S. operations, said the system will be introduced on a non-commercial basis at the Chicago Dental Society's Midwinter Meeting in February.

"We will have one system installed at USC to help us Americanize the product," he added.

A competitor, Siemens Dental, is developing its own computer-based system, Cerec. The Cerec system incorporates several years of research by University of Zurich developers. Siemens officials have also begun demonstrations of their model, which can do inlays, onlays and veneers.

At the University of Minnesota, Dr. Diane Rekow is developing the third prominent system. A biomedical engineer-turned-dentist, Dr. Rekow began exploring computerized manufacturing for orthodontics because "it was a nice synergy and a good challenge." She planned to demonstrate a system in early December that will initially be used to do full crowns.

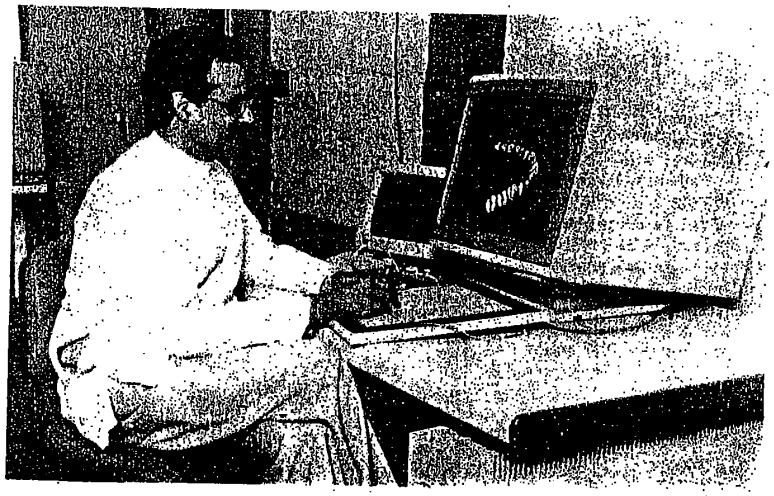
Dr. Reggie Caudill, a robotics expert and professor of mechanical engineering at the University of Alabama, is also working on a system that he hopes will initially be able to cut crowns. Caudill is collaborating on the project with Dr. Earl Hydrick, a local dentist with an engineering background. Several developmental questions still need answers and make it likely that Caudill will finish work later than the others.

The fifth developer, Air Force Col. Bruce Altschuler, enjoys a unique status in the dental CAD/CAM (computer-aided design, computer-aided manufacturing) effort. Dr. Altschuler is a liaison collaborating on dental research with Col. Lewis Lorton of the U.S. Army.

Dr. Altschuler's research originally paralleled the others. But it has since been diverted to a three-dimensional, forensic tooth-mapping project for NASA and all the armed forces. The project seeks to obtain maps for each individual that will enable post-mortem identification from a single tooth.

"Once we have that, we can very easily modify it from a forensic to a CAD/CAM system," Dr. Altschuler said.

Unless civilian interest in a technology-transfer project were to change things, however, Dr. Altschuler faces no constraints to see the technology quickly adapted to commercial dental restorations. When a military version is available, he indicated that it will probably have a sophistication far exceeding any system currently under development.



Dr. Francois Duret developed system to create dental prostheses.

Price Patterns

The price patterns of dental CAD/CAM devices may mimic the personal computer, VCR or compact disk player. Although very expensive at the outset, prices may taper.

"If you're looking at the technology we're dealing with," Dr. Caudill said, "the cost is going down exponentially."

For now, Haas said, the Duret system will be set up and priced on a case-by-case basis. He estimated a $200,000 cost for a complete system.

John Schweiker, division sales manager for Siemens, estimated their system

continued on page 53

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nputers hint at futuristic technolo

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will cost $40,000 to $45,000.

Dr. Rekow projected costs for a complete version of her system between $100,000 and $150,000.

Dr. Caudill placed costs for his equipment at $80,000 to $90,000—an estimate that will ultimately depend on still uncertain variables of precision, size, and data storage and management capacity.

Dr. Preston and many of his colleagues anticipate that a dentist may simply buy components of the systems that acquire data, capture an image and display it. The data would then be sent, perhaps via modem, to a lab facility for milling. A group of dentists might jointly own the milling equipment in order to diminish costs.

Expect the partial systems to begin in the range of $5,000 to $30,000.

FDA Review

The Duret system is in the final pre-application stages for FDA approval, which will take at least three months to obtain. Haas said it will be late 1989 at the earliest. Dr. Preston said it could take two years or more.

The Siemens system is pending FDA review. Agency spokesman Dave Duarte said he could not comment on the progress of any pending application, but Schweiker said it will take at least until July and could take until mid-1990.

Dr. Rekow said she hoped her design would be on the market in 1989 and planned to approach the FDA after her December 1988 exhibition. The product will be marketed by Digital Dental Systems, a company formed for the CAD/CAM device and working in conjunction with the University of Minnesota.

Dr. Caudill has made no commitments for marketing and has no definite plans for when he will approach the FDA. "We are probably 1 1/2 to two years from the marketplace," he said.

Dr. Altschuler said he had no idea when his research may translate to a CAD/CAM dental restoration system reaching the market.

Gathering Data

A critical component of each system is the optical sensor that gathers initial data.

The Duret system employs a laser-imaging device that captures a picture of the tooth in three dimensions and also measures mandibular movements across time, according to Dr. Preston. The computer can look at a series of cross sections of the work area and blow up any sections that the user wants to examine further.

Haas said the Duret system employs holography and a derivative of the Moret technology. The Moret system is analagous to several others in that it involves projecting a three-dimensional grid of dots onto an object, viewing it through the grid and obtaining measurements based upon how the object distorts the otherwise flat surface of the grid.

But purely Moret-based systems can be ambiguous. Making surface distinctions, such as between an indentation of the tooth or a transient saliva bubble, can be difficult, Dr. Rekow said.

Dr. Rekow's system also allows cross-sectional, three-dimensional views, using a camera with a specially designed lens and a stereophotogrammetric device. It captures an image that can be digitized and resolved into pixels—yielding 16 million microscopic pieces of data for every view of the tooth. She crafted the system without using a Moret pattern and designed it so that the camera can be replaced as new technology becomes available.

Siemens' Cerec system is another Moret-based product, according to Dr. Karl Lienfelder, a member of the biomaterials faculty at the University of Alabama School of Dentistry. Although it also offers three-dimensional viewing, it does not have the cross-sectional view capacity of some of the other systems, he said. Its miniature camera makes its calculations by obtaining 70,000 pixels, Schweiker said.

Dentists may buy components of the system to acquire data, then send the data to a lab for milling.

Dr. Caudill's optical probe is still in the design phase, but will also employ a camera, he said. It, too, will be Moret-based, but will use a Fourier transform to measure the way in which the object distorts the flat grid surface. He does not know how many reference points the final design will have. He is working on the design with Electro-Optical Systems of California.

Dr. Altschuler's three-dimensional system completely rejects cameras and Moret technology. His system generates thousands of reference points using "structured light." Dr. Altschuler likens it to creating an tiny laser beams onto the decayed or broken tooth. His method of coding the beams of light offers a precision impossible with Moret, he said.

Unlike the others, the structured-light sensor can obtain measurements at a distance. It need not be placed in the mouth. Since all of the sensors must be placed in the mouth, they must be sterilizable and fall under the approval jurisdiction of the Food and Drug Administration.

Establishing precision levels has also been a complicating developmental factor.

Accuracy Standards

When it comes to measurements inside the tooth, the accuracy standards are in microns—millionths of a meter.

The internal measurements of the Duret system are reportedly accurate to within 20 microns. Researchers behind the Cerec system suggest a final accuracy of fit should be 50 microns, which requires the Siemens imaging system to be accurate to within 15-20 microns in obtaining measurements. Dr. Caudill is also aiming for that accuracy level. Dr. Rekow hopes to prove her system already possesses that level. Dr. Altschuler said his technology can obtain an accuracy level of 13 microns.

Each system allows the dentist to intervene as desired.

The Duret system, according to Hennson's Haas, is the most automated system available, least 11 questions [illegible] puter.

The Siemens system is designed for the dentist to intervene to check the accuracy of the computer design and to make final decisions about such factors as marginal fit.

The Rekow system allows for user intervention, but it is fully-automated and requires no guidance except in rare cases, which might occur only once in a dental career. They were omitted from the design for cost-effectivness.

The Caudill system, similarly, can be almost fully automated.

Dr. Altschuler said he would seek an entirely automated system, particularly for the initial design phases.

Hennson expects the Duret system to soon adapt to large-scale bridges, pin crowns, attachments, splints and brackets.

The Siemens system may eventually be able to do full crowns and bridges, Dr. Lienfelder said. Schweiker said this is probably five to 10 years away.

The Rekow system will soon be able to do onlays, inlays, partial-coverage crowns, short-span bridges and eventually long-span bridges and maybe denture work, Dr. Rekow said.

Dr. Caudill said his system may eventually do bridges and dentures.

Dr. Altschuler anticipates an unprecedented ability for baseline data that could provide a definitive occlusal theory and a means for wear studies, dental medication evaluations and cleft palate research. In addition, his technology could do crowns, bridges and dentures and virtually eliminate impressions. ■

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DENTIST
SEPTEMBER 1990

Risk Audits: Lawsuit Prevention —Pages 15-16

Insider

5 Dr. Steven Mackler asserts in his Guest Editorial that non-surgical periodontal therapy has an important role to play for practitioners who recognize that it has limitations as well as advantages.

7 Our showcase of dentistry's hottest **New Products**, begins here with full-length features, detailed assessments of recent introductions, and a gallery of short synopses of the latest professional products and literature.

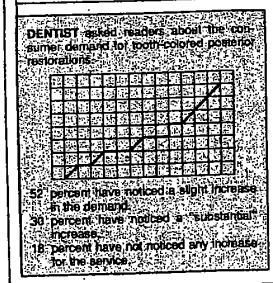
15 Jim & Suzanne Du Molin share their financial expertise in the first installment of an analysis on how to realize the greatest gains from your hygienists and auxiliaries.

22 Dr. Jeffrey Golub-Evans reviews the techniques and considerations essential for natural and esthetic colors with veneers.

22 Dr. Howard Strassler reviews a half century of clinical experience with acrylic resins and explains how earlier objections have been overcome, examining the role resins have to play today.

31 Dr. Stewart Leavitt offers a careful synopsis of the treatment and care steps necessary to arrest the progress of periodontal diseases.

36 Dr. Robert Bagramian, relying on his extensive expertise in preventive dentistry and public health, discusses how to motivate children to develop lifelong habits sustaining successful oral hygiene.



Technology

Inventor's CAD/CAM may transform dentist

Computer-made crowns only first step in vision of sweeping change

By Jim Pinkham
Managing Editor

When Francois Duret peers over his short spectacles, with their thick lenses and thin wire frames, the effect brings to mind the portraits of Ben Franklin.

The resemblance extends to more than mere eyeglasses. Like Franklin, Duret has created quite a stir on both the French and American sides of the Atlantic.

Like old Ben, Francois' inventive imagination and unconventional approaches have evoked the sometime scorn of lesser minds.

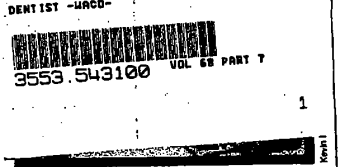
Although Duret has yet to stand drenched in a thunderstorm, beckoning the strike of lightening, two decades ago he was considered sufficiently radical by dentistry's stodgy conservators at the University of Lyon in France to be locked out of lecture halls.

Duret's radicalism consisted of a proposed wedding of the technology of computers and lasers to dentistry (computer-aided design/computer-aided manufacture). The CAD/CAM proposal became reality when, in early 1987, he first began exhibiting a device that could design and mill crowns in one office visit.

A laser probe captures an image of a tooth, measures boundaries of existing tooth structure, relays the data to a computer. The dentist can intervene as much or little as he wishes to calculate

continued on page 35





Francois Duret uses laser probe to measure a restoration's dimensions.

Esthetics

Resins offer an alternative for correcting bad bites

Despite scoffers, options exist beyond crowns

By Dr. Norman Felgenbaum

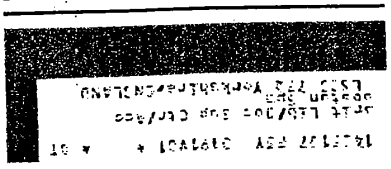
You have a new patient coming in during the next hour. She was referred by a recently satisfied "esthetic smile enhancement" patient. She, too, wants her teeth lengthened and brightened. She arrives and takes a seat. You look over her history form before seeing her and find that she has answered "yes" to the question about grinding her teeth at night.

She's a bruxer and suddenly the easy smile makeover has turned into a complicated rehab situation. You enter the operatory with some concern. The initial examination confirms that the patient has indeed created an edge-to-edge anterior bite relationship.

Upon further examination, the patient shows a solid posterior occlusion with many "clean" virgin teeth and several molar onlays. The edge-to-edge situation (in centric occlusion) exists between the central and lateral incisors, mostly, with some cuspid incisal loss as well. (See illustration #1.) Some faceting of the incisal surfaces has left dentin exposed on the lower incisors and nearly exposed on the maxillary incisors.

The net result is the foreshortening of

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Profile

Passion for Orioles keeps dentist out at ballgame

Scoreboard operator provides entertainment

By Dr. Howard Strassler



Dr. Howard Strassler

Dr. Charles Steinberg masterminds entertainment and scoreboard information for the Baltimore Orioles.

Pick almost any summer afternoon, and Dr. Charles Steinberg is as apt to be diagnosing the swing of Baltimore Orioles slugger Cal Ripken as he is a TM disorder, bruxism or the need for a restoration.

In fact, Dr. Steinberg's Owings Mills, Md. general practice gets a mere 20 hours of his busy week. The major league baseball team, for whom he serves as director of productions, gets anywhere from 70 to 100 hours a week during the season.

It's been almost 15 years now since Dr. Steinberg first walked into Memorial Stadium's public relations department as a star-struck high school senior. "I was completely excited to be at Memorial Stadium, going to the Orioles' offices," he recalls.

It began almost undiscernibly. After the internship in that Bicentennial summer of 1976 Dr. Steinberg decided that spending the rest of the summer with the team would make a satisfying summer job. So he became a veritable boy Friday, cleaning store

continued on page 20

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CAD/CAM to revolutionize dentistry

continued from page 1

the dimensions of the restoration. The computer then sends the data to a milling machine that cuts and fashions the final product.

In late 1988, his machine reached the French dental market. At the 1989 Chicago Midwinter, it was previewed to Americans. It's expected to reach the U.S. market next spring with refinements derived from the French experience.

Despite Duret's success, his excommunication has never been lifted at Lyon. But he is becoming a familiar sight at major dental schools and lecture halls in this country.

These days, Duret would find warm welcome at almost any dental school in the world. In fact, he now serves as co-director of the Dental Imaging Department at the University of Southern California School of Dentistry. There he is doing research and clinical tests on CAD-CAM systems and developing curricula for graduate, post-graduate, and continuing education.

His pioneering work has earned him the label of genius by people who don't use the term lightly, including some of his current colleagues at USC.

Duret is quick to parry such compliments: "I have a family, a wife, three children, and I make my own breakfast in the morning," he said. "Above all, I love what I'm doing. Because of that, I may be thinking more about my work than other people, and that keeps me in ideas.

"I feel I have come to a land of high technology and that is the kind of environment I need to finish my research. I feel at home here, and the longer I can stay, the better I will feel."

As Duret's sojourn at USC continues, his American colleagues will find that a machine for milling crowns constitutes only the periphery of his high-tech vision for dentistry's future.

"With a CAD/CAM probe, we will reach the point someday where a machine can asseas [the interior of the mouth] mathematically, describe it, and diagnose an increasing number of dental problems," he said.

He offers this example: suppose a dentist examines three adjacent teeth, suspecting that one is flawed. With the CAD/CAM, he can take an optical impression of all three. The machine can study and compare the suspect tooth with its neighbors and make a differential diagnosis of the nature of the problem.

In Duret's vision of the next 20 years, three of modern dentistry's primary instruments will soon become dinosaurs.

"We will have CAD/CAM for everything in a very short time,"

continued on page 39

Baseball dentist masterminds show

continued from page 20

that will accompany the national anthem and the seventh-inning stretch.

Dr. Steinberg and his proteges have become almost too good for him to give up his baseball career easily now. He says, "It is the love of the work that sustains them." But what about him? "It's still a thrill coming to the ballpark," he says.

For a long time, his Birds did not fare nearly so well on the playing field. Last summer, however, the Orioles ran in the thick of the pennant race until the last day of the campaign—counterpointing an egregious '88 season most noticeable for its 21 consecutive losses. Dr. Steinberg and his Breakfast Clubbers captured just about every think of this dramatic metamorphosis, distilled it into a highlight film and premiered it at a black-tie, white-limo, red-carpet affair at the city's prestigious Art Deco Senator Theater.

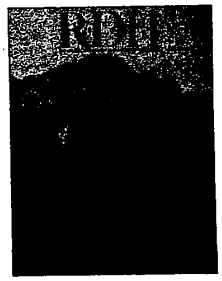
The highly acclaimed result has sold almost 20,00 copies.

It is significant now, that when Dr. Steinberg says he still expects to give up one of his jobs someday, there is a curious ambiguity—*which* job is left unmentioned.

"I have no clue what is in my future," he says. "A reason will come that will not allow me to do both. When that happens, I won't do both. When this dream is over, I'll wake up. Meanwhile, do not disturb." ■

Howard Strassler, DMD, FADM, is an associate professor and coordinator of operative dentistry in the department of fixed restorative dentistry at the University of Maryland's Baltimore College of Dental Surgery.

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Duret: CAD/CAM to usher in new era

continued from page 35

he said. "We will have a computer-programmed articulating device that will be four-dimensional, able to see the bite in function, able to assess and describe mandibular movement. Within eight to 10 years, there will be a machine to replace the handpiece. We will also have an X-ray that provides images in three dimensions. All of these machines will be connected to the same computer, and dentists will work at a very small terminal."

The computer will take a pronounced role in the specialties, too.

"Orthodontic treatment will be visualized beforehand on the computer," Duret said. "This visualization will allow the orthodontist to design the treatment and do the follow-up. In addition, all of the care and treatment in periodontics and prosthetics will be based on computer-generated mathematical analyses."

These analyses presuppose that as computer-linked optic probes size up a multitude of patient mouths, the data on healthy teeth and dysfunctional or diseased teeth will be stored and refined. Duret has already begun building data bases using such information, but he envisions the dental offices of the future as having a computer link to a central data base.

A dentist can compare and contrast the case before him with information from countless others. Continuously updated dental software will incorporate broader patient population data, as well as applications of research advances. It may even develop experimental models to incorporate new theories that the dentist can consider as alternatives.

"The software will contain the most recent advances in real time," Duret said. "This will be a new form of continuing education. All dental offices will have the latest equipment and software."

As a teacher himself, the famous Frenchman asserts that to accommodate all of this the current orthodoxy of dental school curricula must give way.

"The teaching part of dentistry will have to change completely. There will be a substantial decrease in the importance of biology in dentistry and a substantial increase in the importance of other scientific things, particularly mathematics and physics," he said. "In the future, 90 percent of dentistry will be based on physics. Science will then be used by the clinician, and no longer be so much the sole province of the researcher."

Of course, Duret doesn't rule out a significant role for the biological sciences, either. Within the next 40 to 60 years, he expects significant microbiological advances in the prevention of oral pathology. He even envisions learning to prevent pathology at the molecular level by working with the DNA molecule and its double-helix structure.

Consider Duret's background and the radically innovative course of his dental career comes as no great surprise.

Born into a family of dentists, Duret also early cultivated a great love of science, ultimately pursuing and attaining a doctorate in biochemistry.

"I loved science for a very long time," he recalls. "When I was at university, an uncle said to me, 'Francois, you could appreciate work in dentistry. Perhaps you could experiment with that.' After six months, I loved the work, and it's now my life. It's the scientific aspect of this work of dentistry that attracts me."

It was in this context, while simultaneously pursuing his biochemical and dental coursework (he ultimately earned a DCD, the French equivalent of a DDS) at two separate universities, that Duret developed his initial CAD/CAM ideas.

As he tells it, he was taking an impression with stone and dust one autumn day during his sophomore year and, deciding there had to be a better way to do things, he began correlating his science and dental studies.

Later, one night while home on Christmas vacation, after a particularly hearty meal that kept him awake, he mapped out in his mind the first plans for a CAD/CAM device.

He considers that work completed now, and his job as much one of persuasion as application.

"My biggest challenge is to make dentists understand that this new approach to dentistry is a tool that comes as a help to them in the way they do dentistry," he said. ■

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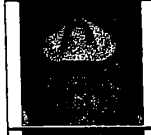
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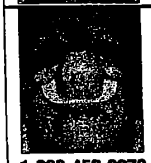
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Invisible retainers

Robert J. Ponitz, B.S., D.D.S., M.S.
Ann Arbor, Mich.

Methods of retention in orthodontic treatment seem to have undergone more drastic change than have many other aspects of practice. For this reason, the changes in retentive appliances will be reviewed briefly and experience with the invisible retainer will be presented.

History

Retainers used around 1914 by Hawley and others[10] were basically fabricated from gold wire and vulcanite. Since about 1937, steel wire and acrylic retainers have been used extensively. Many variations of the original design of the wire have been made through the years. The circumferential wire first was used by Paul Ponitz[10] in 1946. Combinations of body wire, auxiliary wires, and elastics also have been used. Autopolymerizing methyl methacrylate was first used clinically by me in 1952. Cobalt wires first became available around 1955.[7] Conventional premolar and second molar clasps and also ball-and-arrowhead clasps have been used.

On July 21, 1923, Remensnyder[1] introduced a rubber[2] Flex-O-Tite "gum-massaging appliance" which was first patented on Nov. 13, 1928. He described minor movements of teeth achieved with his first patented appliance.[3] Remensnyder's second patent[3] used the term "orthodontic appliance"—a one-piece rubber device.[4]

Vulcanite positioning retainers were popularized by Kesling,[5] Rocke, and others after 1943. Plastic finishing appliances have been used by others and myself for the past 10 years, but black vulcanite rubber is still preferred by many clinicians[6] because of its special physical properties.

Godwin,[11] Torbet, and others have pioneered in the fabrication, at modest cost, of large numbers of mouth guards for athletes.[8] Shanks first showed mouth guards, transparent retainers, and a machine capable of producing them in 1963. Cellulose acetate butyrate, polyurethane, polyvinylacetate-polyethylene polymer, polycarbonate-cycolac, and latex are the materials most frequently used in these applications. Special vacuum units that can be used to make plastic finishing appliances have been developed. Heating element capacity

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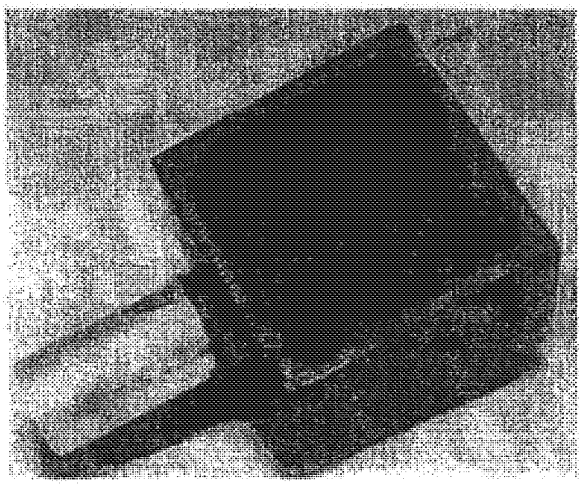


Fig. 1. Vacuum box with grid and tube.

has been found to be insufficient for the present application in some commercially available vacuum units.

Fabrication of appliance

The vacuum unit (Fig. 1) consists of a box, grid, and tube. A tank type of vacuum cleaner is used to provide the suction required. A frame (Fig. 2) is used to hold a plastic blank securely in place during heating over an electrical source of heat. A surface unit of 220 volts is more convenient, but two 110 volt units can be used satisfactorily. The second element is placed, heating downward, about 9 inches above the first element, which is placed heating upward (Fig. 2). The temperature should be from 340 to 420° F., although the preferred range of temperature is 370 to 390° F.

An impression of either arch is made by the method of one's choice. A model, without a base, is poured with improved stone or die stone. The model is placed with the anterior teeth toward the source of vacuum (Fig. 3). If protective packaging sheets are present, they are removed from the square of plastic to be used. The clear plastic, 5 inches square, is preheated in an oven for 15 minutes at 250° F. A sheet of preheated clear plastic is placed in the frame and heated over the electrical burner. The frame is kept moving in a horizontal pattern to avoid overheated spots which cause bubbles in the finished appliance. When the plastic slumps or begins to smoke, the vacuum device is turned on and the frame of heated plastic is placed immediately over the model on the vacuum unit (Fig. 3). An asbestos-gloved hand or a hot pad can be used to provide pressure in adapting plastic closely to the model. The speed of the motor will increase as the grid on the unit is sealed. A foot switch frees both hands for use in forming the appliance.

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Fig. 2

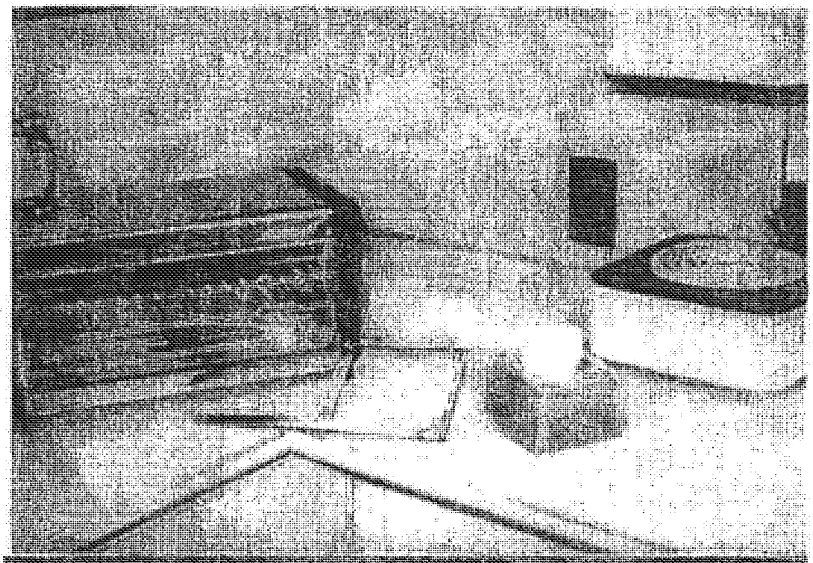


Fig. 3

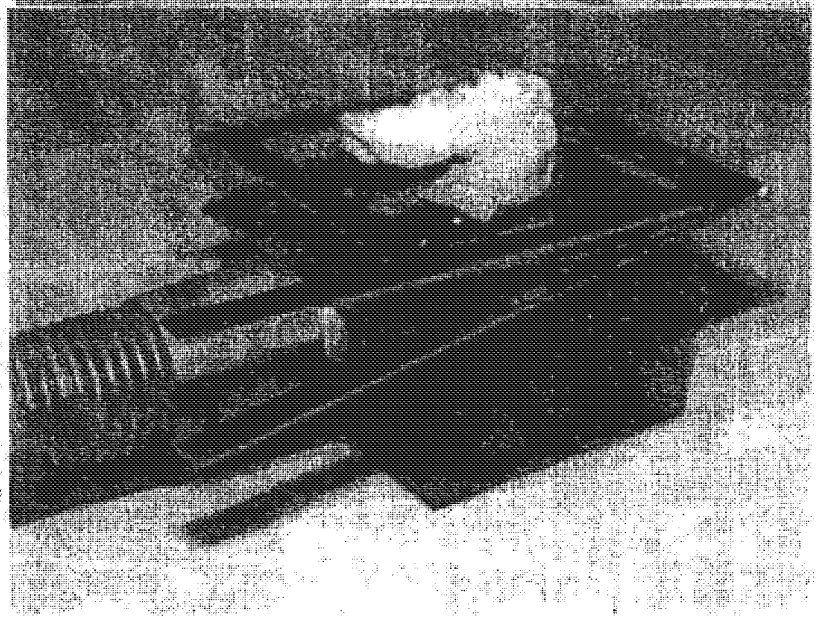


Fig. 2. Preheating oven at left. Twin 110 volt heating elements at right.
Fig. 3. Invisible retainer formed.

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Fig. 4. Invisible retainers ready for use.

The flash is trimmed away with coarse tin snips. A Vulcarbo, Joe Dandy, or knife-edge disk in a mandrel is used to carve the approximate periphery of the retainer. At this point, the retainer is lifted off the model with the large end of an inverted No. 7 wax spatula and trimmed with curved, nonserrated crown-and-bridge scissors. Finally, the edges are polished with an Indianhead pear-shaped stone. The patient's name can be carved in the flange with a small half-round bur or a vibrating stylus instrument of the type usually used to mark metal objects.

Teeth can be moved and repositioned in pink baseplate wax on the master model before the appliance is formed. The patient's teeth then can be moved to reasonable new positions by means of the retainer (Fig. 5). Bite planes can be formed on the model with asbestos material, and retainers can be formed over the asbestos with or without acrylic between the retainer and the patient's tissue. Acrylic bite planes can be formed over or under the clear plastic and bonded to the plastic with self-curing acrylic liquid. Denture teeth can be attached in edentulous areas in the same way. Plastic denture teeth usually are chosen for convenience. They bond to the appliance if covered with a drop of self-curing liquid just before the appliance is formed. Vinyl[17] is customarily used to form mouth guards and appliances for the correction of bruxism. This type of material is readily available from supply houses and can be used to gain greater changes in the position of teeth than the harder and clearer invisible material for the retainer will permit.

Final finishing, positioning appliances can also be made from vinyl blanks or wafers. Some blanks are heated in boiling water, while others are softened with dry heat. The heated wafer then is placed over the model, and a squared coffee can with a petrolatum-lubricated rubber dam banded to place is quickly placed over the plastic to form it on the vacuum unit.

When both surfaces of the clear plastic sheet are smooth, either side may be

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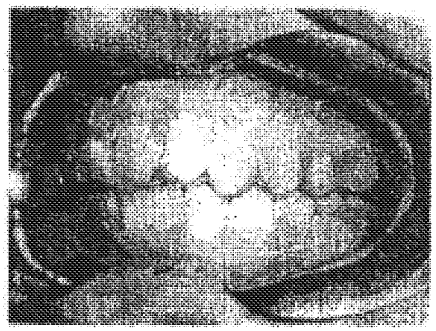


Fig. 5. Invisible retainers being worn.

placed up or down in forming the appliance. If one surface is a matte or has a dull finish, the matte should be placed toward the model when the invisible retainer is formed. Should the plastic sheets be packaged with a protective polyethylene thin-film wrapping or interlining, the protective sheets should be removed before preheating, as mentioned previously.

Additional implications

At the present time, invisible retainers usually last many months to a few years. The standard appliances made of wire and acrylic or of rubber usually last many years. As materials improve, comparable life expectancies may be anticipated in the future. Today's challenges for plastics seem to result in tomorrow's accomplishments.

Invisible retainers fit as accurately as the impression and model permit. Usually, no adjustment is needed. Occasionally, the periphery will require reduction for the attachments of muscles. Heat guns can be used to join cracks, separations, or split areas in the plastic. Usually it is preferable to make a new appliance after considerable wear has occurred. The ease of fabrication, the speed of insertion, and the almost complete lack of need for adjustment have amazed all who have used these appliances. It is usually easier to remake than to repair an invisible retainer.

Periodontists[18] have found invisible retainers valuable for keeping surgical packs in place with maximum comfort for the patient. These appliances have been used successfully as splints to stabilize traumatic and surgical fractures of the maxilla, premaxilla, and mandible until the bony fragments heal. Temporary partial dentures[18] have been made and used with excellent acceptance. These appliances also have been used as splints for the treatment of bruxism,[19] traumatized teeth, and the correction of oral habits. A maxillary and a mandibular retainer can be fused to make a surgical splint or a finishing appliance.

Webbing or folding of the appliance upon itself is a common problem encountered in the use of thermoformed materials. Usually this fault comes from excessive temperature when the appliance is being formed, leaving an extended base on the model, insufficient vacuum or pressure, delay between heating and

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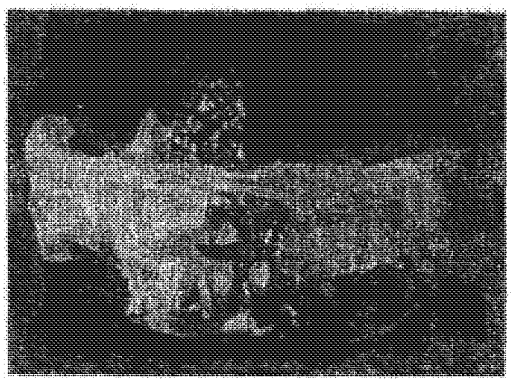


Fig. 6. Maxillary and mandibular invisible retainers used as a surgical splint. Note acrylic bead on superior portion of the maxillary retainer. Two invisible retainers—one maxillary and one mandibular—are fused on an articulator, with a bead of acrylic added to the superior border of the upper retainer. The maxillary portion of the appliance thus formed is wired to the skull from below the bead. The bead is added to prevent the wire from being pulled through the appliance. The mandibular portion of the appliance is wired around the mandible in two places. In this manner, the previously determined jaw sections are secured until healing has taken place.

forming, or any other failure in technique during formation of the appliance can cause undesirable webbing.

Heat and pressure have provided the best methods found for producing appliances of acrylic and rubber that are dense. Heat, vacuum, and pressure have been used in fabricating invisible retainers. The thicker the plastic sheet and the more sophisticated the composition of the plastic, the greater the porosity that develops.

Preheating of the clear plastic sheets for about 15 minutes at 250° F., plus or minus 10 degrees, has been recommended for the material currently available. The preheating removes moisture from the plastic and thereby eliminates the bubbles that cause porosity in the finished appliance. Since it is impractical to store the material in an airtight environment, preheating is desirable before any group of appliances is fabricated. A sealed container with an adequate dehydrating agent might be developed and used. Future development of material may require modifications of present methods, but most plastics are not available for experimentation in these developmental stages.

Summary

A review of the literature provided surprisingly little historical information of value on retainers. This dearth of material in the literature indicates that, although many innovations have been made by persons in the profession, few busy practitioners find time, encouragement, or facilities to publish them. As a result, the present article reports in detail the findings of earlier investigators

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and describes the technique used in the production of invisible retainers. When an orthodontist or other specialist perfects this method, he will find it a rewarding, time-saving and valuable addition to his treatment procedures.

REFERENCES

1. Remensnyder, Orrin: A gum-massaging appliance in the treatment of pyorrhea, Dent. Cosmos 46: 381-384, 1926.
2. Burchard, H. H., and Inglis, G. E.: Textbook of dental pathology and therapeutics, Philadelphia, 1926, Lea & Febiger, p. 758.
3. Remensnyder, Orrin: United States Patent 1,691,785, dental massage device, Nov. 13, 1928.
4. Remensnyder, Orrin: Treatment of pyorrhea, Dent. Econ. 1: 32-35, 1929.
5. Kesling, H. D.: The philosophy of the tooth positioning appliance, AMER. J. ORTHODONT. ORAL SURG. 31: 297-304, 1945.
6. Remensnyder, Orrin: United States Patent 2,479,780, orthodontic appliance, Aug. 23, 1949.
7. Ponitz, R. J.: Tensile properties of heat-manipulated stainless steel orthodontic wires, Thesis, University of Michigan, School of Dentistry, Ann Arbor, Mich., 1955.
8. Kesling, P. C.: Practical application of the Kesling tooth positioner, Thesis, Westville, Ind., 1954.
9. Craig, R. G., and Godwin, W. C.: Physical properties of materials for custom-made mouth protectors, J. Mich. Dent. Ass. 48: 34-40, 1967.
10. Shepard, E. E.: Address presented at American Association of Orthodontists' Golden Anniversary Luncheon, St. Louis, Mo., April 24, 1967.
11. Godwin, W. C.: Simplified mouth protector technic, J. Mich. Dent. Ass. 44: 132-133, 1962.
12. Horii, A. A., and Keyes, P. H.: A vinyl applicator for assessing drugs in the treatment of caries and periodontal diseases in the hamster, J. Dent. Res. 43: 153, 1964.
13. Blackburn, M. M.: One-year evaluation of twelve mouth protectors for Edmonton hockey players, J. Canad. Dent. Ass. 30: 500-504, 1964.
14. Nahoum, H. I.: The vacuum-formed dental contour appliance, New York J. Dent. 33: 385-390, 1964.
15. Michnick, B. T., Demauro, James, and Reinhart, Ellen: A simplified temporary bridge technique, New York J. Dent. 32: 73-75, 1966.
16. Fiasconaro, J. E., and Sherman, Harold: Vacuum-formed prostheses. 1. A temporary fixed bridge or splint, J. Amer. Dent. Ass. 76: 74-78, 1968.
17. Goodman, S. F.: Plastic guard held to cushion effects of bruxism, clenching, Dent. Times 11: 2, 1968.
18. Ponitz, P. V.: Personal communication, Feb. 15, 1946.
19. Godwin, W. C.: A simplified mouth protection technic. Part II, J. Mich. Dent. Ass. 44: 227-234, 1962.
20. Cottingham, L. L.: Gnathologic clear plastic positioner, Amer. J. Orthodont. 55: 23-31, 1969.

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PROCERA™

Research Projects 1993

Abstract Collection

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This publication presents finished and ongoing research projects with connection to the PROCERA method.

The different contributions have been either published in scientific journals, in which case these are referred to, or submitted for the specific purpose of this publication.

PROCERA wants to express gratitude to all authors/investigators for their contribution to this publication which will be updated on a regular basis.

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A 1-year clinical evaluation of a new high strength all-ceramic crown

Field of research:
Clinical trial, all ceramic crowns

Status:
Published

Journal:
AADR March 1-14, 1992, abstract nr 1064

Names of investigators:
Agneta Odén
Matts Andersson
Ivana Krystek
Dagmar Magnusson

Center:
Karolinska Institutet, Stockholm, Sweden

Abstract:
A one year follow-up study of 93 PROCERA all-ceramic crowns with the distribution: 49 molars, 27 premolars and 17 incisors. The clinical registrations were made in accordance with CDA criteria by two independent calibrated examiners. The CDA examination showed that after one year 100% of the crowns were rated satisfactory.

ΔΔΔ

A new ceramic crown according to the PROCERA concept

Field of research:
Clinical trial, all ceramic crowns

Status:
In progress

Names of investigators:
Per Ödman
Bernt Andersson
Matts Andersson

Centers:
University of Gothenburg, Sweden
The Special Clinic for Implants and Material Development, Mölndal, Sweden
Nobelpharma PROCERA, Sweden

Abstract:
This is a ceramic crown where the dental porcelain is baked on a densely sintered alumina core. The core contains >99.7% AL2O3. The technique is developed by Nobelpharma AB and AB Sandvik Hard Materials. Using the PROCERA method for copy milling, a metal die is manufactured that is 12-20% larger than the original stone die. AL2O3 powder is pressed onto the die under high pressure and the sintered at 1550° C. The core is adjusted and dental porcelain is fired on the coping. An ongoing clinical study in the County of Bohuslän shows promising results.

ΔΔΔ

A 2-year clinical evaluation of a new high strength all-ceramic crown

Field of research:
Clinical trial, all ceramic crowns

Status:
In progress

Names of investigators:
Agneta Odén
Matts Andersson
Ivana Krystek
Dagmar Magnusson

Center:
Karolinska Institutet, Stockholm, Sweden

Abstract:
A two year follow-up study of 98 PROCERA all-ceramic crowns with the distribution: 55 molars, 26 premolars and 17 incisors. The clinical registrations were made in accordance with CDA criteria by two independent calibrated examiners. After two years, one crown has been replaced after a porcelain fracture in a marginal ridge. All other 97 crowns were rated satisfactory and were consequently in function after two years of service.

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Dental implant treatment of patients with Sjögren's Syndrome

Field of research:
Clinical trial, Implant Supported Prostheses

Status:
In progress

Names of investigators:
Knud Brøndum
Jørgen Hansen
Flemming Isidor
John Jensen
Steen Sindet Petersen

Centers:
Aarhus University, Denmark
Aarhus University Hospital, Denmark

Abstract:
Ten edentulous patients who were unable to use conventional dentures and, furthermore, with Sjögren's syndrome, have been selected for the study. 4-6 BRÅNEMARK SYSTEM implants are to be placed in the lower jaw and, if neccessary, also in the upper jaw of each patient. Implant retained full arch titanium and ceramic bridges will be constructed with the PROCERA method. Implant installation has been performed in 8 patients and the prosthetic treatment is completed in 2 of these.

Δ Δ Δ

PROCERA Implant Supported Prostheses

Field of research:
Clinical trial, Implant Supported Prostheses

Status:
In progress

Name of investigator:
Jeffrey Rubenstein

Center:
University of Washington, United States of America

Abstract:
In 1992, ten patients were treated with mandibular fixed/detachable implant supported prostheses according to the PROCERA method. To date, the patients are between thirteen and nineteen months post insertion. There has been no evidence of gold screw, abutment screw or fixture loosening, fracture or loss at any implant site. To date, recognizing the relative short length of service for this group of patients, the overall experience has been positive without any clinical complications noted to occur. A five-year multicenter prospective clinical trial involving a total of 96 patients is now underway to compare PROCERA titanium frameworks to cast frameworks at the University of Washington and seven other United States centers.

Δ Δ Δ

Fixed Implant-Supported Prostheses with Welded Titanium Frameworks

Field of research:
Clinical trial, Implant Supported Prostheses

Status:
Published

Journal:
Int J Periodont Rest Dent 1992;12:177-183,Quintessence Publishing Co, Inc

Names of investigators:
Torsten Jemt
Bengt Lindén

Center:
The Brånemark Clinic, Gothenburg, Sweden

Abstract:
Eighty-six edentulous patients provided with BRÅNEMARK SYSTEM implants were randomly selected for fixed prostheses with modified framework designs. This study describes alternative laboratory techniques in which premachined titanium components are welded together to form the framework. Clinical experience, following the patients for 1 year after placement, indicates that it is a predictable technique with a similar pattern of complications as experienced by patients with cast frameworks supported by implants. The prostheses are considered to be slightly more bulky than cast frameworks, but seem to have, on a clinical level, a better fit to the implants.

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Der implantatgetragene, nichtgegossene Titansteg

Field of research:
Clinical trial, Implant Supported Prostheses

Status:
Submitted for publication

Names of investigators:
V P Meyer
P-D Reppel

Centers:
Knappschaft Hospital of Bochum, Germany
Private Practice, Bochum, Germany

Abstract:
The success of a prosthetic treatment on implants depend basicly on the chosen implant system, the surgical procedure and the prosthodontic restoration. The correct clinical prosthetic design and the choice of the most suitable materials and their special processing should be considered when creating the meso- and supraconstruction. In this paper the authors present the prefabricated titanium-elements and the -bar (PROCERA system) developed by them in 1991 which they are using since March 1992 for clinical applications of overdenture type. This study reports low plaque accumulation on the supraconstruction during a wearing period from March 1992 to May 1993.

ΔΔΔ

PROCERA Framework Precision of Fit –5-year Longitudinal Multicenter Study

Field of research:
Multicenter Clinical trial, Implant supported Prostheses

Status:
In progress

Names of investigators:
Brien Lang
William LaVelle
Jeffrey Rubenstein
John Chai
Ronald Desjardins
Eric Adrian
Drs Monaco, Synott and Flinton
Robert Cronin

Centers:
University of Michigan
University of Iowa
University of Washington
Northwestern University
Mayo Clinic
U.S. Army
U.S. Navy
U.S. Airforce

Abstract:
8 major institutions in the United States are just beginning a 5-year longitudinal multi-center study comparing the accuracy and precision of fit of the PROCERA laser welded titanium implant framework to a framework cast from an alloy by the conventional method. It has been hypothesized that the precision of fit of a framework to the implant abutments will contribute significantly to the lifetime survival rate of the dental implants supporting these implant bridges. A multicenter prospective investigation has been initiated by Nobelpharma AB in cooperation with the prosthodontic departments in several major institutions and universities in the United States, and the US armed services. Among those participating are Mayo clinic, Northwestern University, University of Iowa, University of Washington, US Air Force, Navy and Army, and the University of Michigan. A total of 96 randomly selected edentulous patients will be assigned blindly to two groups. The patients will be treated with a maxillary complete denture and a mandibular implant supported fixed prosthesis. One group will receive the PROCERA laser welded titanium implant framework, while the other will be provided the conventional cast alloy frame- work. All other aspects of treatment will be controlled and follow the same identical protocol. Evaluations will include the initial data gather process at insertion of the prosthesis and annual follow-up data collection appointments. Factors to be measured are the accuracy of fit of the frameworks to the abutments, in vivo serial radiographic assessments, and various periodontal indices.

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Laser Welded Implant Superstructures: A 5-year Multicenter Study

Field of research:
Multicenter Clinical trial, Implant supported Prostheses

Status:
One year results published

Journal:
Int J Oral Maxillofac Implants 1993;8: Abstract from 8th Annual Meeting of the Academy of Osseointegration

Names of investigators:
Birgitta Bergendal
Sigvard Palmqvist

Centers:
Specialist clinic of Jönköping, Sweden
Specialist clinic of Örebro, Sweden
17 other Specialist clinics, Sweden

Abstract:
The aim of this study conducted at 19 specialist clinics in Sweden was to evaluate the clinical performance of laser welded titanium frameworks for implant supported prostheses. 100 prostheses in 93 patients are being followed. The total number of loaded fixtures was 484. 88 patients with together 95 prostheses attended the one year follow-up. All 95 titanium framework were clinically intact after one year of function. A control group with cast frameworks has retrospectively been incorporated in this study. Results from the two year follow-ups of the test and control group are currently being put together.

ΔΔΔ

Carbonfiber reinforced long-term temporary fixed prostheses

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
Johan Blomgren
Per Ödman
Bernt Andersson
Matts Andersson

Centers:
The Special Clinic for Implants and Material Development, Mölndal, Sweden
Nobelpharma PROCERA, Sweden

Abstract:
A new type of semipermanent fixed prosthesis has been developed, on which repairs and modifications can easily be made. The abutment teeth are provided with titanium copings, manufactured with the PROCERA method. The prosthesis is made of carbonfibre reinforced methyl-metacrylat and prefabricated denture teeth. The results so far show that this type of long-term temporary prostheses can provide a valuable alternative therapy for patients whose treatment prognosis, because of various odontological and/or medical reasons, is less promising.

ΔΔΔ

Clinical controlled follow-up study of 134 PROCERA units over the period of 3 years

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
W-D Grimm
Th Pilecki
M Pilecki
A Blocher
S Deutschmann

Institution involved:
Private University of Witten/Herdecke, Germany

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Abstract:
The aim of this study is to evaluate the quality of PROCERA units using a quality evaluation rating system.

ΔΔΔ

Research in public dental care: An evaluation of titanium framework crowns and bridges according to the PROCERA technique.

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
Rolf Lövgren
Sven Bergqvist
Per-Fredrik Ekström
Bengt Sundqvist
Björn Adielsson

Centers:
Bohuslandstinget, Clinic of Kungshamn, Sweden
Nobelpharma PROCERA, Sweden

Abstract:
A unique decision by the Kungshamn clinic in 1992 to treat all crown and bridge patients with PROCERA restorations initiated this study. The stable patient and staff situation creates excellent conditions for clinical follow-up. The restorations are evaluated and other important study parameters are gingival health and caries incidence. The inclusion period will be at least three years and the minimum follow up period at least two years. During the first year approximately 140 patients were included.

ΔΔΔ

Clinical evaluation of porcelain veneered titanium crowns

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
Percy Milleding
Ingo Renz
Björn Neroth
Per Haag

Centers:
University of Gothenburg, Sweden
Public Dental Health, County of Kristianstad, Sweden
Nobelpharma PROCERA, Sweden

Abstract:
The aim of the study is to evaluate the clinical performance of ceramic veneered titanium crowns. By using machine duplication and spark erosion standardized pure titanium copings were fabricated and subsequently veneered. A new type of low fusing ceramic was used for the veneering. A total of 41 crowns were fabricated and cemented on the intraoral preparations. The crowns were rated by two examiners using the CDA (California Dental Association) criteria regarding colour, form, surface, marginal fit and gingival reactions. Evaluations at baseline and after 1, 2 and 4 years. According to the CDA criteria the one year clinical results showed that the titanium crowns, veneered with the new ceramic material - PROCERA porcelain - performed satisfactory.

ΔΔΔ

Clinical study and performance of titanium restorations using the PROCERA method

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Name of investigator:
M Ch Sommer

Center:
University of Cologne, Germany

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Abstract:
Fixed partial dentures (crowns and bridges) machined by milling and spark erosion are used for restorations in a clinical study. The aim is to evaluate the clinical performance (marginal fit, durability and esthetics of titanium ceramics) of this system.

ΔΔΔ

3 years of clinical experience with titanium restorations (PROCERA System, Nobelpharma)

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Name of investigator:
Stephan Syndikus

Center:
Private Practice, Burghausen, Germany

Abstract:
Since november 1990, 300 crown and bridge restorations have been fabricated in titanium by the PROCERA method, most of them were metalceramic. 9 of them had corrections related to the metalceramic part. Excellent fit and color match in the range of acceptability or excellence were found. Plaque accumulation and inflammation index were recorded and statistically analysed.

ΔΔΔ

Clinical performance of machined titanium restorations

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
W Walter
K Böning
PD Reppel

Center:
Free University of Berlin, Germany

Abstract:
This clinical follow-up study based on 65 crowns and 19 fixed partial dentures including 138 prosthodontic units of which 106 were metalceramic and 32 non-veneered. All reconstructions had been fabricated by mechanical milling and electrical discharge machining (PROCERA system, Nobelpharma) during the period March 1990 to March 1991. The longest interval between insertion and the date of the last examination amounted to 3 years. Clinical assessment was carried out according to the quality evaluation rating system of the California Dental Association. The statistical evaluation was performed using the survivor estimator of Kaplan and Meyer. The charasteristics surface and colour, anatomic form including occlusion, margin integrity, and total quality rating were found to be in the range of excellence or acceptability in most cases. However, metalceramic failure occured more frequently in comparison with data known from conventional PFM sytems. Most of the defective veneers were correctable and did not require a removal of the restoration. The vast majority of reconstructions is still in function. From the results, conclusions concerning indication and construction of machined titanium restorations are drawn.

ΔΔΔ

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

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
Published

Journal:
Acta Odontol Scand 1989;47:279-286

Names of investigators:
Matts Andersson
Bo Bergman
Christer Bessing
Gunnel Ericsson
Peter Lundquist
Hans Nilson

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Centers:
Public Dental Health Service, County of Jämtland, Sweden
University of Umeå, Sweden

Abstract:
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 obatined 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.

ΔΔΔ

A 2-year follow-up study of titanium crowns

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
Published

Published in:
Acta Odontol Scand 1990;48:113-117

Names of investigators:
Matts Andersson
Bo Bergman
Christer Bessing
Gunnel Ericson
Peter Lundquist
Hans Nilson

Involved Institution:
University of Umeå, Sweden

Abstract:
In 1986, 149 patients were provided with titanium crowns. The method used for fabrication of the titanium copings involved two principles: machine duplication of models and electric discharge machining. For the veneering of the copings, Isosit was used for the first 90% of the crowns in the series, and the Dentacolor-Silicoater technique for the last 10%. Of 205 individual crowns cemented in 1986, 167 could be examined after 2 years. The crowns were rated by four independent examiners using the CDA quality evaluation system. Bleeding Index and Margin Index were also used. The Margin Integrity score was recorded as satisfactory for all crowns examined over the period studied. A vast majority of the margins were rated as excellent. Isosit (n=145) disclosed shortcomings including fractures and substantial deteriorations of Surface and Color and of Anatomic Form. With Dentacolor as veneering material (n=18) the results with the factors Surface and Color and Anatomic Form were still rated statisfactory after 2 years, and no fractures of the veneering material were registered. Bleeding Index and Margin Index showed comparatively small changes after 2 years.

ΔΔΔ

Metallkeramischer Zahnersatz aus Titan – eine Nachuntersuchung

Field of research:
Clinical trial, Tooth Supported Prostheses

Status:
Published

Journal:
Dtsch Zahnärztl Z 1992;47:524-526

Names of investigators:
PD Reppel
M Walter
K Böning

Center:
Free University of Berlin, Germany

Abstract:
The results of this clinical follow-up study of porcelain veneered crowns and bridges made by the PROCERA-System confirm the lower bonding strength. In 39 restorations with 62 PFM units the rate of defects was 15% at 18.5 month after insertion.

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Titanium copings veneered with PROCERA Ceramics

Field of research:
Multicenter Clinical trial, Tooth Supported Prostheses

Status:
Accepted for publication

Names of investigators:
Hans Nilson
Bo Bergman
Christer Bessing
Peter Lundquist
Matts Andersson

Centers:
University of Umeå, Sweden

Abstract:
In 1989 47 titanium copings veneered with a low-fusing ceramic were fabricated for 24 patients. Fourty-four crowns could be examined after a period varying between 26-30 months. The crowns were rated according to the CDA-system.

ΔΔΔ

PROCERA Single Crown and 3-unit Bridge Multicenter Study

Field of research:
Multicenter Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
Brien Lang
Charles Goodacre
Glen McGivney
Jeffrey Rubenstein
Shane White
Lee Jameson

Centers:
University of Michigan
Indiana University
State University of New York-Buffalo
University of Washington
University of Southern California
Northwestern University

Abstract:
University of Michigan is just completing the first years data collection for a multi center study on the PROCERA single crown and 3-unit bridge restoration. Investigators from the State of University of New York at Buffalo, Northwestern University, University of Washington, University of Southern California, Indiana University, and the University of Michigan provided 55 PROCERA units for each of their respective patient populations. The post cementation and one-year follow-up appointments included criterion base evaluation using the CDA (California Dental Association) quality assessment criteria for surface color and anatomy, anatomic form and margin integrity. The preliminary results have demonstrated an excellent response by these restorations in the oral environment.

ΔΔΔ

Clinical follow-up study of titanium and high-gold fixed partial dentures

Field of research:
Multicenter Clinical trial, Tooth Supported Prostheses

Status:
In progress

Names of investigators:
PD Reppel
W Walter
K Böning
C Köhler

Centers:
Private Practice, Bochum, Germany
Free University of Berlin, Germany
Private Practice, Dresden, Germany

ClearCorrect Exhibit 1002, Page 1845 of 3373

Abstract:

This clinical study based on a total of 73 patients in which three and four units PFM bridges were inserted in three participating insitutions during the period April 1991 to February 1992. All 40 titanium restorations including 134 prosthodontic units were fabricated by machining and spark erosion (PROCERA, Nobelpharma). A control group consisted of patients with 41 fixed partial dentures that were made from a conventional AuPt alloy. Clinical assessment included periodontal evaluation of abutment and control teeth as well as quality rating according to the quality evaluation system of the California Dental Association. Appointments were planned 14 days, one, two, and three years after insertion. In this paper, the one year results are presented. No significant differences between titanium and gold restorations concerning the periodontal parameters were found. There was a relatively high rate of defective veneers in the titanium group. However, most of the defects were correctable and did not require a removal of the restorations. Furthermore, grouping the reconstructions according to their date of insertion leads to the conclusion that the occurence of metalceramic complications was strongly decreasing in those bridges that were inserted in the later phases of the insertion period. This may be attributed to the accumulation of experience in the processing technique. Improvements of the quality standard of titanium machining and veneering have been reported recently and were referred to.

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BRÅNEMARK SYSTEM and PROCERA Method Accuracy and Precision of Fit

Field of research:
Precision of fit in vitro

Status:
In progress

Names of investigators:
Jack Edge
Merle Jaarda
Brien Lang
Kenneth May
Michael Razzoog
Melinda Russel
John Wataha
Rui Wang

Center:
University of Michigan, United States of America

Abstract:
This project involves four separate experiments to measure the accuracy and Precision of fit of the BRÅNEMARK SYSTEM/PROCERA Method components.
1. The first experiment involves the measurement of the various implant components using a laser coordinate measurement system to determine the accuracy and quality control of the parts and their interchageability.
2. The second experiment involves measuring the accuracy in the individual assembly of a gold cylinder or a PROCERA machined titanium component with an abutment or abutment replica, and to determine the precision of fit.
3. The third experiment involves measurement of six different welding sequences to determine the optimum PROCERA laser welding protocol.
4. The fourth experiment involves the measurement and comparison of the PROCERA laser welded framework with a cast alloy framework for accuracy and precision of fit with the implant abutments in a controlled laboratory setting.

Δ Δ Δ

PROCERA Framework Precision of Fit

Field of research:
Precision of fit in vitro

Status:
In progress

Names of investigators:
Jack Edge
Merle Jaarda
Brien Lang
Kenneth May
Michael Razzoog
Melinda Russel
John Wataha
Rui Wang

Center:
University of Michigan, United States of America

Abstract:
A project has been initiated with the support of Nobelpharma AB to assess the fit between the implant abutment and the PROCERA laser welded titanium implant framework using a laser digitizer as the micro measurement system to determine the accuracy at this important interface. A total of twenty-four frameworks and their corresponding master casts are being measured and compared.

Δ Δ Δ

PROCERA Crown and Precision of Fit to its Corresponding Die

Field of research:
Precision of fit in vitro

Status:
In progress

Names of investigators:
Jack Edge
Merle Jaarda
Brien Lang
Kenneth May
Michael Razzoog
Melinda Russell
John Wataha
Rui Wang

ClearCorrect Exhibit 1002, Page 1847 of 3373

Abstract:
A project has been initiated with the support of Nobelpharma AB to assess the fit between a PROCERA crown and the die from which it was made. This same die is then used to wax and prepare a cast alloy crown for fit measurements and the data compared with the measurements for the PROCERA crown. The measurement system is a 3-dimensional laser digitizer that is capable of determining differences at the micron level. Also to be included in this project are similar measurements comparing the 3-unit titanium/porcelain PROCERA bridge with a conventionally cast 3-unit restoration using one of the precious metal alloys.

ΔΔΔ

The effect of tooth preparation form on the fit of PROCERA crowns

Field of research:
Precision of fit in vitro

Status:
In progress

Names of investigators:
Charles Goodacre
Carlos Munoz

Center:
Indiana University, United States of America

Abstract:
This project is evaluating the effect of different tooth preparation forms and finish lines on the fit of PROCERA crowns.

ΔΔΔ

An In-vitro evaluation of the marginal and internal adaptation of an all-ceramic crown fabricated by the PROCERA method

Field of research:
Precision of fit in vitro

Status:
In progress

Names of investigators:
John Phelps
Charles Goodacre
Carlos Munoz
Keith Moore

Center:
Indiana University, United States of America

Abstract:
This project is evaluating the marginal and internal adaptation of all-ceramic copings and crowns to other all-ceramic systems.

ΔΔΔ

PROCERA Accuracy of Fit

Field of research:
Precision of fit in vitro

Status:
In progress

Name of investigator:
Shane White

Center:
University of Southern California, United States of America

Abstract:
University of Southern California is currently completing its part of the PROCERA multicenter crown and bridge clinical trial. Also, a laboratory study of the accuracy of PROCERA crowns has started. The study is investigating variables related to tooth and die preparation. The results will help dentists and lab technicians to achieve optimal results.

ΔΔΔ

An In-vitro evaluation of the marginal and internal adaptation of titanium copings and metal ceramic crowns

Field of research:
Precision of fit in vitro

ClearCorrect Exhibit 1002, Page 1848 of 3373

Status:
Investigation completed

Names of investigators:
Silvia Valderrama
Charles Goodacre
Carlos Munoz
Keith Moore

Center:
Indiana University, United States of America

Abstract:
This study compared the fit of gold-platinum-palladium (Au-Pt-Pd) and PROCERA titanium copings both before and after the fusion of porcelain and before and after cementation. No statistical difference was found in the marginal fit of the cemented or uncemented Au-Pt-Pd and titanium restorations either before or after the fusion of porcelain. All restorations were found to be within the clinical acceptable range of 50 µm or below.

ΔΔΔ

A comparison of fit of spark eroded titanium copings and cast gold alloy copings.

Field of research:
Precision of fit in vitro

Status:
Submitted for publication

Name of investigator:
Ian R Harris

Center:
Eastman Dental Hospital, London, England

Abstract:
The overall fit of PROCERA titanium copings was compared with that of cast gold alloy copings in vitro. Silicone " cement film analogues" were retreived, sectioned and measured using an image analyser. Whilst the overall fit of titanium and gold alloy copings was comparable, in the marginal areas the space between die and coping was larger for PROCERA copings; the difference was statistically significant.

Festsitzender Zahnersatz aus gefrästem/funkerodierten Titan

Field of research:
Precision of fit, in vivo

Status:
Published

Journal:
Dtsch Zahnärztl Z 1991;46:756-758

Names of investigators:
PD Reppel
K Böning
M Walter

Center:
Free University of Berlin, Germany

Abstract:
In a clinical study the accuracy of fit of 82 crowns manufactured with the PROCERA system was investigated. The average space width was 71 µm. Roughness of the eroded surface was found to be similar to that of coarsely ground metal.

ΔΔΔ

Non-cast Titanium restorations in fixed prosthodontics

Field of research:
Precision of fit, in vivo, in vitro

Status:
Published

Journal:
J Oral rehabil 1992;19:281-287

Names of investigators:
K Böning
M Walter
PD Reppel

Center:
Free University of Berlin, Germany

ClearCorrect Exhibit 1002, Page 1849 of 3373

Abstract:
The accuracy of fit of crowns, fabricated by the PROCERA system, was examined before and after ceramic veneering in vitro as well as in vivo. Before veneering, on conical surfaces space widths were approximately 53 µm in vitro and 69 µm in vivo. At shoulders and occlusal surfaces, spaces around 430 µm were measured in vitro and 500 µm were measured in vivo. After ceramic veneering slight increases of space widths could be observed.

ΔΔΔ

The fit of PROCERA titanium crowns

Field of research:
Precision of fit, in vivo, in vitro

Status:
Published

Journal:
Acta Odontol Scand 1993;51:129-134

Name of investigator:
Stig Karlsson

Center:
University of Gothenburg, Sweden

Abstract:
Inner and marginal discrepancy or fit of PROCERA titanium crowns have been investigated by means of a replica technique. The fit was evaluated to the stone die and in vivo to the tooth before cementation. The marginal adaptation, 60 mikrometers, was significantly better than the occlusal areas and the axial surfaces respectively.

ΔΔΔ

A measuring method to determine the adaption of implant supported prostheses

Field of research:
PROCERA in house project

Status:
In progress

Name of investigator:
Lennart Carlsson

Center:
Nobelpharma AB, Sweden

Abstract:
An in-vitro method to measure the fit of implant supported prostheses is developed. This method uses a coordinate measuring machine for data collection and a special software to calculate the misfit in five degrees of freedom for each implant-abutment junction. The method has shown to be useful for determination of the misfit between the mastercast and the bridgework both before and after veneering with acrylic or porcelain. Furthermore, the method has been used to evaluate the precision of different methods for impression taking, and mastercast fabrication.

ClearCorrect Exhibit 1002, Page 1850 of 3373

Aluminiumläckage från aluminiumoxid och aluminiumplåt

Field of research:
Biocompability

Status:
Published

Journal:
Tandläkartidningen 1991;83:634-6

Names of investigators:
A Odén
E Wiatr-Adamczak
S Olsson

Center:
Karolinska Institutet, Stockholm, Sweden

Abstract:
Leakage of aluminium from dense sintered high purity alumina and aluminium into artificial saliva at 37° C with pH 5, 6 and 7 was studied during 1 month. No release of aluminium from dense sintered high purity alumina could be detected.

ΔΔΔ

Fatigue Bending Test of Homogeneous and Laser Welded Beams

Field of research:
PROCERA in house project

Status:
Investigation completed

Name of investigator:
Anders Boss

Center:
Nobelpharma PROCERA, Sweden

Abstract:
Beams with the dimension 3.5 x 2.5 mm were subjected to a fatogue bending test. The maximal numbers of cycles were 1 x 106. Three different types of beams were tested. The first group consisted of homogeneous beams of commercially pure titanium, the second of homgeneous gold alloy (Esteticor), and the third of beams cut by wire electric discharge machine and subsequently laser welded together. Results showed that the homogeneous commercially pure titanium beams were the most resistant, while the welded commercially pure titanium beams were only slightly less resistant than the homogeneous gold alloy beams.

ΔΔΔ

Fatigue Bending Test of Porcelain Veneered Titanium Beams

Field of research:
PROCERA in house project
Status:
Investigation completed

Name of investigator:
Anders Boss

Center:
Nobelpharma PROCERA, Sweden

Abstract:
During firing of porcelain, the commercially pure titanium porcelain compound is subjected to multiple heat exposures. A fatigue bending test was performed with porcelain veneered, commercially pure titanium beams, that have previously been cut by wire electric discharge machine, and subsequently laser welded together. Results indicated an increased strength of the veneered beam compared to the unveneered EDM cut welded beam.

ΔΔΔ

Studies on laser welded titanium

Field of research:
Properties and design of supportive structure

Status:
Accepted for publication

ClearCorrect Exhibit 1002, Page 1851 of 3373

Names of investigators:
M Roggensack
M Walter
K Boening

Center:
Free University of Berlin, Germany

Abstract:
The PROCERA laser welding unit and a plasma welding unit were investigated for their suitability to fuse crowns and pontics. mechanical tests were carried out using the woehler method (permanent bending test). Both units delievered similar mechanical properties. Micro-morphological pictures exhibited a zone of increased grain sizes (thermal influence zone) after plasma welding. For dental purposes the laser unit seems to be more suitable, because the thermal influence zones are much smaller.

Δ Δ Δ

Mechanical behaviour of dental ceramics

Field of research:
Properties and design of supportive structure

Status:
In progress

Names of investigators:
David Rowcliffe
Kaiyang Zeng

Center:
Royal Institute of Technology, Stockholm, Sweden

Abstract:
The main goal is to evaluate the mechanical behaviour of alumina, alumina/porcelain 2-layer composites and porcelain, and also to compare the strength of PROCERA porcelain/full ceramic, with the strength of the porcelain used in the above mentioned clinical study. A further goal is to characterise the bond between alumina and porcelain. The porcelain to be used for PROCERA all-ceramic crowns show similar values regarding mechanical strength as the porcelain used in the clinical study.

A new all-ceramic crown

Field of research:
Properties and design of supportive structure

Status:
Published

Journal:
Acta Odontol Scand 1993;51:59-64

Names of investigators:
Matts Andersson
Agneta Odén

Center:
Karolinska Institutet, Stockholm, Sweden

Abstract:
A method of manufacturing an all-ceramic crown composed of a coping of dense-sintered, high-purity alumina with dental porcelain is described. This method takes the sintering shrinkage of alumina into consideration and makes it possible to produce individual dental copings in dense-sintered, high-purity alumina. which is a biocompatible implant material. The alumina used has density, grain size, and flexural strength within the limits of the values required in ISO 6474-1981, "Implants for surgery, ceramic materials based on alumina".

Δ Δ Δ

Die Gestaltung nichtgegossener Titangerüste für die keramische Verblendung

Field of research:
Properties and design of supportive structure

Status:
Published

Journal:
Zahnärztl Welt 1993;102:94-98

Names of investigators:
P-D Reppel
M Walter
K Böning

ClearCorrect Exhibit 1002, Page 1852 of 3373

Center:
Free University of Berlin, Germany

Abstract:
Macined titanium substructures with an approximate metal thickness of 0.5 mm and a veneer covering the whole surface were compared to frameworks with a palatal metal surface using the VOSS-test. Crowns without palatal veneer stood a mean force of 1258 N, while the fully covered crowns exhibited a mean value of only 563 N.

ΔΔΔ

Laser welding of titanium in dentistry

Field of research:
Properties and design of supportive structure

Status:
Published

Journal:
Acta Odontol Scand 1988;46:247-253

Names of investigators:
Göran Sjögren
Matts Andersson
Maud Bergman

Centers:
University of Umeå, Sweden
Public Health Service, Fåker, Sweden

Abstract:
Unalloyed titanium of the quality used for osseointegrated implants by BRÅNEMARK SYSTEM is also sometimes used for the metallic part of the prosthetic superstructure placed on the fixtures and for crowns and bridges of conventional type. Forty bars of titanium, 8 of ASTM B 348-grade-1 quality and 32 of ASTM B 348-grade-2 quality, were laser-welded, using dissimilar laser joint variables. Tensile strength, 0.2% proof stress, and percentage elongation of the welded bars were measured and compared with the corresponding values for the titanium bars as delivered with those of brazed type-3 gold alloy bars of similar dimensions. The type of fracture was evaluated from fractographs. The result showed that the use of certain defined laser joint variables during welding produced values for the mechanical properties studied with were more favorable than those obtained from the brazed gold bars. The fracture of the titanium specimens was ductile, with dimples occuring at the fracture surfaces.

ΔΔΔ

A comparison of the hardness of titanium ceramometals

Field of research:
Properties and design of supportive structure

Status:
Submitted for publication

Names of investigators:
A King
E Lautenschlager
J Chai
J Gilbert

Center:
Northwestern University, Chicago, United States of America

Abstract:
The purpose of this study was to compare the hardness of machine milled titanium and cast titanium. Five specimens of each group underwent one of the three treatments: 1. No heat treatment, 2. A standard heat treatment, 3. An extended heat treatment. Results indicated that the Knoop hardness arranged by significant groups was as follows: as cast titanium < cast titanium standard treatment group < cast titanium exteded treatment group and as milled titanium < milled titanium standard treatment and milled titanium extended treatment groups.

ΔΔΔ

Untersuchung der keramischen Haftung auf lasergeschweißtem Titan

Field of research:
Properties and design of supportive materials

Status:
Accepted for publication

ClearCorrect Exhibit 1002, Page 1853 of 3373

Names of investigators:
M Walter
K Böning
PD Reppel

Center:
Free University of Berlin, Germany

Abstract:
Metalceramic bonding of laser welded titanium specimens was tested according to ISO 9693 without and after corrosion in comparison with unwelded specimens. Basing on metallographical examination, x-ray analyses and microsclerometric measurements, informations on the character of fractures were gained. An increased metalceramic failure rate due to the laser welding process has not to be expected. The weakest part of the metalceramic compound in welded and unwelded, not corroded specimens was found to lie in a zone of extremely increased hardness on the metal side, very close to the interface.

ΔΔΔ

Cast versus Milled/Spark-Eroded Titanium Restorations–Castability and Porosity of Titanium Samples

Field of research:
Properties and design of supportive structure

Status:
Investigation completed

Name of investigator:
M Ch Sommer

Center:
University of Cologne, Germany

Abstract:
The castability of 6 titanium castings devices was tested using 3 different wax patterns. Radiograph and density measurements according to DIN 53479 were made in order to determine defects and porosities in the castings. Radiographs revealed that most of the cast titanium specimen showed internal defects which was supported by density measurements (values below 4.5g/cm3). No porosites were measured in the milled/spark eroded samples.

Solubility of Cast and Milled/Spark-Eroded Commercially Pure Titanium.

Field of research:
Properties and design of supportive structure

Status:
Published

Journal:
Deutsche Zahnärztliche Zeitschrift. 47
Jahrgang 1992

Names of investigators:
M Ch Sommer
P Pfeiffer
H U Kasper

Center:
University of Cologne, Germany

Abstract:
The solubility of cast and milled/spark eroded commercially pure titanium for crown and bridge restorations was examined in lactic acid/saline solutions at different pH values by means of atomic absorption spectrophotometry. The solubility values of the milled/spark eroded discs was slightly below those of the cast discs with the oxide layer removed. Improvements in the quality of cast titanium surfaces can be acheieved by using refined investment materials (Zirconium-based materials).

ClearCorrect Exhibit 1002, Page 1854 of 3373

Dentacolor as veneering material for titanium

Field of research:
Multicenter Clinical trial, Tooth Supported Prostheses

Status:
Submitted for publication

Names of investigators:
Bo Bergman
Hans Nilson
Matts Andersson

Center:
University of Umeå, Sweden

Abstract:
Fifty-one patients who had been provided with 104 Dentacolor veneered titanium copings/pontics were recalled after periods varying between 51 and 72 months. Fourty-two patients with 85 units - 67 crowns and 18 pontics - attended. In this retrospecitve study the condition of the veneering material was rated.

Δ Δ Δ

Bonding characteristics of the titanium-porcelain system used by PROCERA

Field of research:
Porcelain, bonding properties

Status:
In progress

Name of investigator:
Jeremy Gilbert

Center:
Northwestern University, Chicago, United States of America

Abstract:
Three point flexural tests and shear tests of the PROCERA porcelain to titanium bond have been performed. The failure mode as well as the nature of the interface between metal and porcelain have been characterized using scanning electron microscopy and energy dispersive analysis of x-rays. The goal of this research is to understand the nature of the interfacial bond and to determine how it is affected by the process parameters used to for the bond. For comparison, a noble metal porcelain system (A-37 with Ceramco II porcelain) was also tested in three point bending and in shear. Both the three point bending results and the shear results indicate that the Ti with bonding agent had a small but statistically significant increase in the failure strength compared to the A-37 porcelain system

Δ Δ Δ

Bond strength of bonding materials to milled pure Titanium (PROCERA)

Field of research:
Porcelain, bonding properties

Status:
In progress

Names of investigators:
W-D Grimm
Th Pilecki
M Pilecki
A Blocher
S Deutschmann

Center:
Private University of Witten/Herdecke, Germany

Abstract:
The aim of this study is to investigate the bond strength of bonding materials (composite and glass ionomer cements) to Titanium specimens in relation to wetability (surface energy and surface tension) by using "microscopial waterdrop surface angle", radioactive labeled (In111-oxinat) bacteria and four-point flexure test (ZWICK-machine).

ClearCorrect Exhibit 1002, Page 1855 of 3373

Cast versus Milled/Spark-Eroded Titanium-Ceramic Restorations – Bond Strength of Different Ceramics

Field of research:
Porcelain, bonding properties

Status:
Investigation completed

Names of investigators:
M Ch Sommer
R Marx

Centers:
University of Cologne, Germany
University of Aachen, Germany

Abstract:
The aim of this study was to determine the bond strength of 5 different titanium ceramics to cast and also to milled/spark-eroded (PROCERA-System) commercially pure titanium. Also the fatigue strength of complete ceramo-metal systems (crowns) was evaluated. The results seem to indicate that bond strength and fatigue strength of crowns of the milled/spark-eroded specimen showed higher values than those of the cast c.p. titanium samples.

Δ Δ Δ

Metall-Keramik-Verbund von gegossenem Titan

Field of research:
Porcelain, bonding properties

Status:
Published

Journal:
Dtsch Zahnärztl Z 1991;46:750-753

Names of investigators:
K Böning
M Walter

Center:
Free University of Berlin, Germany

Abstract:
The metal-ceramic bonding strength of cast and machined titanium was tested according to DIN draft 13927. Cast specimens with the alpha-case not being removed showed the worst results (24 N/mm2). Cast specimens without alpha-case and machined specimens showed similar results around 35 N/mm2, but did not match the reference (AuPt-Alloy/Biodent Ceramics) with 45 N/mm2

Δ Δ Δ

Dental Ceramics for Titanium Restorations

Field of research:
Porcelain, bonding properties

Status:
Published

Journal:
Deutsche Zahnärztliche Zeitschrift, 46 Jahrgang 1991

Names of investigators:
M Ch Sommer
H Schwickerath
R Marx
G Witt

Centers:
University of Cologne, Germany
University of Aachen, Germany

Abstract:
Bending, splitting tensile and bond strengths of four ceramic systems for veneering titanium frameworks as well as the fatigue strength of the complete ceramo-metal crown were evaluated. In the laboratory test, the mechanical properties of these systems were comparable with those of conventional dental ceramics.

Δ Δ Δ

Metallkeramik mit nicht gegossenem Titan- In -Vitro- und In-Vivo-Untersuchungen

Field of research:
Porcelain, bonding properties

ClearCorrect Exhibit 1002, Page 1856 of 3373

Status:
Published

Journal:
Zahnärztl Welt 1992; 101:364-368

Names of investigators:
M Walter
K Böning
PD Reppel

Center:
Free University of Berlin, Germany

Abstract:
The metal-ceramic compound of non-cast titanium was tested in a laboratory as well as in a clinical study. Only one of two ceramics passed the bending test (ISO). On the contrary, this ceramic mass exhibited a significantly lower shear stress in the 3-point bending test (DIN). After a storage in a corrosion solution for 30 days this difference was no longer detectable. In summary, a reduced bonding strength was found in comparison with conventional PFM systems. Microscopic examination and energydispersive x-ray analyses indicated that the interface between metal and opaque mass respectively bonder is the weak point of the compound. The results of the clinical study underline those of the laboratory tests. After an average period of wear amounting to 12.5 months the failure rate was 13% in 39 restorations including a total of 62 metal-ceramic units.

Δ Δ Δ

A study of bond strength of low fusing porcelain to titanium and palladium-copper alloy

Field of research:
Porcelain, bonding properties

Status:
Submitted for publication

Names of investigators:
I Pang
J Gilbert
E Lautenschlager
J Chai

Center:
Northwestern University, Chicago, United States of America

Abstract:
The bond strength among palladium-copper alloy/VMK 68 porcelain, cast titanium/Duceratin, and machine-milled spark-eroded titanium/PROCERA porcelain combinations was examined using a three point bending test. Two completely debonded specimens and two longitudinally sectioned specimens of each group were studied under a scanning electron microscope to determine the mode of bond failure. The results showed that the bond strength of Pd-Cu/VMK 68 was significantly higher than those of two titanium/porcelain combinations.

Δ Δ Δ

The effect of multiple firings on bond strength of low fusing porcelain to titanium

Field of research:
Porcelain, bonding properties

Status:
Submitted for publication

Names of investigators:
I Pang
J Gilbert
E Lautenschlager
J Chai

Center:
Northwestern University, Chicago, United States of America

Abstract:
The purpose of this study was to investigate the effect of multiple firings on the bonf strength of a low-fusing porcelain to machine-milled pure titanium using a three-point bending test. Samples were divided into five groups of different porcelain firing schedules. Results showed that there was no significant difference in the bond strengths among these five porcelain firing schedules.

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PROCERA Porcelain Color Stability

Field of research:
Porcelain, color stability

Status:
In progress

Names of investigators:
Jack Edge
Merle Jaarda
Brien Lang
Kenneth May
Michael Razzoog
Melinda Russell
John Wataha
Rui Wang

Center:
University of Michigan

Abstract:
A project has been initiated with the support of Nobelpharma AB to assess the color stability of the porcelain used with a PROCERA crown or the PROCERA laser welded implant-supported fixed prosthesis. Porcelain samples of varying shades, both with and without surface staining, have been measured using the Minolta Chromometer II Reflectance colorimeter prior to an accelerated aging process. The samples will be re-measured after 100 hours (equivalent to 1 year) and 300 hours to determine if any color change has occured. Very early data on the color stability of PROCERA porcelain subjected to aging (one year equivalent) is showing:
1. No noticable color change of PROCERA porcelain as determined by National Bureau of standard Units (NBS Unit= $\Delta E^*ab \times 0.92$)
2. No statistically significant difference in color change between PROCERA porcelain and conventional porcelain when subjected to accelerated aging.

Δ Δ Δ

Effect of topical fluorides on the surface of different porcelain systems

Field of research:
Porcelain, effect of fluorides

Status:
Investigation completed

Names of investigators:
David Brown
Carlos Munoz
Charles Goodacre

Center:
Indiana University, United States of America

Abstract:
This project evaluated the effect of a 1.2% acidulated phosphate fluoride solution (APF) and an 8% stannous flouride solution (NaF) on the surface of PROCERA, Dicor, Vitadur-N and VMK-68 porcelains. The APF solution produced an almost imperceptible etching of PROCERA and an obvious etch on all the other materials. The stannous fluoride solution had a little or no effect on the PROCERA specimens and a slight effect on the other porcelains.

Δ Δ Δ

A comparison of the tensile strength of titanium ceramometals

Field of research:
Porcelain, other areas

Status:
Submitted for publication

Names of investigators:
A King
E Lautenschlager
J Chai
J Gilbert

Center:
Northwestern University, Chicago, United States of America

Abstract:
The aim of this study was to compare the mechanical properties of machine milled pure titanium and cast titanium. Each group was treated under three different conditions: as cast (or as milled), standard heat treatment and extended heat treatment. There was no difference in the mechanical properties of as cast and as milled titanium.

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CONTEMPORARY ORTHODONTICS

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with

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and

James L. Ackerman
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Chapter 15

The First Stage of Comprehensive Treatment: Alignment and Leveling

Goals of the first stage of treatment
Alignment
  Principles in the choice of alignment arches
  Alignment arches for 18-slot edgewise
  Alignment with 22-slot edgewise
  Alignment with Begg technique
Special problems in alignment
  Crossbite correction
  Impacted or unerupted teeth
  Diastema closure
Leveling
  Leveling by extrusion (relative intrusion)
  Leveling by intrusion

The idea of dividing treatment into stages, which makes it easier to discuss technique, is particularly associated with the Begg technique. The three major stages discussed in this and the following two chapters are those traditionally used to describe the stages of Begg treatment,[1] but the division is reasonably applicable to edgewise treatment as well. These major stages of comprehensive treatment are: (1) alignment and leveling, (2) correction of molar relationship and space closure, and (3) finishing. The latter two stages are covered in Chapters 16 and 17, respectively. Not every patient will require the steps of each treatment stage, but whatever the technique, it is likely that both the archwires and the way they are utilized will be changed at the various stages. In theory at least, there is more to be done in the finishing stage with the Begg appliance, particularly torquing of incisors and root uprighting of canines and premolars, than if a contemporary edgewise appliance is used. Nevertheless, the considerations are the same, and at least some appliance adjustment is needed to finish comprehensive treatment with even the most cleverly preadjusted edgewise appliance.

Goals of the First Stage of Treatment

Treatment for any patient should be undertaken only after a thorough analysis of the patient's problems, the preparation of a treatment plan to maximize benefit for that patient, and the development of a sequence of orthodontic treatment steps (mechanotherapy) to produce the desired result. The procedure outlined in Chapters 6 and 7, culminating in an outline of the steps in treatment, is recommended.

In almost all patients with malocclusion, at least some teeth are initially malaligned. The great majority also have either excessive overbite, resulting from some combination of an excessive curve of Spee in the lower arch and an absent or reverse curve of Spee in the upper arch, or (less frequently) anterior open bite caused by excessive curve of Spee in the upper arch and little or none in the lower arch. The goals of the first phase of treatment are to bring the teeth into alignment and correct vertical discrepancies by leveling out the arches. In this form, however, neither goal is stated clearly enough. For proper alignment, it is necessary not only to bring malposed teeth into the arch, but also to specify and control the anteroposterior position of incisors, the width of the arches posteriorly, and the form of the dental arches. Similarly, in leveling the arch, it is necessary to determine and control whether the leveling occurs by elongation of posterior teeth, intrusion of incisors, or some specific combination of the two (see Chapter 7 for treatment planning details).

The form of the dental arches obviously varies between individuals. Although the orthodontist has some latitude in changing arch form, and indeed must do so in at least one arch if the upper and lower arch forms are not compatible initially, more stable results are achieved when the patient's original arch form is preserved during orthodontic treatment (see Chapter 12 for a discussion of arch form and archwire shape). The light resilient archwires used in the first stage of treatment need not be shaped to the patient's arch form as carefully as the heavier archwires used later in treatment, but from the beginning, the archwires should reflect each individual's arch form. If preformed archwires are used, their shape should be selected and adjusted with this in mind.

Because the orthodontic mechanotherapy will be different depending on exactly how alignment and leveling are to be accomplished, it is extremely important that the desired position of the teeth at the end of each stage of treatment be clearly visualized before that stage is begun (Fig. 15-1). The best mechanotherapy for alignment will result in incisors that are far too protrusive, for instance, if the extractions necessary to prevent protrusion were not part of the plan. Similarly, unless leveling by intrusion is planned when it is needed, the appropriate mechanics are not likely to be selected.

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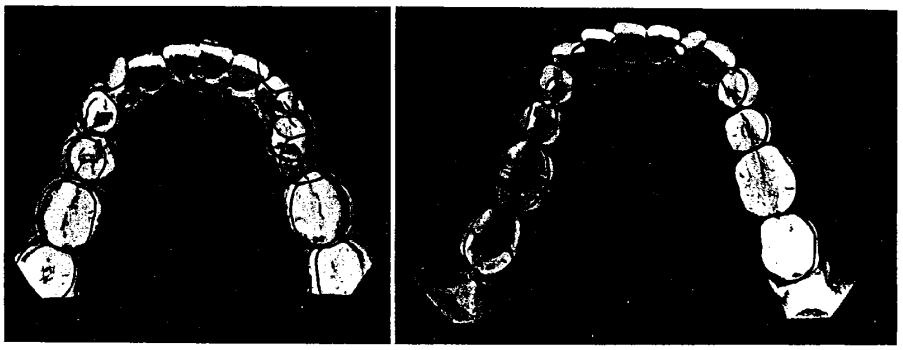


Fig. 15-1 ■ Goals of the first stage of treatment can be visualized on a print (from an ordinary office copying machine) of the dental arches. **A,** Expansion of the arch in a 12-year-old girl, to provide space for a blocked-out second premolar. Some anterior movement of the incisors will occur, but this can be partially prevented by including a component of lateral expansion. **B,** Alignment of crowded incisors with premolar extraction in a young adult. With the incisors aligned in the same anteroposterior position, about half the extraction space on each side will remain. This view does not show space required for leveling, which must not be overlooked in planning (see Chapter 6).

In this and the subsequent chapters, it is expected that the appropriate goals for an individual patient have been clearly stated, and the discussion here concerns only the treatment techniques necessary to achieve those goals. Orthodontic treatment without specific goals can be an excellent illustration of the old adage, "If you don't know where you're going, it doesn't matter which road you take."

Alignment

■ Principles in the Choice of Alignment Arches

In nearly every patient with malaligned teeth, the root apices are closer to the normal position than the crowns, because malalignment almost always develops as the eruption paths of teeth are deflected. Putting it another way, a tooth bud occasionally develops in the wrong place, but (barring surgery that displaces all tissues in the area, as sometimes happens in cleft palate repairs, or the severe tipping from lip pressure that displaces maxillary central incisors in Class II, division 2 cases) the root apices are likely to be reasonably close to their correct positions even though the crowns have been displaced as the teeth erupted. To bring teeth into alignment, a combination of labiolingual and mesiodistal tipping guided by an archwire is needed, but root movement usually is not. Several important consequences for orthodontic mechanotherapy follow from this:

1. Initial archwires for alignment should provide light, continuous forces, to produce the most efficient tipping tooth movements. Heavy forces, in contrast, are to be avoided.

2. The archwires should be able to move freely within the brackets. For mesiodistal sliding along an archwire, at least 2 mil clearance between the archwire and the bracket is needed, and 4 mil clearance is desirable. This means that the largest initial archwire that should be used with an 18-slot edgewise bracket is 16 mil, whereas 14 mil would be more satisfactory. With the 22-slot bracket, an 18 mil archwire would be close to ideal from a bracket clearance point of view. Whatever the archwire, it should be ligated loosely in the bracket (indeed, this is probably the critical factor in determining frictional resistance to sliding).

3. Rectangular archwires, particularly those with a tight fit within the bracket slot so that the position of the root apex could be affected, normally should be avoided. The principle is that it is better to tip crowns to position during initial alignment, rather than displacing the root apices; the corollary is that although a highly resilient rectangular archwire such as 17 × 25 NiTi could be used in the alignment stage, this is not advantageous because the rectangular archwire will create unnecessary and undesirable root movement during alignment (Fig. 15-2). Round wires for alignment are preferred.

The wires for initial alignment purposes require a combination of excellent strength, excellent springiness, and a long range of action. Ideally, there would be an almost flat load-deflection curve, with the wire delivering about 50 gm (the optimum force for tipping) at almost any degree of deflection. The variables in selecting appropriate archwires for alignment are the archwire material, its diameter, and the distance between attachments (interbracket span). These factors have been discussed in Chapter 10 but are briefly reviewed here. Considering them in turn:

Archwire Material. The titanium-based archwires, both nickel-titanium (any of the NiTi wires) and beta-tita-

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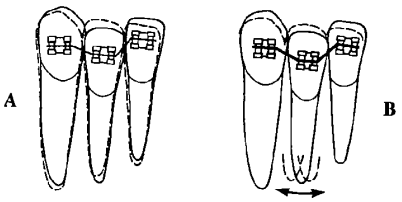


Fig. 15-2 ■ A tightly fitting resilient rectangular archwire for initial alignment is almost always undesirable because it produces back-and-forth movement of the root apices as the teeth move into alignment. This occurs because the moments generated by the archwire change as the geometry of the system changes with alterations in tooth position. **A,** Diagrammatic representation of the alignment of a malposed lateral incisor with a round wire and clearance in the bracket slot. With minimal moments created within the bracket slot, there is little displacement of the root apex. **B,** With a resilient rectangular archwire, back-and-forth movement of the apex occurs before the tooth ends up in essentially the same place as with a round wire. This has two disadvantages: it increases the possibility of root resorption, and it slows the alignment process.

nium (TMA), offer a better combination of strength and springiness than do steel wires (see Chapter 10). The NiTi wires, however, are both springier and stronger in small cross-section than beta-Ti. For this reason, NiTi wires are particularly useful in the first stage of treatment, and the remarkably flat load-deflection curve for austenitic NiTi (A-NiTi) makes it the preferred material. If steel is used at this stage, either multistranded wires or loops to increase springiness (see following) are needed. Beta-Ti rarely is the best choice for an initial archwire.

Size of Wire. For the superelastic A-NiTi wires, the manufacturer's preparation of the material determines the clinical performance. For M-NiTi, beta-Ti, or steel wires, wire size is an important criterion. As wire size increases, strength increases rapidly, while springiness decreases even more rapidly. For alignment, the smallest diameter (and therefore the springiest) wire that has adequate strength would be preferred. When multiple strands of the same diameter wire are used, strength is added while springiness is relatively unaffected. This method of combining steel strands that individually would not be strong enough makes steel wires without loops practical at the initial stage of treatment.

Distance Between Attachments. As the distance increases between the points of attachment of a beam, strength decreases rapidly while springiness increases even more rapidly. The width of brackets is an important factor: the wider the individual brackets, the smaller the interbracket span. A powerful means of gaining increased springiness and range of action, without sacrificing too much strength, is to bend a loop into an archwire between two teeth, thus increasing the distance along the archwire between attachments.

Four archwire segments with equivalent springiness are displayed in Fig. 15-3. The loop designs for the 14 and 16 mil steel wires were deliberately configured to produce this response. Note that with the addition of more wire to produce a typical vertical loop (the average vertical loop is 5 to 6 mm high), the spring properties of 16 mil steel would be somewhat better than M-NiTi or multistranded steel, whereas 14 mil steel would be markedly superior.

Based on this information, what combinations of bracket widths, bracket slot size, and archwire characteristics would be logical choices for initial alignment? As the analysis in Chapter 10 illustrates, it is most logical to use narrow brackets with 18-slot edgewise, because in the latter stages of treatment the rectangular steel archwires that fill the slot are more effective with larger interbracket spans, and sliding teeth along the archwire is relatively unimportant. With 22-slot edgewise, wider brackets are logical, since the larger slot provides the clearance needed for sliding but makes it difficult to obtain close engagement of rectangular archwires for space closure with loops. The different slot size affects the choice of archwires at each stage of treatment. Accordingly, the selection of initial archwires for the two major systems seen in clinical practice, 18-slot with narrow brackets, and 22-slot with wider brackets, is described separately in the following section.

■ Alignment Arches for 18-Slot Edgewise

The principle that there should be 2 mils of clearance for initial wires means that a 16 mil round wire is the largest that should be considered for initial alignment in the 18-slot appliance. The three major possibilities for alignment arches are multistranded steel wires, nickel-titanium

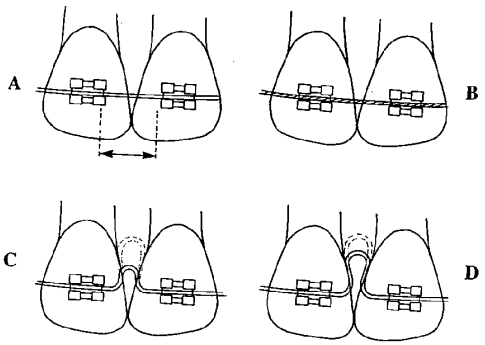


Fig. 15-3 ■ Four equivalently springy archwire segments: **A,** 16 mil M-NiTi; **B,** 17.5 mil (3 × 8) twist steel; **C,** 14 mil steel; **D,** 16 mil steel. The small amount of wire added in the loops to give equivalent springiness in 14 and 16 mil steel *(solid red)* may be surprising. With the addition of more wire to produce the size of loops normally used *(dashed red),* spring properties of these solid wires, particularly 14 mil steel, can be superior to M-NiTi or braided steel wires. Loops in 14 mil steel remain superior even to A-NiTi when only one area of the dental arch is malaligned and springiness is desired just in that section of the archwire.

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wires, and single-stranded steel wires with loops. Considering each in turn:

Multistranded Steel Wires. Despite its excellent properties, 17.5 mil multistranded steel wire (3 × 8) is too large for effective use in 18-slot brackets. The difficulty of sliding teeth along a 17.5 mil wire in 18 brackets is compounded by the irregular surface of the twisted strands, which can bind against the corners of the bracket. A 15 mil twist wire (3 × 7) gives adequate clearance, but its physical properties are markedly inferior, and so this size of twist wire also can be eliminated as impractical.

Nickel-Titanium. In contrast to steel wires that tend to be too stiff and not strong enough for good alignment, nickel-titanium (NiTi) wires have outstanding properties of springiness and range and also good strength. The original martensitic NiTi wire (Nitinol) has very little formability, which means that the wire distorts only a small distance beyond its elastic limit before it breaks. A newer formulation of M-NiTi (Titanal) does provide good formability, with other physical properties similar to Nitinol. In clinical practice, Nitinol wires do have a tendency to break, whereas the newer M-NiTi wires would remain intact but permanently distorted if stressed to the same extent. The fact that Nitinol breaks in this circumstance is not a sign that it has less strength than its competitors, only that the consequences of exceeding its strength are more immediately obvious.

For alignment with M-NiTi, 16 mil is the usual choice, but 14 mil M-NiTi can be useful with wide brackets and a consequently reduced interbracket span. The newer A-NiTi wires, however, have made M-NiTi all but obsolete for alignment.

The nonlinear (superelastic) responses characteristic of A-NiTi (Ni-Ti, Sentinol) means that they are almost always outside the linear (elastic) portion of their load-deflection curve, and that makes them somewhat difficult to compare with other materials in terms of elastic properties as a function of wire size (see Chapter 10). Furthermore, the manufacturer can control the austenite-martensite transition, so that A-NiTi wires of the same diameter can have different force-deflection curves (Fig. 15-4). With these wires, the appropriate choice for initial alignment is the wire that delivers about 50 gm along its unloading curve (Fig. 15-5). Normally, this is the "light" 16 mil wire. The great advantage is that the wire will deliver this optimum force over a large range, almost independently of the distance the wire was deflected initially.

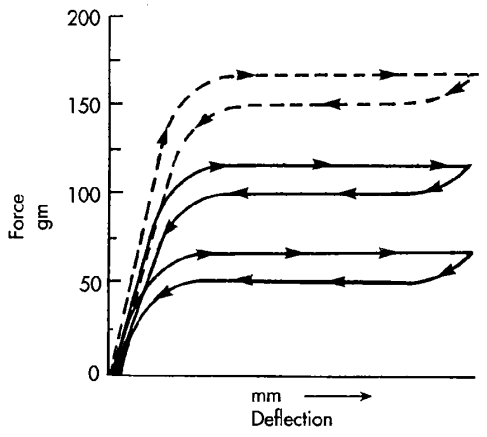


Fig. 15-4 ■ Force-deflection curves for 16 mil A-NiTi wires (Sentinol) prepared by the manufacturer to have different force delivery characteristics of 50, 100, and 150 gm.

The advantages of A-NiTi over M-NiTi are compelling, and there is little or no reason now to choose the older type of NiTi for alignment. As we discuss in Chapter 17, however, M-NiTi may retain some advantages in the larger rectangular sizes used in the later stages of treatment.

Steel Wires with Loops. Excellent performance in alignment also can be obtained by using a 14 mil steel wire, incorporating loops as necessary. Although loops in larger wire sizes (16 mil, for example) can provide acceptable springiness, elaborate loops that incorporate a great deal of wire are both time-consuming to fabricate and potentially troublesome in clinical use. With 14 mil initial archwires, three basic loop designs, as illustrated in Figs. 15-6 and 15-7, suffice for almost all purposes. It is important that the loops not be too long occlusogingivally. Keeping the height of loops between 5 and 6 mm makes them short enough to avoid almost all problems with impingement on the gingiva or irritation of the lips. Loops with a greater vertical height are much more likely to be troublesome.

The decision on whether to use 16 mil A-NiTi or 14 mil steel with loops now is made on exactly how the teeth are arranged. Until A-NiTi became available, the greater range of a 14 mil steel archwire with loops as compared to a 16 mil M-NiTi wire without loops (see Fig. 15-3), which meant fewer reactivations of the loop archwire to complete the alignment process, had to be balanced against the extra clinical time required to make and insert a loop archwire. A-NiTi has better properties in every respect, and there is no reason now to bend loops except in special circumstances.

The primary indication now for choosing loops in a 14 mil steel wire is when the arch is well aligned except at one spot, where a tooth is badly malpositioned (Fig. 15-7). If a highly flexible wire is tied into the malpositioned tooth, there is a risk of distorting arch form. What is needed is an archwire that is reasonably stiff except at the one spot where springiness is needed, and loops produce just that effect. Since only one or two loops are needed, there is also not much of a time investment in using the steel wire.

In patients with severe crowding of anterior teeth, extraction of a premolar on each side often is indicated, and

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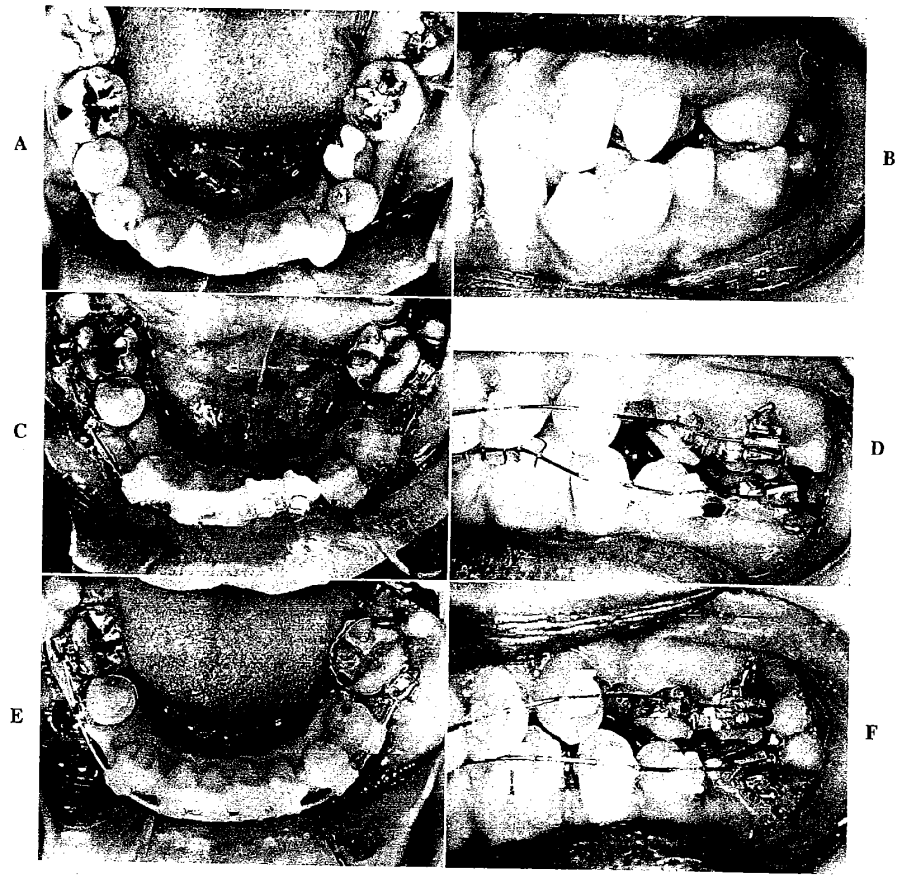


Fig. 15-5 ■ Alignment with A-NiTi wires in a patient with extremely severe crowding. **A** and **B,** Initial condition—16 mil A-NiTi wires designed to deliver approximately 50 gm were placed in both arches. **C** and **D,** 8 weeks later; **E** and **F,** 4 months after the A-NiTi wires were first placed. No archwire adjustments were necessary. Note that the less severely crowded maxillary arch was nearly aligned in 2 months.

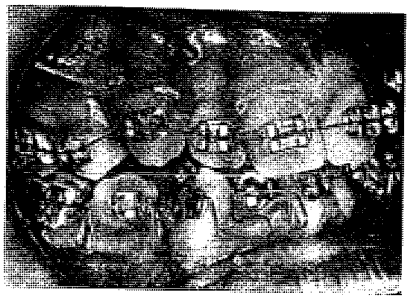


Fig. 15-6 ■ In the mandibular arch, vertical (teardrop) and horizontal (boot) loops in 14 mil steel wire are being used for alignment of severely irregular mandibular anterior teeth. Note the relatively short (5 to 6 mm) vertical height of the loops, which is important for prevention of gingival or lip irritation. In this patient from the mid-1980s, a twist wire is being used in the less severely malaligned maxillary arch. At present, 16 mil A-NiTi probably would be employed in both arches.

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it is necessary to retract the canines into the extraction sites while aligning the incisors. In extremely severe crowding, it is better to retract the canines independently before placing attachments on the incisors. This can be done either with segmental retraction loops (Fig. 15-8), or by sliding the canines along an archwire (which produces more stress on the posterior anchorage). In more typical and less extreme crowding, it is possible to simultaneously tip the canines distally and align the incisors. Until recently, the best way to do this was to use a loop archwire of the design shown in Fig. 15-9, *A*. The principle is that

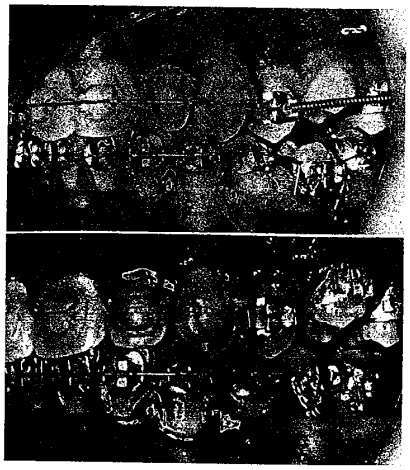


Fig. 15-7 ■ Box loop in 14 mil steel wire to elevate a mandibular second premolar into occlusion. **A,** Loop at initial placement; **B,** 8 weeks later. Use of a highly resilient wire like A-NiTi in this situation risks distortion of arch form; the loop remains the preferred approach when only a single tooth is badly malaligned.

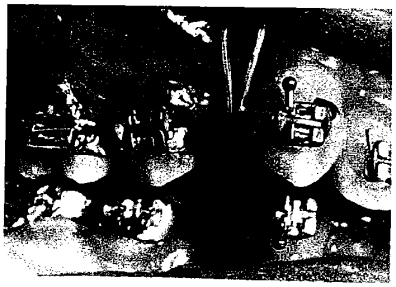


Fig. 15-8 ■ In this severely crowded child, initial retraction of the maxillary right canine is being done with a loop in 19 × 25 beta-Ti wire. The loop can be adjusted to tip the crown distally or produce bodily retraction. Independent retraction of the canine in this way is most applicable when the canine is severely displaced mesially or when the anchorage control strategy (see Chapter 16) calls for canine retraction as a first stage procedure.

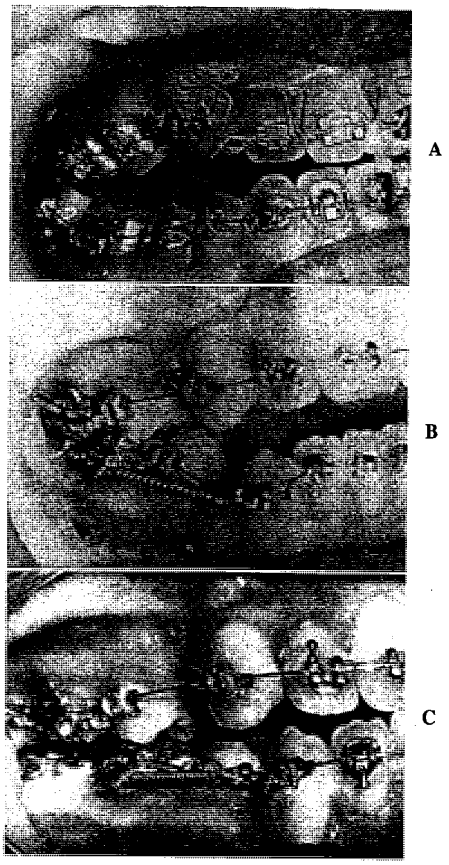


Fig. 15-9 ■ **A,** For this patient a rolled or drag loop in 14 mil steel wire is being used in the maxillary arch to tip the canine distally into the extraction site while the incisors are being aligned independently. If the loop in the extraction site is gently activated by pulling the posterior end of the wire 1 to 1.5 mm through the molar tube and bending it up, a force is generated to tip the canine distally, as the wire segment passing through the canine is prevented from sliding distally by the loop configuration to the mesial. As the canine tips distally, however, the mesial loop opens up, and the canine retraction provides space for alignment of the incisors without either proclining or retracting them. **B,** An alternative method for distal tipping of a canine while incisors are aligning is to use an A-NiTi archwire and an auxiliary A-NiTi coil spring, which delivers a nearly constant 50 gm force over a large range. **C,** 6 weeks after **B,** showing the retraction and alignment that was obtained.

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described by Stoner[2] as a "drag loop." The loop in the extraction site is gabled sharply and activated slightly, producing a gentle space-closing force with an anti-tip moment on the posterior teeth. As the activated distal loop closes, the loop mesial to the canine opens, allowing the canine to tip back independently while the incisors are being aligned.

The same independent distal movement of the canines now can be obtained with an A-NiTi archwire without loops, and A-NiTi coil springs from the first molars to tip the canines distally (Fig. 15-9, *B*). When this is done, the spring should be chosen to deliver only 50 gm, and an archwire preformed by the manufacturer to have an exaggerated reverse curve of Spee should be chosen, to limit forward tipping of the molars. As with the drag loop, the idea is to pit distal tipping of the canines against forward bodily movement of the molars. A stop can be crimped on the archwire just ahead of the first molars to further control their forward movement.

■ Alignment with 22-Slot Edgewise

In 22-slot edgewise, twin brackets are typically used on all teeth. The reduced interbracket span makes archwires stiffer and also means that loops, if they are used, must be located more precisely. The same choice of wires is available as for 18-slot edgewise.

Multistranded Wires. With a 22 mil bracket slot, there is optimum clearance for a 17.5 mil twist archwire, and this can be an excellent choice as an initial alignment archwire if malalignment is not too severe (Fig. 15-10). Although 19.5 mil twist wire also would fit well within the bracket slot, this wire is undesirably stiffer. Another form of multistranded wire has a central core wire with multiple smaller wires wound around it (coaxial wire). The spring properties of the best-known example (Respond, Ormco/Sybron) are such that 19.5 mil Respond is quite similar to 17.5 mil twist, which means that 19.5 mil Respond is the better choice if for some reason a larger diameter wire is desired. Because coaxial wires cost more than twist wires, the smaller twist wire usually is the more logical choice.

Nickel-Titanium Wires. Both 16 and 18 mil NiTi can be used as initial archwires with 22-slot edgewise, but in M-NiTi, 18 mil wires are undesirably stiff, and A-NiTi is most readily available in 16 mil. With 16 mil NiTi, the 6 mil clearance within the bracket, though large, is not enough to cause clinical problems. Since the stiffness of 17.5 mil twist and 16 mil NiTi wires is quite similar at small deflections, it makes good economic sense to use the twist wire initially with the 22-slot appliance when the teeth are reasonably well aligned initially, and to use 16 mil A-NiTi when greater range is needed.

Steel Wires with Loops. With 22-slot appliances as with 18-slot appliances, the major indication for loop arches now is severe localized crowding so that greater flexibility is needed in one area (see Fig. 15-7). When loops are needed, 14 mil steel usually is the best choice, but 16 mil steel also can be used. The 16 mil wire fits better in the 22 slot, but its greater stiffness requires more complex loop designs.

■ Alignment with Begg Technique

The narrow brackets used in Begg technique provide the maximum possible interbracket span without placing loops in archwires. It was originally common practice with this appliance to use loops in 16 mil steel archwires to facilitate initial alignment (Fig. 15-11). Indeed, loops for alignment were introduced into American edgewise orthodontics from the early Begg appliance. The long posterior span of archwires used in the Begg technique makes it difficult to use a highly flexible titanium-based archwire at the initial stage without losing control of molar position (see leveling, following). Although alignment loops are used less in current Begg therapy than they were previously,[3] this remains a valuable adjunct to Begg treatment.



Fig. 15-10 ■ 17.5 mil twist wire remains a good choice for initial alignment in the 22 slot edgewise appliance, if the teeth are not severely irregular. **A,** Note that the twist wire in the mandibular arch is not fully engaged in all the brackets at this point; replacement of the wire and elastomeric ligatures will be needed to complete the alignment. **B,** Occlusal view of the maxillary arch of a different patient. Elastomeric ties to lingual attachments are being used to facilitate correction of rotations. It is important to tie isolated lingual attachments so they will remain attached to the appliance if they come loose from the tooth, so they will not be swallowed.

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Fig. 15-11 ■ **A,** Alignment loops in 16 mil steel wire, in a patient wearing the Begg appliance in the upper arch. **B,** Alignment with the modern combination anchorage technique, with a dual-flex wire. The anterior section is NiTi, and the posterior section is steel. This dual-stiffness wire allows the elimination of loops in Begg technique, while retaining the needed stiffness of the posterior part of the initial archwire. (**B,** Courtesy Dr. WJ Thompson.)

Special Problems in Alignment

■ Crossbite Correction

It is important to correct posterior crossbites and mild anterior crossbites in the first stage of treatment. Severe anterior crossbites, in contrast, are usually not corrected until the second stage of conventional treatment, or might remain pending surgical correction. For both posterior and anterior crossbites, it is obviously important to make the appropriate distinctions between skeletal and dental problems, and to quantitate the severity of the problem. The appropriate diagnostic steps are discussed in Chapters 6 and 7. The assumption here is that appropriate treatment has been selected, and the discussion is solely about implementing a treatment plan based on differential diagnosis.

Transverse Maxillary Expansion by Opening the Midpalatal Suture. It is relatively easy to widen the maxilla by opening the midpalatal suture before and during adolescence, but this becomes progressively more difficult as patients become older. The chances of successful opening of the suture are nearly 100% before age 15, but begin to decline thereafter because of the increased interdigitation of the sutures that must respond.[4]

Patients who are candidates for opening the midpalatal suture may have such severe crowding that even with this arch expansion, premolar extraction will be required. In these patients, however, separation of the suture should be the first step in treatment, before either extraction or alignment. The first premolar teeth are needed as anchorage for the lateral expansion and can serve for that purpose even if they are to be extracted later, and the additional space provided by the lateral expansion facilitates alignment.

Occasionally, transverse maxillary expansion can provide enough additional space to make extraction unnecessary, but rarely is it wise to use sutural expansion as a means of dealing with an alignment problem in an individual who already has normal maxillary width (see Chapter 8). Opening the midpalatal suture should be used primarily as a means of correcting a skeletal crossbite, increasing a narrow maxillary width to a normal dimension.

The basic mechanism for separation of the midpalatal suture is a jackscrew built into a fixed appliance that is rigidly attached to as many posterior teeth as possible. The appliance can be made so that it has plastic palate-covering shelves or can consist solely of a metal or plastic framework against the teeth, not contacting the palatal tissue (Fig. 15-12).[5] In theory, the flanges extending into the palate could cause a more bodily repositioning of the alveolar processes,[6] but in fact, there seems to be little or no difference in the skeletal or dental response to the two types of appliances. Because the palate-covering appliance remains in contact with the soft tissue for an extended period, however, it is quite likely to cause tissue irritation. For this reason, an appliance that does not contact the palate is preferred.

When the maxillary teeth move transversly, some extrusion may occur, and even if it does not, cuspal interferences are produced that cause the mandible to rotate down and back. In deep bite patients who are still growing or in patients with a mild Class III tendency, this can be advantageous, but it is a problem in long face patients with a narrow maxilla. Adding bite blocks to a bonded expander is the best way to overcome this problem (Fig. 15-13).[7]

Separation of the midpalatal suture can be produced by either rapid (Fig. 15-14) or slow expansion, and the same type of palate-separating appliance can be used for either approach (see Chapter 8). Whether the expansion is done rapidly or slowly, the fixed appliance remains in place for approximately the same length of time, because a shorter period of stabilization is sufficient with slow expansion. With rapid expansion, the expansion itself is carried out in approximately 2 weeks, but the screw should then be stabilized and the appliances maintained in place for 3 to 4

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