The Invisalign® System

Edited by
Orhan C. Tuncay, DMD



quintessence books



Orhan C. Tuncay, DMD, currently serves as chairman of the Department of Orthodontics and director of the graduate program at Temple University in Philadelphia, Pennsylvania. A member of the Academic Advisory Board of Align Technology, Dr Tuncay has been involved in the development of the Invisalign System since its inception, and his private orthodontic practice is devoted exclusively to Invisalign treatment. He earned his dental degrees from the University of Ankara, Turkey, and Temple University and received his orthodontic training at the University of Pennsylvania. Upon completion of his studies, he served as chairman of the Department of Orthodontics at the University of Kentucky in Lexington and subsequently held the same position at the University of Mississippi in Jackson. Dr Tuncay is the founding editor of four periodicals and the author of nearly 200 publications in the clinical and scientific literature. He is a diplomate of the American Board of Orthodontics and an active member of numerous scientific and professional organizations, having formerly held such notable positions as chairman of the Council on Scientific Affairs of the AAO, president of the Greater Philadelphia Society of Orthodontists, and president of the Craniofacial Biology Group of the IADR/AADR. Recently, the AAO Foundation honored Dr Tuncay by establishing a fellowship in his name.

ISBN-10: 1-85097-127-7
ISBN-13: 978-1-85097-127-6
9 781850 971276
www.quintpub.co.uk

The Invisalign System

Orhan C. Tuncay, DMD
Professor and Chairman
Department of Orthodontics
School of Dentistry
Temple University
Philadelphia, Pennsylvania

Quintessence Publishing Co, Ltd
London, Berlin, Chicago, Tokyo, Barcelona, Beijing,
Istanbul, Milan, Moscow, Mumbai, Paris,
Prague, São Paulo, and Warsaw

British Library Cataloging in Publication Data
1. Orthodontics, Corrective 2. Orthodontic appliances
3. Orthodontics – Diagnosis
I. Tuncay, Orhan C.
617.6'43'00284

ISBN-10: 1850971277



© 2006 Quintessence Publishing Co, Ltd

Quintessence Publishing Co, Ltd
Grafton Road
New Malden
Surrey KT3 3AB
United Kingdom
www.quintpub.co.uk

All rights reserved. This book or any part thereof may not be reproduced, stored in a retrieval system, or transmitted in any form or by any means, electronic, mechanical, photocopying, or otherwise, without prior written permission of the publisher.

ISBN-10: 1-85097-127-7
ISBN-13: 978-1-85097-127-6
Printed in Germany

ClearCorrect Exhibit 1016, Page 4 of 335

Table of Contents

Preface xi
Contributors xiii

SECTION I—HISTORY OF THE CONCEPT



Chapter 1 **The Dental Contour Appliance: A Historical Review** 3
Henry I. Nahoum

Chapter 2 **Essix Technology: Tooth Movement and Retention** 11
John Sheridan

Chapter 3 **History and Overview of the Invisalign System** 25
Trang Duong

ClearCorrect Exhibit 1016, Page 5 of 335

SECTION II—MODELING IN THE INVISALIGN SYSTEM





Chapter 4 **Polyvinyl Siloxane Impression Materials** 35
John M. Powers

Chapter 5 **Align's Standard on Quality Impressions** 43
David Chenin

Chapter 6 **Scanning Process and Stereolithography** 47
Srinivas Kaza

Chapter 7 **Invisalign Software** 55
Andrew Beers

Chapter 8 **Virtual Diagnostic Setup** 67
David Chenin and Kent Verdis

Chapter 9 **Attachments** 77
Peter Knopp and Mitra Derakhshan

Chapter 10 **Invisalign Attachments: Materials** 91
Eric Kuo and Trang Duong

ClearCorrect Exhibit 1016, Page 6 of 335

Chapter 11 **ClinCheck: Overview and Preparation** 99
Craig Crawford

Chapter 12 **Staging** 105
Rene Sterental

Chapter 13 **Overcorrection: Principles and Considerations** 115
Eric Kuo

Chapter 14 **Three-Dimensional Superimposition Tool** 121
C. Van Nguyen and Jihua Cheng

Chapter 15 **Virtual Invisalign Practice** 133
David Chenin

Chapter 16 **Computer-Oriented Dental Measurements** 137
Vadim Matov

ClearCorrect Exhibit 1016, Page 7 of 335

SECTION III—PERFORMANCE CHARACTERISTICS OF THE INVISALIGN SYSTEM





Chapter 17 **Mechanics of Tooth Movement with Invisalign** 149
Andrew Beers and Trang Duong

Chapter 18 **Applications of Mechanics with Invisalign** 153
Heng Cao and Trang Duong

Chapter 19 **Biologic Elements of Tooth Movement** 163
Orhan C. Tuncay

Chapter 20 **Properties of Aligner Material Ex30** 177
Robert Tricca and Chunha Li

Chapter 21 **Ex40 Material and Aligner Thickness** 187
Trang Duong, Eric Kuo, and Mitra Derakhshan

Chapter 22 **Extraction Treatment with Invisalign** 195
David E. Paquette

Chapter 23 **Force Application with Invisalign: Constancy and Compliance** 207
Trang Duong and Robert Tricca

ClearCorrect Exhibit 1016, Page 8 of 335

SECTION IV—CLINICAL CONSIDERATIONS IN USING THE INVISALIGN SYSTEM



Chapter 24 **Advantages of the Invisalign System** 215
Trang Duong and Mitra Derakhshan

Chapter 25 **Review of the Diagnostic Process** 223
Robert L. Boyd

Chapter 26 **Interproximal Enamel Reduction** 255
Rainer-Reginald Miethke and Paul-Georg Jost-Brinkmann

Chapter 27 **Facial Esthetic Examination and Analysis** 269
Marc B. Ackerman

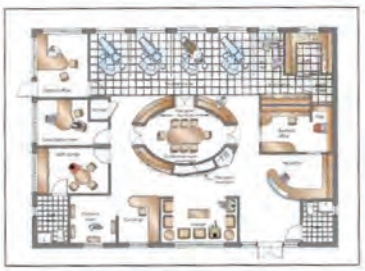
Chapter 28 **Surgical Treatment and Invisalign** 281
Ross Miller and Trang Duong

Chapter 29 **Feasibility Study of the Invisalign System in Treatment of Adolescents** 291
Andrew Trosien and Robert Fry

Chapter 30 **Data Mining: Principles and Considerations** 299
Eric Kuo

ClearCorrect Exhibit 1016, Page 9 of 335

SECTION V—OFFICE DESIGN AND TECHNOLOGY



Chapter 31 **Invisalign Office Design and Technology** 307
Orhan C. Tuncay, Marc S. Lemchen, and Agnes A. Kan

ClearCorrect Exhibit 1016, Page 10 of 335

Preface

The long-awaited paradigm shift in orthodontics arrived with the introduction of the Invisalign System. This unique treatment approach has been instrumental in removing the ever-present shroud of mystery surrounding orthodontics by allowing both dental practitioner and patient to develop a visual understanding of orthodontic tooth movement. In this way, it has founded a culture of true and attainable visual treatment objectives. Moreover, the esthetic and practical advantages of the system have extended orthodontic services to a greater population.

The Invisalign System is multilingual. Its spoken languages are image acquisition, software (ClinCheck), and the Invisalign aligner. The dialects are the generation of forces, attachment designs, and response of periodontal tissues to the forces generated by the aligner. The regional accents were born through the various applications of ClinCheck, spectrum of cases treated, attachment preferences, and instructions to patients. The adoption of the Invisalign System into a practice, however, is a language unto itself. It has its roots in two different tongues: biology and technology. To be fluent in all of these languages and dialects, the clinician must know the root of the language and how the dialects have been derived.

This book, the first to be written about the Invisalign System, was compiled as an educational tool for all of the languages, dialects, and accents spoken in the world of Invisalign. It is not a how-to manual. Instead, it is designed to expose the clinician to behind-the-scene elements of customization that underlie the production of Invisalign aligners. Equipped with such information, the clinician will better understand the nature of tooth movement with the Invisalign System.

Our deepest gratitude goes to the authors from Align Technology. These individuals took precious time from their daily schedules to write about the inner workings of their operation. The Invisalign System is primarily company driven; therefore, it is their contribution that makes this textbook possible. In particular, Dr Trang Duong's indefatigability in collecting chapters from Align Technology authors is greatly appreciated. We gratefully acknowledge the monumental commitment of Align Technology, through the leadership of Amir Abolfathi, to this project. Finally, we thank Jonathan S. Simmons, whose efforts in the editing, organization, and overall preparation of the manuscript have been invaluable.

ClearCorrect Exhibit 1016, Page 11 of 335



Contributors

Marc B. Ackerman, DMD
Associate Professor
Department of Orthodontics
School of Dentistry
Temple University
Philadelphia, Pennsylvania

Andrew Beers, PhD
Director of Engineering Systems
Align Technology, Inc

Robert L. Boyd, DDS
Professor and Chairman
Department of Orthodontics
School of Dentistry
University of the Pacific
San Francisco, California

Heng Cao, PhD
Research and Development Engineer
Align Technology, Inc

Jihua Cheng, PhD
Algorithm Specialist
Align Technology, Inc

David Chenin, DDS
Orthodontist Resident
Department of Orthodontics
School of Dentistry
University of the Pacific
San Francisco, California

Craig Crawford, DDS
Orthodontist
Align Technology, Inc

Mitra Derakhshan, DDS
Clinical Manager of European Operations
Align Technology, Inc

Trang Duong, DDS
Senior Staff Orthodontist
Align Technology, Inc

Robert Fry, DDS
Private Practice in Orthodontics
Olathe, Kansas

Paul-Georg Jost-Brinkmann, Prof Dr Med Dent
Senior Lecturer
Department of Dentofacial Orthopedics and Orthodontics
University Hospital Charité
Humboldt University of Berlin
Berlin, Germany

Agnes A. Kan
Architect
Philadelphia, Pennsylvania

Srinivas Kaza
Product Engineer
Align Technology, Inc

Peter Knopp
Senior Manager and Product Engineer
Align Technology, Inc

Eric Kuo, DDS
Director of Product Development
Align Technology, Inc

Marc S. Lemchen, DMD
Private Practice in Orthodontics
New York, New York

Chunha Li, PhD
Manager of Materials Research
Align Technology, Inc

Vadim Matov, PhD
Senior Alogrithm Specialist
Align Technology, Inc

Rainer-Reginald Miethke, Prof Dr Med Dent
Professor and Chairman
Department of Dentofacial Orthopedics and Orthodontics
University Hospital Charité
Humboldt University of Berlin
Berlin, Germany

Ross Miller, DDS
Private Practice in Orthodontics
Sunnyvale, California

Henry I. Nahoum, DDS
Professor
Department of Orthodontics
School of Dentistry
Loma Linda University
Loma Linda, California

C. Van Nguyen, DDS
Private Practice in Orthodontics
Houston, Texas

David E. Paquette, DDS
Private Practice in Orthodontics
Charlotte, North Carolina

John M. Powers, PhD
Professor of Oral Biomaterials
Director, Houston Biomaterials Research Center
University of Texas Dental Branch at Houston
Houston, Texas

ClearCorrect Exhibit 1016, Page 13 of 335

John Sheridan, DDS
Professor
School of Dentistry
Louisiana State University Health Sciences Center
Baton Rouge, Louisiana

Associate Professor
Department of Orthodontics
Jacksonville University
Jacksonville, Florida

Rene Sterental, DDS
Staff Orthodontist
Align Technology, Inc

Robert Tricca, PhD
Director of Product Development
Align Technology, Inc

Andrew Trosien, DDS
Consulting Orthodontist
Align Technology, Inc

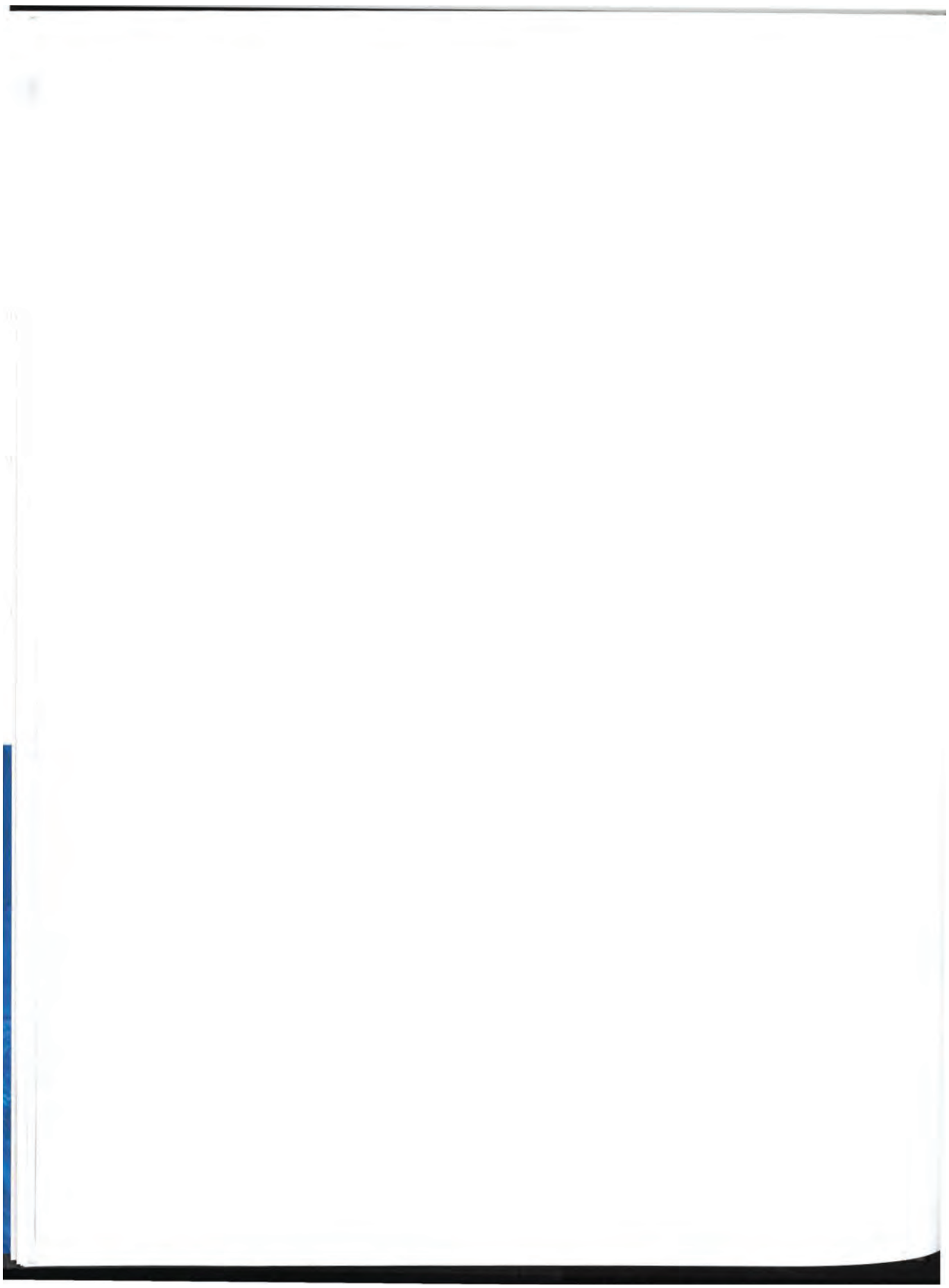
Orhan C. Tuncay, DMD
Professor and Chairman
Department of Orthodontics
School of Dentistry
Temple University
Philadelphia, Pennsylvania

Kent Verdis
Manufacturing Process Engineer
Align Technology, Inc

ClearCorrect Exhibit 1016, Page 14 of 335

SECTION I

HISTORY OF THE CONCEPT



chapter 1

The Dental Contour Appliance: A Historical review

by
Henry I. Nahoum, DDS

ClearCorrect Exhibit 1016, Page 17 of 335

Background and Process of Thermoforming

Although thermoplastic sheets were manufactured as far back as 1896,[1] plastic sheet forming, or thermoforming, was not well known before 1950. This process shapes a plastic product by applying air pressure or vacuum to a heat-softened sheet. On occasion, pressurized steam or hot oil has been used instead of air pressure.

As pressure-forming machines improved—for example, by combining the heating and forming processes on a single machine—the development of materials advanced concurrently. Acrylics and styrene were developed in the 1930s. Ethyl cellulose, polyethylene, the vinyls, oriented styrene, cellulose acetate, and cellulose acetate butyrate followed quickly. There is a plethora of calendered plastics available for different uses (eg, packaging, food trays, accessories). Sheet feeding and roll feeding are available in various sizes. The material varies from 0.001 to 0.375 inches in thickness (0.025 to 9.12 mm).[2] Today, machines are highly automated and can be precisely controlled with computers.



FIG 1-1 A commercial vacuum former.

When a piece of thermoplastic is heated to temperatures between 250°F and 450°F, depending on the plastic, it will become soft enough that it can be formed over a surface either mechanically or by positive air pressure. Unlike casting and injection molding, which require a three-dimensional mold, a two-dimensional surface is all that is required for thermoforming: the surface becomes the mold. Vacuum forming is the simplest type of pressure forming since it uses atmospheric air pressure.

When the plastic is held over the mold and allowed to cool, the plastic will retain the exact shape of the mold. With the proper equipment and the appropriate material, the finest details can be duplicated on the mold side of the plastic, like an impression. The side away from the mold is less distinct. The final product is thinner than the original sheet because the plastic stretches during the forming process.

In 1959, an industrial-grade vacuum former, produced by The Tronomatic Machine Manufacturing Company of New York, was used to make appliances that could be used to maintain or change contours[3] (Fig 1-1). This was a novel way to fabricate dental appliances that were suitable for various procedures in orthodontics, periodontics, restorative dentistry, dental surgery, and for other purposes in dental practice.

The dental contour appliance is made by a drape-forming method in which the heated plastic is clamped and pushed or allowed to drape over a plaster cast.[1] The sheet is sealed at the edges of the mold and then vacuum is applied, forcing the sheet to adapt to the surface of the model (Fig 1-2).

To ensure that the maximum vacuum pressure (28 inches Hg) is obtained, an auxiliary tank is evacuated before the process begins. The vacuum pump is kept on through-

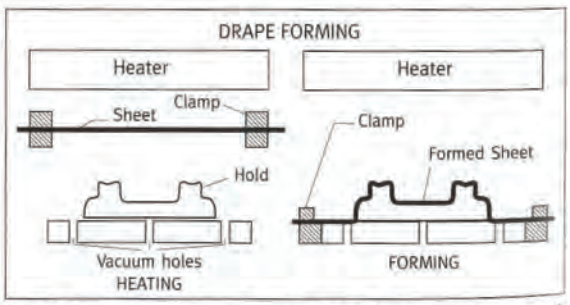


FIG 1-2 The vacuum-forming process. (After Butzko and Stratton.[1])

ClearCorrect Exhibit 1016, Page 18 of 335



FIG 1-3 A clear plastic vacuum-formed maxillary appliance (*left*), and an opaque vinyl vacuum-formed mandibular appliance (*right*). Note the excellent detail in both appliances.

out the process so that both the vacuum pump and the tank operate simultaneously. The negative atmospheric pressure created by the combination of the evacuation tank and the pump ensured excellent draping of plastic over the plaster cast. Atmospheric pressure equivalent to approximately 14 psi molds the plastic instantaneously. Excellent detail is achieved with acetates, vinyl, styrene, polyethylene, and butyrate, in clear, translucent, opaque, or colored films and sheets (Fig 1-3). Positive air pressure can also be used, but this is not necessary for these plastics. Small vacuum-forming machines that use a vacuum-cleaner motor do not achieve this level of efficiency.

Rationale for Material Selection

Plastics differ in their characteristics. The selection of the material to be used in producing a dental contour appliance depends on such factors as the length of time that the appliance is to be used, the thickness of the material, and the purpose of the appliance. For nightguards, a hard material may be used, whereas for orthodontic purposes a soft, resilient plastic is desired. In all cases, it is necessary for the material to be inert, nontoxic, odorless, tasteless, and unaffected by the chemicals of the body. It should have a minimum of water absorption and it must not warp. In addition, molding qualities must be good or excellent. After the appliance is molded, it is washed in a mild alkaline solution or detergent to remove any surface impurities and excess plasticizer.

Orthodontic Applications

It is readily apparent that this contour appliance can be used as an immediate retainer, to prevent teeth from moving, following orthodontic treatment. If clear plastic is used, the result is a cosmetically innocuous appliance that can be worn all the time. Each dental arch is treated independently.

This type of appliance can 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 of the dentition, and the teeth are numbered for identification. The teeth that require correction are sawed off the cast with a fine jeweler's saw or fissure bur, as is done for a Kesling rubber positioner[4] (Fig 1-4). The teeth are then repositioned on the model and held in the corrected positions with pink baseplate wax (Fig 1-5). The contour appliance is vacuum formed over the altered model. Since the forming process is instantaneous, the teeth that are held by the baseplate wax do not move because the plastic will mold before the wax melts (Figs 1-6a and 1-6b). After the mold cools, the excess plastic is trimmed with a razor, and the appliance is removed from the cast. Final trimming is done with a fine scissors. The appliance is then cleaned and inserted in the mouth.

Several appliances can be made on the altered cast, which is used over and over. A hole may be made in the center of the base of the cast to assist in the vacuum-forming process. After the appliance is made and trimmed, compressed air directed into the hole helps in removing the appliance.

Movement of teeth occurs as a result of the pressure exerted on the irregular teeth by the appliance that was

ClearCorrect Exhibit 1016, Page 19 of 335



FIG 1-4 Teeth are sawed off the cast with a fine jeweler's saw.



FIG 1-5 Teeth are repositioned on the cast with pink baseplate wax.

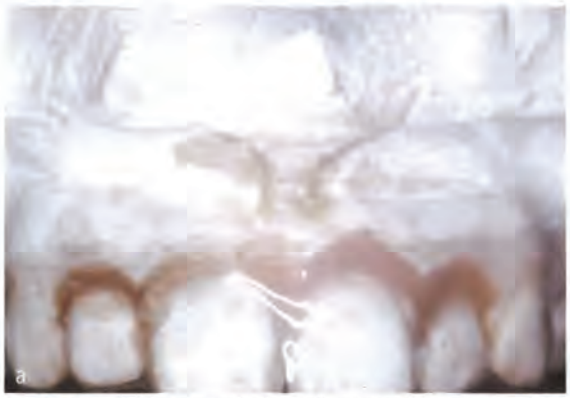




FIG 1-6 (a and b) A clear plastic appliance made on a cast where the maxillary incisors were repositioned and held in place with wax. Note that a thin film of molten wax was spread around the teeth.

made on the corrected model. The appliance is resilient and snaps over the teeth and the mucosa. It exerts pressure until the teeth attain their predetermined positions. This type of appliance is very effective for contraction of a dental arch but not as effective for expansion. A patient treated by the author with this type of appliance had a mandibular incisor that was crowded out of the dental arch and was in crossbite with the maxillary lateral incisor (Figs 1-7a to 1-7e). The incisor was slenderized with a disk on the mesial and distal surfaces so that it could be pushed into the dental arch. Treatment time was 2 months. Note that the appliance extended a convenient distance over the mucosa, past the gingival margin. It was not scalloped.

When the correction is too great to be done in one step, adjustments may be made in increments using two or more appliances. Partial and progressive adjustments are made by moving the teeth gradually and holding them in place with wax. A new vacuum-formed appliance is made for each phase. When the teeth are properly aligned, the final appliance is used as a retainer to maintain the teeth in their corrected positions. Corrections made with this type of appliance are most effective when they are limited to the six anterior teeth.

Contoured orthodontic appliances are made for either one or both dental arches and may be worn at all times. If only one arch is being treated, the patient is able to eat

ClearCorrect Exhibit 1016, Page 20 of 335

FIG 1-7 A patient with the mandibular right lateral incisor crowded out of the dental arch and in crossbite (September 1960).



FIG 1-7a The mandibular right lateral incisor has been slenderized. A disk was used on the mesial and distal surfaces.



FIG 1-7b Occlusal view of the cast.

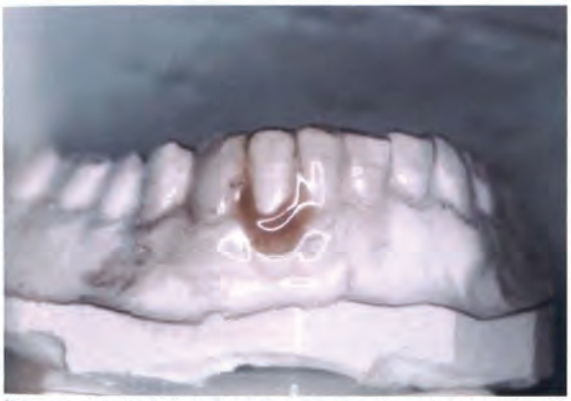


FIG 1-7c The mandibular incisor was repositioned and held with wax. A clear plastic appliance was made on the altered model.



FIG 1-7d View of the appliance in place after 2 months. The appliance is not scalloped.

with the appliance in position. When maxillary and mandibular appliances are used simultaneously, hooks for maxillomandibular elastics can be bonded with acrylic, or another compatible adhesive, in appropriate locations. Unfortunately, stability of the appliances then becomes a problem. When indicated, a maxillary and a mandibular contour appliance can be bonded together for finishing of an orthodontic case (Fig 1-8). Minor intercuspal corrections can be made in this way. Repositioning of the mandible, of course, is questionable.

For en masse movement of teeth with an extraoral appliance, tubes may be bonded to the appliance over the maxillary first molars. An extraoral facebow is inserted into



FIG 1-7e Correction completed (November 1960).

ClearCorrect Exhibit 1016, Page 21 of 335



FIG 1-8 Maxillary and mandibular contour appliances bonded together for final finishing.



FIG 1-9 A clear plastic appliance made over a model with bands on the maxillary first molars. A facebow, for extraoral force, is inserted into the tubes on the bands through an opening in the plastic.



FIG 1-10 A template for a partial denture for the maxillary left quadrant. Note the wax pontic.

the tubes and activated with elastics from a head cap or neck strap. An alternative method is to fit and cement molar bands with buccal tubes on the first molars. Impressions are taken with the bands in place, and a model is made for a thermoplastic appliance that fits over the bands. In this case, the vacuum-formed appliance can be used in conjunction with an extraoral facebow that is inserted directly into the tubes on the molar bands through an opening in the plastic (Fig 1-9).

Other Uses in Dentistry

The contour appliance is not limited to orthodontic procedures. It has many dental uses.[5] Dental contour appliances can be used as a splint to limit the mobility of loose or periodontally involved teeth. When used as a nightguard to prevent bruxism, the contour appliance is made with a maxillary biteplate or a smooth, rigid mandibular occlusal plane that prevents intercuspation with the opposing dentition. Self-curing, clear acrylic is processed over the appliance into the grooves and over the cusps of the teeth to create a smooth occlusal plane. Acetate is not used for the thermoformed appliance because acrylic does not bond to acetate. Contour appliances may also be used to carry medicaments to the gingival tissues, hold a surgical pack in place, and control hemorrhage following a surgical procedure. They also can transport chemicals, such as fluoride gels, to the teeth.

In restorative dentistry, it is a fast, convenient way to make an esthetic provisional crown or partial denture. An impression is taken and a plaster cast is made. Missing teeth are replaced with artificial teeth and held in place on the cast with baseplate wax. Any teeth that require recontouring are corrected with wax or trimmed with a finishing stone (Fig 1-10). The occlusion is checked, and then a full, clear acetate thermoformed appliance is made. The teeth that require preparation for crowns are ground down in the mouth. The provisional partial denture, splint, or crowns are made by pouring quick, self-curing acrylic of an appropriate shade into the appropriate area of the contour appliance. The appliance is insert-

ClearCorrect Exhibit 1016, Page 22 of 335

ed in the mouth, and the excess acrylic is removed. The acrylic can be observed through the clear appliance so that color, contour, and voids may be corrected. The occlusion is established by having the patient close his or her mouth onto the appliance. As soon as the acrylic begins to set, it becomes hot (flash setting point). It is possible to feel the warmth through the clear plastic and remove the appliance immediately, thus avoiding trauma to the tissues. The final set takes place out of the mouth. The appliance requires very little trimming of excess acrylic, and there is no need for polishing. The final product is as smooth as glass. Veneers can be made in the same way within a clear plastic appliance. These veneers are useful for photography, performances, speeches, etc. These procedures have been illustrated and described in detail in the dental literature for the past 40 years.[6-8]

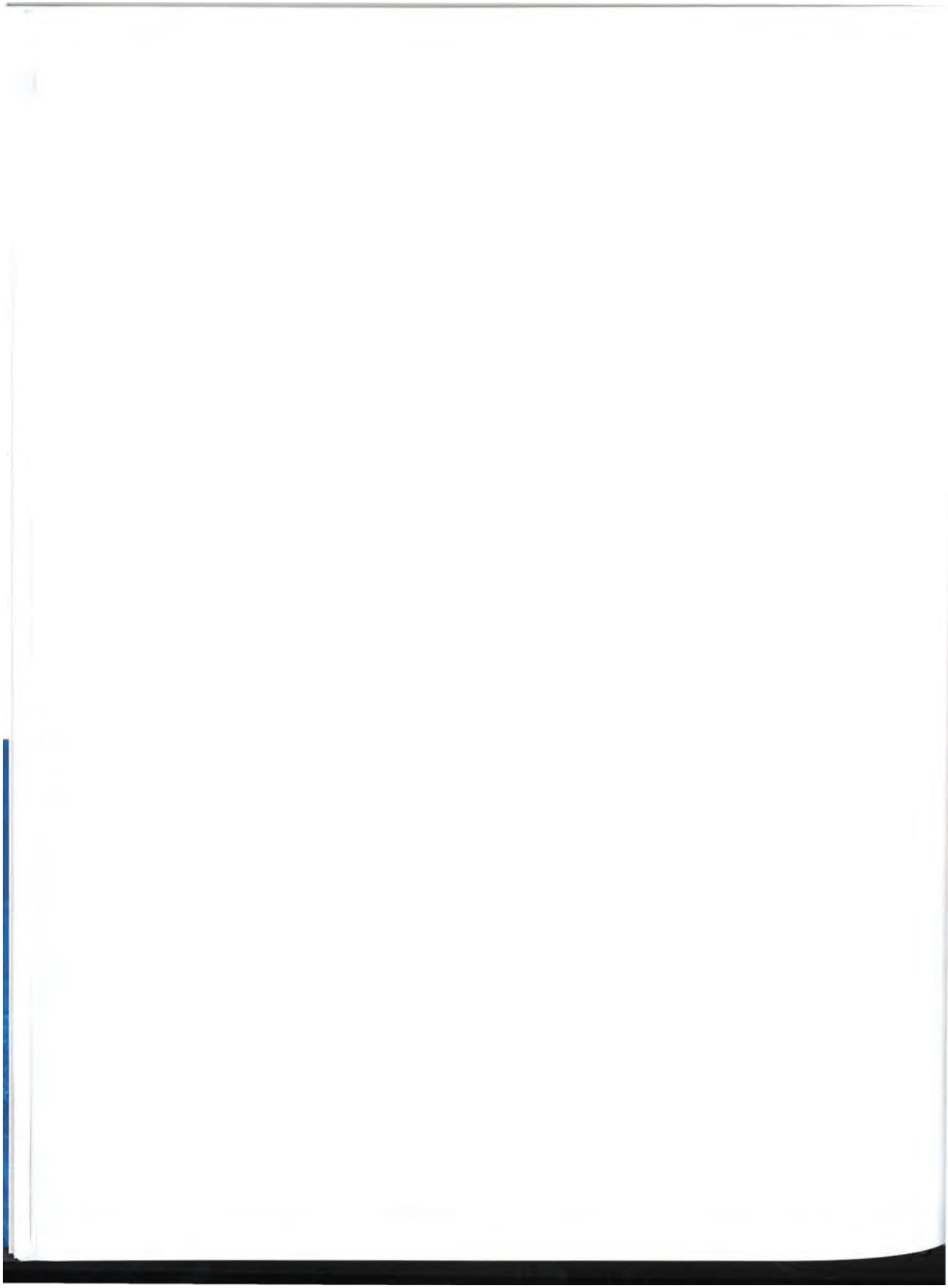
Summary

The introduction of pressure forming of calendered thermoplastics to make dental appliances has had a significant impact on the practice of dentistry. This process simplified many existing procedures and facilitated the introduction of new concepts for treating patients. Since these appliances can be made of clear plastic, which is inconspicuous, they are readily accepted by patients. New materials are constantly being introduced, accuracy has improved, and the fabrication processes have become automated. The process keeps evolving.

References

1. Butzko R, Stratton E. Thermoplastic sheet forming. Modern Plastics Encyclopedia 1957;35:736.
2. Butzko R. Plastic Sheet Forming. New York: Reinhold, 1958.
3. Nahoum H. The vacuum formed dental contour appliance. N Y State Dent J 1964;9:385–390.
4. Kesling H. The philosophy of the tooth positioning appliance. Am J Orthod 1945;31:297–304.
5. Nahoum H. What price progress? Am J Orthod Dentofacial Orthop 2002;122:15A–16A.
6. Fiasconaro JE, Sherman H. Vacuum-formed prostheses. I. A temporary fixed bridge or splint. J Am Dent Assoc 1968; 76(1):74–78.
7. Hirshfeld L, Geiger A. Minor tooth movement in general practice, ed 2. St Louis: Mosby, 1966.
8. McNamara J Jr, Brudon W. Orthodontics and Dentofacial Orthopedics. Ann Arbor: Needham Press, 2001.

ClearCorrect Exhibit 1016, Page 23 of 335



chapter 2

ESSIX TECHNOLOGY: TOOTH MOVEMENT AND RETENTION

by
John Sheridan, DDS

ClearCorrect Exhibit 1016, Page 25 of 335

The two contemporary systems for moving teeth with plastic appliances are the Invisalign and Essix systems. The Invisalign System is unique in that the clinician must be able to plan the path to optimal results before treatment is initiated so that a series of aligners can be constructed to achieve treatment objectives. The Essix System is based on in-course adjustments of what is essentially a single appliance to achieve the treatment goals.[1–3] This chapter presents the concepts and techniques of the Essix System.

Clear plastic tooth-moving appliances are excellent options for adults or responsible adolescents who might be reluctant to wear fixed appliances, who will follow the clinician's directions, and whose chief complaint centers around mild to moderate alignment problems. But, this discipline requires the essential elements of orthodontic tooth movement, force, space, and time (ie, there must be adequate force to move a tooth without inducing pathology, there must be enough space to accomplish the desired tooth movement, and the appliance must be in place for an appropriate length of time for the force to be effective). The clinician can control two of these essential prerequisites: force and space. As with any dynamic removable appliance, however, the patient must provide the third essential: time. Therefore, the target population that is most eligible for tooth movement with plastic appliances is, primarily, adults. In adult patients, the dentition has been milling itself in for perhaps decades. Although the occlusion may not have ideal dental relationships, the bite has usually adapted to a nonpathologic efficiency that is satisfactory for that particular patient. In the absence of functional distress or the resolution of extant or impending pathology, the focus of treatment with Essix appliances should be directed at the patient's chief complaint, and that is usually the appearance of the anterior teeth. The clinician, of course, is responsible for maintaining the pretreatment symptom-free functional occlusion.

Adolescents are usually not included in the plastic alignment population because strict adherence to clinical instructions is not predictable in that age group. Some clinicians believe that children and adolescent patients are best treated with conventional fixed appliances. The occlusion in the younger population, unlike in adults, has not had the chance to adapt to decades of function. It is hoped that the establishment of accepted occlusal parameters will be of value in adapting the masticatory system to the impending variables of diet, lifestyle, age, and stress.

The Essix Tooth-Moving System

Conventional fixed appliances are constantly modified because of the multiple variables that arise during treatment; so it is with Essix technology. Tooth movement is possible in all planes of space, and the fabrication expense is a fraction of the cost of multiple laboratory-fabricated appliances that must be used sequentially. Because Essix plastic appliances can be fabricated in the office, the cost of fabrication is minimal.

Creating space

There are two types of space that must be evident for tooth movement with Essix appliances: space within the appliance and space within the dentition. Space within the appliance is obtained by blocking out the working cast or cutting a window in the thermoformed appliance. The clinician has the option of using the method that is most efficient for the particular circumstance.

Creating space within the appliance: Blocking out the cast or cutting a window into the plastic

Blocking out the cast to create space into which the target tooth can move is achieved by placing a thickness of time-cured or light-cured composite on the working cast that is proportional to the amount of projected tooth movement (Fig 2-1). The cast must not be blocked out with wax because it will melt during thermoforming. The blockout material forms a bulge in the thermoformed appliance, and if normal overbite and overjet are evident, the bulge in the plastic can cause incisal interference if it is on the lingual of the maxillary incisors or the facial of the mandibular incisors. Additionally, if the blocked-out area is on the facial of the appliance, the bulge in the thermoformed plastic will slightly detract from the esthetic presentation. These conditions seem to be well tolerated by the patient.

The alternative method of creating tooth-moving space within the dental arches is to cut a window into the thermoformed appliance with a plastic trimming bur in a slow-speed handpiece. The bur causes a frayed border to the window that can be smoothed with a scalpel (Fig 2-2). Because tooth movement must be unimpeded, particular attention must be given to the size of the window. It is best to err on the side of a bigger rather than a smaller

ClearCorrect Exhibit 1016, Page 26 of 335



FIG 2-1 Space within the appliance is obtained by blocking out the cast.

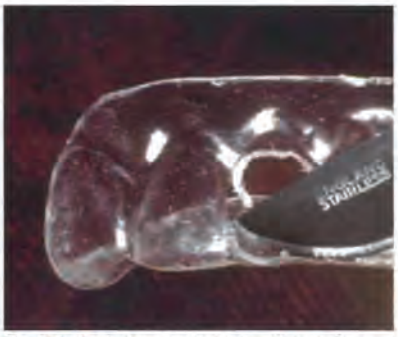


FIG 2-2 A window cut into the thermoformed appliance with a plastic trimming bur and finished with a scalpel creates space into which the tooth can move.

window. A 2.0- to 3.0-mm gingival border of plastic is necessary for adequate strength and resiliency.

Tongue irritation may develop from the presence of a lingual window because patients have a tendency to rub their tongue against the window's border. Patients can be supplied with bracket wax to wipe into the lingual window to alleviate this aggravation.

Creating space within the dental arches with interproximal reduction

Creating space within the dental arches usually involves expansion, extraction, or interdental reduction. Extraction is not a suitable option for gaining space with plastic appliances because it is difficult to upright roots and to efficiently close any remaining extraction space after the crowding is resolved. Expansion with a clear plastic appliance is possible, but arch coordination is difficult during the finishing stage and there is the liability of possibly moving the teeth past the limits of alveolar bone. Additionally, the patient's chief complaint frequently involves the resolution of crowding in a single arch. If, for instance, maxillary incisor crowding were the patient's chief complaint, expanding this arch would necessarily involve the complexity of adapting the mandibular arch to it to establish incisor or canine guidance. Caution is advised when rearranging established occlusal patterns by expansion when the patient's chief complaint is centered on mild to moderate incisor alignment problems and not functional distress.

To avoid the complexities associated with extraction or expansion, the judicious removal of interproximal enamel, if possible, is indicated. There are various techniques to do this. Using hand-pulled abrasive strips is too laborious



FIG 2-3 Interproximal reduction with the air-rotor stripping technique.

and is minimally effective for other than very modest dimensions because forcing the metal strip between proximal surfaces moves the teeth laterally into the periodontal space and does not create the needed interdental reduction.

Handpiece-mounted reducing disks can be dangerous because of the proximity of the tongue and cheeks to the rotating disk. This risk can be decreased with a disk guard, but this obstructs the clinician's vision of the reduction site. The safest and most efficient system for gaining space within the arch is by interproximal reduction with the disciplined utilization of an air-turbine handpiece. The Invisalign and Essix techniques recommend this method.

Air-rotor stripping (ARS) is a contemporary clinical procedure that involves the use of an air-turbine handpiece to reduce interproximal enamel for the alleviation of mild to moderate crowding (Fig 2-3).[4-5] There is ample evidence that ARS does not induce pathology of the hard or soft tissues.[6-9] Additionally, the space generated by ARS does not have to be estimated; it can be measured in increments of 0.10 mm with commercially available gauges (Fig 2-4).

ClearCorrect Exhibit 1016, Page 27 of 335



FIG 2-4 Commercially available gauges can be used separately or in tandem to measure the space generated by interproximal reduction.



FIG 2-5 The Intensive Ortho-Strip System reduces proximal enamel with appropriate blades in a handpiece that generates a back-and-forth shuttle action.



FIG 2-6 Force can be directed on any part of the clinical crown to create the most desired effect.

A conservative guideline would be to remove no more than 0.75 mm of interproximal enamel between the anterior contact points, and no more than 1.0 mm for contact points (0.5 mm for proximal surfaces) in the buccal sections. The suggested guidelines for ARS are as follows:

- Prior to ARS, establish a slight open field with coil springs or separators to improve the visual and mechanical access to the contact area.
- Contour the reduced proximal surfaces to resemble the acceptable morphology.
- Finish the reduced proximal surfaces to acceptable smoothness with fine-grit diamond burs.
- Prescribe a fluoride gel or rinse to supplement the already powerful remineralization potential of the reduced proximal surfaces. Data indicate that when the fully reacted outer layer of enamel is removed, the abraded (stripped) enamel surface is more prone to remineralization. When that occurs, the remineralized enamel surface is more, not less, resistant to caries initiation.[7,8,10]

The Intensive Ortho-Strip System (GAC) is an alternative method of reducing interproximal enamel with a handpiece but without a rotating bur. It involves the use of handpiece-driven abrasive strips with different configurations and abrasive potentials (Fig 2-5). The instrument removes enamel with a 0.8-mm oscillation movement (back-and-forth shuttle action). Metallic strips with different abrasive grain sizes may be used for the initial reduction of proximal surfaces. Also, there are flexible blades to contour and smooth the reduced proximal surface with abrasive grain sizes from 15 to 125 µm (see Fig 2-5).

Inducing Tooth-Moving Force in an Essix System

With Essix tooth-moving mechanics, the clinician has the option of placing force wherever on the crown surface would have the most desirable effect. Unlike an edgewise bracket that confines force application to the bracket slot, an Essix appliance permits force application on any area of the clinical crown. This, in turn, determines the type of tooth movement. For instance, if the force is placed incisally, more tipping is evident on the target tooth. If the force is placed gingivally, more bodily movement occurs. If the force is placed distally, movement about the mesial vertical axis occurs, and if the force is directed medially, movement about the distal vertical axis is evident (Fig 2-6).

There are two primary systems of creating a tooth-moving force with an Essix appliance. The first uses Hilliard thermopliers to alter the appliance by spot-thermoforming it. The second system, called mounding, does not involve altering the appliance to induce force. It involves the sequential placement of small mounds (layers) of bonding composite to the surface of the tooth.[10] These two force-inducing systems will be described separately.

Hilliard thermoforming pliers: Inducing force by altering the appliance

The Hilliard thermoplier technique efficiently induces a tooth-moving force into an Essix plastic appliance usually within a few seconds, and it can be done at chairside. The pliers can spot-thermoform a projection into the appliance that induces force as the resilient plastic returns to its resting state. These projections in the plastic can be mod-

ClearCorrect Exhibit 1016, Page 28 of 335



Fig 2-7 Various Hilliard thermopliers can induce a variety of biomechanical effects.



Fig 2-8 The thermoformed tooth-moving bump is always made toward the tooth surface, and an adequate gingival amount of plastic should be apparent on the gingival aspect of the window (*arrow*).



Fig 2-9 A 1.0-mm depression in the working cast allows the plastic to have maximum thickness for future adjustments.

ified to induce additional force on the same appliance as the case progresses. Various pliers are designed to induce force, create space within the appliance, create bite ramps, tighten an Essix appliance for a better fit, and create attachment hooks for Class II or III elastics (Fig 2-7). These pliers are capable of generating forces that can move teeth in all three planes of space and can move teeth that are adjacent to each other in different directions at the same time.

The force-inducing thermoformed projection (bump) created by the pliers is always made toward the tooth surface (Fig 2-8). To spot-thermoform this projection into the Essix plastic, the thermoplier tip is heated to approximately 200°F for Essix C+ plastic. When this temperature is achieved and measured, handles of the thermoplier are gently squeezed together to create a force-inducing projection in the plastic appliance. It must be cautioned, however, that in subsequent adjustments this periodic stretching of the plastic causes the projection to become thinner and decreases its force potential. Creating the first projection, by cutting a 1.0-mm depression in the working cast, allows the material to have a maximum thickness for future adjustments (Fig 2-9).

A heat source that generates temperatures in the 180°F to 215°F range is necessary to heat the thermoplier tip for spot-thermoforming the plastic. Because thermopliers are usually used at chairside, an open flame near the patient is a safety concern. A touch-activated burner is recommended for this reason (Fig 2-10). It has a "dead man's switch" that turns off automatically when the operator's hand is removed from the activation button. Heat sources such as a butane flame or a bead sterilizer may be used in the lab, but caution dictates that they should not be used at chairside.

Measuring the temperature of the thermoplier tip prior to thermoforming is required. If the thermoplier temperature is below the thermoforming range, the plastic will only stretch and tend to revert back to its original sheet form, thereby compromising tooth movement. If the temperature is too hot, the pliers will burn through the plastic. To preclude these difficulties, the exact thermoforming temperature can be recorded with a Hakko digital thermometer that displays on a readout scale the precise temperatures, in Fahrenheit or centigrade (Fig 2-11).

Mounding: Inducing force by placing composite on the tooth surface

Mounding reverses the technique of altering the plastic appliance by placing a force-inducing projection into it. Instead, a small mound of composite is placed on the enamel surface of the tooth to be moved. The resilient plastic presses against the mound and induces tooth movement. Whether there is a thermoformed projection in the plastic appliance or a small mound of composite on the tooth makes little difference because the biomechanical principle is the same; both methods deliver force to the target tooth as a result of the interference of the resilient plastic returning to its resting state (Fig 2-12).

The mound is placed on the enamel surface after the Essix appliance has been thermoformed. The technique is described below.

A conventional acid-etch procedure is done on the enamel surface that is to receive the mounding composite. The etched area should be of sufficient dimension to place a 1.0-mm thick composite mound. It is not necessary, or desirable, to etch the complete enamel surface. A 1.0-mm thick composite mound (any bonding composite is

ClearCorrect Exhibit 1016, Page 29 of 335



FIG 2-10 The touch-activated burner is a safe method of heating the tips of the thermopliers at chairside.



FIG 2-11 The Hakko digital thermometer can accurately record the temperature at the tip of the thermopliers.



FIG 2-12 A projection in the plastic or a composite mound on the enamel surface delivers equivalent forces on the target tooth as the resilient plastic returns to its resting state.

adequate) is placed on the prepared surface and cured. The height of the mound can be determined with before-and-after readings with a Boley gauge (Figs 2-13a and 2-13b).

The Essix appliance is placed on the teeth. The only modification made to the appliance is to create enough space for the tooth to move into by the methods previously described (ie, cutting a window in the plastic or by blocking out the cast prior to thermoforming the appliance).

At the subsequent visits, additional force can be induced to create additional tooth movement by adding 1.0-mm composite layers to the original mound. If the patient feels force on the target tooth, the force is usually adequate. If the patient feels no force, a slight amount of additional composite should be placed on the established mound. Occasionally, the patient feels no force when the appliance is seated but experiences a proprioceptive feeling of pressure on the target tooth after it has been placed and then removed. If the force is so great that it is difficult to seat the appliance, the height of the composite mound should be decreased with a sandpaper disk or a fluted plastic trimming bur.

Types of Tooth Movement That Can Be Achieved with Essix Mechanics

Labial and lingual movement

Labial and lingual movement is accomplished by placing the force-inducing projection in the plastic or a composite mound on the enamel surface, on the side that the tooth is to tip away from, and by relieving the cast with blockout compound or a window cut into the plastic on the side the tooth is to tip towards. If, for example, an incisor is to tip lingually, a composite mound (or Hilliard thermoplier projection) is placed on the facial enamel surface. Space for the tooth to move into is obtained with blockout relief or a window cut into the plastic. Additionally, adequate proximal space must be evident or obtained with interproximal reduction. If the tooth is tipped too far, the force-inducing composite mound or thermoplier projection can be reduced. This allows the target tooth to rebound to the desired position. The case report described below illustrates this principle.

An adult male had a maxillary left lateral incisor that was conspicuously out of alignment (Fig 2-14). It required proximal lateral incisor stripping and 2.5 mm of maxillary lateral incisor movement to the lingual. The buccal section intercuspation was acceptable. After the Essix appliance was fabricated, a mound of composite was placed on the facial surface of the aberrant lateral incisor. A lingual window was cut out of the plastic to establish the space for the tooth to move into. When the resilient plastic pressed against the composite mound, tooth movement was initiated. Using the same appliance, three separate mounding modifications (two of 1.0 mm and one of 0.5 mm) induced the force necessary for alignment of the lateral incisor.

ClearCorrect Exhibit 1016, Page 30 of 335



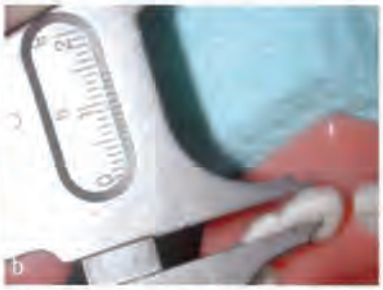


FIG 2-13 Before (*a*) and after (*b*) Boley gauge readings can ensure the correct dimensions of the composite mound.



FIG 2-14 The maxillary left lateral incisor is flared to the facial and requires 2.5 mm of lingual movement.

Treatment time was 3 months. Adjustment appointments were scheduled every 2 to 3 weeks. Chair time was minimal and involved making impressions, bonding the initial mound to the facial enamel, and adding the additional composite layers to the initial mound.

Lateral movement

On the working cast, blockout material—preferably Triad light-cured gel (Dentsply)—is placed on the side of the tooth where the lateral movement is to be accomplished. This creates a channel within the thermoformed plastic for the tooth to move into. For example, if a maxillary central incisor is to move to the mesial, blockout material is placed in the mesial interproximal area on the working cast before fabricating the Essix appliance (Fig 2-15). Space in the arch is obtained with interproximal reduction after the appliance is thermoformed. The blockout relief must be slightly above the incisal edge of the target tooth to prevent the incisal edge from contacting the inside of the Essix appliance and interfering with tooth movement.

Once space is obtained within the appliance and within the arch, the seated appliance induces initial movement. For additional movement, this force can be augmented with composite additions to the original mound or amplification of a thermoplier projection during the patient's sequential visits.

Torque

Torque is routinely established in an edgewise bracket by creating a couple, established with equal and opposite moments, within the bracket-to-wire complex. In effect, the tooth rotates around the bracket slot axis with the root moving one way and the crown moving in the opposite direction. Because of this, the efficiency of the edgewise moments are constrained because the width of the bracket limits the distance between the torquing moments to 0.022 inch or 0.018 inch (ie, the slot width of commercially available brackets). Essix-induced torque is more efficient because the distance between the opposing moments is only limited by the length of the clinical crown, measured in millimeters, rather than the width of a rectangular bracket slot measured in thousandths of an inch (Fig 2-16).

Essix torque is accomplished by creating a force-inducing projection in the plastic with Hilliard thermopliers or by mounding composite on the enamel surface. This is done in conjunction with a blockout material on the cast to allow tooth movement. For instance, if incisor torque involves moving the incisal edge lingually and the root labially, the working model is prepared by placing a force-inducing projection, or composite mound, on the incisal third of the labial surface of the crown and on the lingual surface on the gingival third of the crown. These forces induce a mechanical couple that will torque the incisor, moving the incisal edge lingually while the gingival section of the crown moves labially.

If incisor torque involves holding the incisal edge of the target tooth stationary and obtaining exclusive root movement, the Essix appliance is constructed to have 2.0 mm of the incisal edge covered with plastic and is, therefore, locked within the appliance. This incisal edge plastic cap holds the incisal edge in place while the root rotates under it due to the induced gingival force (Fig 2-17). The following case report illustrates this principle.

A middle-aged female had a lingually positioned mandibular central incisor that required significant facial tipping and labial root torque (Fig 2-18a). After appropriate

ClearCorrect Exhibit 1016, Page 31 of 335

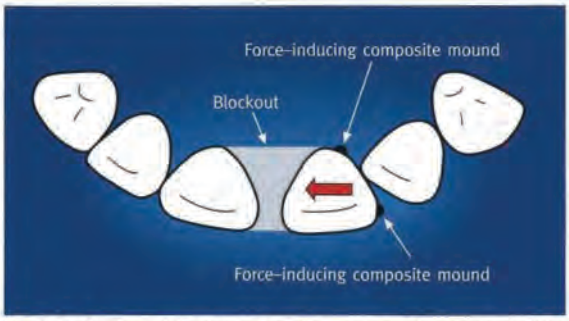


FIG 2-15 A channel for lateral tooth movement is constructed by placing blockout compound on the working cast before thermoforming the appliance.

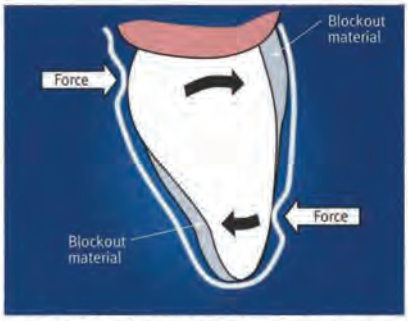


FIG 2-16 An efficient torquing couple, to move the root while slightly rotating the incisal edge, is established with an induced force and appropriate sections of the working cast blocked out.



FIG 2-17 An incisal edge plastic cap and a cervically placed mound or thermoplier bump torques the root while holding the position of the incisal edge.

interproximal reduction, a canine-to-canine Essix appliance was constructed, a 1.0-mm mound of composite was bonded to the lingual surface of the out-of-line incisor, and a facial window was cut into the appliance to create space into which the incisor could move. The initial mound was amplified twice with additional 1.0-mm layers of composite. These mechanics tipped the incisor into alignment, but the root still needed to be torqued under the crown. A second appliance was constructed with an incisal cap and a cervically placed lingual mound to induce facial root movement. After the addition of two 1.0-mm composite layers to the original torquing mound, root position was acceptable, as is evidenced by the lingual alignment of the mandibular incisors (Fig 2-18b). An Essix retainer for nighttime wear was constructed to retain the correction.

Rotation

To rotate an incisor about a central axis, it is necessary to induce a rotational force on diagonally opposed tooth surfaces and block out the appropriate space on the working cast. For example, if an incisor is to rotate lingually on one side and labially on the other side, the mounds or force-inducing projections would be distolingual and mesiolabial, and the relief would be distolabial and mesiolingual (Fig 2-19).

Interproximal reduction is usually necessary to create the room for the proximal surfaces to rotate into. It is best to reduce these surfaces incrementally in conjunction with the applied rotational force during subsequent visits. If one does all the reduction at one time, there is a possibility of generating too much space. A more conservative approach would be to reduce a little, then rotate the tooth a little. This sequence can be maintained until the target tooth is aligned. The rotational efficiency of an Essix appliance is apparent in the following case report.

This adult female's chief complaint was "crooked upper front teeth." Resolving this situation required minor interproximal reduction mesial and distal to the maxillary left central incisor to rotate it into arch form, a slight rotation about the distal contact point of the maxillary right lateral incisor and facial movement of the maxillary left lateral incisor (Fig 2-20a).

A rotational plastic appliance was constructed after blockout space was obtained on the working cast to create room for the proximal surfaces to move into. Air-rotor stripping was not done at one time but a little at each sequential appointment (ie, stripped a little, then moved

ClearCorrect Exhibit 1016, Page 32 of 335



FIG 2-18a The out-of-line incisor needs to be moved labially, and the root needs to be torqued under the crown.



FIG 2-18b The finished case indicates that the tooth was tipped and then torqued into acceptable alignment.

a little). After the rotations were resolved, the minor facial movement of the left lateral incisor was achieved. Satisfactory alignment was achieved (Fig 2-20b).

Additionally, rotation can be induced in an out-of-line proximal surface while maintaining the proximal surface that is acceptable. For example, to rotate the tooth on the mesial while holding an acceptable distal contact point, the distolingual aspect of the tooth is not blocked out while space for movement of the out-of-line mesial contact point is obtained with blockout compound. This absence of relief on the distal of the tooth locks the acceptable contact point in place and the target tooth pivots mesiolingually like a door on a hinge as a result of the force induced by the resilient plastic returning to its resting state. A guideline for the amount of tooth to have held within the appliance is 10% of the acceptable proximal surface. This approach is demonstrated in another case.

The distal contact point of the maxillary right lateral incisor is acceptable (Fig 2-21a). The mesial contact point needs to be rotated about a distal vertical axis to achieve acceptable alignment. Additionally, the right central incisor needs to be slightly tipped facially after appropriate and sequential interproximal reduction.

The progress photograph indicates that the rotation of the right lateral incisor has been partially corrected and that the central incisors are in approximate alignment (Fig 2-21b). Figure 2-21c shows the successful alignment of the rotated lateral incisor about an acceptable distal contact point in conjunction with alignment of the central incisors.

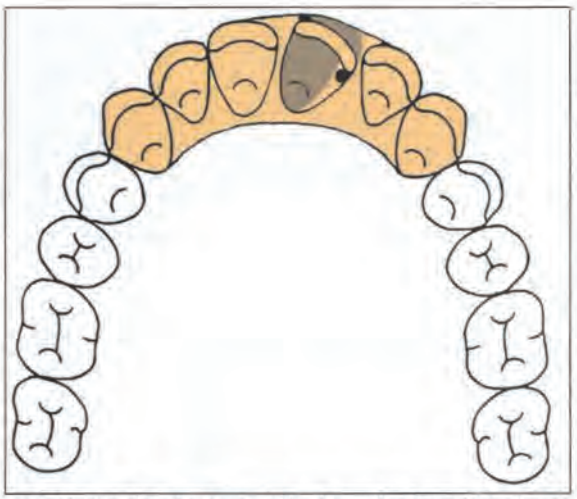


FIG 2-19 Rotation about a central axis requires force induction on diagonally opposed tooth surfaces and blocking out space on the working cast.

Extrusion and intrusion

The Essix appliance can serve as an anchor for elastics to extrude or intrude an anterior or posterior tooth. The suggested appliance for anterior teeth involves cutting a complete window into the thermoformed plastic to create the space for the target tooth to move into and to allow the bonding of a clear plastic button to the facial enamel for attachment of an intrusive or extrusive force-inducing elastic. Elastic attachment tabs are constructed, and light elastics, to be changed every day, are attached from the tabs on the appliance to the button bonded on the facial enamel. A diagram of the extrusion appliance used to intrude anterior teeth is shown in Fig 2-22.

ClearCorrect Exhibit 1016, Page 33 of 335



FIG 2-20a The maxillary central incisor needs to be rotated about its center line to be placed in acceptable arch form.



FIG 2-20b The center-line rotation was achieved by periodic interproximal stripping and incremental additions to the initial composite mound.



FIG 2-21a The mesial of the lateral incisor is rotated out of arch form. The distal contact point is acceptable.



FIG 2-21b The out-of-line contact point is being corrected by periodic stripping while the force on the same Essix appliance is gradually increased.



FIG 2-21c The incisor has been rotated about the distal axis and is in acceptable alignment.

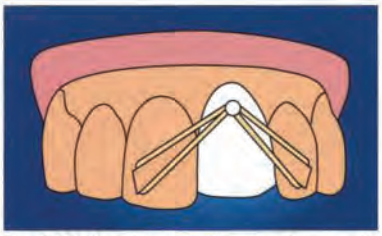


FIG 2-22 Anterior extrusion appliances utilize an elastic force stretched between elastic attachment tabs and strategically placed on a clear plastic button on the clinical crown.

Elastic attachment tabs can be constructed in various ways, such as cutting two horizontal slits, 3 to 4 mm apart, into the appliance with a scalpel and extending them 2 to 3 mm from the center of the facial surface toward the interproximal. A vertical scalpel cut is then made near the interproximal to connect the horizontal slits (Figs 2-23a to 2-23c). To minimize tissue irritation, the vertical edge of the tab should be well into the curvature of the interproximal area, and the corners of the tab should be rounded. The created tab is then flexed away from the body of the plastic, elastics are attached, and the patient is instructed as to their use.

Additionally, Hilliard thermopliers can be used to construct elastic attachment buttons on plastics. Two thermopliers are necessary to construct the elastic attachment button. The first plier thermoforms a cylindrical projection in the appliance when the tip of the pliers is heated and pressed into the plastic. A Hakko digital thermometer is used to determine the appropriate thermoforming temperature. Then, the heated thermoplier is placed at the desired location on the appliance and the handles are gently squeezed to create the initial cylindrical indentation into the plastic (Fig 2-24a). After 15 seconds, the pliers are removed with a rolling motion (rather than being pulled straight out of the plastic).

Next, the second slot-forming plier is heated, the "lipped" edge is placed around the base of the previously formed cylinder, and the plier handles are squeezed together. This indentation on the base of the cylinder forms an undercut to which an elastic can be attached (Fig 2-24b). The elastic will be held in place even when it is oriented up to 30 degrees away from the button (Fig 2-24c).

ClearCorrect Exhibit 1016, Page 34 of 335

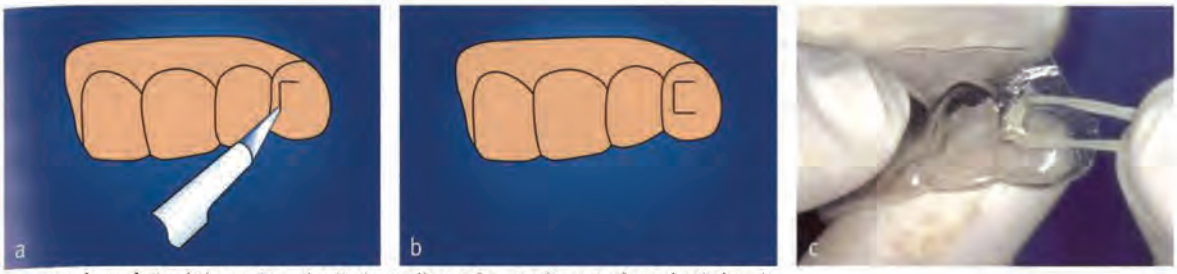


FIG 2-23 (a to c) A tab is cut into the Essix appliance for attachment of an elastic band.



FIG 2-24a The initial heated plier thermoforms a cylinder into the appliance.



FIG 2-24b The second heated plier crimps the base of the cylinder to form an elastic attachment.

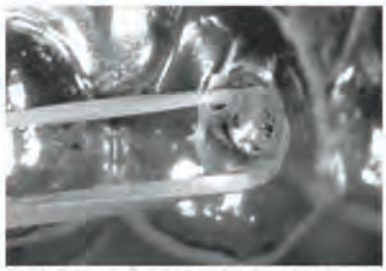


FIG 2-24c An elastic can be attached to the thermoformed button.

Intruding posterior teeth

Resolving excessively erupted posterior teeth with fixed appliances is biomechanically frustrating because, all things being equal, the simultaneous extrusion of adjacent teeth will be more evident than intrusion of the targeted teeth. This imbalance inevitably induces orthodontic complexities that can be avoided when intrusion is achieved with minimal, if any, effect on adjacent teeth. When intrusion or extrusion is indicated, an initial stage with an Essix appliance can reduce the complexities that are associated with trying to resolve the condition with fixed appliances.[11] Construction of the posterior intrusion appliance is described below.

The working cast is fabricated from die stone and subsequently trimmed to no more than 2.0 cm in height. Excessive undercuts, such as the three-cornered spaces that are gingival to contact points, are blocked out on the working cast with acrylic or stone.

Essix 1.0-mm C+ plastic is thermoformed over the unaltered cast, and the basic outline of the appliance is obtained by cutting the extraneous plastic away from the cast with a serrated metal disk. The plastic, gingival to the tooth to be intruded, is extended to give a plastic base for the elastic attachments. When the appliance is removed from the cast, the plastic outline is established with a curved Mayo scissors and extends 2 to 3 mm onto the gingival surface. The plastic covering the crown of the tooth to be intruded is then cut away.

A small rubber band (3/8 inches, 4.5 oz) exerting light force is secured to the facial and lingual tabs so that it crosses the crown of the extruded tooth. The rubber band is rotated to form an X. The rubber band, because of this configuration, does not slide into the interproximal area. The effectiveness of this appliance is apparent in Figs 2-25a and 2-25b.

The reciprocal force of the stretched elastic tends to unseat the appliance. Therefore, it is critical for the plastic to be well adapted to all retentive undercuts gingival to contact points. The retention potential of the appliance can be increased further by emphasizing the retentive undercuts gingival to contact points with a Hilliard thermoplier specifically designed for that purpose. Additionally, small composite mounds can be placed on the facial of selected teeth prior to making the impression. When the appliance is seated, it will snap over these composite mounds, and consequently form mechanical locks that will make the appliance resistant to displacement.

ClearCorrect Exhibit 1016, Page 35 of 335

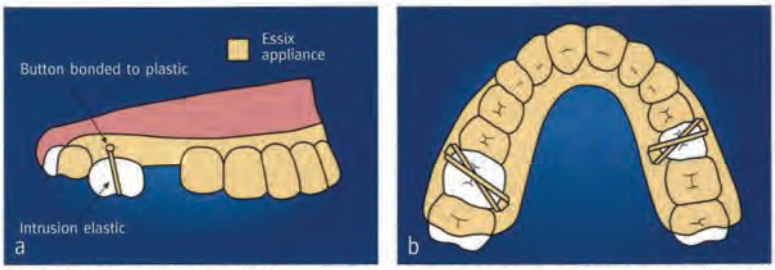


FIG 2-25 The intrusive elastic force is applied directly to the excessively extruded tooth. The effectiveness of the molar intrusion appliance is apparent. (*a*) Mechanics of the intrusion appliance. (*b*) Intrusion elastics in place.



FIG 2-26a The right canine had excessively erupted until it was touching the tissue of the opposing side.



FIG 2-26b The elastic force directed a pure intrusion effect on the canine.



FIG 2-26c The canine was intruded into successful alignment without affecting the occlusal status of the bordering teeth.

The intrusion elastic is attached to the attachment tabs or buttons. Since intrusion requires light force, the elastic should induce no more than 50 to 75 g of force. Also, as the target tooth starts to intrude, any occlusal force on the rubber band is eliminated and the tendency for it to break is reduced.

The following case report illustrates the intrusive capabilities of an Essix appliance. This case involved full-mouth rehabilitation. The right maxillary canine had excessively erupted until it was touching the tissue in the opposing arch (Fig 2-26a). A full-arch Essix intrusion appliance was constructed from a 1.0-mm Essix C+ plastic sheet. An elastic-securing notch could be cut into the tip of the canine because a veneer was to be constructed during the prosthetic phase of the patient's treatment. Alternatively, composite mounds could be bonded on each side of the tip of the canine and would serve to stabilize the intrusive elastic.

To induce an intrusive force, elastic attachment tabs were cut into the periphery of the appliance, and an elastic was placed from these tabs over the notch on the canine (Fig 2-26b).

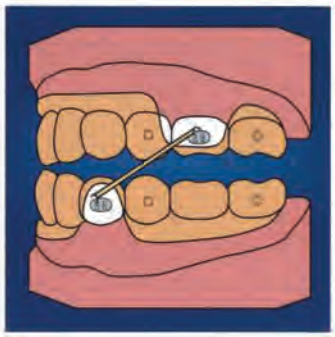
The appliance was worn for 3.5 months. The canine was intruded 4.5 mm while the occlusion of the remaining teeth was not disturbed (Fig 2-26c). The elastic attachment notches cut into the tip of the canine were reduced with a sandpaper disk to approximate normal morphology. The canine remained vital and the facial periodontal defect did not improve or worsen; however, a tissue graft was planned to resolve the facial periodontal defect.

Class II and Class III elastic applications

The biomechanical effects of Essix appliances are significantly increased when Class II or Class III elastics can be used to adjust arch relationships. A full-arch Essix appliance is required to support these elastics. Interarch elastics, in conjunction with removable plastic appliances, require two essentials: a method of attaching the elastics to the appliance, and a method of stabilizing the Essix appliance to counter the displacement effect of the elastic force.

In addition to the construction of elastic attachment methods previously described, a cemented band, or a bonded bracket can be used. Sokolina and Bloomstein,

ClearCorrect Exhibit 1016, Page 36 of 335



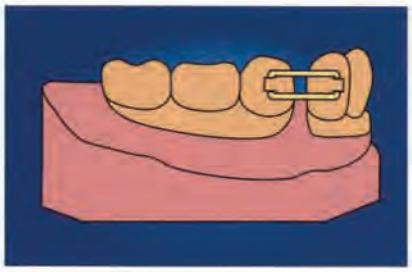


FIG 2-27 (*right*) The bonded molar attachment is the base for the Class II elastic. The molar is encapsulated in the Essix appliance and is therefore resistant to displacement.

FIG 2-28 (*far right*) A stretched elastic between the sections of the Essix appliance creates the force necessary to close the buccal section space. A stretched elastic between the sections of an anterior Essix appliance induces enough force to close the midline diastema.

combining ARS and Essix anchor technology, first described this method.[12] It involves (1) bonding an attachment (bracket or button) to the facial surface of a tooth that is the base for the elastic vector (a hook on a cemented band would work as well), and (2) constructing the full-arch Essix appliance and cutting a facial window over the area of the bonded attachment (Fig 2-27). The appliance still covers the occlusal and lingual surfaces of the tooth that has the attachment bonded to it and, because of this configuration, the appliance counteracts any extrusive elastic force on the anchor tooth.

Closing spaces: Reopened buccal section extraction and anterior diastema spaces

Clinicians are frequently frustrated when an extraction site, diastema, or idiopathic spacing becomes evident during retention because no one is enthusiastic about another round of fixed appliances to correct the problem. The offending space can be quickly resolved with a modified Essix appliance. The advantages to the patient are that the device is unnoticeable and very thin (< 0.5 mm), it does not interfere with function, and it is not difficult to place.

The biomechanical principle of closing spaces with an Essix appliance is to induce an elastic force across the space to be closed without tipping the teeth into said space. To close a reopened extraction space or, for that matter, any relatively minor buccal section space, 0.040-inch Essix plastic is thermoformed over the full-arch working cast, and the cast is removed from the plastic by cutting around the periphery of the appliance with a serrated disk and prying it out of the plastic with a thin-bladed instrument. The resultant appliance is trimmed 2 to 3 mm above the gingival margin with a curved Mayo scissors, thereby incorporating the retentive undercuts that are gingival to the interproximal contact points into the appliance. The technique used to close a reopened extraction site is described below.

The appliance is sectioned in the opened extraction space, which converts the Essix appliance into two pieces. (Or, to close reopened bilateral premolar extraction sites, for instance, one anterior and two posterior sections would be created.)

With the appliance placed, thin-walled elastics, approximately 0.25 in, 4.5 oz, are attached to the elastic attachment tabs on each side of the space (Fig 2-28). These relatively thin-walled elastics are stretched tightly and with enough force to move multiple roots bodily through bone.

The patient is instructed to change the elastics at least every 2 days. The appliance is to be cleaned with a toothbrush and water or a commercial retainer cleaner, but not with dentifrice. The abrasive particles in dentifrice dull the surface of the appliance and compromise its esthetic appeal.

Because the teeth are in slightly different positions after the extraction space is closed, it is advisable to equilibrate the occlusal surfaces to coordinate centric relation with centric occlusion.

Appliance construction to close a midline diastema

Midline diastemata are frequently the patient's chief complaint because this unsightly space is evident in the middle of his or her smile. Additionally, when retention instructions have not been followed, diastemata frequently reoccur. The offending space can be closed with a clear Essix appliance.

Presuming that the incisal spacing is not due to forces induced by the occlusion, the previously described procedure for closing extraction spaces with

ClearCorrect Exhibit 1016, Page 37 of 335



Fig 2-29a The midline diastema was the patient's chief complaint. (Figs 2-29a to 2-29c courtesy of Dr Anacar.)



Fig 2-29b The canine-to-canine plastic appliance was sectioned in the diastema area, and an elastic was stretched across the offending space.



Fig 2-29c The diastema was closed in 3 months; when the incisal edges of the central incisors are esthetically contoured, the esthetic improvement will be evident.

a sectioned Essix appliance and elastics can be applied to close a midline diastema. Following is the technique to be used.

A canine-to-canine Essix appliance, fabricated from 1.0-mm Essix plastic, is sectioned in the diastema space. Half of the appliance is placed on each side of the midline, and each section is extended 2 to 3 mm onto the gingiva. Previously described elastic attachment tabs are placed in the distal of each section. A clear thin-walled rubber band (approximately 0.25 in, 4.5 oz) is attached to the tabs and stretched tightly across the diastema space to create enough force, approximately 150 g, to bodily move the canine and lateral and central incisors on each side of the diastema through bone.

The appliance is worn full-time, with the exception of cleaning and eating, and the elastics are replaced every day. A diastema space of up to 3 mm should be closed within 5 or 6 weeks. At that time, the midline diastema will be closed but half of that space is now distal to the canines, and the teeth can move back into it. This redistributed space should be filled with a small composite thickness on the mesial of the first premolar or distal of the canine. This step may decrease the tendency for relapse. For additional retention, it would be advisable, bite permitting, to bond a lingual wire to the teeth on each side of the closed diastema. A conventional Essix retainer can be fabricated to fit over it to amplify the retention potential. And since the anterior bite will be slightly affected by the diastema closure, the anterior teeth should be equilibrated to assure balanced incisal coupling.

The following case report illustrates the effectiveness of Essix diastema-closing mechanics. This adult patient's chief complaint was the significant midline diastema (Fig 2-29a). A canine-to-canine Essix appliance was fabricated on the working cast, trimmed, and sectioned at the midline. An elastic with moderate force was secured to the elastic attachment tabs that were cut into the appliance (Fig 2-29b). The diastema was closed within 3 months (Fig 2-29c). Additional esthetic contouring of the incisal edges and composite bondings in the midline three-cornered space completed the esthetic treatment goal.

References

1. Sheridan JJ, LeDoux W, McMinn R. Essix retainers: Fabrication and supervision for permanent retention. J Clin Orthod 1993;27:37–45.
2. Sheridan JJ, LeDoux W, Robert MC. Essix appliances: Minor tooth movement with divots and windows. J Clin Orthod 1994;28: 659–663.
3. Sheridan JJ, McMinn R, LeDoux W. Essix thermosealed appliances: Various orthodontic uses. J Clin Orthod 1995;29:108–113.
4. Sheridan JJ. Air-rotor stripping. J Clin Orthod 1985;19:43–59.
5. Sheridan JJ. Air-rotor stripping update. J Clin Orthod 1987;21: 781–788.
6. Sheridan JJ. The physiologic rationale for air-rotor stripping. J Clin Orthod 1997;31:609–612.
7. el-Mangoury NH, Moussa MM, Mostafa YA, Girgis AS. In-vivo remineralization after air-rotor stripping. J Clin Orthod 1991;25:75–78.
8. Brudevold F, Tehrani A, Bakhos Y. Intraoral mineralization of abraded dental enamel. J Dent Res 1982;61:456–459.
9. Pinheiro ML. Interproximal enamel reduction. World J Orthod 2002;3:223–232.
10. Sheridan JJ, Armbruster P, Nguyen P, Pulitzer S. Tooth movement with Essix mounding. J Clin Orthod 2004;38:435–441.
11. Armbruster P, Sheridan JJ, Nguyen P. An Essix intrusion appliance. J Clin Orthod 2003;37:412–416.
12. Sokolina M, Bloomstein R. Air-rotor stripping technique for treatment of Class III malocclusion: Case report. World J Orthod 2002; 3:233–238.

ClearCorrect Exhibit 1016, Page 38 of 335

chapter 3

History and Overview of the Invisalign System

by
Trang Duong, DDS

ClearCorrect Exhibit 1016, Page 39 of 335

Several major developments have changed the field of orthodontics in the second half of the 20th century. Digital imaging and computers, for example, have improved the diagnostic process. Similarly, the introduction of prescription brackets, bonding, glass-ionomer cements, and nickel titanium and other alloy wires have improved treatment efficiency and efficacy.

The latest technological advance in orthodontics is the Invisalign System, which combines the idea of using overlay appliances and the application of three-dimensional technology to move teeth (Figs 3-1a and 3-1b).

History of Overlay Appliances

Moving teeth with overlay appliances was popularized by Kesling, who in 1945 reported the use of a Vulcanite tooth-positioning appliance[1] (Fig 3-2). As early as 1926, however, Remensnyder had introduced the Flex-O-Tite gum-massaging appliance, with which he reported achieving minor tooth movements.[2] Since then, various types of overlay appliances, such as invisible retainers, have been used.[3–7] Following the approach of Nahoum (see chapter 1), Sheridan popularized the Raintree Essix technique of using clear aligners formed over plaster models[6] (see chapter 2).

History of Align Technology

Align Technology was founded in 1997 to develop the next-generation esthetic appliance. Invisalign takes the principles pioneered by Remensnyder, Kesling, Nahoum, Sheridan, and others and integrates CAD/CAM (computer-aided-design/computer-aided-manufacture) technology. This innovative approach combines orthodontic principles with three-dimensional computer and mass-customization technologies.[1,3–7] Advances and innovations in these technologies have further improved and enhanced the Invisalign System. This chapter tells the story of Invisalign: how it was conceived and how it has evolved.

The Invisalign Concept

Kelsey Wirth and Zia Chishti, two MBA students from Stanford University, founded Align Technology in April 1997. The concept on which the company was founded came from Chishti, who had undergone adult orthodontic treatment, but like many patients was not consistent in wearing his clear retainer. After experiencing recrowding of his mandibular teeth, Chishti returned to wearing his overlay retainer, and this realigned his anterior teeth. Frustrated with the relatively slow and modest progress achieved with his overlay retainer, Chishti came up with the idea of using multiple appliances and computer imaging technology to effect

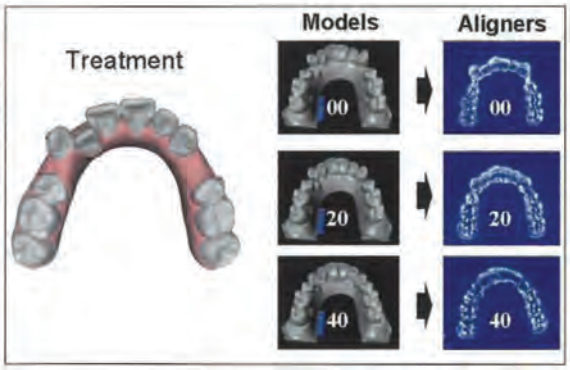


Fig 3-1a The Invisalign System generates gross tooth movements via a series of smaller tooth movements.



Fig 3-1b Invisalign appliances on a model.

ClearCorrect Exhibit 1016, Page 40 of 335

major tooth movements. From this revolutionary concept, Chishti and Wirth, two orthodontists, along with a software engineer, formed Align Technology in a garage in Palo Alto, California. Today, the company is based in Santa Clara, California, employs over 800 employees, and has divisions in Europe, Mexico, and Costa Rica.

The Invisalign Process

The Invisalign process involves several steps. The first step is the acquisition of complete patient records from the treating orthodontist. Once received at Santa Clara, the records go through a series of steps from scanning to case setup and then back to the clinician for a review called ClinCheck (see chapter 11). The process of manipulating virtual tooth movements is completed when the clinician approves the ClinCheck. Once the ClinCheck is approved, the aligners are processed and sent to the clinician. Figure 3-3 shows the Invisalign process and the individual steps within the entire process from beginning to end.



Fig 3-2 Positioner appliance.

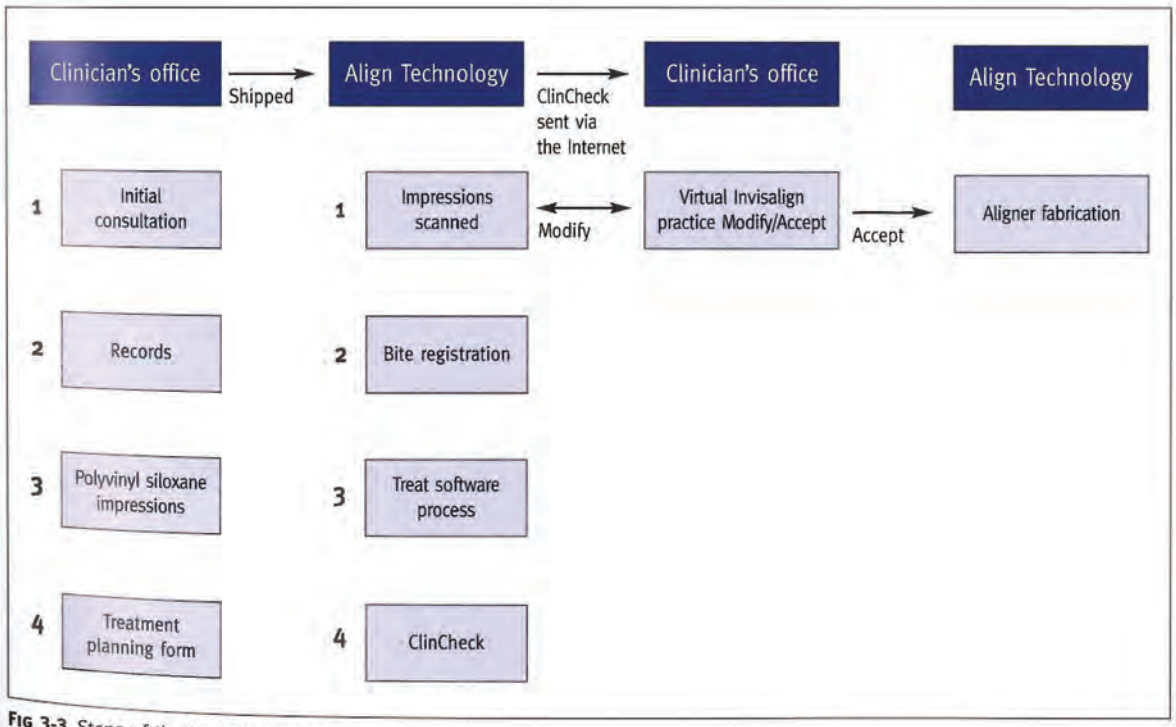


Fig 3-3 Steps of the Invisalign process.

ClearCorrect Exhibit 1016, Page 41 of 335

Polyvinyl siloxane impressions

An essential component of the Invisalign process is getting an accurate representation of the teeth. When the Invisalign process was in development, several potential impression materials were tested, including alginate and various polyvinyl siloxane (PVS)–based materials. PVS was chosen because it provided the greatest degree of accuracy and stability. Today, PVS impressions are still required; however, the clinician can use the one- or two-step technique (Fig 3-4). Tests are currently in progress to evaluate an alginate-based material that can provide the accuracy and stability of PVS while allowing easier and more efficient handling.

Scanning

The first Invisalign patient's dental images were initially captured by laser scanning. By the time Invisalign was commercially launched, however, an altogether different scanning technique was used: the PVS impressions were poured in dental plaster and encased with epoxy and urethane (Figs 3-5a to 3-5c). The models were destructively scanned with rotating blades that made numerous passes over the epoxy-encased models. After each pass, an image of the newly shaved surface was captured. A computer linked to the scanner then assembled the scan data to create a three-dimensional reconstruction of the models. Today, the impressions are scanned directly using a computerized tomography (CT) scanner, thereby bypassing the steps of pouring and encasing the models. This method greatly increased the efficiency of the scanning process. More information on the scanning process can be found in chapter 6.



FIG 3-4 Example of a one-step PVS impression.

Bite registration

To accurately capture the occlusion of the two arches together, a bite registration is required. The bite registration is based on centric occlusion because a virtual typodont with a virtual hinge axis is not currently available. The proper occlusal registration of the two arches is created using the bite registration material (Figs 3-6a and 3-6b).

Treat software

After the bite has been established, an Invisalign virtual orthodontic technician uses software to "cut" the virtual models and separate the teeth, thus allowing them to be moved individually. In 1997, because of the limitations of the software tools used to perform the cutting of the teeth, each virtual tooth had to be separated and



FIG 3-5a Preparation of plaster models for encasing in epoxy in preparation for early method of destructive scanning.



FIG 3-5b Machines used to encase the models.



FIG 3-5c Plaster models after they have been encased in epoxy.

ClearCorrect Exhibit 1016, Page 42 of 335



FIG 3-6a Polyvinyl siloxane registration material.



FIG 3-6b Bite registration.



FIG 3-7a Early image with no virtual gingiva.



FIG 3-7b Current image with virtual gingiva.

sectioned, which was a time-consuming process. This process took about 48 hours for a single case. The resulting images were grainy and had defects. The file size for one case was about 10 MB. There was no virtual gingiva at this time, so the extension of the cuts was visible (Figs 3-7a and 3-7b). When the Invisalign process was in its earliest stages of development, the clinician was required to fill out not only a treatment planning form but also a staging form on which he or she indicated which teeth were to be moved and in what sequence. The clinician then sent the forms to the company. This approach demanded a great deal of time from the clinician, who was compelled to determine, based on the treatment goals, the best sequences for moving the teeth into the desired alignment. Today, the staging is done by Align Technology based on the clinician's treatment plan.

However, the clinician can still specify changes to the staging via ClinCheck. Once the case is set up and staged based on the clinician's prescription, the virtual data are converted to a ClinCheck file that can be sent electronically to the clinician's Virtual Invisalign Practice (VIP) website for review (see chapter 15). After reviewing the ClinCheck file, the clinician can either accept it (thus, authorize production and delivery of the aligners) or modify it by providing instructions through the VIP website (Figs 3-8a and 3-8b).

Aligner production

Once the clinician approves the ClinCheck, the three-dimensional computer images are converted to physical models using a process called rapid prototyping. Specifically, stereolithography is the rapid prototyping technology used to create the models (Fig 3-9). These models are still used to fabricate the aligners on a Biostar (Scheu-Dental) pressure-molding machine (Figs 3-10 and 3-11). Previously, the aligners were manually trimmed, laser-etched, disinfected, packaged, and sent to the clinician. Today, the trimming process is performed robotically on a mechanical five-axis milling machine.

ClearCorrect Exhibit 1016, Page 43 of 335

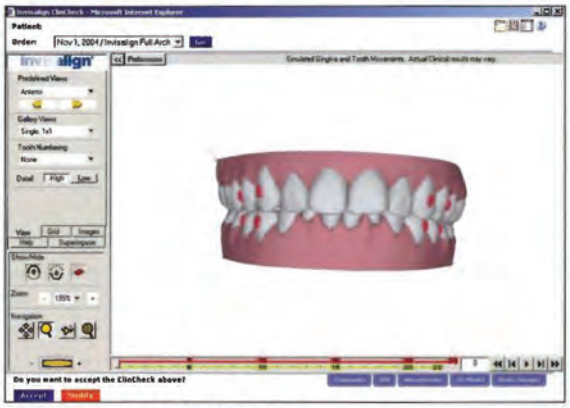


FIG 3-8a ClinCheck virtual image.

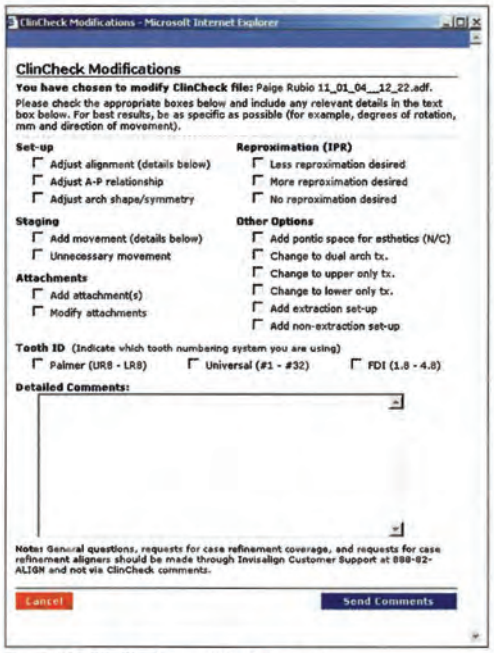


FIG 3-8b ClinCheck modification page.



FIG 3-9 Stereolithography model.



FIG 3-10 Biostar machine used to fabricate the aligners.



FIG 3-11 Pressure-formed aligner over the stereolithographic model.

ClearCorrect Exhibit 1016, Page 44 of 335

Invisalign Patents

Given the unique and innovative nature of the Invisalign System, Align Technology filed patents to protect the Invisalign technology. Align Technology, Inc, holds approximately 60 patents covering a wide range of techniques for scanning teeth and designing and manufacturing removable dental appliances. The patents also cover computer techniques for modeling dental structures and compressing and transmitting the dental data to the orthodontist and general practioner's workstation through ClinCheck. Patents range from defining tooth-moving appliances computationally to methods and systems for incrementally moving teeth.

Invisalign: The Future

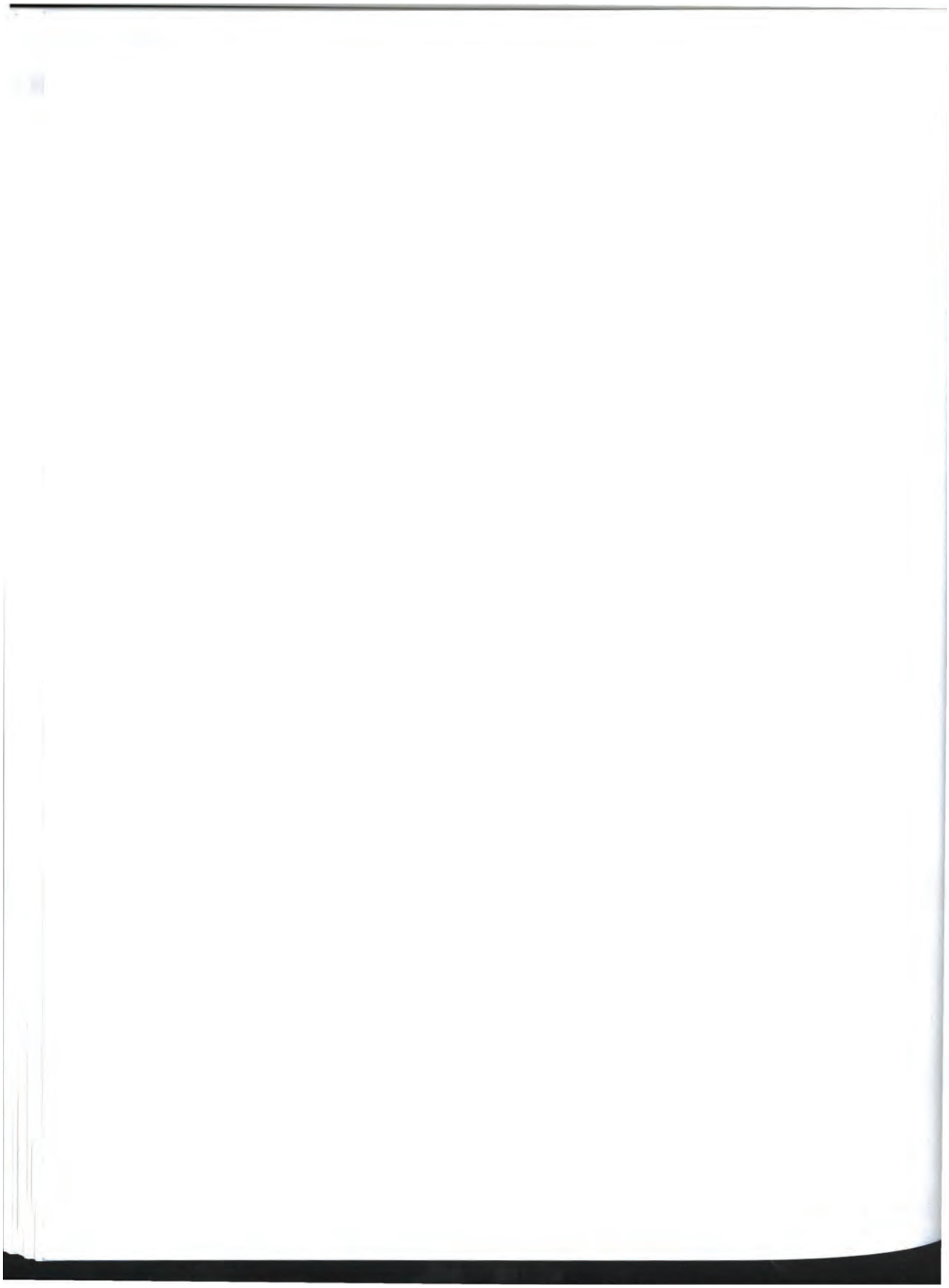
The concept of moving teeth with clear overlay appliances has been around since 1926. Align Technology, however, is the first company to incorporate modern technology in a way that makes this concept a feasible, viable, efficient, and effective orthodontic treatment option. Without the innovative computer technology and advanced manufacturing processes, which are the hallmarks of the Invisalign System, it would be extremely difficult—if not impossible—to produce aligners in such large numbers and with such great accuracy.

The Invisalign process has evolved and improved since 1997, and even today continues to change and adapt to better meet the needs of clinicians and their patients. In the chapters that follow, each step in the Invisalign process will be discussed in detail to provide information on the technology behind this innovative process.

References

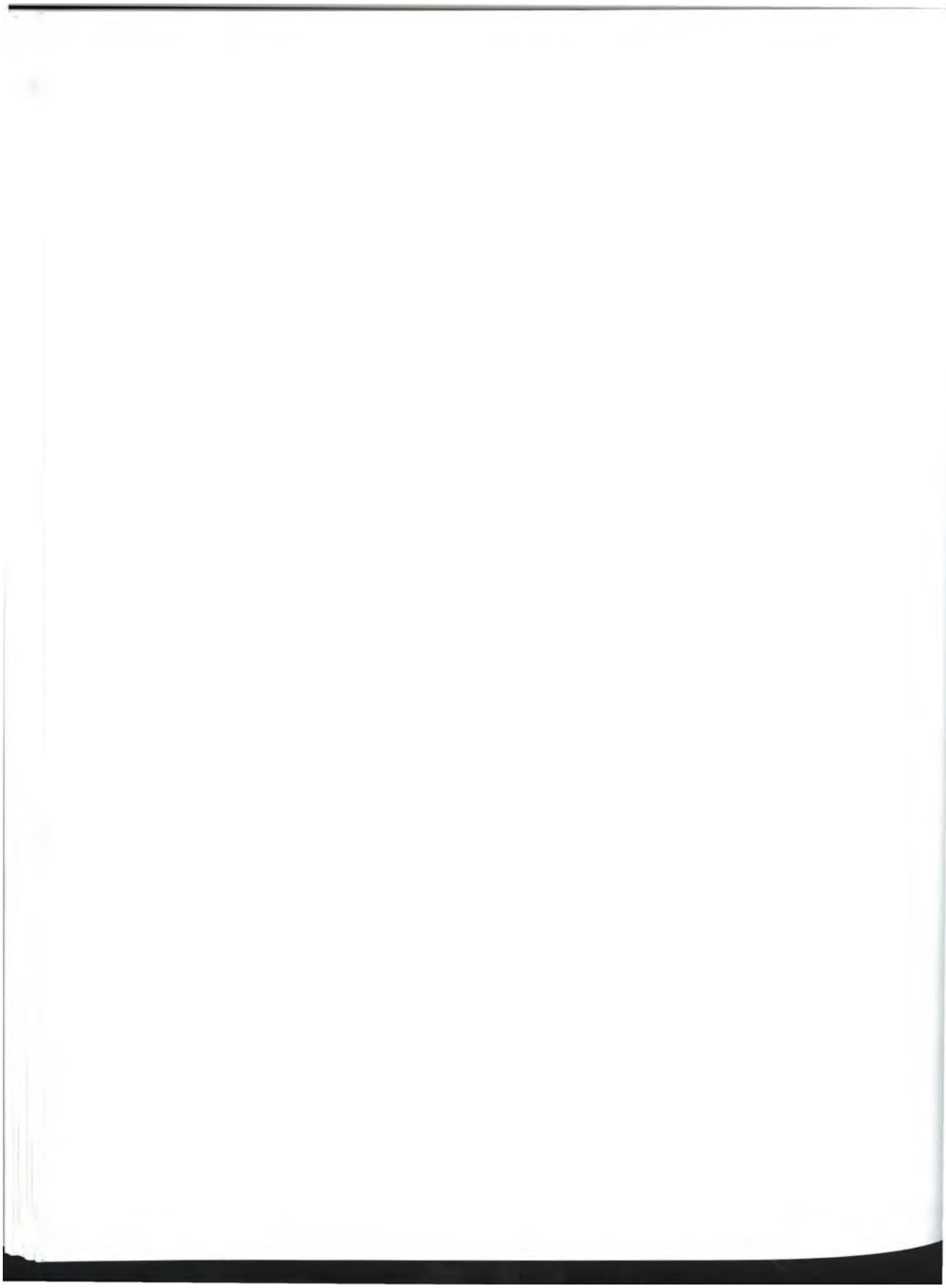
1. Kesling HD. The philosophy of the tooth-positioning appliance. J Dent Res 1945;31:297.
2. Remensnyder O. A gum-massaging appliance in the treatment of pyorrhea. Dent Cosmos 1926;28:381–384.
3. Nahoum H. The vacuum-formed dental contour appliance. N Y State Dent J 1964;9:385–390.
4. Pontiz RJ. Invisible retainers. J Dent Res 1971;59:266–271.
5. McNamara JA Jr, Kramer KL, Juenker JP. Invisible retainers. J Clin Orthod 1985;19:570–578.
6. Sheridan J, LeDoux W, McMinn R. Essix retainers: Fabrication and supervision for permanent retention. J Clin Orthod 1993;27:37–45.
7. Rinchuse DJ, Rinchuse DJ. Active tooth movement with Essix-based appliances. J Clin Orthod 1997;31:109–112.

ClearCorrect Exhibit 1016, Page 45 of 335



SECTION II

MODELING IN THE INVISALIGN SYSTEM



chapter 4

POLYVINYL SILOXANE IMPRESSION MATERIALS

by
John M. Powers, PhD

ClearCorrect Exhibit 1016, Page 49 of 335

Impression materials are used to accurately record the dimensions and spatial relationships of oral tissues.[1] Alginate hydrocolloid impression materials have been used for many years in orthodontics to produce study models. Improvements in alginates have allowed the orthodontist to send alginate impressions to the dental laboratory for fabrication of study models. However, for increased accuracy and durability of full-arch impressions, elastomeric impression materials, such as addition silicone and polyether, are used. Desirable features of elastomeric impression materials include[2]:

- Appropriate consistencies (tray, wash, monophase) for the desired technique
- Ease of use (automix with static or dynamic delivery)
- Lack of taste or odor
- Wetting of the tissues without bubbles
- Quick setting to minimize deformation in the mouth
- Flexibility (easy to remove from the mouth)
- High elastic recovery on removal from the mouth
- Excellent detail reproduction
- Ease of disinfection
- Long-term dimensional stability

Wax bite registrations are traditional but are highly susceptible to distortion on removal from the mouth and during storage.[3] Elastomeric bite-registration materials offer improved accuracy and dimensional stability. Desirable features of elastomeric bite-registration materials include:

- Ease of use (automix cartridge)
- Adequate working time with quick setting in the mouth
- Resistance to deformation
- Long-term dimensional stability[4]

Types, Composition, and Setting

Silicones

Addition silicone (polyvinyl siloxane, PVS) impression materials are most commonly used in the dental office, whereas the older condensation silicones are primarily used in the dental laboratory for duplicating procedures. Examples of commercial addition silicone impression materials and their manufacturers are listed in Table 4-1.

Addition silicones are available as two pastes or putties, one of which is the base and the other the catalyst. Many consistencies are available, including light (syringe, wash), medium (tray), monophase, heavy, and putty. In most instances, the two pastes are mixed from a cartridge using an automix gun with static mixing tips or a benchtop dynamic mixer (MixStar, Zenith/DMG; Pentamix 2, 3M ESPE). Two-putty systems are usually mixed by hand-kneading, but injectable putties are now available. The newest addition silicones contain nonionic surfactants that achieve increased wettability of the dental tissues. Many products are available in regular and rapid-set formulations.

The polymerization reaction of addition silicones occurs between vinyl and hydrogen groups with no by-product being formed, so the addition silicones are dimensionally stable. Latex rubber gloves contain sulfur compounds that adversely affect the setting reaction of addition silicones.[5]

TABLE 4-1 Impression materials by type, product name, and manufacturer

Product	Manufacturer
Addition silicone	
Affinis	Coltène/Whaledent
Aquasil Ultra	Dentsply/Caulk
Correct Plus	Pentron Clinical Technologies
Examix NDS	GC America
Flexitime	Heraeus Kulzer
1st Impression	Den-Mat
Genie	Sultan Chemists
Honigum	Zenith/DMG
Imprint II Penta	3M ESPE
Splash	Discus Dental
Standout	SDS Kerr
Take 1	SDS Kerr
Virtual	Ivoclar Vivadent
Polyethers	
Impregum Penta Soft	3M ESPE
P2	Heraeus Kulzer
Alginate substitute	
Dimension Penta	3M ESPE
Alginates	
Identic	DUX
Jeltrate	Dentsply/Caulk
Kromopan	LASCOD

ClearCorrect Exhibit 1016, Page 50 of 335

These compounds can be transferred to the teeth and soft tissues during preparation for the impression. Vinyl gloves should be used to avoid contamination. The teeth and soft tissues can be rinsed with 2% chlorhexidine to remove contaminants if needed.

Polyethers

Polyether impression materials are available in light, medium, and heavy consistencies. Mixing can be done by hand, using an automix gun with a static mixing tip, or by using a benchtop dynamic mixer. There is no volatile by-product during polymerization of the polyether. Contamination with water can cause an expansion of the setting material and should be avoided. Examples of commercial polyether impression materials and their manufacturers are listed in Table 4-1.

Alginates

Alginate impression materials can be mixed by hand or by a mixing machine (Alginator, Cadco). Because alginates are hydrogels, they shrink on storage as a result of syneresis and evaporation. Disinfection can be accomplished by either spray or immersion. Examples of commercial alginate impression materials and their manufacturers are listed in Table 4-1.

Alginate substitute

An alginate substitute (actually an addition silicone) is available from several manufacturers (see Table 4-1). This material is mixed by a bench-top dynamic mixer.

Properties of Elastomeric Impression Materials and Their Clinical Relevance

A number of physical and mechanical properties affect the performance of impression materials (Table 4-2).[3,6]

Working and setting times

Working time is a measure of the maximum time available before the impression should be seated in the mouth. Setting time is a measure of how long the impression must remain in the mouth before removal can occur. The accuracy of an impression may decrease if the impression is removed from the mouth too early. A snap set will minimize distortion while the impression is in the mouth. A slight improvement in accuracy may result from leaving the impression in the mouth for an additional 30 seconds beyond the manufacturer's recommendation.

Detail reproduction and wettability

Detail reproduction is influenced by the viscosity of the impression material and its ability to wet the tooth structure and soft tissues, especially in the presence of moisture. Wettability is best with a hydrophilic impression material that forms a low contact angle (20 to 60 degrees) with tooth structure. Poor wetting results in bubbles and voids, often requiring that the impression be remade. Addition silicones are formulated to be hydrophilic by the addition of surfactants or by modification of

TABLE 4-2 Properties of addition silicone, polyether, and alginate impression materials

Property	Addition silicone*	Polyether	Alginate
Working time (min)	0.5–5.0	2.5–3.3	1.2–4.5
Setting time (min)	2.0–4.0	3.3	1.5–5.0
Wettability of tissues	Good to fair	Good	Good
Shrinkage on setting (%) 24 hours	0.08–0.40	0.07–0.27	0.6–2.7
1 week	0.08–0.40	0.21–0.55	Not recommended
Flexibility during removal (%)	2.0–11.0	2.5–8.5	14.0
Elastic recovery (%)	98.9–99.9	98.2–99.7	95.7–96.4
Detail reproduction	Excellent	Excellent	Good

**Alginate substitute has similar properties to addition silicone.*

ClearCorrect Exhibit 1016, Page 51 of 335

the polymer structure. Polyether impression materials are naturally hydrophilic. In general, light-bodied impression materials provide better detail reproduction than other consistencies.

Flexibility

Flexibility is a measure of the ease of removal of the impression from the mouth. An impression that is stiff may become locked into undercuts in the oral structure and be difficult to remove.

Elastic recovery

When an impression is removed from the mouth, it is subjected to tensile and compressive forces that could result in distortion. The set impression must be sufficiently elastic that it will return to its original dimensions with minimal distortion (< 2%).

Dimensional stability

Dimensional change (shrinkage) occurs when an impression material sets and may increase during the time the impression is stored. At 24 hours, the shrinkage of addition silicones and polyethers is similar. After 1 week, the shrinkage of addition silicones does not change much, but the shrinkage of polyethers increases. Some addition silicone impressions are sufficiently stable that a second gypsum cast can be made several weeks after the impression is made.

Manipulation of Elastomeric Impression Materials

Several steps must be taken to achieve a quality impression. Troubleshooting the impression after removal from the mouth can save time and money in the event that the impression needs to be remade (Table 4-3). There are a number of strategies dental assistants and clinicians can use to improve impressions (Box 4-1). Figures 4-1a to 4-1d show an example of an unusable impression.

Selection of a tray

Full-arch trays are available in metal or plastic. A tray of proper dimensions and extension should be selected. The tray can be extended with wax if needed. A rigid tray is desirable to minimize distortion during the impression procedure. It is best to use a rigid tray even if the impression material itself is rigid. The Invisalign System provides plastic mandibular and maxillary trays.

Tray adhesive

Both addition silicone and polyether impression materials require a tray adhesive for metal and plastic trays. The adhesives vary with the type of impression material and are not interchangeable. Although some trays have perforations and other retention modes, use of a tray adhesive can minimize distortion when the impression is removed from the mouth. The tray adhesive should be allowed to dry before the impression material is added.

TABLE 4-3 Troubleshooting orthodontic impressions

Criteria for a good impression	Troubleshooting tips
Impression uniformly mixed	Make sure dispensing tips (base and catalyst) of automix cartridge are open.
Impression supported by the tray	Make sure impression material is uniformly distributed in the tray. Extend the tray with wax if necessary.
No visible defects	Make sure there are no voids or tears.
Impression adheres to tray	Make sure the impression has not detached from the tray, or the impression will be distorted.

ClearCorrect Exhibit 1016, Page 52 of 335

BOX 4-1 Tips for improving impressions

Tips for dental assistants

- Apply the proper adhesive to the tray and allow it to dry completely.
- Make sure the tips of the automix cartridge are open.
- Minimize bubbles when loading the impression tray.
- Pay attention to working times to achieve desired viscosity and detail.

Tips for clinicians

- Select a tray of adequate size and extension. Ensure that the tray allows space for 2 to 4 mm of impression material. Provide occlusal stops if needed.
- Avoid touching the teeth with latex gloves. Chemicals in the latex can prevent the silicone from setting.
- Seat the impression in a timely fashion. Minimize movement of the tray after seating to minimize distortion.
- Do not remove the tray too early, to minimize distortion.
- Remove the tray with a uniform motion to minimize distortion; do not rock or twist the tray.

Mixing the material

Nearly all addition silicones are available in 50-mL automix cartridges; some products are provided in 75-mL cartridges. Benchtop dynamic mixers utilize large cartridges that contain 360 mL or more of material. The benchtop mixers are cost effective when multiple impressions are made daily.

The tips of the cartridges must be open for the base and catalyst pastes to dispense properly for mixing. Improper mixing of the catalyst and base may result in a poor impression (Figs 4-2a and 4-2b).

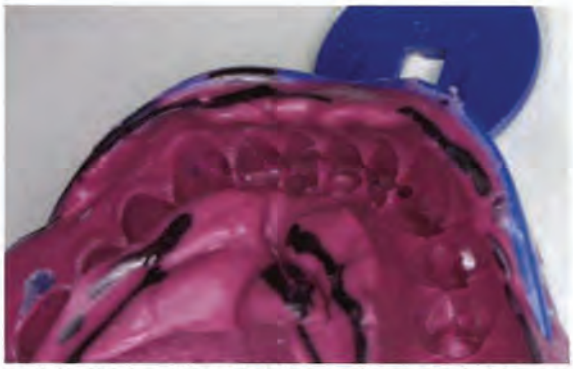


FIG 4-1a Minute voids and bubbles are often overlooked because they might be covered by salivary bubbles.

Impression techniques

- *One-step technique (monophase)*: The shear thinning property of the monophase consistency allows the impression material to be placed into the tray with minimal slumping.
- *Double-mix technique (tray/wash)*: A wash material is injected around the teeth using a syringe, and the tray filled with a heavy-bodied material is placed.

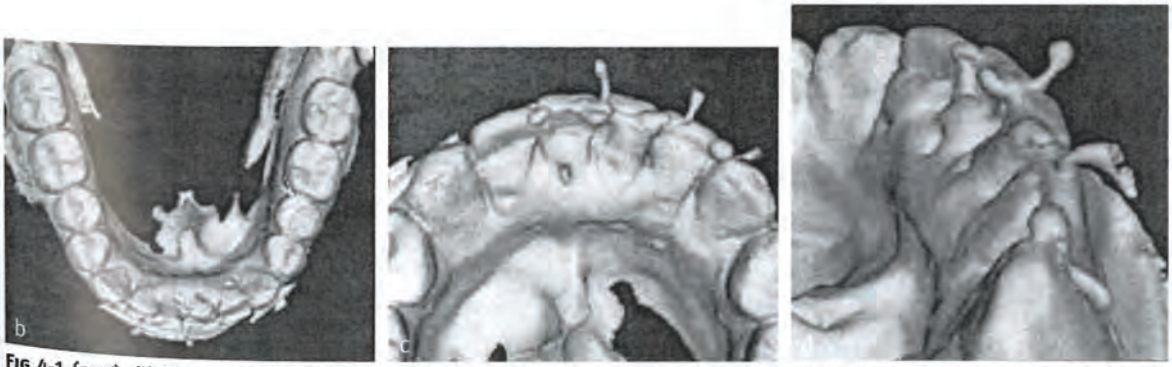


FIG 4-1 (*cont*) (*b*) The scanned image discloses the defects in the impression in the Align return report. As much as Align Technology is reluctant to reject impressions, this impression is not usable. (*c and d*) Closeup views of the scanned image.

ClearCorrect Exhibit 1016, Page 53 of 335



FIG 4-2a At times, the catalyst does not mix in well when the clinician first presses the button on the bench-top automix. It is advised for a modicum of paste to be expelled before the tray is filled. Failure to do so will create nondescript, bubblelike topography.



FIG 4-2b The Align return report reveals that the corresponding scanned image lacks detail around these molar teeth. If this impression were to be used, the aligner tray would not fit properly.

- *Two-step technique (tray/wash)*: A preliminary impression is made with the heavy-bodied material (medium consistency or injectable putty) with a cellophane spacer on top. Wash material is added (after removal of the spacer) to the preliminary impression for the final impression. The best accuracy can be achieved by using a tray/wash technique.

TABLE 4-4 Addition silicone bite-registration materials by product and manufacturer

Product	Manufacturer
Imprint Bite	3M ESPE
Exabite II NDS	GC America
Genie Bite Registration	Sultan Chemists
Memoreg 2	Heraeus Kulzer
Occlufast Rock	Zhermack
Perfectim Systems 30 Second Blue Velvet	J. Morita
Regisil Rigid	Dentsply/Caulk
Registrado X-tra	Voco

Removal and trimming of impressions

Before the impression can be removed, the seal must be broken in the posterior area. The impression can then be removed—a firm, steady motion is best. Unsupported areas of the impression should be trimmed to minimize distortion.

Disinfection of impressions

A variety of disinfectants is available, including neutral glutaraldehyde, acidified glutaraldehyde, neutral phenolated glutaraldehyde, phenol, iodophor, and chlorine dioxide. Addition silicone impressions can be disinfected by immersion per the manufacturer's directions.[7] Polyether impressions can change dimensions on immersion in some disinfectants, so only short times (2 to 3 minutes) in chlorine-type disinfectants are recommended for polyether impressions. Some clinicians prefer to disinfect polyether impressions by a spray-and-wipe technique.

BOX 4-2 Tips for improving bite registrations

Tip for dental assistants

- Make sure the tips of the automix cartridge are open.

Tips for clinicians

- Use trays to improve accuracy.
- Avoid use of excess bite-registration material to minimize rebound.
- Trim carefully since the material is brittle.

ClearCorrect Exhibit 1016, Page 54 of 335

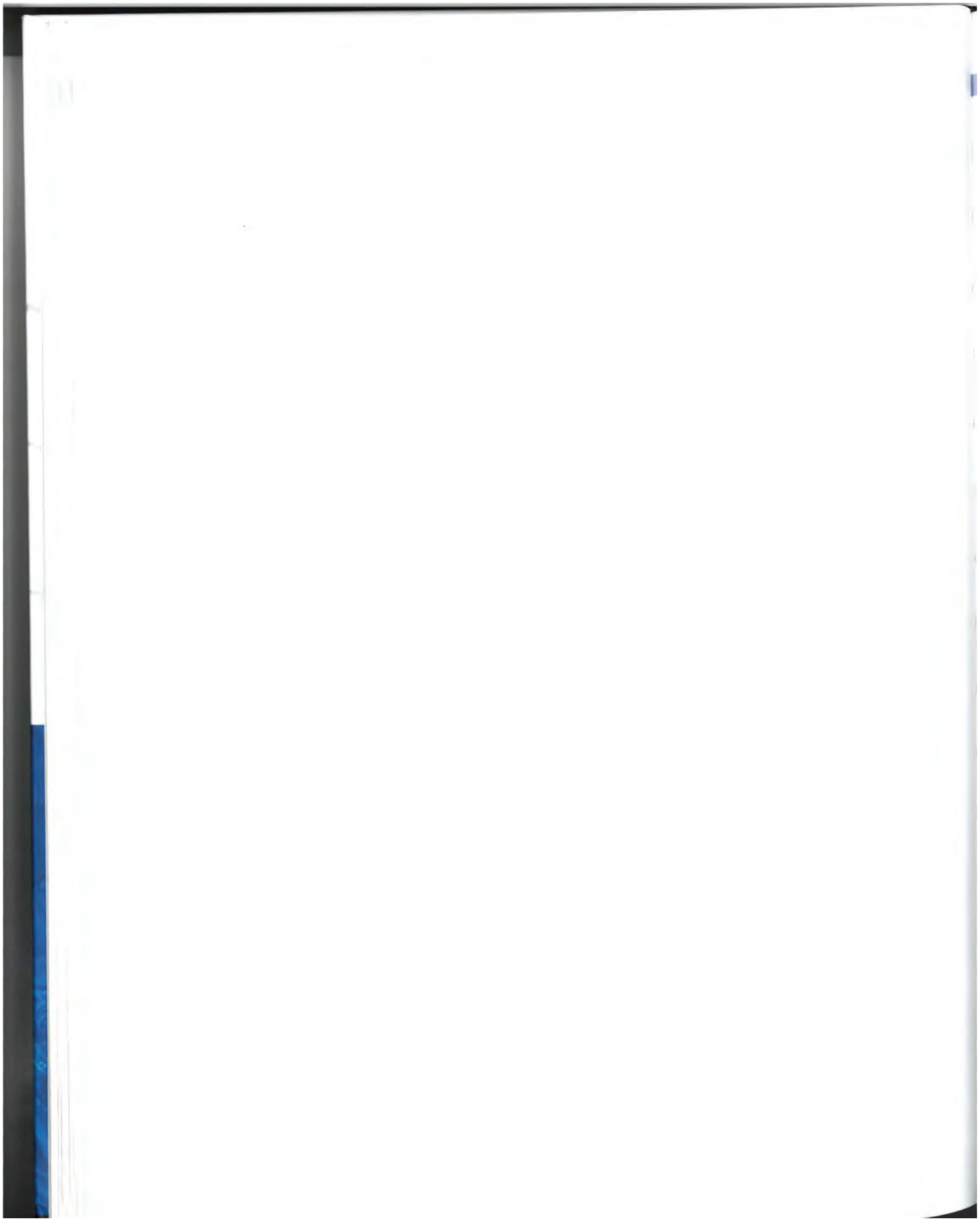
Bite registration

Addition silicone bite-registration material is injected using a syringe with a broad tip. Use of a tray improves accuracy. Setting times of addition silicone bite-registration materials vary from 40 to 60 seconds. A number of commercial addition silicone bite-registration materials are available (Table 4-4). Tips for the dental assistant and the clinician for improving bite registrations are listed in Box 4-2.

References

1. Anusavice KJ (ed). Phillip's Science of Dental Materials, ed 11. St Louis: Saunders, 2003.
2. Farah JW, Powers JM (eds). Elastomeric impression materials. Dent Advisor 2003;20(10):2–4.
3. Powers JM, Sakaguchi RL. Craig's Restorative Dental Materials, ed 12. St Louis: Mosby, 2006.
4. Farah JW, Powers JM (eds). Elastomeric bite registration materials. Dent Advisor 2004;21(3):5.
5. Baumann MA. The influence of dental gloves on the setting of impression materials. Br Dent J 1995;179(4):130–135.
6. Lu H, Nguyen B, Powers JM. Mechanical properties of 3 hydrophilic addition silicone and polyether elastomeric impression materials. J Prosthet Dent 2004;92:151–154.
7. Drennon DG, Johnson GH. The effect of immersion disinfection of elastomeric impressions on the surface detail reproduction of improved gypsum casts. J Prosthet Dent 1990;63:233–241.

ClearCorrect Exhibit 1016, Page 55 of 335



chapter 5

ALIGN'S STANDARD ON QUALITY IMPRESSIONS

by
David Chenin, DDS

ClearCorrect Exhibit 1016, Page 57 of 335

Making the polyvinyl siloxane (PVS) impression is the most critical stage in the treatment process. A good impression helps to ensure proper identification of tooth anatomy and the manufacture of aligners that fit. After the impression is scanned (see chapter 6), it is inspected by Align technicians. Thus, it is the virtual three-dimensional positive of the impression that is inspected. Technicians are trained and tested in specific protocols and standards. The primary reference used gives technicians who inspect PVS impressions defined visual criteria for the acceptance or rejection of an impression. The clinician's and patient's perspectives are always kept in mind during the inspection process.

The rejection of an impression is taken very seriously. All options and considerations are taken into account and attempted prior to the rejection of an impression. Some of the major areas that are evaluated include the following:

- The impression extends more than 2 mm beyond the free gingival margin (cementoenamel junction if recession is present) on the buccal and lingual surfaces. When high-quality intraoral photographs are provided by the treating clinician, occurrences of small discrepancies along the gingival border can be restored by the technician (Figs 5-1a and 5-1b).



Fig 5-1a Gingival margins are not clearly defined in the scan image.



Fig 5-1b Clinical photographs aid the technician in drawing the gingival border.



Fig 5-2a Not all poorly made impressions are rejected.

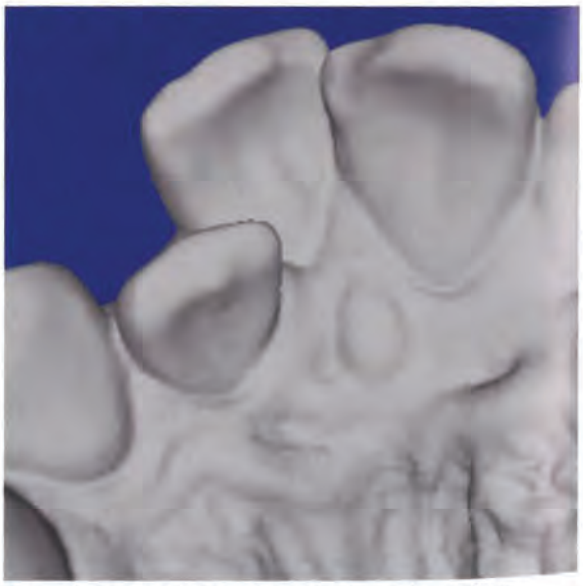


Fig 5-2b The same image after reshaping and smoothing.

ClearCorrect Exhibit 1016, Page 58 of 335

- Distortions, bubbles, voids, and wrinkles of teeth are reshaped if they are less than 2 to 3 mm, depending on the location and if the surrounding contours are clearly visible (Figs 5-2a and 5-2b). To properly restore the correct anatomy, high-quality intraoral photographs provided by the treating clinician are critical.
- Incomplete capture of terminal molars may be addressed by trimming away the distal portion of the tooth, which eliminates the part of the tooth where the distortion lies (Figs 5-3a and 5-3b). This may only be possible if the treatment plan outlined on the prescription and diagnosis form allows. For example, the distorted molar may be trimmed if no distalization is requested, no premolar extraction is requested, if the case is for anterior treatment only, if the arch is not being treated, or if the prescription indicates extraction of the distorted tooth.
- More significant distortions may be accepted if the arch is not being treated, since the opposing arch is being used primarily to set the occlusal bite relationship (Fig 5-4).

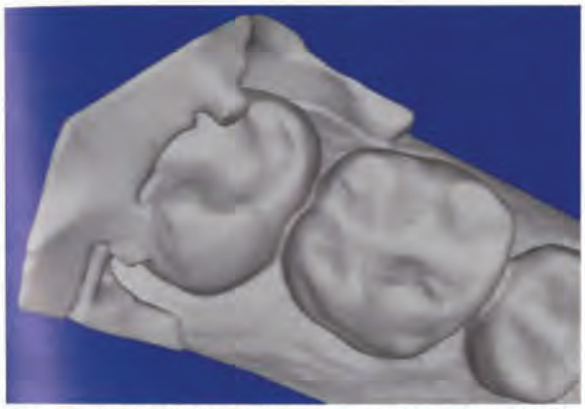


FIG 5-3a The distal side of the second molar is not provided in the impression.

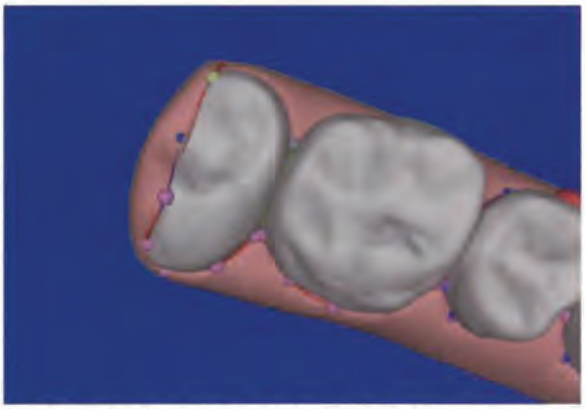
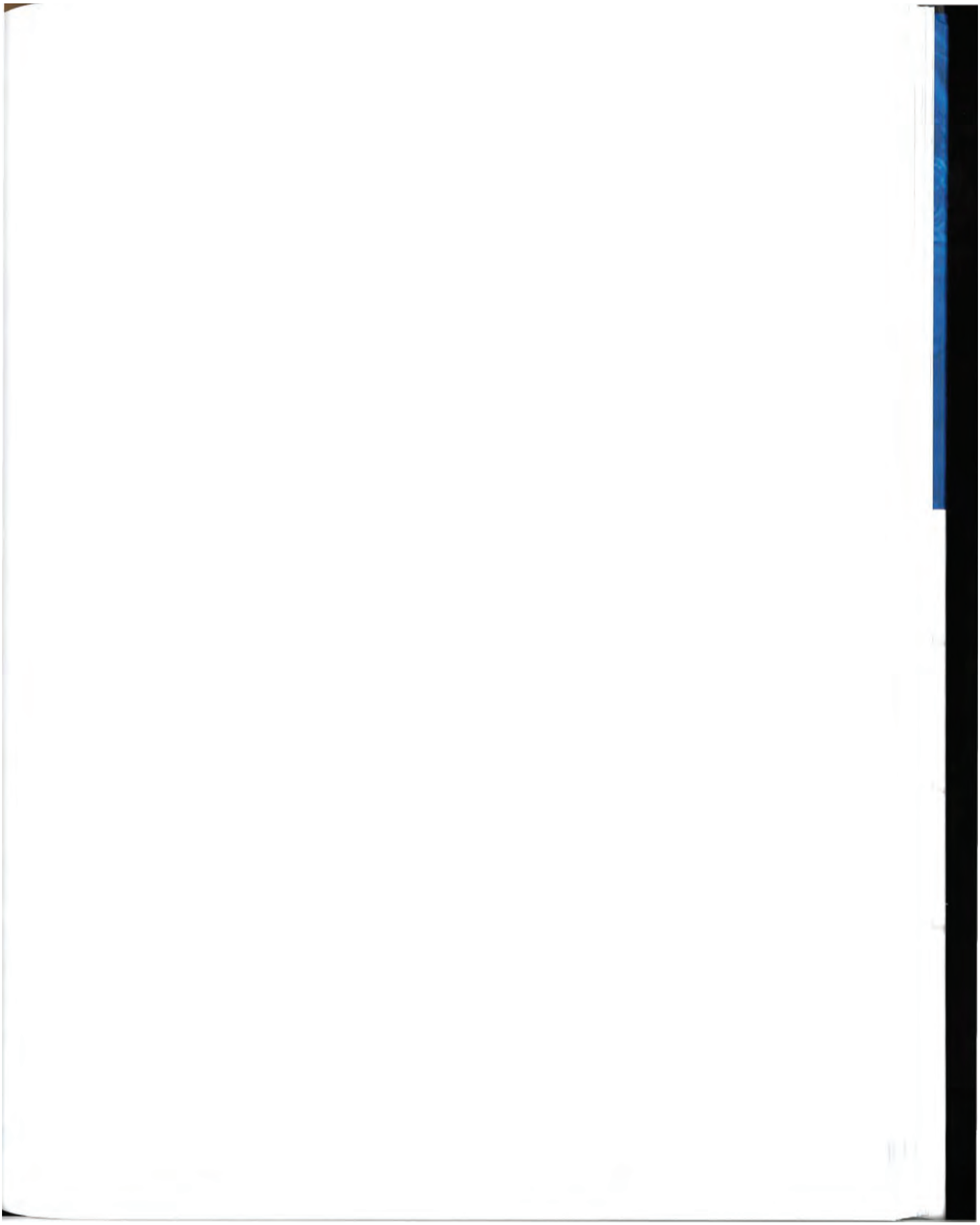


FIG 5-3b The aligner can be created only for the portion of the dentition represented in the image.



FIG 5-4 This impression is very poor but is usable if only the mandibular arch is being treated. Occlusal surfaces of teeth are adequate to occlude the maxillary and mandibular arches.

ClearCorrect Exhibit 1016, Page 59 of 335



chapter 6

SCANNING PROCESS AND STEREOLITHOGRAPHY

by
Srinivas Kaza

ClearCorrect Exhibit 1016, Page 61 of 335

The term *image acquisition* (or *scanning*) is used to describe the process of converting a physical object into three-dimensional (3-D) electronic data. The scanning process is used in various applications ranging from reverse engineering to nondestructive or destructive testing. Methods and technology of image acquisition have made remarkable progress over the last few years. The Invisalign System uses state-of-the-art scanning technology to accurately capture tooth geometry. This chapter outlines the evolution of scanning technology at Align Technology.

Laser Scanning

Laser scanning was the first scanning technology used by the Invisalign System. In laser scanning, a laser beam is projected on the object being scanned, and the reflection of the beam is recorded. The object being scanned is rotated to several predetermined positions so that multiple views can be recorded. The recordings made from these different views are incorporated together to produce a 3-D electronic image of the object. This scanning technique is one of the most widely used for a variety of applications and is offered by several companies. The scanner used in the Invisalign System was made by Cyberware, located in Monterey, California. During the time laser scanning was used with Invisalign, it posed certain challenges—for example, acquisition speed and the ability to capture undercuts and small interproximal spaces. In an effort to improve on these aspects, Align Technology turned to the use of destructive scanning technology.

Destructive Scanning

In destructive scanning, cross-sectional information of an object is captured and used to construct a 3-D image. The technique is undertaken as follows (Fig 6-1):

1. Plaster casts are poured for the impressions submitted.
2. The plaster casts are detailed by a lab technician to remove any defects and/or reconstruct partially missing information (see chapter 5).
3. Multiple plaster casts are placed on a plate and encased in a black polymer. The polymer is allowed to solidify, encasing the plaster models in it.
4. The encased block is mounted on a milling machine, and a thin section is sliced off the top.
5. The object is moved to a camera system to capture a two-dimensional view of the top.
6. Additional cross sections are milled and scanned. The process is repeated until the bottom of the object is reached.

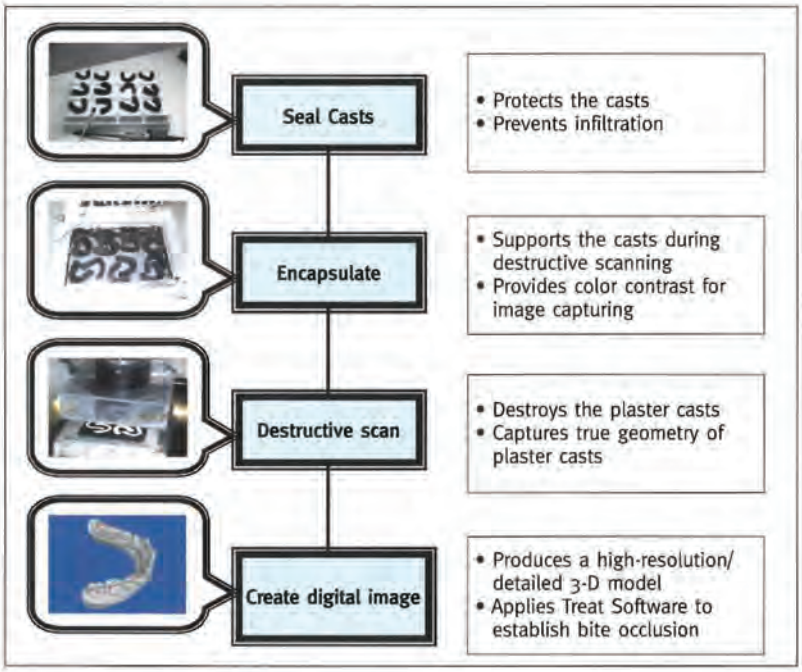


FIG 6-1 Destructive scanning process.

ClearCorrect Exhibit 1016, Page 62 of 335

7. Postprocessing software identifies the plaster casts using the contrast between the white plaster casts and the black encasement material. The images of plaster on each layer are then aligned and stacked together to create a 3-D image of the plaster casts being scanned.

Destructive scanning is one of the best methods available to capture intricate geometries, undercuts, and the like. The process of preparing a plaster cast for scanning, however, can be messy, time-consuming, and expensive. For the Invisalign System, the main problems revolved around time, cost, and the fact that the cast is destroyed (necessitating the pouring of two casts, which further increases the cost).



FIG 6-2 Impressions placed in foam fixture.

White-Light Scanning

White-light scanning uses a white-light pattern to capture images of the object being scanned. A pattern of white light (most commonly used is the moiré pattern) is projected on the object, and the reflection is captured by a camera. The captured image is stored, and the process is repeated with the object at a different orientation relative to the camera. Several images are taken at various positions, and the views are then aligned and combined to create a 3-D image of the object.

White-light and laser scanning are the most popular scanning technologies available. For a time, Align Technology utilized white-light scanning in conjunction with destructive-scanning technology. Although this combination of scanning methods offered high accuracy and resolution, the Invisalign System required an imaging technique capable of providing even greater detail to capture deep undercuts and small interproximal gaps. This prompted the move to computerized tomography (CT) technology.

Computerized Tomography

CT uses X-rays to scan an object. A set of impressions is loaded onto a fixture (Fig 6-2) and mounted on a rotary table in the scanner. X-rays are then beamed onto the target. The X-rays pass through the impressions, and the resulting image is captured by a detector positioned behind the impressions. The rotary table is then rotated by a small angle, and another image is captured. Multiple images are acquired at high speed and stored. Postprocessing software is used to extract information about the teeth, based on the attenuation of the X-ray beams that pass through the impression. CT scanning allows the direct scanning of an impression, thereby eliminating the intermediate step of pouring a plaster cast (Figs 6-3a and 6-3b).

Rapid Manufacturing of Molds

Rapid manufacturing is a term used to describe processes that can fabricate complex geometries in a matter of hours without any tooling. Rapid manufacturing techniques typically involve layered manufacturing processes where objects are produced one layer at a time. The rapid manufacturing process currently used at Align Technology is known as *stereolithography* (SLA) (Figs 6-4 and 6-5). In SLA, a solid object is constructed by curing the part in layers. A 3-D electronic representation (computer-assisted design [CAD] model) of the object to be built is first divided into thin cross sections. The cross-sectional information is then transferred to the SLA machine.

The machine has a vat of liquid photopolymer that cures when exposed to light of a certain wavelength. A laser beam at this wavelength is then used to cure the bottom-most cross section of the object. A layer of liquid photopolymer is then applied on top of the cured layer, and the next layer is cured on top using the laser. The process is repeated until the last layer is cured, resulting in the desired solid object.

ClearCorrect Exhibit 1016, Page 63 of 335

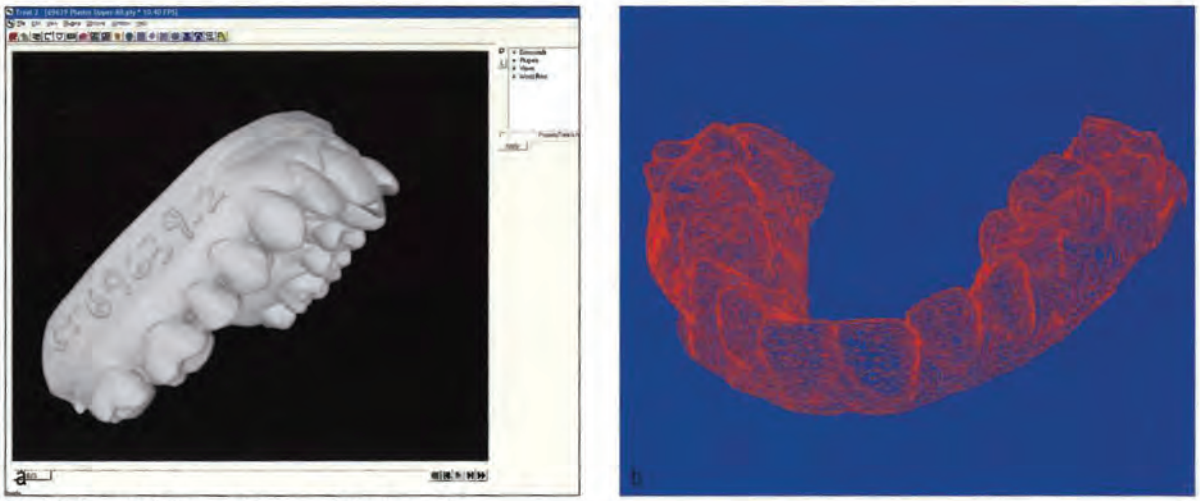


Fig 6-3 (a and b) Scanned images of the impression.

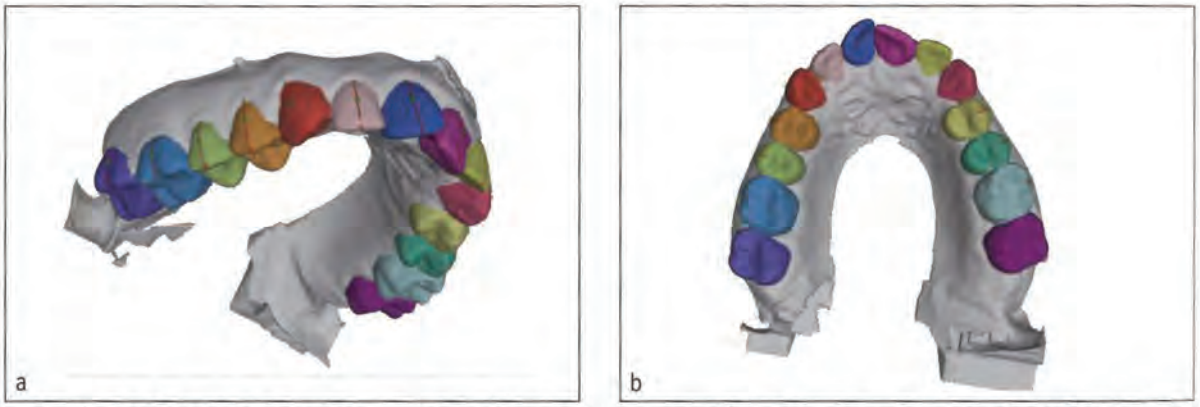


Fig 6-4 (a and b) Scanned data is segmented using the ToothShaper process. (See chapters 7 and 8 for a detailed explanation of ToothShaper.)

SLA Technology and the Invisalign System

The first step in the production of an aligner is the acceptance of the planned treatment by the submitting clinician through ClinCheck (see chapter 11). A clinician's acceptance of the proposed treatment triggers Invisalign's internal information systems. The case information—such as patient information, number of stages in the maxillary and mandibular jaw treatment, tooth movements, attachment designs, and the like—are fed into the custom software designed for the Invisalign SLA system. Subsequently, the treatment files are converted into a triangulated file format. The software then lays out the various cases within the build area of the SLA machines (currently 500 × 500 mm) to optimize space utilization. The electronic data are separated into multiple slices of a specified thickness. The slice data are then transferred to the SLA machine for manufacturing. The SLA molds are built on a platform that is located about one-slice thickness below the resin surface. The first layer from the bottom is then drawn by a laser (Figs 6-6a and 6-6b).

The photosensitive resin cures and turns solid upon contact with the laser beam. Once the first layer is completely traced, the build platform moves down a distance equivalent to the thickness of one layer. The second layer is then traced and cured on top of the previous layer. The process is repeated until the top of the object is reached. At the end of the process, the build platform consists of the molds; the rest of the photopolymer in the vat remains liquid.

ClearCorrect Exhibit 1016, Page 64 of 335

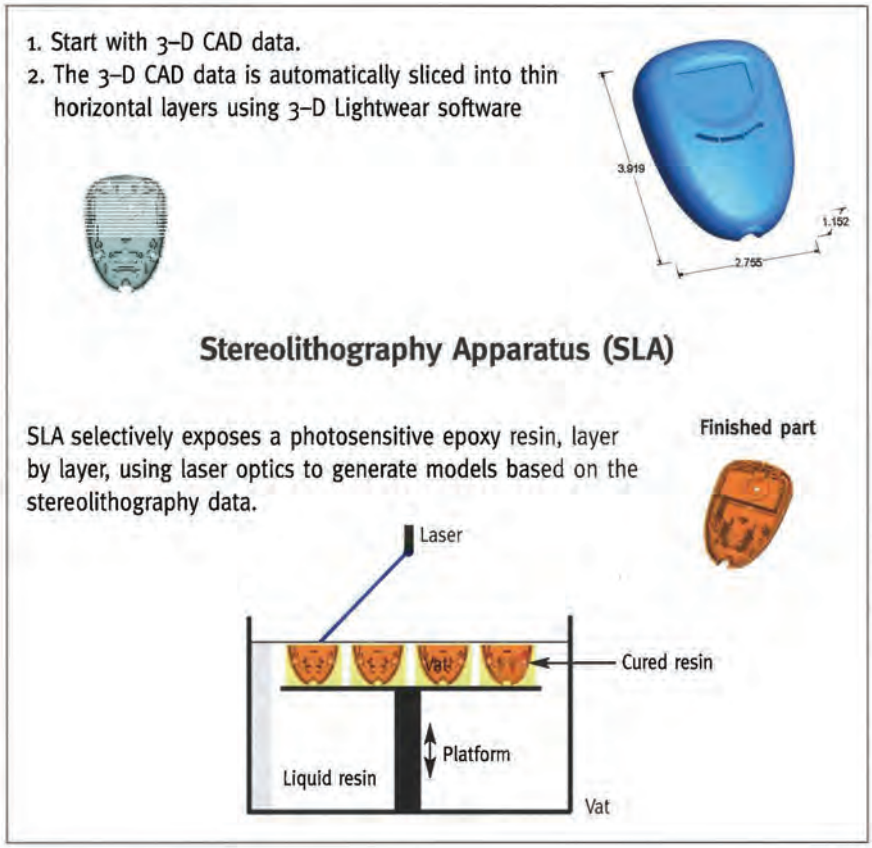


FIG 6-5 SLA build process. (Images courtesy of Hong Kong Polytechnic University.)

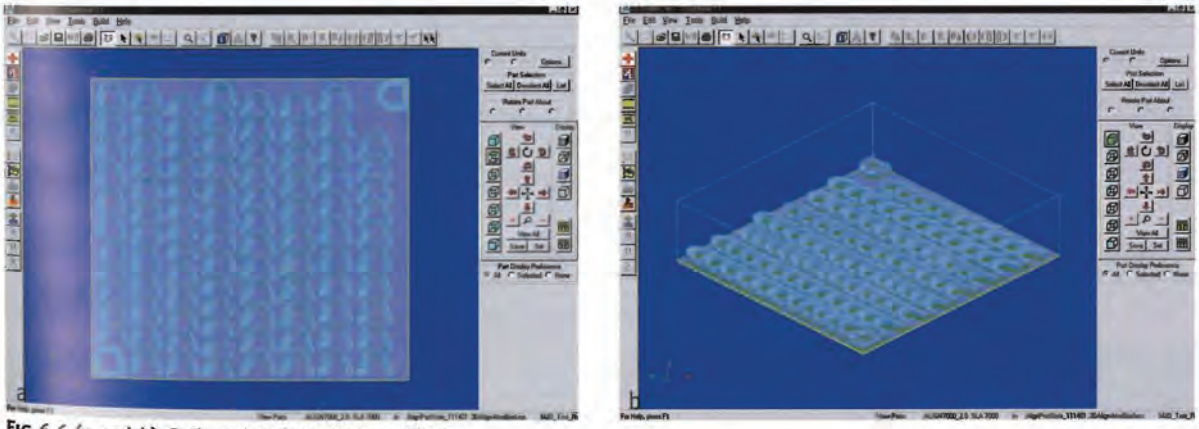


FIG 6-6 (a and b) Patient data layout on an SLA tray.

After the process is complete, the build platform that contains the molds is removed from the machine and transferred to an automated postprocessing line (Fig 6-7). In postprocessing, the platform is first spun at high speeds to remove any excess liquid resin on the molds. Upon completion of the spin, the platform is automatically loaded into a wash system that uses high-pressure water to clean the molds of any remaining uncured resin and debris. The platform is then automatically transferred to an ultraviolet (UV) curing station. The molds are exposed to specific wavelengths of high-intensity UV light that completely cures them. The molds are then automatically transferred to a

ClearCorrect Exhibit 1016, Page 65 of 335



FIG 6-7 Postprocessing system for SLA molds.

mold-and-support-removal machine that removes the molds from the platform and cleans them to ensure that no debris remains on the molds. The molds are then packaged and shipped to the facility in Mexico for the aligner fabrication process (Fig 6-8).

An SLA mold created at Align has some embedded tracking features in it. First, readable text is engraved on the side of the mold to indicate the patient identification and the stage number (Fig 6-9a). Second, each SLA mold has two-dimensional bar code information (commonly known as the data matrix), which contains similar information (Fig 6-9b). The bar code is used by the automation processes to automatically detect the information on the mold and direct the part accordingly.

Aligner Fabrication

Aligner fabrication represents the back end of the process, whereby a sheet of plastic is formed over the SLA molds, trimmed, removed from the mold, polished, and packaged.





FIG 6-9 Side-lettering identification feature (*a*) and two-dimensional bar code information (*b*).



FIG 6-8 Fabricated SLA molds.

The process of creating an aligner starts when the SLA molds are received in the forming area. Upon arrival in the forming area, the molds go through an automated marking machine where the two-dimensional data matrix is hot-stamped with black ink to provide contrast that allows bar code readers to process the information. Next, the molds are sprayed with an organic silicone release agent to help with the aligner removal process after forming (Fig 6-10). Each mold is then read with a bar code reader to ensure that the information can be accurately read and verified.

ClearCorrect Exhibit 1016, Page 66 of 335



FIG 6-10 SLA molds are loaded onto a machine that reads the bar code information and applies a release agent for forming.



FIG 6-11 SLA molds being processed in an automation line.

The molds are then placed on a 20 s 20–inch pallet and loaded onto a conveyer line. The pallets are routed to an automated forming machine (Figs 6-11 and 6-12). Each SLA mold is picked up from the pallet by a robot. Prior to further processing, the bar code is read by a reader. Once the read is complete, plastic is formed on the SLA mold. This plastic mold then goes under a laser marker, which downloads information from the network as to where to place the aligner information for that particular aligner (for each aligner, the Invisalign software automatically creates and stores a marking box that indicates where the aligner can be marked without compromising its esthetic quality).

After the forming and marking process is complete, the molds are automatically routed to one of several five-axis trimming machines (Fig 6-13). Of course, prior to loading on the trimming machines, the relevant cut information (based on the bar code) is downloaded into the trimming machine. This information indicates where the gingival line is located for that particular stage, thus ensuring that the trimming machine cuts along a line that produces an accurate aligner fit. A robot loads the mold onto the trimming machine, and the cutter trims the aligner along the specified path (Fig 6-14). Upon completion of the trimming process, the aligners are removed from the SLA molds and transferred to a tumbling/deburring machine that removes most of the aligner's sharp edges (Fig 6-15). After the tumbling cycle is complete, each aligner is hand finished and polished to ensure that no sharp edges remain (Fig 6-16). The aligners are then disinfected in an ultrasonic bath to ensure they are safe to



FIG 6-12 SLA molds being loaded onto the forming machine.

ClearCorrect Exhibit 1016, Page 67 of 335



FIG 6-13 After forming, the formed parts are loaded onto a five-axis cutting machine for aligner trimming.



FIG 6-14 Aligner trimming process.



FIG 6-15 Aligners go through a tumbling process to remove rough edges.



FIG 6-16 Final trim and polish by hand.

wear. This is the final product that is now ready to ship (Fig 6-17). At the end of the disinfection cycle, the aligners are removed and placed and sealed in Invisalign packaging. The packages are then shipped to the prescribing clinician.

Summary

The manufacturing systems described above produce aligners that perform well. Further streamlining of the process, however, has the potential to expedite the process. To this point, clinicians can look forward to self-starting machines, self-diagnosing machines, pallet changer and conveyer systems, automated postprocessing systems, and part tracking and work flow routing.



FIG 6-17 Final product.

ClearCorrect Exhibit 1016, Page 68 of 335

chapter 7

INVISALIGN SOFTWARE

by
Andrew Beers, PhD

ClearCorrect Exhibit 1016, Page 69 of 335

From Invisalign's inception in early 1997, software was envisioned as a key component of the technology of the system. Advances in scanning and rapid prototyping systems allowed physical objects to be scanned, manipulated digitally on a computer system, and re-created as a physical object. Actually, these technologies had been in place for computer-aided design (CAD) applications. For Invisalign, what was needed was CAD software that could be readily applied to orthodontic appliance design. The software would allow a virtual model to replace the standard dental cast used in conventional orthodontic appliance manufacture. The virtual model could ultimately be called upon to be much more than a simple replacement for a dental cast. Analyses difficult to perform on a physical model may be more easily done on a virtual model. For instance, "what if" treatment scenarios could be performed on a computer model with greater ease than on a physical model. At a minimum, sophisticated computer algorithms would facilitate the automation of some aspects of the appliance design process, allowing the company to support a broad customer base.

What other advantages does the virtual model offer? Manual, laboratory-based methods have already been used to create appliances similar to those used in the Invisalign System.[1] In these methods, individual teeth are cut from dental casts, set into wax or a similar substance, and manually repositioned into a new configuration. An appliance is then created from this new configuration using common processes—typically, vacuum-forming or pressure-forming. By repeating the process and generating multiple configurations from the segmented dental cast, appliances can be created for each configuration (see chapters 1 and 2).

Such manufacturing methods present clear limitations. The detailed, manual nature of the process can be tedious and prone to errors. Fundamentally, manually prescribed tooth movements on cut plaster teeth cannot be precisely calibrated for the force systems they will generate. In turn, the envisioned tooth movement may never happen. Finally, creating a series of appliances that put the teeth in good final positions is difficult because the ideal final position could exist only in the mind of the person preparing the models but not be orthodontically feasible. Planning each appliance in the series such that the teeth in each model lie along a sensible path to the final position could be impossibly challenging by manual methods.

Many of these limitations disappear when virtual three-dimensional (3-D) models are used. They are unfettered by the physical constraints that make up the core of the limitations described above. The key is to design software that creates a virtual model that can facilitate the manufacture of a physically attainable device. To meet this requirement, the software behind the Invisalign System had to successfully achieve several challenging tasks:

- Model the hard and soft tissues of the mouth
- Plan a final, treated position for the teeth that takes into account proper occlusion
- Plan and execute how the movement from the initial to the final position will take place
- Produce a virtual model that could be fabricated using rapid prototyping technology, to allow the forming of the individual aligners through conventional processes

The software performs these key modeling functions in the context of a larger manufacturing process that begins with the acquisition of the initial dental model and ends with the creation of the dental models used to make the Invisalign appliance. Between these steps, the teeth are only represented virtually.

The Invisalign manufacturing process, from the perspective of the software technology, was broken into a series of steps: segmentation, final setup, staging, review, and fabrication. The initial dental model is one surface and looks like a virtual dental cast. In segmentation, this virtual cast model is divided into a set of smaller surfaces, one for each tooth. Additionally, a model of the gingiva is created. Software called ToothShaper is used during this step.

In final setup, the individual teeth are placed into a clinically and esthetically acceptable final position. A key requirement at this step is to provide methods to evaluate the final position of the teeth. Software called Treat is used during this step. Once the final position is defined, the path that each tooth will take from its initial position to its final position needs to be defined. These motions are planned during the staging process, which also includes projections of the rate of movement for each tooth as well as the time required. The Treat software is also used here. In the review step, the clinician is shown the virtual treatment model and is given the opportunity to comment and request any changes to the final position, tooth movements, or both. The clinician uses ClinCheck software to view the virtual models (see chapter 11). In fabrication, the virtual model is prepared for production into physical models that can be used to create the final appliances. Software called Fab finishes the preparation of the virtual model for manufacture.

ClearCorrect Exhibit 1016, Page 70 of 335

History and Background of 3-D Software

The genesis of the Invisalign software lies in a variety of areas, including two-dimensional (2-D) and 3-D computer geometry and graphics, human-computer interaction, and imaging. Advances achieved in such engineering disciplines as image and surface acquisition further pushed these areas to create ways of processing new kinds of data. In dentistry, these ideas have already been applied in oral surgery and in the treatment of craniofacial deformities.

A software package named Sketchpad is credited with being the earliest known CAD system.[2] Authored in 1963 as part of Ivan Sutherland's PhD thesis,[2] Sketchpad employed a graphical user interface (the first of its kind) to allow a draftsman to easily and interactively create a drawing on a computer system using a light pen. It pioneered the idea that one could create a subdrawing once as a master drawing and reuse it many times. Furthermore, if the master drawing were changed, then all copies of it would change. This is an idea that many systems employ today.

A system from which the Invisalign process drew inspiration is the "3-D fax machine" described by Levoy et al.[3] This system made possible the sending of a 3-D object over a communications system like the Internet, much in the same way that a fax machine allows a document to be sent over telephone lines. At the sender's end, the object is scanned and a 3-D model of its surface is created. This model is then sent over the Internet to a remote site, where it can be fabricated using, for example, a rapid prototyping process such as stereolithography. Of course, prior to fabrication, the model can be manipulated by either the sender or the receiver.

Numerous CAD techniques have been applied in many fields, including dentistry and orthodontics. For example, computer-assisted orthodontic treatment planning systems use the computer as an analytical tool to aid the orthodontist during the treatment planning process. Some other early systems focused on using the computer to ease the analysis of cephalometric tracings.[4] This model was subsequently extended, and it allowed the practitioner to also view changes to the tracing that would result from treatment.[5] The 2-D models of orthodontic treatment proposed by Biggerstaff[6] provided an early visual means of planning and evaluating posttreatment tooth positions with a computer.

Three-dimensional techniques have been applied to research in dentistry and orthodontics, as well. An early system developed by van der Linden et al that enabled recording of 3-D information from a dental cast was the Optocom.[7] In this system, two dimensions were specified by moving a microscope to bring the desired point on the cast in line with a set of crosshairs. The third dimension was captured with a touch probe attached to the mechanism that supported the microscope.

Later systems relied on scanning and imaging techniques to acquire a 3-D surface model of a cast or impression. The points used in an analysis could then be captured using an interactive computer application. One such system, by Laurendeau et al,[8] scanned a dental impression using a technique that could determine the 3-D location of certain points based on how the impression and the medium it was contained in (colored water) absorbed light. A simple boundary was computed between each tooth on the resulting virtual model. The positional relationship between the roughly segmented teeth was then analyzed to provide a simple, automated diagnosis. Kuroda et al developed a similar system to analyze dental casts and to perform virtual setups.[9] Their system involved the use of a slit-ray laser scanner to acquire approximately 90,000 3-D coordinates to create a 3-D model of a dental cast. A computer system can be used to perform measurements and conduct basic treatment planning on the resultant model.

Another area where 3-D geometric techniques have been applied is in the area of craniofacial research and surgery. Currently, there is significant interest in computer-aided surgical treatment planning. Using techniques described above, Motohashi and Kuroda[10] developed a system for planning orthognathic surgery from a scan of a dental cast. The cast is segmented into individual teeth, which are then moved by a user into their postoperative positions, where they can be evaluated using digital tools. Other approaches begin with a 3-D scan to capture the geometry of the patient's head. This scan is usually a computed tomography (CT) or magnetic resonance imaging (MRI) scan to capture the internal structures of the head and mouth. Hassfeld and Mühling[11] surveyed the technology that has been applied in this area. McCance et al[12] used pre- and postoperative CT scans of surgical patients to illustrate the movements achieved in both soft tissue and bone.

Others contemporaneous with Invisalign have attempted to build complete treatment planning systems that could be used in the orthodontic office. These systems incorporated 3-D input to more accurately capture the patient's unique geometry. Alcañiz et al[13] describe work on a product named Magallanes, which is a treatment-planning sys-

ClearCorrect Exhibit 1016, Page 71 of 335

tem based on a scan of a standard dental impression. A laser scanner is used to scan a dental cast to create a 3-D surface representation of the cast. Automated routines segment the model by detecting boundaries of teeth. It should be noted, however, that these routines work well only when the teeth are nearly vertical. The software allows interactive specification of a treatment plan and the simulation of the tooth motions that would be obtained through the use of specified archwires. The latter is accomplished via a simple biomechanical model of how teeth may behave when a simulated archwire applies mechanical forces.

Recent commercial products such as those produced by OrthoCAD, Geodigm, OraMetrix, and others expand on the ideas listed above, bringing together computer graphics technology and modern scanning systems. OrthoCAD and Geodigm both yield digital models that can replace a plaster cast for diagnosis, treatment planning, and long-term storage. SureSmile by OraMetrix goes one step further: it provides a system[14] that allows detailed treatment planning and the fabrication of a device designed to execute the formulated treatment.

A Brief History of Invisalign Software

The development of the software used in the Invisalign System began in early 1997. At the time, the 3-D graphics on Microsoft Windows–based computers was a niche market—specialized computers that ran Windows and had high-end graphics cards were geared toward the entertainment and design industries, but still did not have much of a following. Most 3-D computer graphics at the time were done on computers manufactured by Silicon Graphics.

In early 1997, the software component of the Invisalign process was broken into two parts: modeling the teeth and moving them. Two corresponding software packages were created: Clipper and Aligner. The Clipper package mimicked what happened in a dental laboratory by allowing a user to "cut" a virtual dental model into multiple pieces, each one representing a tooth. The Aligner package took the virtual model created by Clipper and allowed a user to move the teeth into a final position; Aligner also defined how the teeth moved into those positions over time. It was, essentially, a package for animating the movement of tooth models.

Clipper's basic tools were the eraser and the saw. The eraser did exactly what its name promised: it allowed the operator to eliminate part of the model. This was used, for example, to create a flat base on the bottom of the model, in the same way that a technician might on a plaster cast. The saw allowed the user to create U-shaped cuts. Looking at a tooth from the labial direction, a curve was specified that started above the marginal ridge, descended along the interproximal region and along the gingival line, and finally curved up to the opposite marginal ridge. The same curve was created on the lingual side and connected to the first curve by a flexible surface. This surface would cut the model into two pieces, with the tooth above and the rest of the model below. The saw would be applied to each tooth until all teeth were segmented. The remaining part of the model was left to approximate the gingiva. This model was also represented at two levels of detail: a highly detailed model was used to manufacture the appliances, and a less detailed model was used for quicker interaction with the user of the software. Examples of the two levels of detail are shown in Figs 7-1a and 7-1b.

Aligner was, at its heart, an application that allowed a user to create a key-framed animation[15] of a set of teeth. Put simply, in a key-framed animation, the positions of the teeth are specified by the user at the beginning and the end of the treatment, and potentially at a small number of points during the treatment. These user-specified positions are key frames. The computer fills in the intermediate positions, smoothly interpolating the position and orientation of the teeth between the specified key frames (Fig 7-2).

Over time, the functionality of Clipper and Aligner grew increasingly similar, to the point where they differed in only a few key ways. These programs were eventually merged into a single application called Treat. This new application has the ability to do real-time contact detection,[16] which allows for an analysis of occlusion at the beginning and end of treatment, as well as any time in between.

As Invisalign grew, Align Technology recognized the need to involve the practitioner in the treatment-design process. To accomplish this, a new application called ClinCheck was created to allow the practitioner to view the results of the treatment-design process and provide feedback to the technicians at Align on how it should be improved. This was made possible by advances in personal computers that allowed the display of Invisalign's 3-D models on commercial-grade equipment.

The initial virtual models used by Treat and ClinCheck were very basic. In Treat, the teeth would move during the course of treatment, but the gingiva would not change

ClearCorrect Exhibit 1016, Page 72 of 335

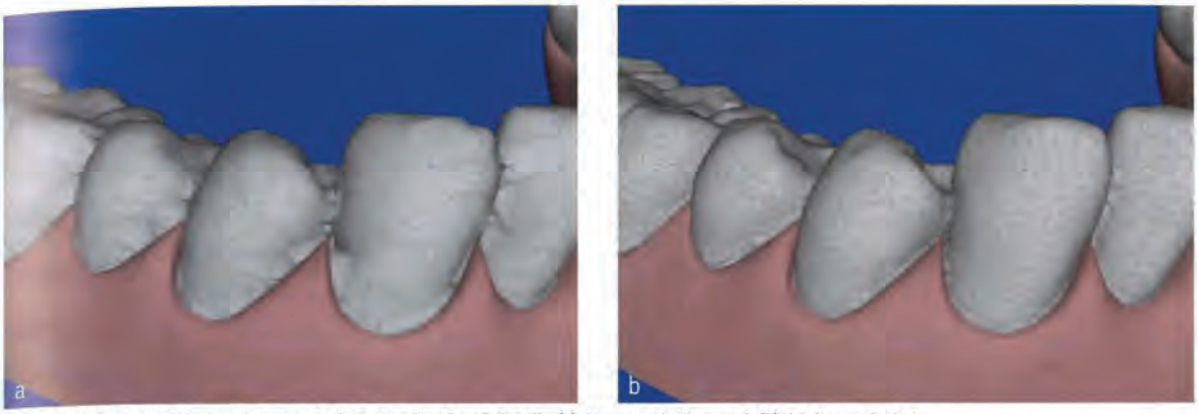


FIG 7-1 Virtual models are represented at two levels of detail: (*a*) low resolution and (*b*) high resolution.

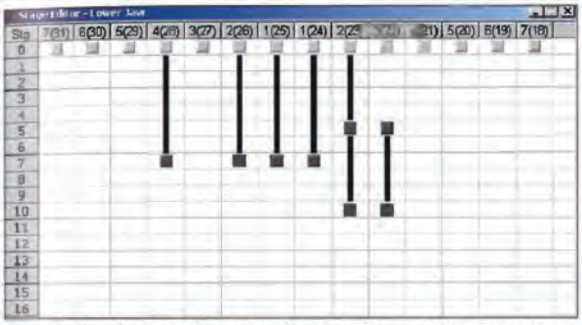


FIG 7-2 Key frame editor. *Gray boxes* indicate when a technician has specified a position for a tooth at a particular stage of treatment. *Black lines* denote periods of time over which a tooth will move between specified tooth positions.



FIG 7-3 The "Stonehenge" model.

shape. The resulting sharp edges and folds in the model were fixed with a virtual wax, which could be stretched and deformed along with the motion of the teeth. The interproximal regions were oddly shaped, and there was a sharp transition at the gingival margin.

Initial ClinCheck models did not have the virtual wax; nevertheless, the virtual models tended to be trimmed more anatomically correctly and smoothly after ClinCheck was in use. The virtual model was, however, still a series of whitish-gray teeth sitting over a horseshoe-shaped whitish-gray approximation of the gingiva (which never changed shape) and was at a much lower level of detail than the model used for manufacturing the aligners. These models quickly earned the name "Stonehenge" for their striking resemblance to the monument (Fig 7-3). To make matters worse, the virtual models ranged in size from 1 to 2 MB. These took a long time to download—between 4 and 10 minutes for the connections typical at the time, at the end of which was a less-than-exciting virtual tooth model.

The next stage in the evolution of the ClinCheck and Treat models happened on two fronts: the models were made smaller, and the virtual gingiva model was added. The models were made smaller by creating a simpler description for teeth (this is described in more detail in the next section), which drastically reduced the size needed to store teeth. It also had the effect of smoothing out the rough, undesirable features of the raw virtual model. Furthermore, this simpler description was based on the highly detailed Treat model, which meant that not only did the models take up less space, but they were also more accurate than the previous ClinCheck models in most cases.

The virtual gingiva was a flexible surface that was attached to each tooth and to a horseshoe-shaped "base." As the teeth moved, the surface deformed to follow the teeth. This behavior, along with its more realistic pinkish color, made the model presentable to a wider audience, including patients. The gingival model is described in more detail in the next section.

ClearCorrect Exhibit 1016, Page 73 of 335



FIG 7-4 A virtual dental model.



FIG 7-5 The surface is composed of many small triangles.



FIG 7-6 The surface is rich with grooves, ridges, and other features.

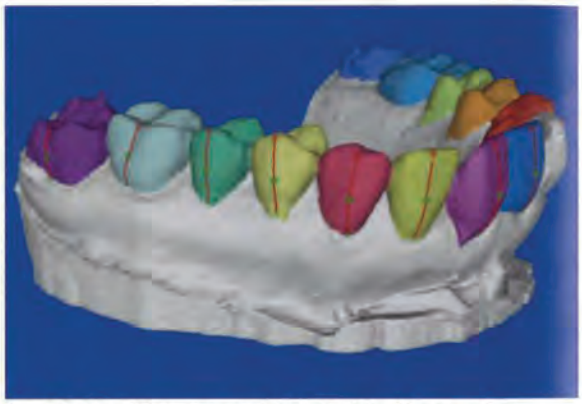


FIG 7-7 Potential crowns are highlighted in different colors.

Modeling

After the impression has been scanned, a 3-D model is created that looks very similar to a dental cast (Fig 7-4). This surface, like many surfaces found in 3-D computer graphics models, is composed of many small triangles (Fig 7-5). These triangles depict the surface of the virtual cast with a high degree of accuracy. The surface is also referred to as watertight, which is to say that the surface is closed and contains no holes. In the modeling step, the model is processed into a form that can be used to create an Invisalign aligner.

A virtual dental model that is appropriate for use in the Invisalign process should satisfy two important criteria. First, the geometry of all tooth surfaces must be captured accurately. Second, the gingiva must be modeled such that it responds to the motion of the teeth in a visually and clinically acceptable way. Accuracy of the crowns is important for two reasons. First, a tight-fitting appliance can only be made from accurate geometry. Second, any inaccuracy in the shape of the teeth may produce planned motions that are not achievable in the patient's mouth, which can lead to complications during treatment. Root geometry should also be included, since evaluation of root position is standard practice at the end of treatment. The roots can also be used in the analysis of possible motions.

To satisfy the first criterion, the single surface of the scanned data must be segmented into multiple surfaces, one surface per tooth. One way to create separate models of the teeth is to take the approach Kesling did in a dental laboratory: cut a stone dental model into several pieces with a small saw to create independent tooth models.[1] While this approach could be more or less directly implemented using a computer system, more accurate and less labor-intensive approaches for segmenting the virtual model are possible and are necessary to create digital models in any quantity.

ClearCorrect Exhibit 1016, Page 74 of 335

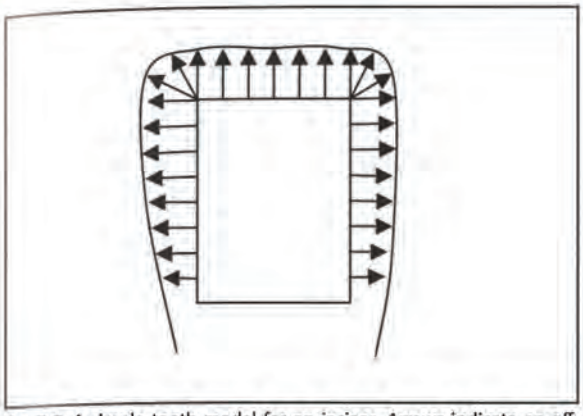


FIG 7-8 A simple tooth model for an incisor. *Arrows* indicate an offset from an underlying basic kernel shape (*solid line*).

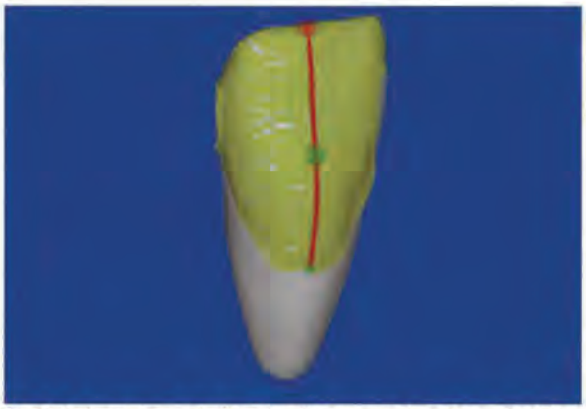


FIG 7-9 A crown and the "best" generated surface. *Red line* denotes user-specified facial axis of the clinical crown.

A more refined approach takes advantage of the rich features of the surface of the virtual model (Fig 7-6), as embodied by Invisalign's ToothShaper software. The surface contains many grooves, ridges, and other features that indicate the boundaries between teeth and also between teeth and the gingival tissue. The approach first looks for high-curvature regions on the surface (ie, regions that are not flat), then connects these regions to form lines of high curvature. For teeth, these lines connect into loops that surround each tooth. The surface contained within each loop is a possible tooth crown, which is displayed to the user in a different color (Fig 7-7).

The crowns identified in this manner are incomplete. They are typically missing geometry in the interproximal regions where adjacent teeth contact each other in the patient's mouth, and no geometry is displayed below the gingival margin. The next step, therefore, is to complete the model of the tooth by creating the missing surfaces. There are two regions in which surfaces need to be added: on the crown region to create interproximal surfaces and below the crown to create a root surface.

While having root geometry would be advantageous, most sources of dental models (ie, impressions and the dental casts created from them) do not have enough data from which to determine the shape of the roots. There are methods of creating approximate root data,[14] but it is the crown data that are most crucial to the Invisalign process. If the model is limited to just crown data, a simple, short surface can be added below the gingival line to complete the model. This short surface is created such that it is parallel to the long axis of the tooth, which helps clarify the overall orientation of the tooth.

To create these missing surfaces, a simple model of tooth geometry is fit to the identified crown (Fig 7-8). The model is a roughly cylindrical surface with its parameters in θ and φ, where φ is the rotation angle around the long tooth axis, and θ represents the parameter along that axis. The function $F(\theta, \varphi)$ represents an offset (the arrows in the picture) from an underlying basic kernel shape (the solid line in the picture). Different incisor shapes are represented by changing the function F (ie, changing the offsets from the basic shape). The shape of this simple model is distorted such that it fits the crown data closely and also satisfies the following set of properties, which describe the "ideal" properties of the missing surfaces:

- The reconstructed surface passes through (or fits to) the border of the scanned part of the crown.
- The horizontal cross section in the root part approximately mirrors the crown cross section and shrinks toward the end of this "approximate root."
- The surface varies smoothly, minimizing the overall curvature.
- The surface is approximately symmetric with respect to the tooth's vertical middle section.

The tooth surface is created by representing the difference of these properties from the simple surface $F(\theta, \varphi)$ as a mathematical "cost" function, and then finding the function $F(\theta, \varphi)$ that minimizes the value of this "cost" function. This surface best matches the original crown data and satisfies these properties most closely (Fig 7-9).

This surface may not be perfect, especially in the interproximal regions. The ToothShaper application therefore provides an interface for shaping these regions. This tool

ClearCorrect Exhibit 1016, Page 75 of 335

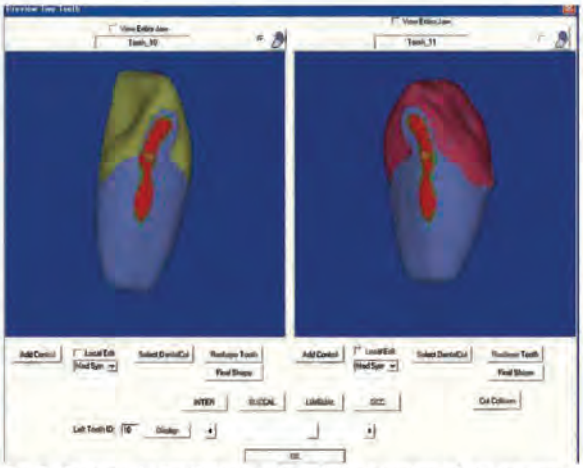


FIG 7-10 A tool in ToothShaper that allows shaping of the interproximal regions and the setup of accurate tooth-to-tooth contacts.



FIG 7-11 Gingival model.

(Fig 7-10) displays regions that are close to neighboring teeth or that contact them and allows a user to accurately shape the teeth in these regions. Photographs are often used as a reference for this operation.

This method of describing tooth geometry does not fully capture all of the details of the tooth surface, but it does come very close. It also has a very small representation on disk that is very similar to those used in early versions of ClinCheck, which were reduced in size so they could be more quickly sent to clinicians.

The final part of the model is the addition of a flexible gingiva model. Align chose a simple flexible surface model for Invisalign. The base data consists of two items: a curve that lies on the tooth and represents the gingival line, and a curve that forms the perimeter of the base of the gingiva. The line on the tooth is derived from the boundary of the segmented crown. It is composed of a lingual half and a buccal half. The line on the base is formed by determining the intersection of the gingival geometry on the scan with a plane that is located below all of the crowns in the model.

To form the gingival surface, the lingual curves are first connected into one continuous curve that forms the overall lingual gingival line. The lingual gingival line is then connected to the lingual part of the base by a surface patch. This process is repeated on the buccal side (Fig 7-11). As the teeth move during the virtual treatment plan, the surfaces of the gingival model change as the line on the tooth changes position with the tooth. This model has a relatively small description, and thus was ideal for quick transfer to the clinician for viewing with ClinCheck.

Display of 3-D Models

The rendering of computer-generated images of 3-D objects as 2-D representations started in 1960 when William Fetter used a plotter to create a series of images of a 3-D model of a human body that he was using to design an aircraft cockpit. A few years later, Ivan Sutherland's Sketchpad system took these images to an early computer screen and made them interactive. In this early system, 3-D models were rendered as a series of lines that represented, very generally, the edges of the original object. Images created in this way were called vector graphics.

In the 1970s, a new technology called the raster display was created and is now in use in virtually all computer systems. In this kind of display, images are represented by a grid of pixels that covers the screen. Pixels can be active (light) or inactive (dark), and in modern systems can take on a variety of colors when active. The process of rendering a 3-D object into a 2-D image thus involves determining which pixels correspond to the various parts of the object and coloring them appropriately.

An image produced in this manner, however, is still 2-D. How do we perceive this image as a 3-D object? The human perceptual system relies on a set of cues to convert a 2-D image into a 3-D conceptualization of the object represented by the image.[17] Binocular vision allows us to integrate two different pictures, each seen with a different eye, to understand 3-D spatial relationships for objects that are relatively close. However, a desktop computer system does not generally have the ability to present a dif-

ClearCorrect Exhibit 1016, Page 76 of 335

ferent image to each eye, though specialized systems for doing this do exist.

Certain features of a 2-D image can allow us to imagine a third dimension. Occlusion of one object by another in a 2-D image suggests that one object is in front of the other. As in perspective drawings, the relative size of images that represent objects known to be similar in size suggests that one object is closer than the other. The shading of an image suggests a reflected light source, which can suggest what the object's 3-D shape might be. Perspective views of familiar objects suggest an overall 3-D orientation of that object and its rough shape.

Series of images taken of an object while it is moving make the 3-D relationships clearer. Images taken of an object in motion often show wildly varying occlusal relationships and shading, which makes the shape and relationships between objects in the image very clear. Changes in shading on moving objects can also suggest the 3-D shape of the object. Finally, parts of the object that are farther away appear to move more slowly than parts that are closer, further reinforcing the perception of depth to the object.

Invisalign's software renders images of the 3-D tooth and gingival models by determining the pixels that correspond to each triangle in the model and coloring them appropriately. The base color of a triangle is determined by what the triangle represents—white for teeth and pink for gingiva. This process is further refined by applying a lighting model to the colors. The software defines the position, color, and intensity of a light in relation to the model. The color of each triangle is then modulated by the intensity of the light falling on it.

The intensity of the light that falls on each triangle is computed through a comparison of the direction between the triangle and the light with the direction that the triangle is facing (called the triangle normal direction). When the triangle directly faces the light, the light intensity will be at its brightest. As the angle between the direction to the light and the triangle normal direction increases, the intensity of the light decreases. The intensity of the light can vary across the surface of the triangle. Computing this at each pixel that corresponds to the triangle would be very expensive. Instead, this computation is performed at each vertex of the triangle, and the results are interpolated across the triangle. This technique is called Gouraud shading.[18]

The rendering style used in the Invisalign software has limitations. The teeth have a simple white color. Real teeth have a semitransparent outer layer that is difficult, but not impossible, to reproduce in real-time rendering. Also, the rendering method does not employ any shadows. The lighting computations are done independent of any objects located between the triangle being rendered and the light source, which would normally cause a shadow. Real-time shadow computations on complex models are difficult to perform. Thus, shadowing cues (similar to the shading cues discussed above) in the mouth that would provide depth and dimension to an image are not captured in the rendering of the virtual teeth.

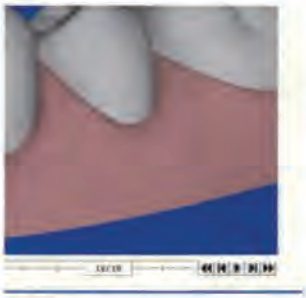


FIG 7-12 Controls along the bottom of the window allow a user to control time.

Final Setup and Staging

After the virtual model is created, the movements of the separated teeth need to be specified throughout the treatment. Invisalign's Treat software performs this function. The process of specifying tooth movements is broken into two steps: specifying the final position of the teeth and then specifying the paths that each tooth will take between its initial and final positions.

The Treat software is similar to the ToothShaper software, but adds a new dimension to the model: time. Time is expressed in units called stages, where one stage corresponds exactly to one Invisalign appliance, and thus represents approximately 2 weeks of elapsed time based on wear times recommended by the company. On the Treat software display screen, time is expressed along the bottom of the window as a slider bar with a set of VCR-like controls that allow time to be played forward and backward (Fig 7-12).

A technician uses the Treat software to arrange the teeth in their final position by moving each tooth individually to a new location. To do this, the technician clicks on a tooth to display a "widget" that allows the tooth to be moved (Fig 7-13). Clicking and dragging on any of the three axes (red, green, or blue) moves the tooth along the indicated

ClearCorrect Exhibit 1016, Page 77 of 335

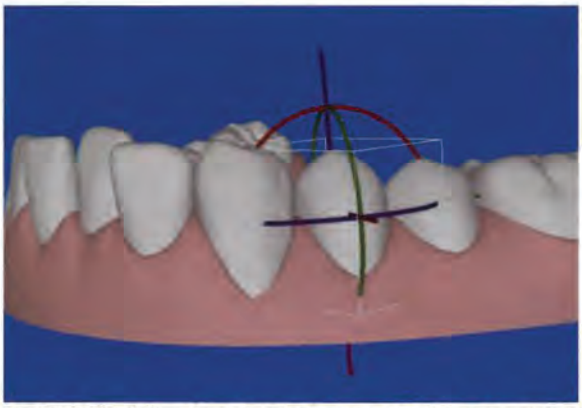


Fig 7-13 The interaction widget allows a user to move a tooth along or around any axis.

axis. Clicking and dragging on any of the three circles (red, green, or blue) rotates the tooth around the intersection of the axes. Alternatively, an input device such as a SpaceBall allows for more direct control of the position and orientation of the selected tooth. The SpaceBall is essentially a computer mouse that responds to movements and rotations in three dimensions.

To help accurately set teeth into their final positions, Treat computes regions that are in "collision" or contact. Areas involved in the collision are shown in red (Fig 7-14a). This visualization can help ensure that the contact between neighboring teeth in the same jaw is appropriate. Additionally, by not displaying one of the jaws, collisions on the occlusal surface can be observed to check for good occlusal contacts in the final position or any intermediate position (Fig 7-14b).

Once a good final position is established, the technician goes through a process called staging to determine all of the intermediate positions of the teeth. The Stage Editor tool in Treat, which allows the technician to specify when each tooth in the jaw is moving, aids in this process. Stage numbers are listed vertically down the left side of the Stage Editor, and tooth numbers are listed horizontally across the top, forming a grid of cells (Fig 7-15).

A box in a cell in Stage Editor means that a tooth position has been specified by the technician (in this case, the initial and final positions for that tooth) for that particular stage. The line connecting the boxes signifies that the tooth will move between those two positions over the specified time period. Between those two positions, the tooth will move linearly (ie, it will move in a straight line, at a constant rate). The tooth's orientation will also change at a constant rate.

Stage Editor also allows the technician to analyze the movements created during the staging process. Tabs on the Stage Editor screen display movement distance per stage, plus the degree of space or "overlap" between teeth during each stage (Figs 7-16a to 16-d). The amount of movement per stage is a key component of the treatment, as it directly relates to the amount of force placed on the teeth by the aligner. If the tooth is moved too quickly, high forces on the tooth will result, which is undesirable.

Two other functions of note are handled by the Treat software. The first is the placement of "attachments." Attachments are extra geometry added to the tooth model that is used clinically to increase the retention of the aligner on the tooth on which the attachment is placed. Treat allows a variety of attachment shapes to be



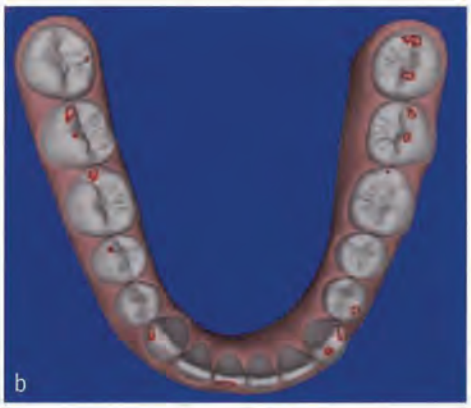


Fig 7-14 (a and b) Colliding surfaces are displayed in red.

ClearCorrect Exhibit 1016, Page 78 of 335

placed. (See chapters 9 and 10 for more information on attachments.) Not all (experimental) attachment types are commercially available, however.

Another function of Treat is the modeling of interproximal enamel reduction (IPR). IPR is modeled in Treat by allowing teeth to overlap in the final stage of treatment. Clinically, it is the clinician who will alter the shape of the tooth to achieve a good contact in the mouth. Stage Editor allows the technician to estimate the amount of IPR in real time while planning the treatment.

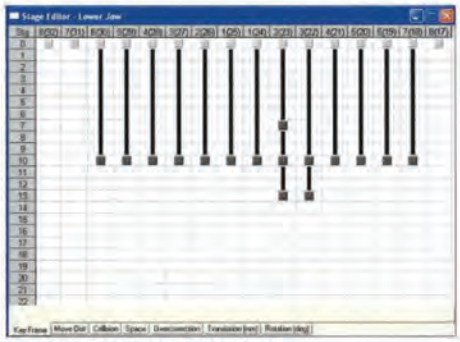


FIG 7-15 The Stage Editor tool.

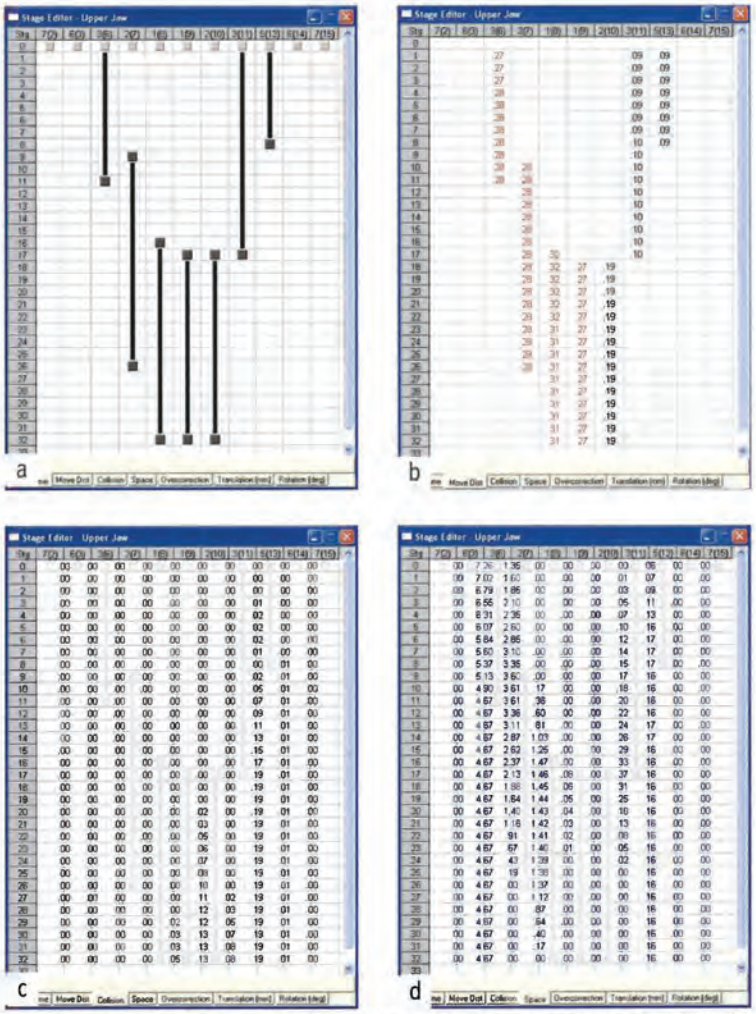


FIG 7-16 (a to d) Stage Editor allows movements to be analyzed in detail. (*a*) Technician-supplied tooth positions and movements. (*b*) Movement of each tooth. (*c*) Contact between adjacent teeth. (*d*) Space between adjacent teeth.

ClearCorrect Exhibit 1016, Page 79 of 335

References

1. Kesling H. Coordinating the predetermined pattern and tooth positioner with conventional treatment. Am J Orthod Oral Surg 1946; 32:285–293.
2. Sutherland I. Sketchpad: A Man-Machine Graphical Communication System [technical report 296]. Cambridge, MA: Massachusetts Institute of Technology, Lincoln Laboratory, 1963.
3. Levoy M, Curless B, Goldman D, et al. Project to build a 3D fax machine. Available at: http://www-graphics.stanford.edu/projects/faxing/. Accessed January 8, 2006.
4. Ricketts R. The evolution of diagnosis to computerized cephalometrics. J Dent Res 1969;55:795–803.
5. Faber RD, Burstone CJ, Solonche DJ. Computerized interactive orthodontic treatment planning. J Dent Res 1978;73:36–46.
6. Biggerstaff RH. Computerized diagnostic setups and simulations. Angle Orthod 1970;40:28–36.
7. van der Linden FP, Boersma H, Zelders T, Peters KA, Raaben JH. Three-dimensional analysis of dental casts by means of the optocom. J Dent Res 1972;51:1100.
8. Laurendeau D, Guimond L, Poussdart D. A computer-vision technique for the acquisition and processing of 3-D profiles of dental imprints: An application in orthodontics. IEEE Transactions on Medical Imaging 1991;10:453–461.
9. Kuroda T, Motohashi N, Tominaga R, Iwata K. Three-dimensional dental cast analyzing system using laser scanning. Am J Orthod Dentofacial Orthop 1996;110:365–369.
10. Motohashi N, Kuroda T. A 3D computer-aided design system applied to diagnosis and treatment planning in orthodontics and orthognathic surgery. Eur J Orthod 1999;21:263–274.
11. Hassfeld S, Mühling J. Computer-assisted oral and maxillofacial surgery—A review and an assessment of technology. Int J Oral Maxillofac Surg 2001;30:2–13.
12. McCance AM, Moss JP, Fright WR, et al. Three-dimensional analysis techniques—Part 4: Three-dimensional analysis of bone and soft tissue to bone ratio of movements in 24 cleft palate patients following Le Fort I osteotomy: A preliminary report. Cleft Palate Craniofac J 1997;34:58–62.
13. Alcañiz M, Montserrat C, Grau V, Chinesta F, Ramon A, Albalat S. An advanced system for the simulation and planning of orthodontic treatment. Med Image Anal 1998;2:61–77.
14. Mah J, Sachdeva R. Computer-assisted orthodontic treatment: The SureSmile process. Am J Orthod Dentofacial Orthop 2001;120: 85–87.
15. Burtnyk N, Wein M. Computer-generated key-frame animation. J Soc Motion Picture Television Engineers 1971;8:149–153.
16. Lin M, Manocha D, Cohen J, Gottschalk S. Collision detection: Algorithms and applications. In: Laumond J-P, Overmars M (eds). Algorithms for Robotics Motion and Manipulation. Wellesley, MA: AK Peters, 1996:129–142.
17. Osterloh K, Redmer B, Ewert U. On human perception of 3D images. NDT [serial onine] 2004; 9(5). Available at: http://www.ndt.net/article/ct2003/v26/v26.htm. Accessed February 15, 2006.
18. Foley J, van Dam A, Feiner S, Hughes J. Computer Graphics: Principles and Practice, ed 2. Boston: Addison-Wesley, 1992.

ClearCorrect Exhibit 1016, Page 80 of 335

chapter 8

VIRTUAL DIAGNOSTIC SETUP

by
David Chenin, DDS and Kent Verdis

ClearCorrect Exhibit 1016, Page 81 of 335

Watercolor painting is a combination of intricately placed strokes and a synthesis of complementary colors. As the artist begins to paint with the end in mind, his or her mental image of the living world is transferred onto blank canvas. Like painting, although much more complex, orthodontic treatment requires one to develop an understanding of an in-depth mental image before any of the initial strokes of paint are applied. Comprehensive visualization and expression of one's objectives, therefore, is a critical step in the creation of the perfect occlusion.

To that end, Invisalign treatment is based on the patient records acquired by the clinician. Five different records are necessary to create a "virtual patient": impressions of the maxillary and mandibular dental arches, bite registration, intraoral and extraoral photographs, panoramic or full-mouth series radiograph, and the prescription and diagnosis form. It is the clinician's responsibility to obtain high-quality impressions and bite registration, along with comprehensive photographs and radiographs, and to devise a clear treatment plan for each patient.

Align Technology converts these patient records into electronic data that can be used to create a three-dimensional (3-D) virtual treatment. To facilitate such conversion of patient records into clinically relevant electronic 3-D data, a series of software-driven steps is incorporated into the manufacturing process. These steps include scanning paper records, generating computed tomography (CT) images of the impressions, and preparing CT-scanned impressions. Once all the records have been digitized, they are sent to a dental technician, who performs additional steps—such as automated tooth segmentation, digital detailing, virtual gingiva creation, and automated occlusion—to prepare the 3-D models for tooth movements, as part of the virtual 3-D treatment plan known as ClinCheck.

Impressions

The polyvinyl siloxane (PVS) impression is the basis of the 3-D representation of a patient's dentition. In the clinical setting, the doctor takes an impression using PVS material with a plastic tray provided by Align Technology (Fig 8-1). PVS is the material of choice because of its extreme accuracy, high dimensional stability, and widespread use in dentistry.[1] The PVS impression is one of the most valuable of the records required for Invisalign treatment (Fig 8-2). The main reason for its importance is because the accuracy of the PVS impression directly correlates to how well the aligners fit. Impressions of the teeth are the raw data used to fabricate ClinCheck and aligners. Once Align Technology receives the PVS impressions, they are directly scanned by computerized tomography (CT) scanning machines (see chapter 6). Although the dental arches are rendered as separate 3-D units, they are saved as a single electronic file without the teeth in an articulated relationship. The 3-D data file is compressed and stored with the other virtual patient records for later use.

Bite Registration

Capture of accurate occlusal relationships is paramount in 3-D dental software applications. An inaccurate starting point of treatment ensures an inaccurate result. If the occlusion at the start of treatment is correct, all of the movements performed to the final alignment will be accurate. Along with the PVS impression, the treating clinician must also supply Align Technology with a PVS bite registration (Fig 8-3a). The Invisalign virtual diagnostic setup does not employ the use of a virtual articulator at this time; hence, centric relation (CR) records are not used. Centric relation–centric occlusion (CO) shifts should be addressed prior to starting Invisalign treatment. The bite registration recorded by the treating clinician in CO, otherwise known as maximum intercuspation, is a full-arch, complete bite-through record (Fig 8-3b). Digitization of the CO bite registration takes place via the same technology used to acquire the impressions digitally (ie, CT scanning).

Although the nature of how the patient's teeth fit together is stored in the bite registration, we will discuss how the actual anatomy of the patient's teeth is reliably used to re-create the CO bite relationship in most patients. In the Invisalign manufacturing process, the bite registration is used only if additional anatomic information is needed.

The primary method by which the CO is created is based on the geometry and shape of the occlusal surfaces of the teeth. An automated software tool (AutoBite) maximizes tooth-to-tooth interarch contacts through algorithms by matching corresponding tooth-surface contacts of the opposite arch (such as contact points and wear facets) into a maximum intercuspated position. As a result, the original nonoccluded maxillary and mandibular 3-D dental arches are moved virtually into an articulated CO relationship.

ClearCorrect Exhibit 1016, Page 82 of 335

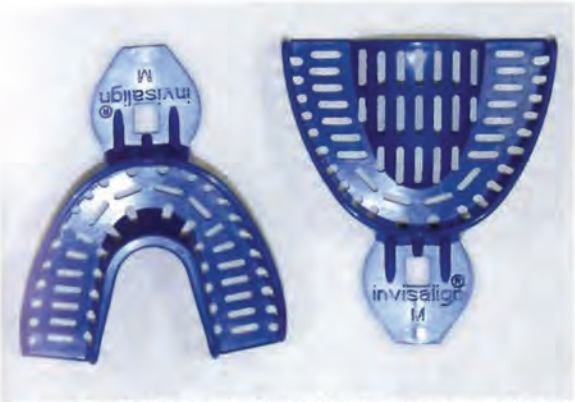


FIG 8-1 Align Technology freely provides impression trays in various sizes for use by the clinician. These trays are robust enough to prevent distortion of the impression material. Perforations provide adequate retention.



FIG 8-2 Detailed impressions of teeth are critical to Invisalign treatment.



FIG 8-3a Full-coverage PVS bite registration must accompany the impressions.



FIG 8-3b Typical clinical appearance of a properly registered bite.

Because of the high level of success achieved with the AutoBite software, bite registration to create CO is required for very few patients. In a small percentage of patients, AutoBite cannot find enough matching tooth surfaces where the teeth uniformly interdigitate in a consistent manner (such as a full cusp molar and canine Class III relationships). Because it is difficult to predict which cases will require PVS bite registration data, treating clinicians must supply it for all of their patients. However, CO is usually created by executing AutoBite based on the shape of the teeth themselves to occlude the models in 3-D space. This process yields highly accurate, consistent, and repeatable CO relationships.[2]

Photographs

Clinical photography supplied by the treating clinician is used for many steps in the manufacturing process. Photographs that are not supplied digitally in jpeg (file interchange format) are scanned by Align Technology via conventional document scanning devices and stored electronically. The eight photographs represented in Fig 8-4 are required for Invisalign treatment.

These images are important for obtaining such additional diagnostic information as a patient's symmetry, facial shape and balance, smile line, restorations, and condition of the dentition and surrounding structures. Such diagnostic information should be interpreted and expressed through the clinician's treatment objectives.

In addition to the diagnostic value for the treating clinician, photographs are used by Align Technology in sever-

ClearCorrect Exhibit 1016, Page 83 of 335



Fig 8-4 Eight intraoral and facial photographs required for Invisalign treatment. All imaging programs offer this template.

al ways. Verification that the dentition shown in the photographs matches that of the 3-D dental models is a quality check performed repeatedly throughout the manufacturing process. Additionally, intraoral photographs can be used for assistance in fixing voids or bubbles in the dental model that may have developed as a result of inconsistencies in the original impression. This ultimately helps to ensure better fit of the aligners. Also, the photographs, particularly the buccal and anterior views, are used in verification of the CO relationship. Photographs are also important in identifying or verifying restorations, tooth movements, and attachments.

Radiographs

Either a panoramic radiograph or a full-mouth series of radiographs may be supplied by the treating clinician (Figs 8-5a and 8-5b) to fulfill the radiograph requirement. Since both types of radiograph are used for the same reasons, there is no advantage or disadvantage in using one type over the other. Radiographs that are not supplied digitally by the treating clinician in jpeg are immediately scanned and stored electronically.

These radiographs are important for the clinician to obtain additional diagnostic information regarding the patient's restorations, caries, skeletal formation, and the condition of the dentition and surrounding bone structures. In addition to their value in quality control (see

ClearCorrect Exhibit 1016, Page 84 of 335

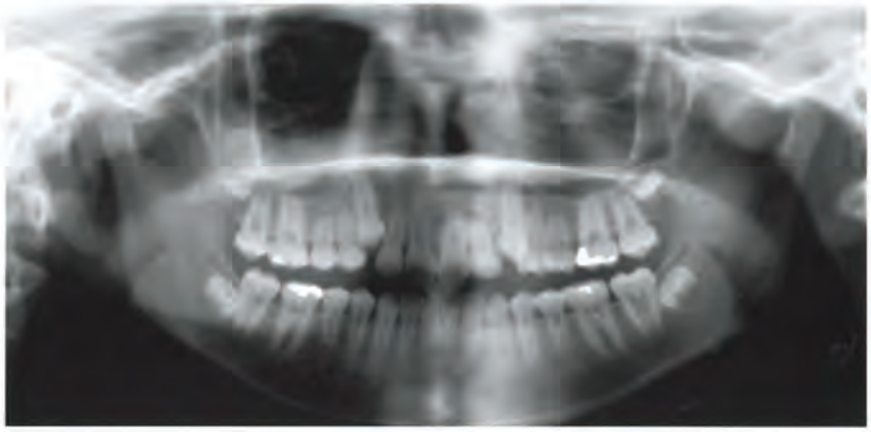


FIG 8-5a The submitted panoramic radiograph should have good definition, especially around the deep periodontal structures.

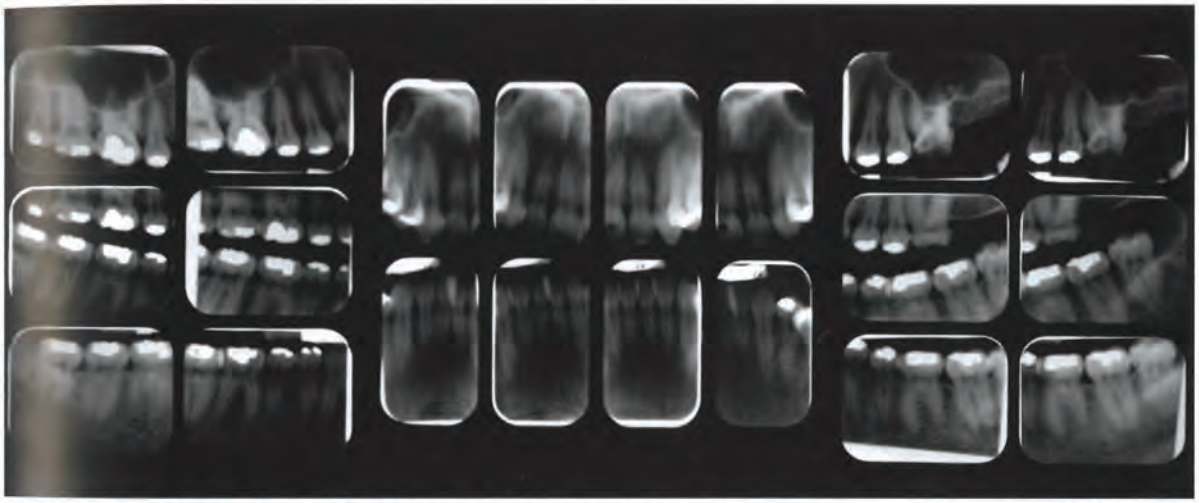


FIG 8-5b Full-mouth periapical series offers more detail, but to set up the ClinCheck images both panoramic and full-mouth radiographs serve equally well.

above), radiographs can reveal the presence of crowns, partial dentures, and implant restorations that may not show on photographs. Therefore, radiographs are also important in identifying or verifying attachments and proper tooth movements.

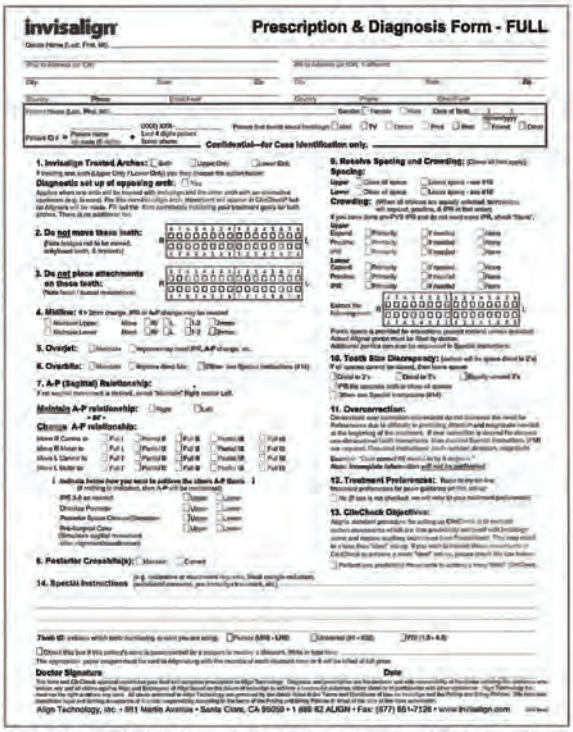
Additional radiographs taken by the treating clinician for diagnostic purposes do not need to be submitted to Align Technology, as their diagnostic information should be incorporated into the treatment goal information.

Prescription and Diagnosis Form

The treating clinician can provide either an anterior treatment or a full-arch treatment form (Figs 8-6) to Align Technology. Prescription and diagnosis forms submitted in paper format are scanned and stored for later use. Forms that have been completed digitally by the doctor in VIP (Virtual Invisalign Practice, on the invisalign.com website) are downloaded and stored by Align once the case is received. Each of the clinician's concerns, goals, and treatment objectives must be clearly incorporated and expressed on the prescription and diagnosis form. This form is also used to provide shipping and billing instructions, to indicate the type of case (anterior or full treatment), and to record patient background information.

The prescription and diagnosis form represents an important part of the communication between the treating clinician and Align Technology's technicians. Specific information provided on the prescription and diagnosis form

ClearCorrect Exhibit 1016, Page 85 of 335


invisalign

Prescription & Diagnosis Form - FULL

FIG 8-6 Prescription form used to submit cases to Align Technology. It may be submitted on paper (shown) or online.

includes the following: arch(es) treated, diagnostic setup, teeth not to be moved, teeth not to have attachments, overbite and overjet goals, sagittal goals and instructions, posterior crossbite correction, information on correction of crowding or spacing, handling of tooth size discrepancies, and other general preferences and special instructions of the virtual setup. Clinicians use this form, which is also available in electronic html format in VIP, to indicate their goals and objectives. An in-depth discussion of how elements of the prescription and diagnosis form are utilized by Align Technology's technicians can be found in chapters 11 and 15.

ToothShaper

ToothShaper is the proprietary name given to the software used to prepare the impression, section the teeth, and remove all virtual gingiva. This software was developed from a rudimentary cutting technique that used a flat "plane"-style cutting tool (Fig 8-7) and has evolved into an almost fully automated cutting and detailing tool. After the PVS impression is scanned, the electronic files are sent to an offshore facility that will send the virtual setup to the prescribing clinician.

The first step undertaken at the offshore (Costa Rica) facility is to inspect all records that are received for each patient. This includes maxillary and mandibular impressions, treatment planning form, patient photos, radiographs (if provided), and bite registration. For each patient, the ToothShaper technician verifies that the information is complete and consistent, and that the quality of the records is acceptable to proceed with treatment.

If all the records pass the initial inspection, the technician begins to cut the teeth—evaluating once again the quality of the impressions. If the impression is of poor quality, the technician captures images of the area(s) that are unacceptable and calls the customer to request another impression. The old impression and the images of the unacceptable area are returned to the clinician so he or she can learn from whatever problems led to the poor quality of the initial impression. Some of the most common reasons for unacceptable impressions are distorted anatomy, bubbles and voids, and incomplete capture of crowns of all teeth.

If the impressions are acceptable, the technician segments the teeth using the ToothShaper software. This process uses many of the same techniques that are used in the traditional dental laboratory; however, it is all done with digital tools in the software. This allows the technicians to get the same or even better quality in significantly less time and with lower scrap rates. There are two basic steps to performing the ToothShaper process: identifying the teeth by marking the facial axis of the clinical crown (FACC), and detailing imperfections in the impression.

The first step is to quickly identify the FACC of each tooth using a point on the incisal edge and a point on the cementoenamel junction (Fig 8-8). The FACCs must be identified first; at the time of this publication, the software cannot fully detect tooth geometry. Identifying the FACC gives the software a starting point from which to run its algorithm. The FACCs are used by the software to estimate the shape and angulation of the crown. When each tooth crown has been identified by the software, the technician fixes any parts that have been missed by the software. This is called "painting" the teeth (Fig 8-9). Once all teeth have been properly identified, the technician simply clicks a button to segment the teeth (Fig 8-10).

The next step is to detail any imperfections in the impression (ie, fill voids, remove excess material, correct

ClearCorrect Exhibit 1016, Page 86 of 335

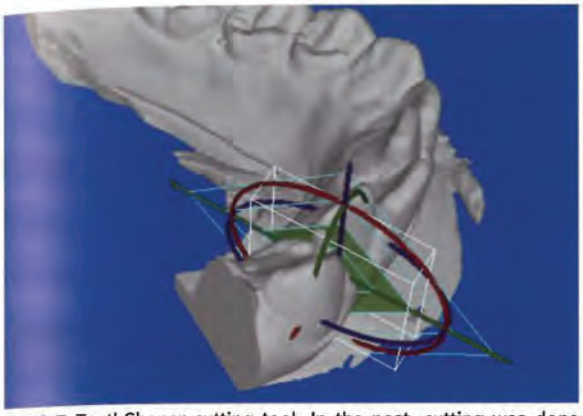


FIG 8-7 ToothShaper cutting tool. In the past, cutting was done manually, but now the cutting and detailing tasks are automated.

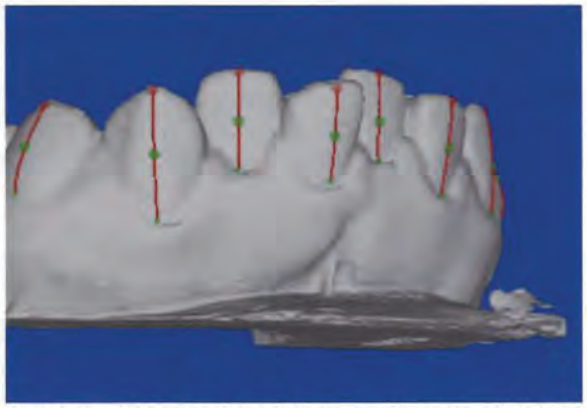


FIG 8-8 The facial axis of the clinical crown for each tooth is identified using a three-point registration.



FIG 8-9 The teeth are painted as an aid to discriminate each tooth.



FIG 8-10 The teeth are segmented at the click of a button.

deficiencies in the scan) (Fig 8-11). Mastery of dental anatomy and tooth morphology is a critical component of Align Technology's internal training program. Align's standard on quality impressions is covered in chapter 5.

When all the teeth have been segmented and cleaned up, the technician prepares the models for the setup process. This begins by setting the axis of each tooth. Again, at the time of this publication, this process is performed manually; however, with each passing software release, gains in both cycle time and quality are achieved. The axes are set in the X, Y, and Z directions, which enables the technician to easily move the teeth in the desired position when performing the virtual setup.

When the segmenting of the teeth, detailing of the model, and setting of the axes have been completed, the bite is set in centric occlusion using an automated tool in the software. The AutoBite tool in ToothShaper has been perfected so that all Class I and Class II, and most Class III, bites are nearly all automated. As discussed above under "Bite Registration," the software tool occludes the virtual models based on the anatomy of the teeth and

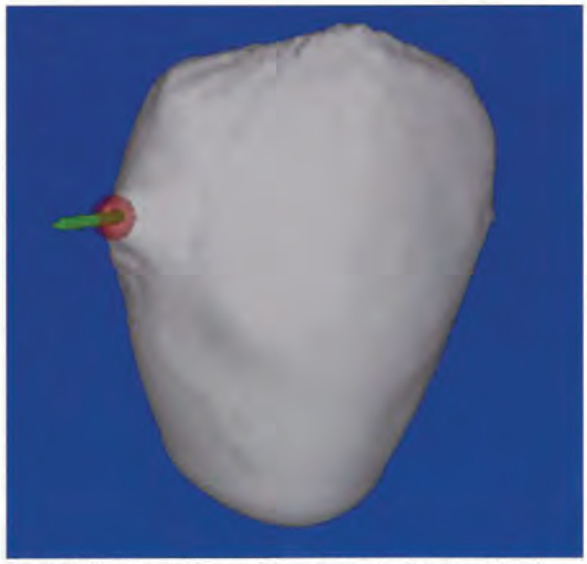


FIG 8-11 The smoothing tool is used to eliminate imperfections.

ClearCorrect Exhibit 1016, Page 87 of 335

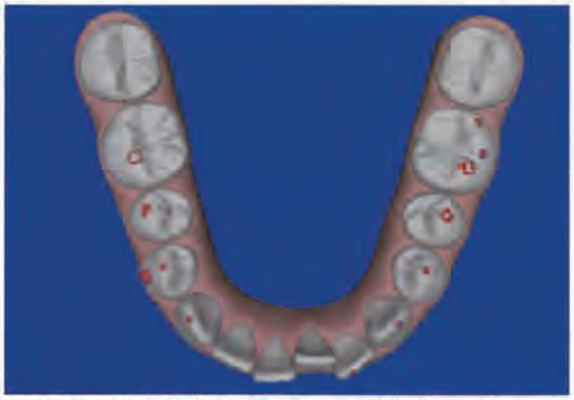


Fig 8-12a Red marks indicate maximum occlusal contact points. These are used to register the occlusion of maxillary and mandibular teeth.

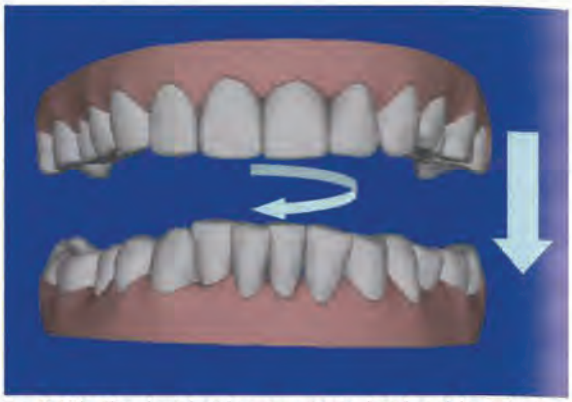


Fig 8-12b The dental arches are manipulated and brought into occlusion.

their maximized occlusion (Figs 8-12a and 8-12b). The technician runs the AutoBite tool and confirms the results with the photos. For cases that feature Class III and open bite conditions, there is sometimes the need to make manual adjustments using the PVS bite registration. The technicians virtually lay the bite registration over one arch and then move the opposing arch to be interdigitated into the bite registrations (Figs 8-13a and 8-13b). AutoBite is the preferred approach to this task because manual adjustments made from the bite registration are difficult, labor intensive, and time consuming. A proper bite set is a key element in a successful Invisalign treatment.

The next and last step for the ToothShaper technician is to adjust the virtual gingiva to replicate the patient's actual gingival tissue. This too is a semimanual step at the time of this publication, but software to automate this step is soon to be released. The virtual gingiva is adjusted with five nodes on the buccal and five nodes on the lingual; the technician moves the nodes to match the gingiva in the original, pre-segmented model (Figs 8-14a to 8-14c). Proper gingiva adjustment is required for a good fitting, comfortable aligner. The file is saved to the patient database and will be submitted to a quality check that is performed by highly trained technicians who again review the pretreated data for records, proper detailing, bite set, and gingiva adjustments. When the ToothShaper process is completed, the case moves onto the setup and stage process, which is explained in chapters 7 and 12.

Summary of Process

Overall, the process of creating the ClinCheck can be summarized in this way: Patient records are scanned into a digital format (unless supplied in digital format by the treating clinician) and stored electronically. Once all records are acquired electronically, a technician uses them to create the virtual patient. The technician locates the facial axis of the clinical crown on all of the teeth, and then the ToothShaper software identifies the shape of all of the teeth. The technician manually adjusts the painting on the teeth so that all of the teeth have only the crowns completely painted. Segmentation occurs automatically. After the segmentation is complete, the technician uses the AutoBite tool to occlude the models into an articulated CO relationship. Finally, the technician manually adjusts the virtual gingiva around each tooth, and the virtual model is complete.

Future Trends

Complete automation is the ultimate goal of almost any manufacturing process. Automation is advantageous because it reduces variability to acceptable levels within controlled ranges. More complex manufacturing processes have variable starting points, contain more steps, and have multiple inputs, which increases the procedure's complexity and variability. As a result of the complexity, incremental improvements are much more achievable and can be implemented in a controlled fashion to ensure reduced variability.

ClearCorrect Exhibit 1016, Page 88 of 335

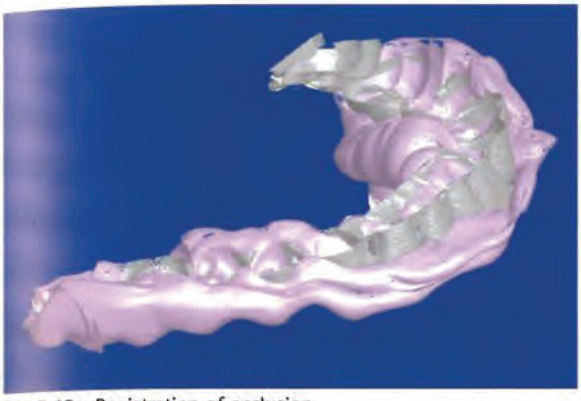


FIG 8-13a Registration of occlusion.



FIG 8-13b Arches registered in occlusion with the aid of occlusal contact points and the bite registration impression.



FIG 8-14a Registration of gingival line on the pre-segmented model.

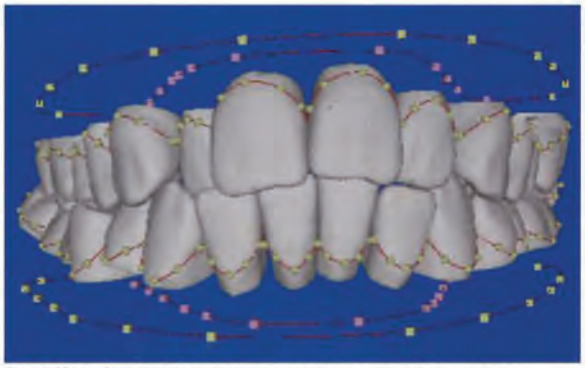


FIG 8-14b Gingival boundaries on the segmented models.

The following timeline of past and expected improvements is presented to better understand the nature of improvements that are in use:

- 1999: Manual cutting with flexible plane-style cutter. Each tooth is manually cut one at a time, with each tooth requiring between 20 and 40 individual slices. Initial detailing was performed on the physical model, which was poured in a dental laboratory.
- 2000: New cutting tool reduces the number of slices to between three and eight per tooth, but is still undertaken one tooth at a time. Initial detailing is still done on the physical model; however, this newer tool and process reduce cutting time by approximately 75%.
- 2002: ToothShaper software was developed, which automates the majority of the cutting and reduces processing time by another 50%. Digital detailing was invented, resulting in the removal of more than 80% of the work done on physically poured models.



FIG 8-14c Finished product.

- 2003: AutoBite tool was developed, which increases bite set accuracy to 99% for most cases and reduces time by 80%.
- 2005: Automation of gingiva process reduces labor time by 30%.

ClearCorrect Exhibit 1016, Page 89 of 335

- 2006: Final automation of ToothShaper steps enables full automation of segmentation and significant amount of detailing, which is expected to reduce labor time to 1/500 of original time from 1999.

References

1. Donovan T, Chee W. A review of contemporary impression materials and techniques. Dent Clin North Am 2004;48:vi–vii, 445–470.
2. Chenin D, Turley A. Analysis of an automated bite creation tool for 3D dental software. 144th Annual ADA Scientific Session Table Clinic, October 2003. Available at: http://www.cheninortho.com/images/Forms-articles/ADA_TableClinic_Handout.pdf. Accessed February 15, 2006

ClearCorrect Exhibit 1016, Page 90 of 335

chapter 9

ATTACHMENTS

by
Peter Knopp and Mitra Derakhshan, DDS

ClearCorrect Exhibit 1016, Page 91 of 335

Traditional orthodontic appliance systems are designed around components that transmit forces (ie, wires) and elements that apply these forces (ie, brackets) to the teeth. The Invisalign System also follows this design: it directs force application to the teeth through intermediary components—aligners and attachments. Where aligners are analogous to wires, attachments are equivalent to brackets.

The discussion that follows presumes a general understanding of the mechanics of tooth movements. The emphasis is on the concepts underlying, and the uses of, the attachments used in Align Technology's Invisalign System.

Basis of Need

Teeth generally do not have operative purchase points on which any appliance system can act effectively. In conventional appliance systems, this is remedied through the bonding of standardized brackets to the teeth. For the Invisalign System, the necessary purchase points are created through the formation and application of predetermined shapes, which are grouped under the appellation *attachment*.

As with brackets, attachments are necessitated by dental morphologies and mechanics. Further, both brackets and attachments afford an experienced practitioner myriad possible clinical benefits. It should therefore be clear that the informed use of attachments is crucial to achieving effective treatments with the Invisalign System.

Terminology

It is important for users to familiarize themselves with the vernacular of their profession and its related processes. To that end, the following words have particular meanings in the context of an Invisalign System treatment:

- *Attachment*: An object added to the computer representation of a tooth's geometry that may or may not also be added to the real tooth. An attachment is readily identified in a ClinCheck presentation as a red geometric body that lies on one or more tooth surfaces. Figs 9-1a to 9-1c show examples of attachments placed on a computer representation of dentition. There are three types of attachment:
  —*Real*: The physical manifestation of any attachment or the computer representation that becomes reality. This is the shape that is formed (in composite or another material) and bonded to a tooth.
  —*Virtual*: The computer representation of an attachment or a shape that is formed in an aligner but not subsequently reproduced as a physical entity bonded on a tooth.
  —*Window*: An attachment formed partially or wholly around a tooth to create space for it to move into or to isolate it from the movements of other teeth. This is a specialized incarnation of a virtual attachment. The shapes are usually created by scaling the associated tooth by more than 100% and then, as needed, removing buccal and lingual portions to reveal tooth surfaces or bonded attachments on which the aligner can act. Window attachments are always shown in a translucent color so the underlying tooth can also be seen.
- *Base*: The portion of an attachment that penetrates the tooth in the computer representation of a treatment. It is the translucent purple geometry that produces a continuous profile between the tooth and the attachment. In the absence of a base, a gap could exist between an attachment and its underlying tooth. Such a gap would lead to an inexact and, likely, difficult bonding of the attachment to the tooth.
- *Cavity*: The shape formed in the aligner by a real or virtual attachment that is present and visible in the computer representation. In an attachment template aligner, this is the mold to form a real attachment and bond it to a tooth. It is also the shape that most directly contacts a bonded attachment.
- *Channel*: A conduit that runs (generally apically) from the gingival aspect of an attachment or its cavity to the gingival edge of an aligner. It is formed in the aligner by placing one or more virtual attachments gingival to the real attachment (see Figs 9-1b and 9-1c). Alternately, it can be created through the use of an attachment that has sufficient length to extend beyond the gingival margin (Fig 9-2). A channel is created to ease appliance seating and removal, or to benefit the interaction of the cavity and attachment. When a separate attachment is used to form the channel, it may be at a prominence different from that of the real attachment. The shape may also differ from the associated real attachment to control the extent and manner of interactions at the gingival aspect.
- *Dynamic attachment*: A concept wherein the virtual attachment and, consequently, its cavity differ in a predetermined way from the real, bonded attachment. The intentional misfit created between appliance and associ-

ClearCorrect Exhibit 1016, Page 92 of 335

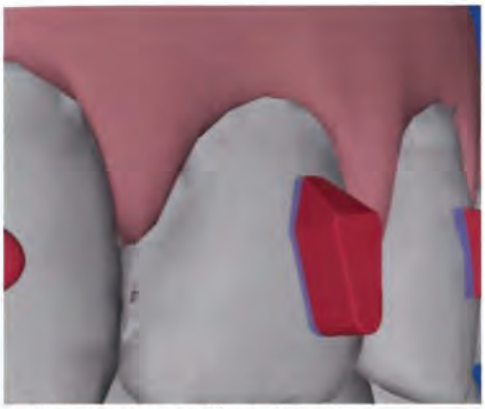


FIG 9-1a Attachment without channel.

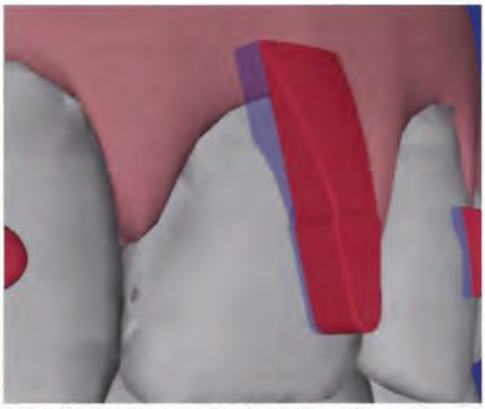


FIG 9-1b Attachment with channel at full.

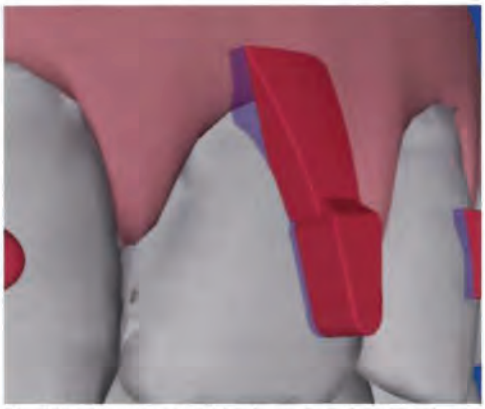


FIG 9-1c Attachment with channel and reduced prominences.

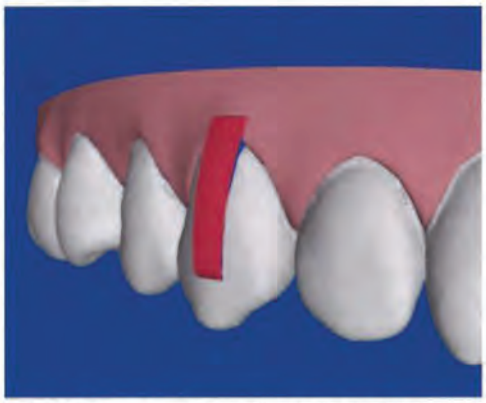


FIG 9-2 A 9-mm curved root tipper on a canine extending past the gingival margin.

ated attachment generates forces and moments to effect tooth movements that could be otherwise problematic with aligners.

- *Engagement*: The degree of attachment and cavity congruence or mating. This is typically more a qualitative than quantitative assessment of how well the two geometries track or join together.
- *Footprint*: The area of contact between a tooth and the attachment bonded to it. The actual footprint of a given attachment varies somewhat among placements because of the wide variations in tooth morphologies.
- *Orientation*: The alignment of an attachment's axes relative to those of another object—usually the underlying tooth. An attachment's default orientation is set at design time. Nevertheless, a practitioner may prescribe any other particular orientation so long as it will not conflict with the footprint and prominence considerations. Figure 9-3 shows two ellipsoid attachments with different orientations.

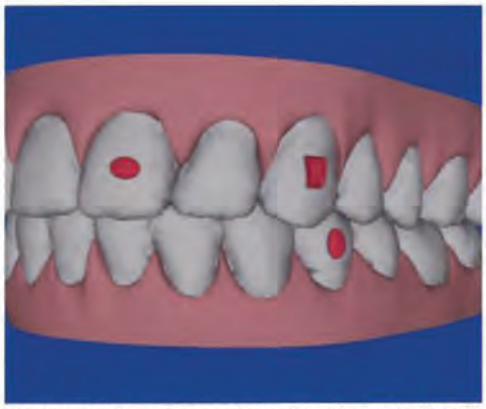


FIG 9-3 Default positions for rectangular and ellipsoid attachments. Note that the orientation has been changed from vertical to horizontal on the maxillary left central incisor.

ClearCorrect Exhibit 1016, Page 93 of 335

- *Position*: Self-explanatory, although it should be noted that it is described relative to the underlying tooth or teeth.
- *Prominence*: The projected distance between an attachment's most labial geometry and the nearest point on the tooth on which it is placed. This value is set in every attachment design; however, it must be kept in mind that this is a nominal value. There are several factors that contribute to the alteration of the true prominence of a bonded attachment. First, the achievable placement accuracy of the virtual attachment varies from tooth to tooth. Second, the production of the physical attachment from a template on a tooth can introduce dimensional differences. And third, the attachment composite wears down over the course of treatment due to brushing and chewing, as well as aligner placement and removal.
- *Staging*: The timing of an event during an Invisalign treatment. As used in the context of attachments, it is when an attachment is present or visible in a treatment. Although they are typically placed by default on the teeth in the initial occlusion (stage 0), attachments can be prescribed by the practitioner at any stage. Further, their presence or visibility can be varied over the course of a treatment.
- *Visibility*: Whether or not an attachment that is present can be seen in the computer representation. As noted above, visibility can be changed stage to stage over the course of treatment. An attachment must be present and visible for its shape to be produced in an aligner.

Classifications

There are three fundamental categories of attachments: those that assist movements, those that augment appliance retention, and those that provide or support auxiliary functions. All three act as force transmitters; however, they do so in different ways.

The movement attachments are intended specifically to induce or aid the repositioning of the teeth to which they are bonded. The retention designs typically promote movements in teeth other than the one to which the attachment is affixed; retention attachments serve as relatively fixed points against which the aligner can act. The auxiliary attachments may be placed to act on the teeth they are attached to, on other teeth in the arch, or—in conjunction with other components (eg, elastics)—on teeth in the opposing arch.

Movement Attachments

As noted earlier, sites on which applied forces can act on the teeth are required to effect the intended tooth movements. The principal motions are, of course, extrusion, rotation, and translation. Within the category of movement attachments there are two basic manners of interaction between an aligner and an attachment.

The first is where the virtual and real attachments are identical (ie, the bonded attachment and its cavity in the aligner are produced from the same shape and are hence congruent). The successful application of this concept is predicated on the expectation that successive, small differential displacements between the bonded attachment and its cavity (as caused by the staging of the tooth's movements) engender the necessary deformation in the aligner cavity for it to stretch over the bonded attachment as the aligner is pressed onto the teeth. The cavity's recovery of the induced strain is transferred through the attachment as the intended displacement of the tooth.

This method has had limited success in both clinical study and commercial treatments. The reasons for this are evident. First, the size of the differential displacements is crucial to effective execution. If the displacements are too large, the cavity cannot locally distend sufficiently to fit the attachment, but will "ride up" on the attachment as the aligner bows outward to accommodate the interference. The broad range of factors that determine aligner geometry make it practically impossible to set the differential displacement at a standard magnitude and direction across all treatments or to vary it as a function of the geometry present. These factors include the target tooth's morphology, mesiodistal and occlusogingival dimensions, accessible facial surface, and its programmed path of movement, as well as these same parameters for the surrounding teeth.

Second, any cavity distention would necessarily need to be isotropic with respect to the attachment for the cavity to be able to regain congruency. However, the morphologic and dimensional conditions cited above, as well as the varying thickness of the aligner material, yield anisotropic distention. That is, a uniform force applied to a geometrically inhomogeneous body will cause differing amounts of deflection in that body. There is no means available to impart the varied forces (or, alternately, deflections) to the aligner to cause the cavity to distend in the manner required. Even if the means were created, there would still be the uncertainty in the determination

ClearCorrect Exhibit 1016, Page 94 of 335

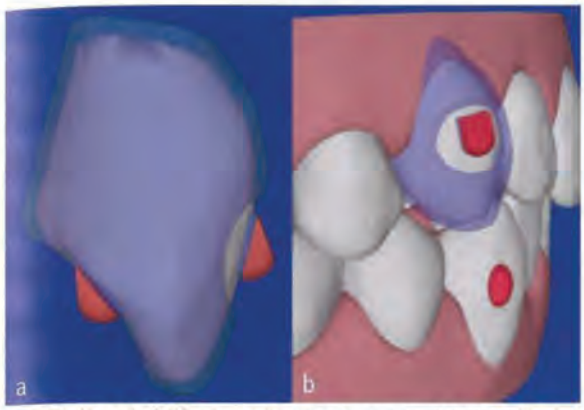


FIG 9-4 **(a and b)** Window attachments surround the tooth, but allow the aligner access to attachments.

of the appropriate magnitudes of forces (or deflections) discussed previously.

Typically, the attachment and cavity track over several stages; ultimately, however, there is the onset of incongruence that worsens over time. This is reported anecdotally and is also evident in the results from the University of Florida attachment study.[1]

The second manner of attachment/aligner interaction is where the virtual and real attachments are calculatedly different in shape. This causes an interaction that can be thought of as a cam (the real, bonded attachment) and follower (the shape formed in the aligner). This interaction allows for the generation of forces from bowing the aligner outward from the teeth. This deformation is more predictable and quantifiable for a given treatment and, within a determinable range, across treatments. Further, the force caused by the deflection can readily be altered through the addition or removal of geometric effects in the surrounding region. This is discussed in the "Auxiliary" section below.

This interaction has another advantage over congruent interactions in that it has the propensity to be self-correcting. This property led to the appellation of *dynamic attachment*. If the tooth does not track with its movement programmed into the aligner, the followers in the aligner will interfere even more with the underlying cam (bonded) attachments. This causes greater outward deflection in the aligner, which yields more force applied to the tooth through the attachments. The increased force tends to compel the tooth back into accord with the programmed movement.

A dynamic attachment setup follows the following progression: Real attachments are applied to the buccal and lingual tooth surfaces at one stage prior to the onset of the desired movement; these are replaced in the next stage with the attachments' virtual versions, and a window attachment appears at this same stage. The translucent purple bodies seen in Figs 9-4 to 9-6 are window attachments. These are typically removed from the treatment at three stages after the programmed movement has ceased. This is done to allow the tooth movement to be fully expressed.

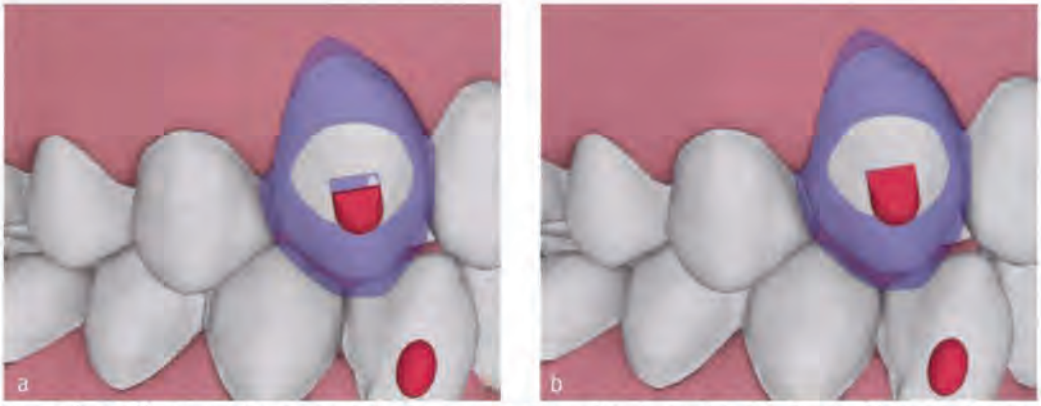


FIG 9-5 **(a and b)** The purple volume will become a space surrounding the tooth in the aligners. (*a*) The attachments on the canine (the identical lingual one is not shown) slope away from the tooth surface in the occlusal/incisal direction. (*b*) The gingival portion of the attachment has been removed. Starting at stage 01, this will form a step in the aligners that will interfere with the actual bonded attachment. The space around the tooth permits it to move if there are not interproximal contacts with the lateral incisor or first premolar (a judicious amount of interproximal reduction could help).

ClearCorrect Exhibit 1016, Page 95 of 335

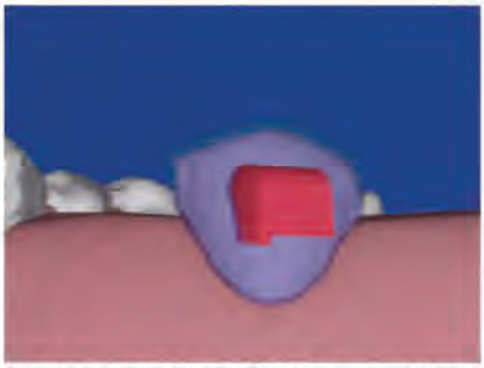


FIG 9-6 The red body is the virtual attachment designed to cause the desired misfit between the aligner and the bonded attachment for both rotation and resistance to intrusion. A scaled-tooth space (translucent purple) is placed around the tooth to eliminate collisions between the tooth and aligner that could impede rotation. (Neighboring teeth were removed for clarity.)

Retention Attachments

Because of factors such as short clinical crowns, insufficient undercuts, missing or extracted teeth, and pronounced tooth-size discrepancies, there are times when appliance retention must be enhanced to ensure that forces of the desired magnitude, direction, and point(s) of application are realized.

This augmented retention is readily accomplished through the inclusion of attachments in the treatment. Since there are no programmed positional changes between the bonded attachment and its cavity in the aligner, attachments placed for retention are always of the congruent type.

The other significant use of retention attachments is for a localized increase in the appliance's resistance to being dislodged on teeth that neighbor a tooth targeted for intrusion. The typical setup is to place one attachment on the buccal surface of each tooth immediately mesial and distal to the tooth that is to be intruded. These bonded attachments provide the leverage points against which the aligner works while the middle tooth's intrusion progresses.

Whether for general or local appliance retention, the current standard is to apply congruent attachments with no greater than 0.75-mm nominal prominence. Nevertheless, it is not unusual for retention attachments of higher prominence to be requested. The obvious risk is that these will be too retentive and the patient will have difficulty removing the aligners. Both in vitro testing and in vivo experience have shown that this does indeed happen. It is therefore advisable to use highly prominent attachments sparingly. Additionally, the patient should be informed of the possible difficulties and receive instruction in proper aligner-removal methods.

When the need for higher-prominence retention attachments is indicated, the use of channel attachments or attachments that extend beyond the gingival margin may be advisable. The placement of these can mitigate excessive removal forces directed approximately along the occlusogingival axes while still providing mesiodistal retention (see Fig 9-2).

Auxiliary Attachments

Attachments have numerous applications as auxiliary treatment elements. These demonstrate the flexibility and potential of the seemingly simple idea of including additional geometric shapes in the computer representation of teeth. Their functions are the same, of course—the creation of orthodontic forces of the desired magnitude and direction—but how they can be generated and employed may not be so readily apparent. Several of the applications that either have been put into practice or are being developed are described below. In each of the following embodiments, the attachments employed are virtual—their shapes are not applied to the teeth as physical entities.

Force augmentation

It is self-evident that all forces generated by an aligner are due to deformations that alter its unloaded shape. The complexity of the deformation does not necessarily allow for a straightforward determination of the resultant forces. Nevertheless, there are areas of the appliance that are clearly of inadequate strength for the tooth movements they are expected to cause. These areas are predominantly found along the aligner's gingival edge and where there are large spaces between adjacent teeth.

Rather than simply allowing the teeth and their programmed motions to determine the shape and, thus, the strength of the appliance, virtual attachments may be added to the treatment to change the aligner's geometry and the consequent forces it applies to the teeth. These attachments will not be bonded to the underlying teeth, so the chief considerations in the selection of their shape, size, and placement are patient comfort and esthetics.

As an example, consider the appliance morphology that surrounds the maxillary central incisors. This region is typ-

ClearCorrect Exhibit 1016, Page 96 of 335

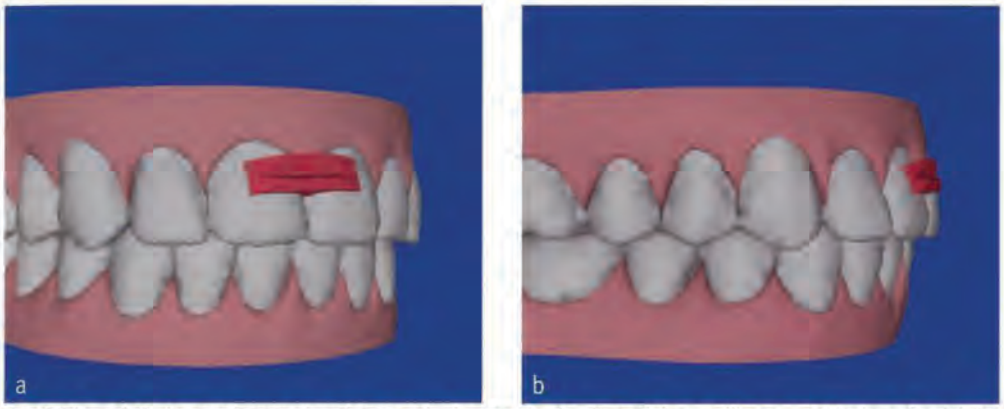


FIG 9-7 (a and b) An attachment placed across the interproximal region of the maxillary central incisors for rigidity.

ically among the weakest points in the aligner for obvious reasons: the teeth are located at what amounts to the keystone of the arch—a distinct inflection point—and they are tall and broad, and have a relatively planar profile. Thus, during appliance formation the plastic thins here more than in any other region. Also, there are no naturally occurring features to add rigidity to the span such as are found with molars. Thickening the plastic over the centrals would tend to make the region stronger; unfortunately, selective thickening of the appliance is not achievable within the constraints of current production methods. Another means of strengthening the region is to cause rigidifying elements to be produced in the aligner. This is easily accomplished through the addition of virtual attachments. Figures 9-7a and 9-7b show a sample ridged attachment placed across the interproximal region of the maxillary central incisors that will form corrugations in the aligner. These will yield more force for a given deformation.

In a similar manner, virtual attachments may be added to other areas to increase an aligner's resistance to shape modification. Their impact on comfort, appliance retention, and esthetics must be kept in mind. It should also be understood that the magnitudes and directions of the resultant forces will be unique to each patient and for each stage of that patient's treatment. So far, no empirical data exist to derive the functional relationship between the attachment's shape and prominence and the ensuing force change.

Fixation points

The production of an attachment that would form a hook or button in an aligner has been a frequent request from practitioners. This is not possible, however, given the means by which both the arch molds and aligners are fabricated. Consult chapter 6 for an explanation of the molding process. Nevertheless, attachments can be utilized to facilitate the use of buttons, hooks, or other linkage components.

Several attachments were created explicitly for the purpose of forming surfaces on which to affix hooks and buttons either through adhesive bonds or mechanical interaction. An attachment on the maxillary arch will create a smooth plateau onto which a linkage component (eg, commercially available button or hook) can be bonded. The body on the mandibular arch will then create a surface with a discernible depression in its center. The diameter and depth of this depression can be altered to serve different purposes (eg, as a more precise locater for component placement on the surface or as a guide to produce a hole for a component that passes through the aligner surface.)

Another particular implementation of virtual attachments as fixation points is created when aligners are used as surgical splints (Figs 9-8a and 9-8b). The attachments form shapes in the aligners that are sufficiently large and rigid to support tying the jaws together through them during postoperative healing. Real attachments may also be placed to augment retention of the appliances.

In a manner similar to perforating the attachments' cavities to use them as fixation points for surgical splints, they may also be slit. The notch that is formed can be used as a hook for elastics. When cutting the slit, care must be taken to ensure that the notch will not propagate into an unwanted tear in the aligner. A way to avoid this is to utilize a rotary tool rather than a fixed blade. The former tends to create a smooth-bottomed crevice whose dimensions are easier to control.

ClearCorrect Exhibit 1016, Page 97 of 335

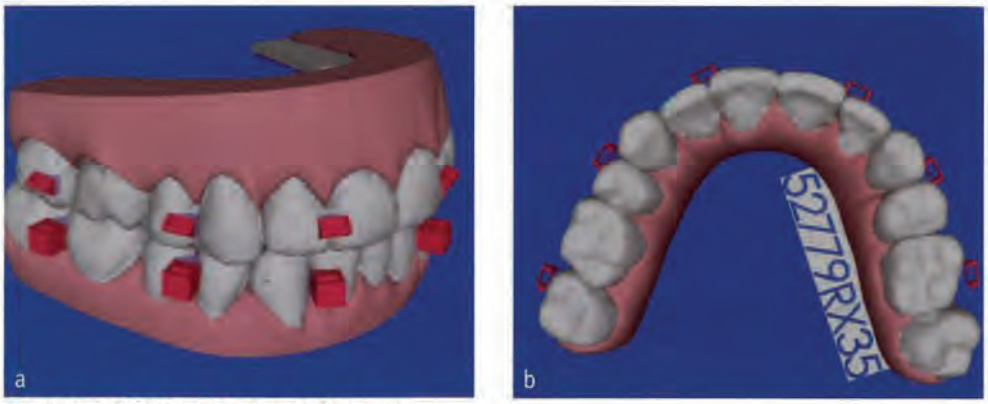


FIG 9-8 (a and b) Surgical splint fixation points.

A fixation point on the exterior surface of an aligner can be viewed as a receptacle on the interior. This concept suggests that additional orthodontic ancillaries may be used in attachments' cavities to place or affix various components. The components could be active (eg, springs) or passive (eg, wedges) and could be changed or adjusted as the treatment progresses.

The advantages of forming fixation points in the aligner are apparent:

- The geometry maintains its position relative to the underlying tooth or teeth over the course of treatment.
- Components can be bonded in the same locations easily and at any stage.
- The geometry can be controlled to be present in the aligner at only those stages it is needed.
- The attachment adds local rigidity to the aligner to reduce unwanted appliance deformation.
- The attachment can be spanned across one or more teeth to cause force systems not otherwise attainable.
- Multiple attachments can be placed adjacently to create a range of fixation points.

Interarch mechanics

Distalization

A novel means of implementing Class II elastics treatment using aligners was proposed by Dr Warren Wakerlin (personal communication, 2002). To this end, an attachment was designed for placement on the maxillary canines. There is a hole through the attachment that runs parallel to the tooth's long axis (Figs 9-9a and 9-9b). This hole is set a distance (prominence) from the tooth surface comparable to that found in canine brackets with hooks. This hole resolves as depressions in the upper and lower surfaces of the attachment when the aligner is formed. These features act as guides to punch holes into which wire hooks are inserted. The use of a high-speed bur or heated wire to form the hole has produced no problems (ie, tearing) with the aligner even after numerous insertions and removals over a 2-week period.

In some cases, attachments may need to be added on teeth distal to the canine to enhance aligner retention. Figure 9-10 shows the mandibular arch setup with brackets as anchors for the elastics. Very much the same result can be achieved through use of an aligner and retention attachments. Irrespective of the choice of a mandibular-anchorage method, from this point the case proceeds as a typical Class II treatment with traditional appliances, but with the hygiene, comfort, and esthetic benefits of an Invisalign System treatment.

Bite props

As with other treatment methods, some Invisalign System cases require that the bite be propped open to allow for tooth repositioning (eg, correction of an anterior crossbite). With conventional appliances, this is frequently done by bonding composite or a component to teeth to form a wedge. Such a prop can be produced in aligners by using a virtual attachment. As is true for any attachment, props can be present, or not, at any stage prescribed by the treating clinician.

Clinical evidence suggests that aligners correct crossbites more efficiently than do conventional orthodontics. This, coupled with the functional, cosmetic, convenience, and chair-time benefits of an aligner-based bite prop, makes a compelling case for the use of Invisalign in preference to fixed appliances to effect crossbite corrections.

ClearCorrect Exhibit 1016, Page 98 of 335

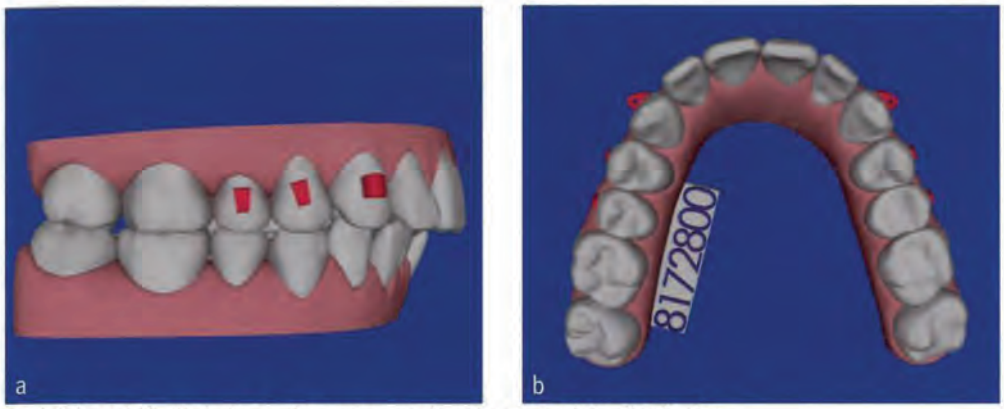


FIG 9-9 (a and b) The holes on the canine attachments are used for distalization.

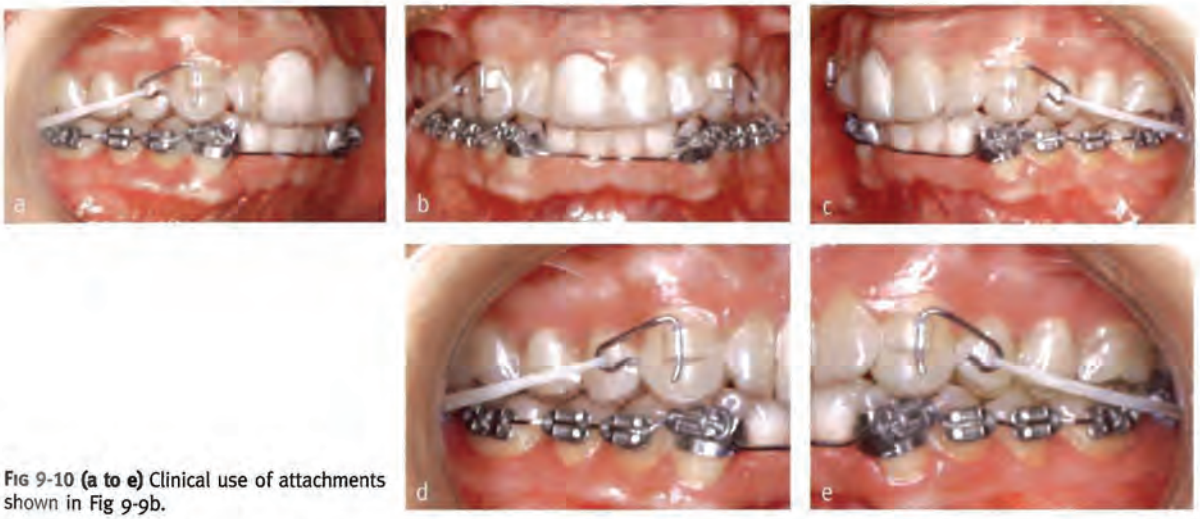


FIG 9-10 (a to e) Clinical use of attachments shown in Fig 9-9b.

Mandibular repositioning devices

Various incarnations of mandibular repositioning devices are available commercially either as laboratory setups or for the practitioner to install. Among them, the mandibular anterior repositioning appliance (MARA) has seen significantly increased usage in recent years—in particular, as an alternative to a Herbst positioner. This has led to MARA design modifications that enhance patient comfort and simplify the installation procedure. Nonetheless, placement of the device remains fairly time-consuming and can require extensive adjustments.

Proponents of a MARA as a mandibular repositioning device cite numerous benefits to both patient and practitioner. Among these are an immediate improvement in profile appearance, more efficient treatment of Class II malocclusions, rapid movement of the maxillary first molars while also causing mesial to buccal rotation, ease of fit, retentive crown coverage, and the ability for simultaneous use with other orthodontic appliances.

The idea of using the Invisalign System to generate a patient-specific, aligner-based device that is very much the same as the MARA was proposed by Dr Robert Fry (personal communication, 2003). Fry is the principal investigator for a clinical study Align has undertaken to evaluate this modified aligner's efficacy. It is expected that this construction will have distinct benefits relative to the existing designs. These include enhanced patient comfort due to the exact custom fit possible with Align's production processes, more precise diagnoses based on the three-dimensional presentation in ClinCheck, greater accuracy and flexibility in setting and adjusting the interarch mechanics by controlling component positioning before committing to device production, and generally

ClearCorrect Exhibit 1016, Page 99 of 335

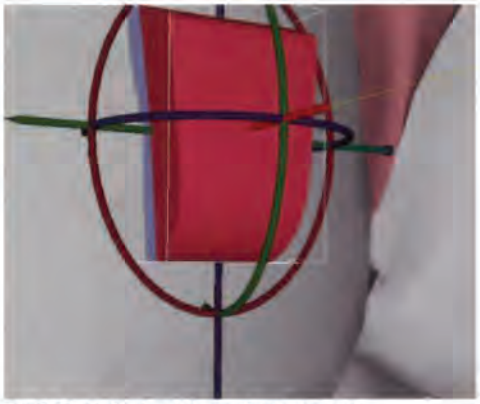


FIG 9-11 Default position of attachments.

improved oral health since the entire appliance is removable and bonding is minimized or eliminated.

Reservoirs

Attachment function need not be confined solely to use as auxiliary components intended to move teeth. The cavity created in an aligner by an attachment can also be exploited as a dispersal point for substances or a receptacle for devices. The former could include drugs to promote an orthodontic treatment (or for a purpose unrelated to orthodontia that has broader health benefits, such as analgesics, antibiotics, etc). The range of devices that could be incorporated into an aligner is fairly extensive, from a wear indicator to modules to monitor a patient's biometrics.

Design Factors

The aspects that drive attachment designs are similar to those that lead to bracket designs—functionality, comfort, and esthetics. As with many other products, interactions and dependencies among these aspects may constrain or guide choices. The following sections provide insight into the attachment development process.

Functionality

The intended output or result is the foremost consideration at the outset of any design. An attachment has several aspects that can be included under the functional designation. For Align's production processes, these aspects include object properties, file size, software compatibility, and appliance fabrication. Only the first and last of these aspects will be discussed here. For the clinician and patient, the functional aspects include performance, which can be defined as the attachment's role to augment and facilitate the aligner's programmed tooth movement. The performance aspect was discussed earlier in this chapter. Ease, accuracy, and precision of transferral are also covered in chapter 10. Therefore, only the design considerations that affect an attachment's durability will be discussed in this section.

From a practical standpoint, a user need not be concerned with the properties of an attachment. The clinician's awareness of a few fundamentals, however, may provide perspectives on the Invisalign System processes that could lead to improved treatment results.

Every attachment is designed to have the same spatial coordinate system so that consistent, predictable placements are attained when they are applied to teeth. The origin of the coordinates is always positioned at the interface of the attachment proper, and its base is typically placed in the geometric center of the attachment's footprint. The default orientation varies among attachments according to their design intents. As can be seen in Fig 9-11, the coordinate system defines the positional and rotational controls that are used to set an attachment in a particular spatial relationship with respect to the underlying tooth. These controls are not currently accessible from ClinCheck, but are reserved for Align's technicians during case setups.

With some exceptions, an attachment's facial profile defines its footprint. One of the attachment design goals is to minimize this area to produce as unobtrusive a body as possible. There is a countervailing design goal, however, in that the attachment and tooth must have sufficient surface contact area to resist shear or other failure modes when the attachment is loaded to move the associated tooth. It has been determined experimentally that an attachment with a prominence of 0.75 mm must have a footprint of no less than about 5 mm^2 when it is formed in composite and bonded to a tooth. The practical limitations on attachment prominence were discussed previously. There is an additional consideration related to prominence: the footprint typically needs to become larger as an attachment's buccolingual dimension increases.

The physical characteristics of spatial location, contact area, and shape largely define the intended attachment morphology. The thermoforming process used to fabricate aligners determines the geometry's actual representation. There are two main factors that create the differences between the intended and the actual attachment cavity.

ClearCorrect Exhibit 1016, Page 100 of 335

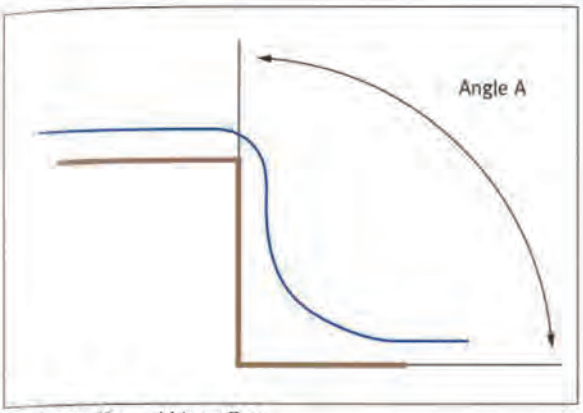


FIG 9-12a The webbing effect.

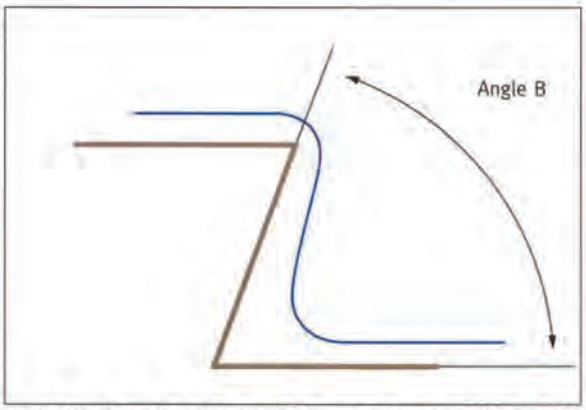


FIG 9-12b An undercut is created to mitigate the webbing effect.

The first is the webbing effect that occurs around the attachment body during aligner thermoforming. Webbing occurs when a material spans a geometric transition rather than conforming to its surfaces (Fig 9-12a). A means of mitigating this effect is shown in Fig 9-12b. It should be clear that if the attachment's profile and consequent cavity are as shown in Fig 9-12a, the aligner will more easily slide over or off the underlying attachment, which diminishes the attachment's effectiveness. To improve the interaction between aligner and bonded attachment, the latter's profile is given an inward bevel. This tends to cause the aligner to form more nearly perpendicular or even inwardly angled surfaces. The slight bevel also helps to reduce the unwanted relative motion between aligner and attachment.

The second main factor that creates differences between the intended and the actual attachment cavity is the bridging effect that results from other local geometries. This is essentially the same phenomenon as seen around the attachment body, but it is caused instead by the proximity of other bodies to the attachment. This is part of the reason for the default placement of an attachment in the locus of the tooth's facial axis point—it is thus removed from the transitions between teeth at the incisal/occlusal edges and between teeth and the gingiva. Webbing and bridging are predominantly beneficial to the comfort and fit of the aligner, but are detrimental to the formation and application of attachments.

The durability of an attachment is a function of three principal components: shape, material, and environment. It had been presupposed and has been effectively demonstrated in actual usage that distinct or sharp edges were not advisable for composite attachments, because they tend to degrade over time more substantially and more quickly than when the attachment's shape flows more smoothly. Where allowable, attachments have limited sharp edges.

The recommended material for attachments has been resin composites, since these are intended for uses not dissimilar to how Invisalign System attachments are employed. Also, the composites' wear resistance is generally well documented and understood. Complete information is provided in chapter 10.

The environment is the unknown and uncontrollable factor in attachment durability. Perhaps the best that can be achieved is to inform patients of some of the caveats given with brackets: avoid hard foods such as nuts and ice and resist over-brushing.

Esthetics

Stating the obvious, the appearance of any geometry bonded to a tooth is determined to a large extent by its size and shape. This is somewhat offset by the fact that the composites used to form attachments can be color-matched to a patient's teeth. The presence of the aligners also mitigates the visual obtrusiveness of the attachments.

Comfort

A patient's comfort is always going to be compromised by bonding anything to the teeth. Efforts are made to minimize the discomfiture by keeping footprints small, prominences low, and shapes free of sharp edges. The edge characteristics are almost exclusively a concern for the short durations when patients are not wearing their aligners. When in place, the appliances create smooth continuous surfaces that minimize discomfort.

ClearCorrect Exhibit 1016, Page 101 of 335

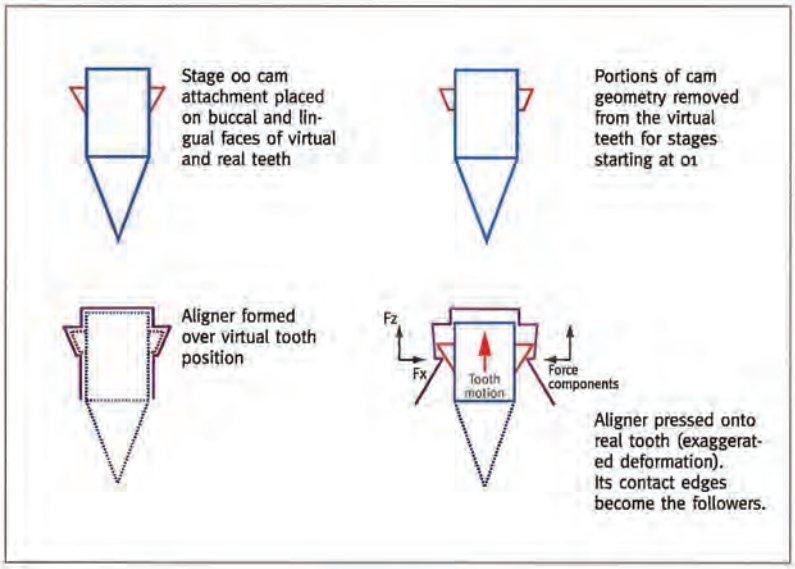


FIG 9-13a Principle behind the dynamic attachment, shown here for extruding a tooth (under development). If the tooth's extrusion begins lagging behind the aligner, the force generated by the deformation will increase, tending to cause the tooth to move more. At a cam angle of 35 degrees, 82% of the force goes to extrusion. Sufficient "head and shoulder" room must be available for the tooth to move into and to avoid binding. This is a simple two-dimensional representation. The complex real geometries of teeth and aligner render actual results less certain.

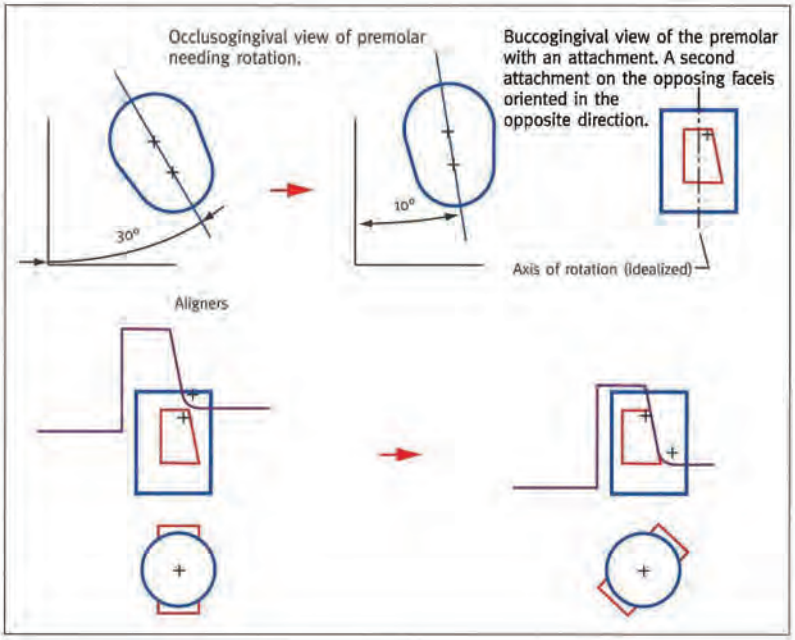


FIG 9-13b Principle behind the dynamic attachment, shown here for rotating a tooth (under development). The vertical motion of the aligner is converted to rotation of the tooth. There is some intrusive force on the tooth, but this can be counteracted or overcome with, for example, an upward sloping ramp as is used for extrusion.

Imminent Developments

Dynamic attachments

The development of this attachment concept began with the determination of the angles needed to impart the maximum force in the intended direction while minimizing the opposing or otherwise detrimentally directed forces (Figs 9-13a and 9-13b). This was followed by the calculation of a footprint large enough to support more than the expected shear forces. The combination of these factors yielded the attachment prominences, which are substantially greater than those of congruent attachments. Because the interaction is distinctly different, however, no significant increase in difficulty of appliance removal in either in vitro or in vivo evaluations has been realized.

ClearCorrect Exhibit 1016, Page 102 of 335

Numerous test cases were set up with the attachments and the respective programmed movements. These cases were produced as models that were mounted on dynamometers to measure the magnitudes and directions of forces. Repeated controlled evaluations demonstrated that the attachments performed as intended and did not pose any additional hazards to the patient.

In August 2003, a study was initiated in several private practices to evaluate two attachment designs—one for rotation and one for extrusion—based on the "dynamic" concept (unpublished data, 2003–2006). The primary objectives of this study were to achieve at least 70% efficacy of movement in more than 70% of the attempts to rotate canines and premolars and attempts to extrude incisors, canines, and premolars. The secondary objective was to obtain and assess clinician and patient reactions to the application and wear of the attachments and appliances.

Subjects were selected from candidates submitted by the participating clinicians for treatment with the Invisalign System. To be enrolled, a patient's treatment had to require 1 mm or more of extrusion for at least one incisor, canine, or premolar or 20 degrees or more rotation for at least one canine or premolar. If an accepted patient evidenced more than one tooth that qualified and the teeth were in the same arch, the teeth were treated consecutively. Teeth in different arches were treated simultaneously when they were not also in opposition, consecutively when they opposed each other. With the exceptions of premolar extraction and orthognathic surgery cases, any type of malocclusion was accepted. It was required that all patients were in adult dentition, had stopped growing, and, if they presented with periodontal disease or active caries, had a clinician or periodontist of record.

Each enrolled patient's treatment was set up using standard Invisalign parameters and methods, but with the following differences: several aligner stages were used to create space around the target teeth, the rotations and extrusions were staged as early as possible in the treatment, the programmed movements were discrete (ie, the teeth were moved along [extrusion] or around [rotation] only one axis), the movement speeds were set based on attachment dimensions, and, of course, the dynamic (buccal and lingual) and window attachments were placed and staged in concert with the timing of the programmed movements.

For each case, attachment usage progressed as follows: All real attachments were bonded at stage 0, the real attachments (in the computer treatment models) were replaced with their virtual counterparts at the first stage of their underlying tooth's programmed movement, the associated window attachments were made visible at this same time, the window attachments were made invisible three stages after the programmed movement ended, and the dynamic attachments remained unchanged for the balance of the treatment.

Though not without some disappointing outcomes, the preliminary results of both motions show great promise. Efficacies are currently distributed over a broad range, but they are generally improving, the range is narrowing, and the contributing elements have been identified. Clinician and patient feedback do not so far suggest complications or negative reactions to the heightened prominence, lingual attachment presence, space-creating window attachment, or outward aligner deflection.

Preformed attachments

Composite attachments can wear noticeably over the course of treatment as a result of repeated removal and replacement of aligners, as well as from speaking, chewing, and brushing. This erosion of their shape may lead to compromised effectiveness.

A possible means of mitigating the wear is being evaluated. This involves preforming attachments and bonding them to teeth in much the same way brackets are. Besides reduced wear, other benefits may arise from the use of preformed shapes. Among these are that the attachment bonding process could become less problematic (eg, reduced flash) and faster, the bonded attachments will have more distinct shapes that could assist efficacy—this is of particular interest for dynamic attachments—and the preformed attachments will likely be even less obtrusive than ones that are currently in use because of the material choices available.

In July 2003, a small investigation was begun, and is still ongoing, to assess the performance and acceptability of preformed shapes. The commercial stalwart attachments curved root tipper (CRT) and ellipsoid were selected as the test vehicles. These were produced in rigid polyurethane. The formation of their attachment template aligner cavities remains unchanged. The preformed attachments are then tacked into the cavities with sticky wax.

The patient selection criteria for this investigation were not particularly restrictive due to the effect in study. The four requirements for inclusion were Class I malocclusion, fully erupted second molars, and no need for premolar

ClearCorrect Exhibit 1016, Page 103 of 335

extractions. Patients received both preformed and composite attachments. Each arch had only one or the other, and this was assigned randomly. Impressions were made at set time points over the course of treatment. Comparisons of the attachments' geometries at different instances will reveal how well the preformed versions have fared relative to the same shape in composite.

Summary

Attachment use is essential to successful Invisalign treatments. The designs currently available for commercial use are of some assistance but are clearly not up to the task of completely reaching the goal of full expression of tooth movements. Several developments on the near horizon in both processes and product, however, hold promise for dramatically improved outcomes.

Reference

1. Wheeler T. Evaluation of different attachments used in Invisalign treatment. Presented at the 105th Annual Session of the American Association of Orthodontists, San Francisco, 23 May 2005.

ClearCorrect Exhibit 1016, Page 104 of 335

chapter 10

INVISALIGN ATTACHMENTS: MATERIALS

by
Eric Kuo, DDS and Trang Duong, DDS

ClearCorrect Exhibit 1016, Page 105 of 335

The term *composite material* refers to a three-dimensional (3-D) combination of at least two chemically different materials with a distinct interface that separates the components.[1] The combination of materials provides properties that could not be achieved with one component alone. Therefore, a dental composite material is one in which an inorganic filler is added to a resin matrix to improve the properties of the matrix. Most of the composite restorative materials use the dimethacrylate monomer (bisphenol glycidyl methacrylate, or bis-GMA) molecule.

Resin-based composites have been used since the 1970s for dental restorations. It is well known that when composite is light cured, stresses develop as polymerization and shrinkage occur.[2] Characteristic properties of composites are dependent on the filler content. In resin-based composites, the filler content is directly related to the mechanical and wear-resistance properties.[3,4] The higher filler content also reduces the shrinkage of the composite during polymerization.[5] Because of its effect on both the elastic modulus and shrinkage, the amount of filler content plays an important role on the material properties of the composite.

Low-Viscosity Versus Nonflowable Composites

Low-viscosity flowable composites contain 20% to 25% less filler than do nonflowable materials.[6] Studies have shown considerable differences between elastic modulus and shrinkage properties in flowable and conventional hybrid composite materials.[7,8] Flowable composites can be hybrids or microfilled. Studies have shown that microfilled composites contain lower filler levels than do hybrids.[4,7] According to Hooke's law, stress is determined by the stiffness of the material when subjected to a given strain. The higher the elastic modulus and polymerization shrinkage, the higher the contraction stress.

Composite in Dental Restorations Versus Invisalign Attachments

In a setting such as a Class I or II preparation, extensive polymerization shrinkage can lead to internal stress and exceed the strength of the bond with the surrounding cavity wall and thus lead to failure of the interface.[9] This marginal gap can lead to tooth sensitivity and may provide a site for recurrent caries to develop. In a setting such as bonding brackets or attachments onto the enamel surface of the teeth, this shrinkage does not pose any significant problems. With attachments, however, treatment can extend several months and even a couple of years, so the wear properties and the strength of the bond to the enamel are important properties for selecting a suitable material. Because attachments serve as bonded extensions of the teeth to help achieve specific tooth movements and add retention, they are an important part of the Invisalign System.

Bonding Attachments

With the introduction of bonding composites, the use of orthodontic bands on anterior teeth slowly became obsolete and bonding became popular in the 1980s.[10] Bonding is based on the mechanical locking of an adhesive to irregularities in the enamel surface of the tooth and to mechanical locks formed in the base of the bracket. Orthodontists have used various light-cured and self-cured flowable composites to bond brackets onto teeth. A successful bonding material must meet a set of criteria: it must be dimensionally stable, fluid, able to penetrate the enamel surface, have excellent strength, and be easy to use clinically. Today, filled acrylic (bis-GMA) resins are the preferred bonding materials. These are available in a variety of formulations that differ in the composition and amount of fillers and also in how they are cured (chemical or light).

Attachments

Attachments are composite geometries that are bonded to the facial or lingual surfaces of the teeth for the purpose of increasing aligner retention to the teeth. Because the aligners work by repositioning the teeth according to the new position defined by the next aligner in sequence, the tendency is for the aligner to be slightly displaced at the onset until the teeth respond and conform to the position(s) defined by the new aligner. Once the teeth have moved, the maximum adaptation to the aligner is reached and the cycle repeats with each successive aligner until the final aligner is reached. The attachments are used to create undercuts to help facilitate maximum adaptation of each aligner to the teeth and help avoid aligner displace-

ClearCorrect Exhibit 1016, Page 106 of 335

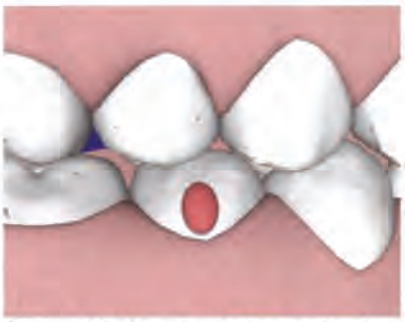


Fig 10-1 Attachments too close to the gingiva may be difficult to bond and maintain.

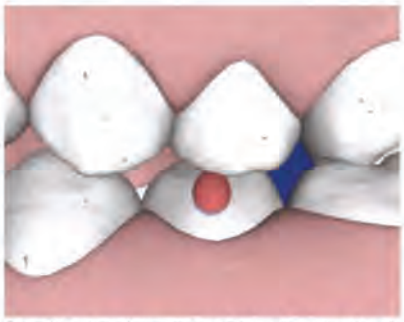


Fig 10-2 Attachments positioned too occlusally or incisally may interfere with the opposing arch.



Fig 10-3 Anterior attachments may pose an esthetic concern for some patients.

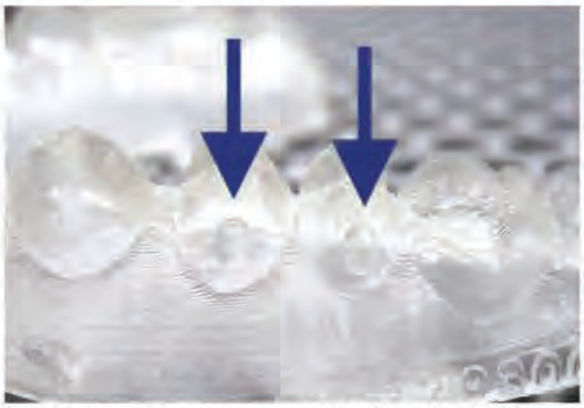


Fig 10-4 Premolar ellipsoid attachments (*arrows*) built into each resin model.

ment, so that the movements programmed into each aligner can be fully expressed. Supplemental retention can also be required in cases where the clinical crowns of the teeth are short or the amount of undercut present is minimal, such as in patients with moderate to severe attrition or gingival hyperplasia. Patients should not be able to remove the aligners with their tongue. Patients with upright teeth or cone-shaped teeth may also experience suboptimal aligner fit without additional appliance anchorage. For these patients, the temporary addition of supplemental undercuts through the use of attachments can significantly enhance aligner retention.

The shape and position of the attachment is determined at the time of the ClinCheck setup. The technician is able to create a virtual attachment on the 3-D model in the Treat software environment that stays on the same position of the tooth at each stage, regardless of the movement programmed for each tooth. The virtual attachment can be positioned anywhere on any tooth, in accordance with the clinician's wishes. Clinical considerations when selecting attachment shape, location, and position should include proximity to the gingiva, proximity to the opposing dental arch, bondability to the tooth surface (metal, porcelain, and dental composite typically require special surface treatment to achieve an adequate bond strength), and esthetics (Figs 10-1 to 10-3).

The attachments placed in the virtual setup are built into the resin models for each aligner stage (Fig 10-4). An attachment template (thin-material aligner) is created to transfer the exact shape and position of the attachment from the 3-D model to the actual tooth. The clinician fills each attachment reservoir in the template with restorative dental composite, etches each tooth to be bonded, seats the filled attachment template on the teeth, cures the composite, and removes the template, leaving the attachments bonded to the teeth in the desired position (Fig 10-5).

ClearCorrect Exhibit 1016, Page 107 of 335



FIG 10-5 Bonded composite ellipsoid attachments on premolars.

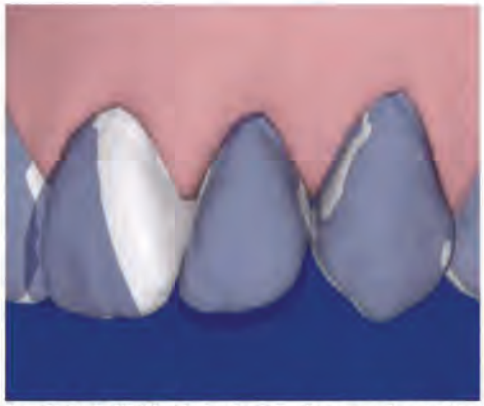


FIG 10-6 A ClinCheck treatment plan superimposition showing the vertical change around the lateral incisor between the initial position and the goal. Mesial-out rotation is planned for the central incisor, mesial-in for the canine.

Biomechanical Considerations

The primary purpose of the Invisalign attachment is to prevent appliance displacement so that the active regions of the aligner can remain in close contact with the teeth until the teeth conform to the desired position within the aligner.[11] This differs from traditional orthodontics, in which the teeth being moved must be included as part of the wire and bracket assembly. With aligner treatment, the teeth being moved do not necessarily have to have an attachment bonded to them. In other words, so long as the aligner material is in close contact with the teeth being moved, the appliance-anchoring attachments may be located on other teeth in the arch and not necessarily on the teeth being moved. This is an important consideration in terms of overall appliance esthetics, since bonding attachments to the facial surfaces of the anterior teeth is esthetically less desirable than bonding attachments to the buccal surfaces of posterior teeth.

Extrusion

The magnitude and direction of tooth movement programmed into each aligner affects the aligner's ability to adapt to the teeth. Tooth movements in the vertical dimension in particular are prone to separating the contact between the aligner and the teeth. With extrusive movements, the aligner by design must pull away from the teeth (Figs 10-6 and 10-7). Since most teeth do not have substantial undercuts along the vertical axis, these movements are least predictable with aligners in the absence of auxiliary treatment with vertical elastics. Composite attachments can help create an artificial undercut to enable the aligner to better grab the tooth; however, because the aligner material is not sufficiently elastic in the vertical dimension, a mismatch can often develop between the aligner and the attachment. If an interference is created on the facial surface, the tooth may be displaced lingually in response to the force generated from the aligner flex (Figs 10-8 and 10-9).

Intrusion

When dental intrusion is programmed into the aligners, an occlusal interference is naturally created that unseats the aligner from the posterior teeth unless attachments are placed on the posterior teeth to help anchor the aligner (Figs 10-10 and 10-11). Once attachments are placed to prevent the separation of the aligner from the posterior teeth (Fig 10-12), the aligner is able to deliver a vertical force to intrude the incisors. An important point to remember is that the attachments for intrusion are not placed on the incisors themselves, since the aligner displacement forces occur on the posterior section of the aligner and not the incisor section of the aligner.

Intrusion of the posterior teeth poses a greater biomechanical challenge than intrusion of the anterior teeth. This is because, for posterior intrusion, the aligner can only be stabilized by a unilateral anchor to resist the reciprocal vertical forces. The result is a cantilever arm design, which is less stable than the bilateral anchor design typically used to intrude incisors (Figs 10-13 to 10-15). When attempting to intrude posterior teeth, it is important that the interproximal surfaces of the intruding tooth be clear from the adjacent tooth surfaces to avoid tooth-to-tooth

ClearCorrect Exhibit 1016, Page 108 of 335



FIG 10-7 Cross-sectional diagram illustrating how extrusion built into the aligner (*yellow*) can lead to separation from the teeth (*white*) because of lack of undercut and insufficient elasticity in the aligner to pull the tooth into the new vertical position.



FIG 10-8 Addition of attachment for creation of undercut requires material to be elastic at the point indicated by the arrow to engage the undercut.



FIG 10-9 The interference created from the aligner-attachment mismatch displaces the tooth lingually (*arrow*) in response to the force generated as the aligner material flexes around the attachment area.



FIG 10-10 The outline of an aligner designed for dental intrusion of the mandibular incisors (*black outline*, movements exaggerated).

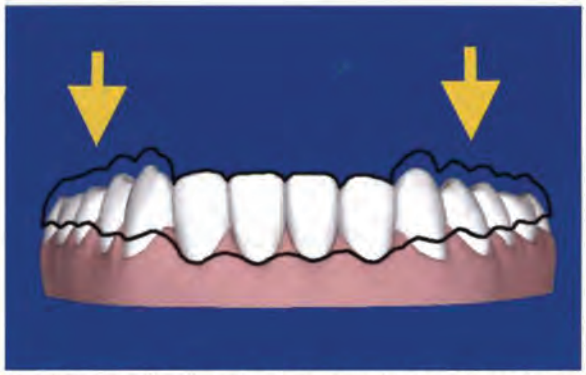


FIG 10-11 How the aligner in Fig 10-10 would sit on the teeth. The point of first contact would be at the incisors, and the posterior section would not seat without additional aligner anchors in the areas indicated by the *arrows*.

binding. Supraerupted molars often present with a coronal tooth width that is greater than the arch length dimension as a result of mesial migration.

Rotation

The derotation of cylindrical teeth also presents biomechanical challenges because of the minimal interproximal surface and undercuts available along the horizontal occlusal plane to the aligner (Fig 10-16). The aligner is prone to slipping along the facial and lingual surfaces as it tries to rotate the tooth. Placement of buccal and lingual attachments is designed to create aligner purchase points for improved tracking during tooth movement (Fig 10-17). Also critical during the derotation of premolars is the absence of friction between the rotated tooth and adjacent teeth, as is the case with the derotation of teeth using conventional fixed appliances.



FIG 10-12 Attachments placed on the premolars to provide additional anchorage to counteract the tendency for the aligner to displace from the posterior teeth during incisor intrusion.

ClearCorrect Exhibit 1016, Page 109 of 335

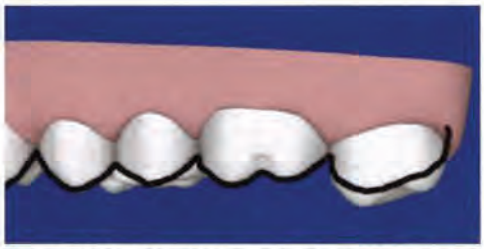


FIG 10-13 Supraerupted second molar with outline of aligner programmed to intrude the second molar.

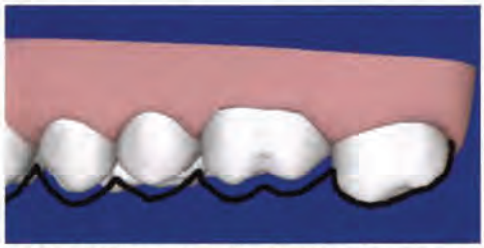


FIG 10-14 Aligner adaptation likely to occur following poor anchoring of the aligner to premolars as a result of inadequate gingival undercuts.

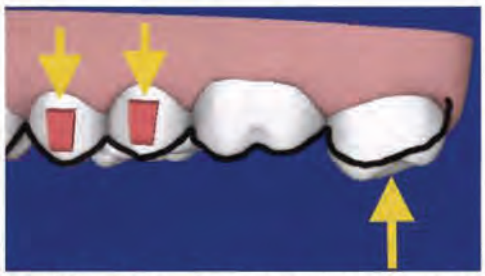


FIG 10-15 Addition of anchoring attachments on the premolars and the resulting cantilever spring designed to deliver intrusion force (*right arrow*) to the second molar in response to the resulting aligner material flex distal to the anchor points. *Left arrows* indicate undercut retention required to deliver intrusion force.

Translation

Improving root translation is a third clinical application for composite attachments. To achieve root translation and avoid tooth tipping, orthodontic force must be generated near the gingival area of the tooth (Fig 10-18). For many teeth, the interproximal surface is suboptimal and must be augmented with additional surface area. Rectangular attachments can be used in this circumstance because the sides of the attachment create additional surface contact with the aligner near the gingival third of the tooth (Fig 10-19).

Attachment Design

A promising development in attachment design is the use of preformed composite attachments. The use of template-formed attachments has three potential areas of improvement. The first is in shape detail and definition. When the template is thermoformed on the stereolithographic (SLA) resin model, some of the attachment edge definition may be lost during the template formation (Fig 10-20). The second area is in the material wear characteristics. Depending on the type of dental composite used for the attachments and the frequency of aligner removal, some attachments may wear or break over time. The third area for improvement is the amount of composite flash formed during the bonding process.

A solution to these problems may be the use of preformed composite attachments. Made from a composite material durable enough to withstand fracture and wear, the preformed attachment can be bonded to the teeth using the attachment template as a guide. The amount of

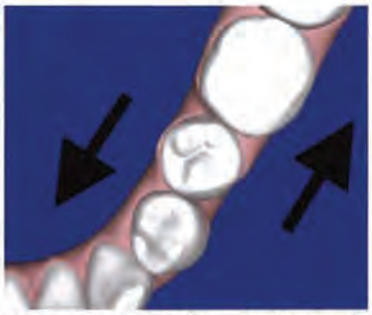


FIG 10-16 Rotation (*arrows*) of a second premolar is needed.

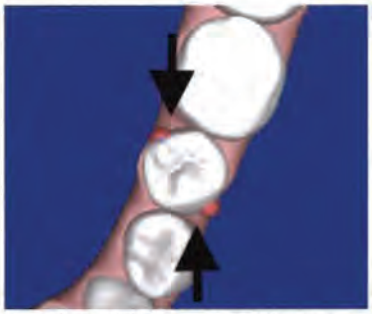


FIG 10-17 Addition of attachments to enhance the undercuts along the horizontal plane to enable better adaptation of the aligner to the tooth during rotational movements. *Arrows* indicate purchase points to facilitate rotation.

ClearCorrect Exhibit 1016, Page 110 of 335

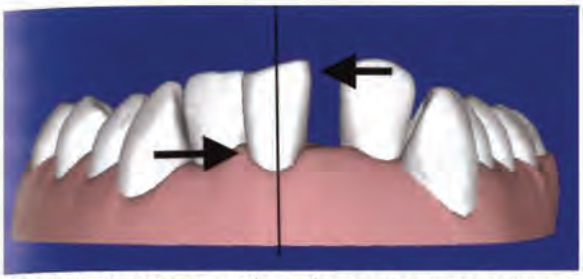


FIG 10-18 The force couple (*arrows*) needed to create root translation.

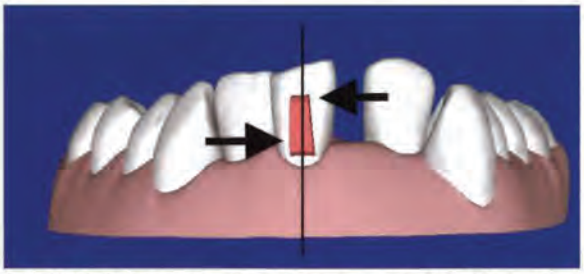


FIG 10-19 Rectangular attachments augment the interproximal surface area near the gingival line to improve the quality of the force couple (*arrows*) needed for root translation.

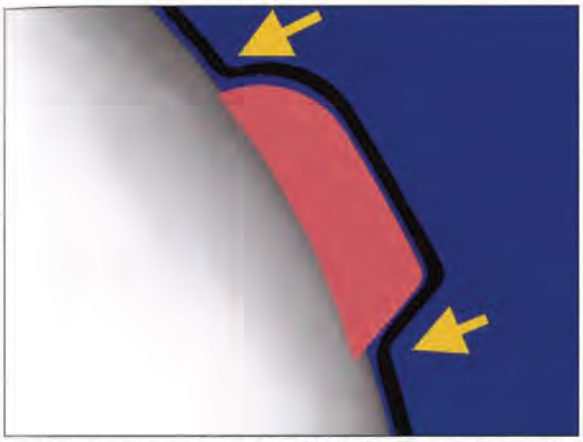


FIG 10-20 Attachment template adaptation can be improved in the areas indicated by the *arrows*.



FIG 10-21 Preformed attachments bonded to the maxillary left canine and second premolar. Note the minimal flash formation and detail preserved in the edges of the attachment.

adhesive flash formed can be minimized, and the attachments can be manufactured with great accuracy to preserve the optimum amount of detail in the shape (Fig 10-21).

References

1. Broutman L, Krock R. Modern Composite Materials. Reading, MA: Addison-Wesley, 1967.
2. Chung KH, Greener EH. Correlation between degree of conversion, filler concentration and mechanical properties of posterior composite resins. J Oral Rehabil 1990;17:487–494.
3. Condon JR, Ferracane JL. In vitro wear of composite with varied cure, filler level, and filler treatment. J Dent Res 1997;76:1405–1411.
4. Braga RR, Hilton TJ, Ferracane JL. Contraction stress of flowable composite materials and their efficacy as stress-relieving layers. J Am Dent Assoc 2003;134:721–728.
5. Munksgaard EC, Hansen EK, Kato H. Wall-to-wall polymerization contraction of composite resins versus filler content. Scand J Dent Res 1987;95:526–531.
6. Bayne SC, Thompson JY, Swift EJ Jr, Stamatiades P, Wilkerson M. A characterization of first-generation flowable composites. J Am Dent Assoc 1998;129:567–577.
7. Labella R, Lambrechts P, van Meerbeek B, Vanherle G. Polymerization shrinkage and elasticity of flowable composites and filled adhesives. Dent Mater 1999;15:128–137.
8. Price RB, Rizkalla AS, Hall GC. Effect of stepped light exposure on the volumetric polymerization shrinkage and bulk modulus of dental composites and an unfilled resin. Am J Dent 2000;13:176–180.
9. Davidson CL, de Gee AJ, Feilzer A. The competition between the composite-dentin bond strength and the polymerization contraction stress. J Dent Res 1984;63:1396–1399.
10. Powers JM, Kim HB, Turner DS. Orthodontic adhesives and bond strength testing. Semin Orthod 1997;3:147–156.
11. Kuo E, Hordt C. Attachments in der Invisalign-Therapie. Kieferorthopädie 2001(special issue):25–28.

ClearCorrect Exhibit 1016, Page 111 of 335



chapter 11

ClinCheck: Overview and Preparation

by
Craig Crawford, DDS

ClearCorrect Exhibit 1016, Page 113 of 335

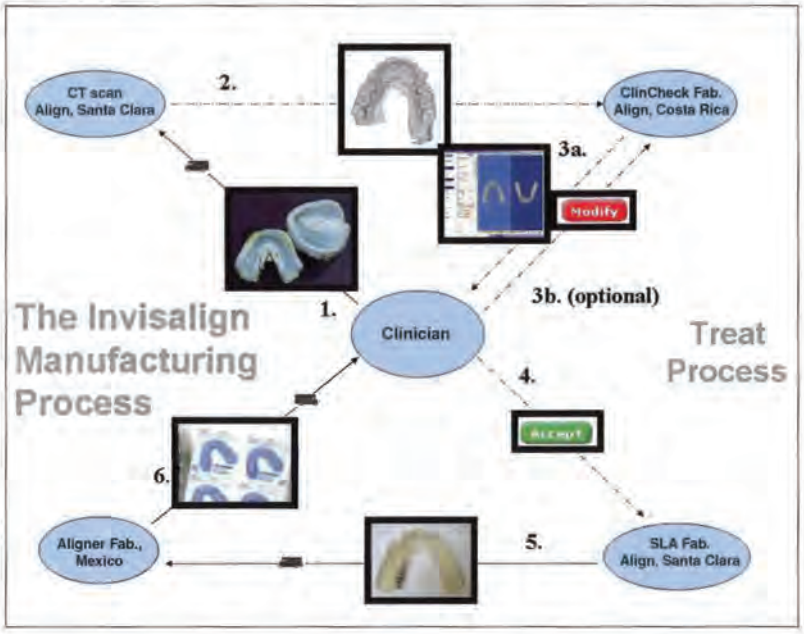


FIG 11-1 Overview of Invisalign process.

A clinician's diagnosis and treatment plan are the two fundamental elements of a successful outcome for any orthodontic treatment. Traditionally, the treatment plan, mechanics, their sequence, and the desired treatment outcome are noted in the patient's chart. These notes trigger visual images in the mind of the operator along the course of the treatment—indeed, the imaginary ideal, or optimal, outcome is always present in the mind of the clinician. In the Invisalign System, however, concrete images replace the mental images.

Once a diagnosis is made (tentative or definitive), the mechanics of treatment are done through a software system called ClinCheck. The ClinCheck file is a three-dimensional (3-D) virtual representation of a clinician's prescribed treatment plan. It reflects the stages of treatment from which aligners are manufactured. ClinCheck software provides viewing and navigation tools that greatly facilitate treatment planning, and ultimately allows for better clinical decisions. The ability of ClinCheck to allow diagnostic setups, treatment planning, and evaluations makes it an invaluable tool for the clinician. Treatment planning should be divided into both a treatment goal (what will be done?) and treatment plan (how will it be done?); ClinCheck enables the clinician to visualize both.

The ClinCheck is made up of two main components: (1) a series of computerized graphic images of the patient's teeth through several stages of movement, from initial to final position; and (2) pressure-formed clear plastic appliances made from stereolithographic (SLA) models of the images in the first component.

The ClinChecks are created by trained technicians using Align Technology's in-house proprietary software along with the supplied patient records (impressions, bite registration, photographs, and radiograph series or panoramic radiograph) and the clinician's treatment form. The ClinCheck is sent via the Internet to the clinician for review, and the clinician can communicate back to the Align technician to accept the ClinCheck or request any changes.

As soon as the clinician accepts the ClinCheck, production of the SLA models begins. Resin models are created for each stage of treatment. These models are sent to Juarez, Mexico, for final manufacture of the aligners. Once completed, the aligners are sent directly to the treating clinician's office (Fig 11-1).

Treat Software

The workforce at the Treat facility consists of specially trained technicians, engineers, clinicians, and managers. The treating technicians and the clinicians undergo rigorous and thorough training in orthodontic principles and the use of Invisalign and the Align software. The Treat

ClearCorrect Exhibit 1016, Page 114 of 335

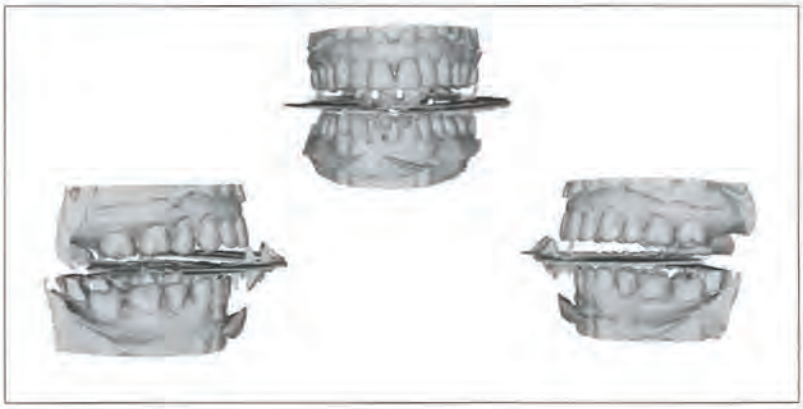


FIG 11-2 Screen shot of Bite Zero, which shows the patient's original occlusion in rough images.

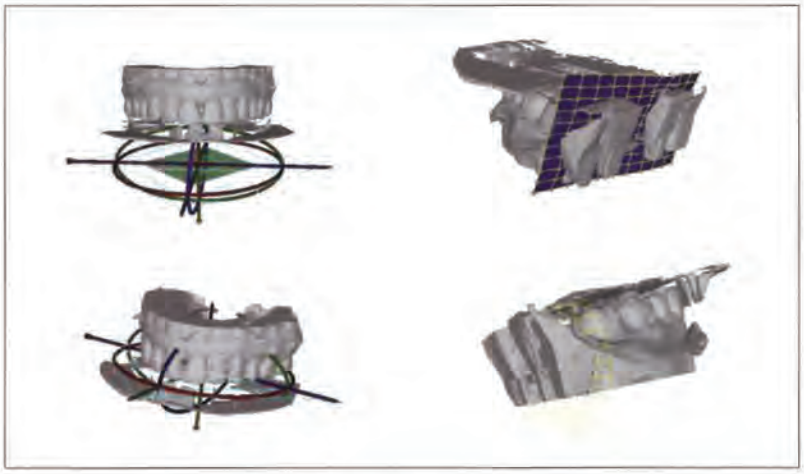


FIG 11-3 Trimming and cutting tools used by the technician to manipulate the teeth.

facility uses two different software programs to create ClinCheck files: ToothShaper is the program that allows for the preparation of the models (cleaning, detailing, sectioning of the teeth, and setting of the bite), and Treat is the program used for positioning the teeth, staging the movements of the teeth, placing attachments, and placing the final simulated gingiva. These programs and their use are described thoroughly in chapters 7 and 8.

The process entails four main steps: detail with a digital detailing tool (DDT), cut and detail, setup and stage, and final gingiva. The first three steps are described here; addition of final gingiva to the images is described in chapter 8.

Digital Detailing Tool

Inspection of the scanned data is the first step undertaken by the Treat facility's technicians. The scanned models are inspected for gross impression defects and for inaccuracies in the scan (Fig 11-2) and are cleaned of any extra artifacts from the impression and scan process (Fig 11-3). The "cleaned bite" models are then inspected for impression accuracy (Fig 11-4); patient records are used to help confirm usability of the impression and to ensure patient match. Finally, the scanned models are digitally detailed using the ToothShaper software (Fig 11-5).

Cut and Detail

The facial axes of the clinical crowns (FACCs) are placed on each clinical crown (Fig 11-6). These help identify the individual teeth. Paint Crowns is an application that gives each tooth's clinical crown a different color (Fig 11-7). The teeth are sectioned by the software to produce separate units for each tooth.

ClearCorrect Exhibit 1016, Page 115 of 335

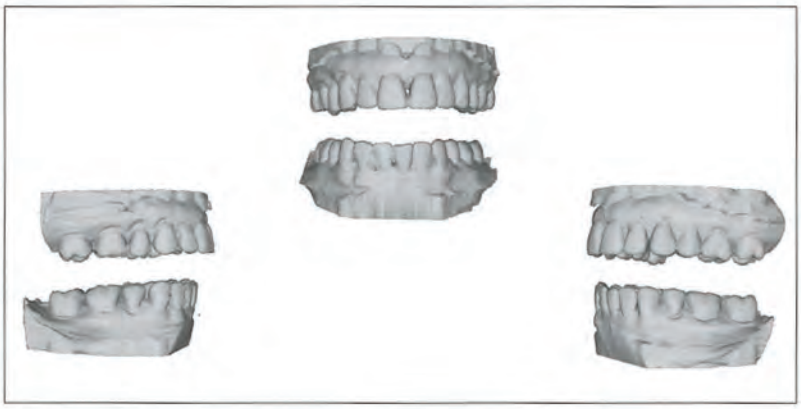


FIG 11-4 Cleaned bite.

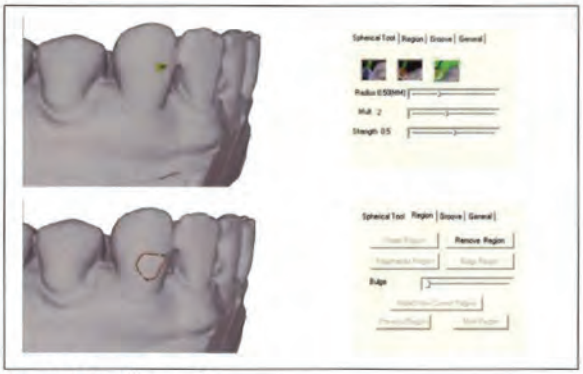


FIG 11-5 Detailing tools.

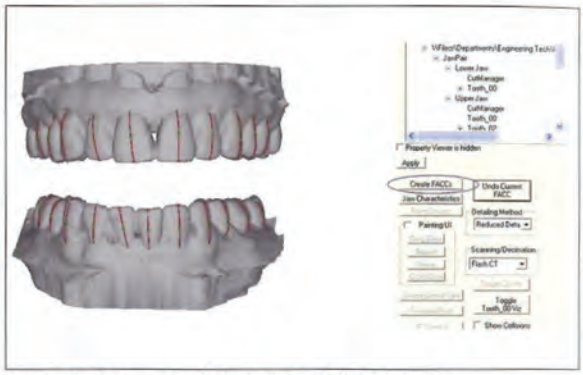


FIG 11-6 Placement of fixed axes of clinical crowns.



FIG 11-7 Painted crowns.

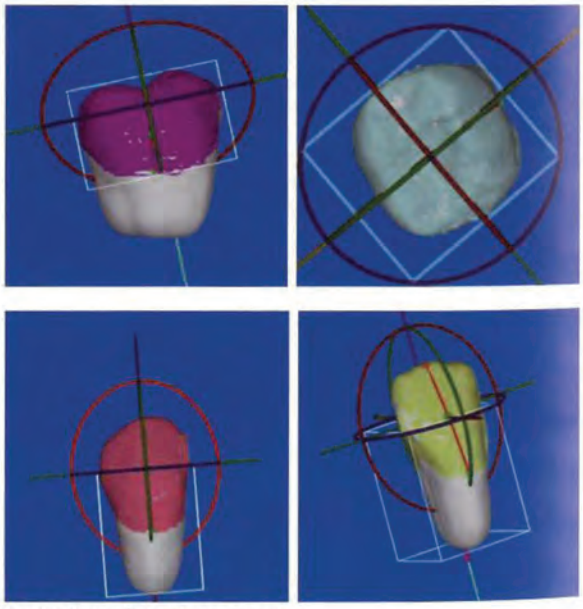


FIG 11-8 Axis/widget placement.

ClearCorrect Exhibit 1016, Page 116 of 335



FIG 11-9 Initial gingiva placement.



FIG 11-10 AutoBite set tool.

Widgets, used to move the teeth later in the process, are positioned in each tooth (Fig 11-8). Next, the simulated initial gingiva is placed (Fig 11-9).

The majority of bite sets are completed using a software application known as AutoBite. This software takes the opposing models and performs a best fit with the models to achieve at least a tripodization of occlusal contacts (Fig 11-10). The bite set is in centric occlusion or maximum intercuspation. Setting of the bite in centric relation has not been automated and is difficult to do manually with accuracy.

If the software has more than one option to set the bite, the technician is alerted, and a manual bite set is performed using the photos and—in difficult cases—the PVS bite registration.

After the bite is set, the records are reviewed, and the bite set is inspected for accuracy. Photographs and the goals and special instructions of the treatment plan are important for this inspection. If the bite does not appear correct, it will be reset or a comment indicating that there was difficulty setting the bite will be sent to the treating clinician via the ClinCheck.

Setup and Stage

At this point in the process, the scanned models have gone through inspection, detailing, sectioning, bite set, and gingiva placement. The next step, setup and stage, is when the teeth are placed in the final or goal position, reproximation is calculated, staging (the sequence of tooth movements from the initial position to the final position) is performed (see chapter 12), attachments are added, and comments to the treating clinician are placed. All of this is completed using Treat software. The technicians responsible for this portion of the process rely on the complete and accurate records submitted by the treating clinician to aid in the completion of the case.

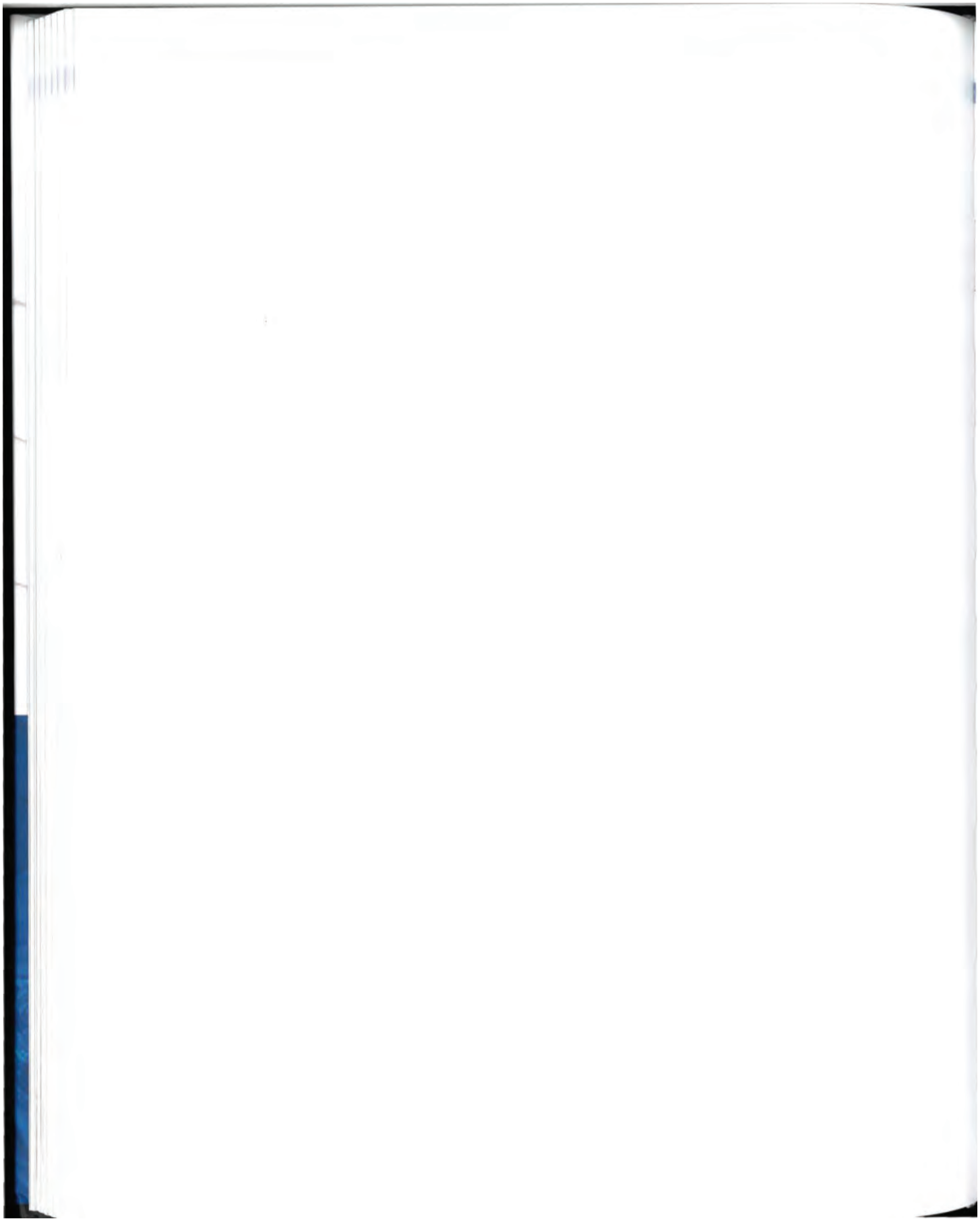
To create the treated file, the technicians rely on the completed treatment planning form, the clinician's treatment preferences, and their extensive training in orthodontics and on the Treat software.

The treatment planning form is of great value and is the most important piece of information that the treating clinician provides the setup and stage technician. This is where the clinician provides in written form the mental picture he or she has for the treatment and that he or she expects to see in ClinCheck. The treatment forms can be completed either as a written form that is mailed or as an electronic form that is sent via e-mail.

The clinician's treatment preferences are completed on the clinician's Virtual Invisalign Practice (VIP) page, which consists of a number of questions about general setup for the case. It also allows for free text of special instructions to be applied to most of the clinician's cases. These preferences and instructions are valuable for reducing the time the treating clinician spends on the completion of the treatment forms for each case in the event the clinician wants similar values in different case setups. The clinician can opt out of using the treatment preferences by marking a designated check box on the treatment form (see Fig 8-6).

The file that the technician creates is called a Treat file, which is converted into ClinCheck to facilitate transfer of the file to the clinician via the Internet. The ClinCheck sent to the clinician is the technician's or Align Technology's interpretation of the treatment form.

ClearCorrect Exhibit 1016, Page 117 of 335



chapter 12

STAGING

by
Rene Sterental, DDS

ClearCorrect Exhibit 1016, Page 119 of 335

Staging is the collection of steps and procedures used to arrive—in sound clinical and biologic fashion—at the final desired position of the teeth using Treat software.

After receiving the final cut model from the ToothShaper technician, the setup and stage technician reads the prescription form and reviews the clinical records that were submitted with the case to determine how the clinician wants to treat the case. The technician also reviews the clinician's preferences for accomplishing the treatment goals, as well as any other details of which the clinician wants the technician to be aware.

The setup and stage technician opens the file in Treat software to begin the ClinCheck setup. The technician aligns and positions the teeth in the Treat file to their final position as determined by the clinician's treatment prescription and preferences. After the correct final position is achieved on both arches, and after the occlusion has been adjusted, two additional stages remain in the setup: stage 0 (the initial position of the teeth before any movements have been applied) and stage 1 (the final position of the teeth).

The technician proceeds to "stage" the setup—that is, set up all the intermediate steps required to guide the teeth from the initial position to the final position, taking into consideration the biologic requirements of tooth movement, the biomechanical requirements of moving teeth with aligners, and any other details that allow the technician to set up the case efficiently and effectively. After the case is staged, the virtual setup contains information on how many stages or steps are required, the velocity at which the teeth are moving (both linear and angular), the timing of the movements for each particular tooth, the amount and timing of interproximal collisions and spaces during the treatment, and the pattern of anchorage that is being used. All this information is presented in the Stage Editor window in Treat, displayed under several tabbed windows to facilitate easy access for the technician.

Stage Editor

The Stage Editor window is used to visualize and quantify how the teeth are moving and comprises seven tabbed windows that display different information. These windows are Key Frame Editor, Move Distance, Collision, Space, Overcorrection, Translation (mm), and Rotation (deg) (Fig 12-1).

Key Frame Editor

The Key Frame Editor is used to set and display, using a graphical format, the staging pattern for the selected case. Lines and key frames are used to show at what stage a particular tooth starts to move, during how many stages it moves, and at what stage it finishes moving. Any intermediate steps are also shown. The pattern used to stage the case can easily be seen and modified; any change to the number of total or individual stages for a particular movement is performed using the Key Frame Editor (Fig 12-2).

Move Distance

The Move Distance window is used to determine the speed at which the crowns of the teeth are moving. Based on the number of stages needed to complete the movement for each tooth, the speed for each movement varies. The maximum speed that a tooth is allowed to move is 0.25 mm/stage. Speeds faster than 0.25 mm/stage are highlighted in red to alert the technician that the speed is too fast and that a larger number of stages is needed for that particular movement (Fig 12-3).

Collision

The Collision window is used to visualize numerically the amount of overlap between adjacent teeth throughout the sequence of stages. The amount of overlap detected and measured by the software is used to determine when adjacent teeth collide while they are being moved. This also determines when the overlap is increased past certain predetermined values, and finally the amount of interproximal reproximation (IPR) needed to create the space that will allow those movements to be performed clinically. These collisions are usually referred to as *microcollisions* and are the reason that contacts have to be monitored clinically with unwaxed dental floss to ensure that they do not become too tight and prevent the teeth from sliding freely against each other.

Per the current Invisalign collision protocol, normal contacts are considered to be those between 0.00 and 0.05 mm; in Treat, they are displayed in black in the Collision window. IPR below 0.2 mm per contact is not allowed, so collisions between 0.06 and 0.14 are highlighted in blue to alert the technician that they need to be removed (Fig 12-4a). A maximum of 0.5 mm of IPR is allowed, unless the clinician specifically overrides it and requests more. Any

ClearCorrect Exhibit 1016, Page 120 of 335

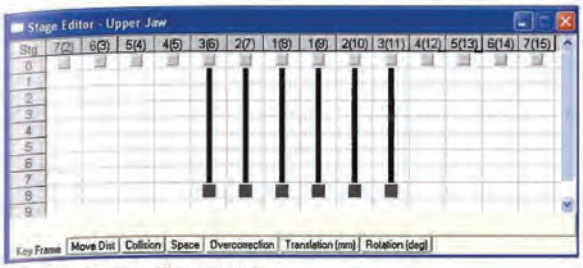


FIG 12-1 Stage Editor window.

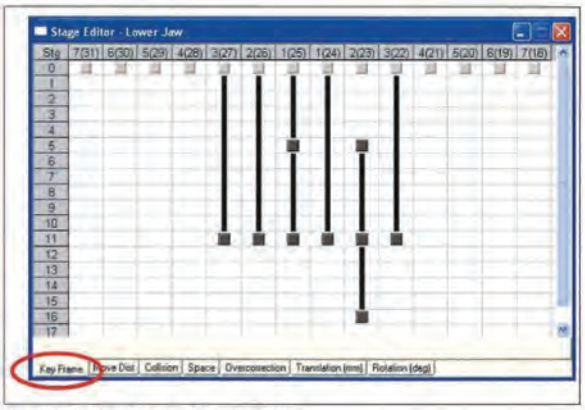


FIG 12-2 Key Frame Editor window.

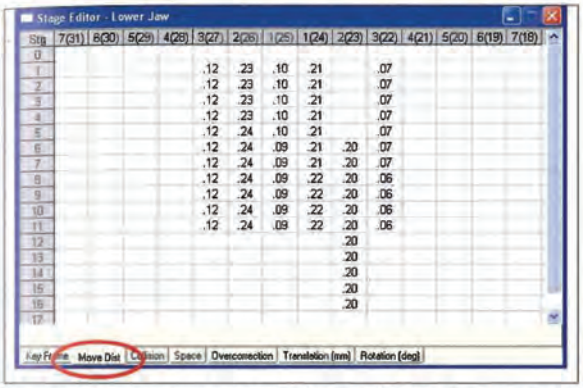


FIG 12-3 Move Distance window (velocity). Excessive velocity is highlighted in red.

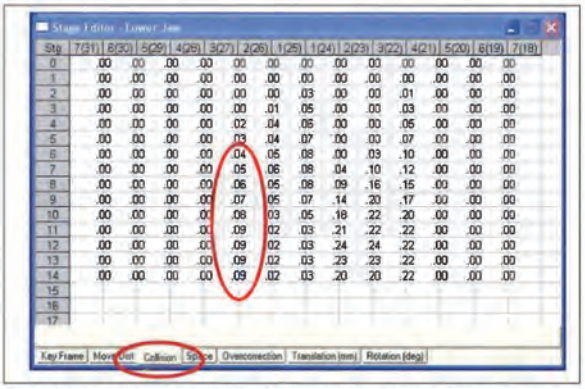


FIG 12-4a Collision window (intra-arch). Normal contacts are in black; high final collision is in blue (IPR < 0.2 mm would result).

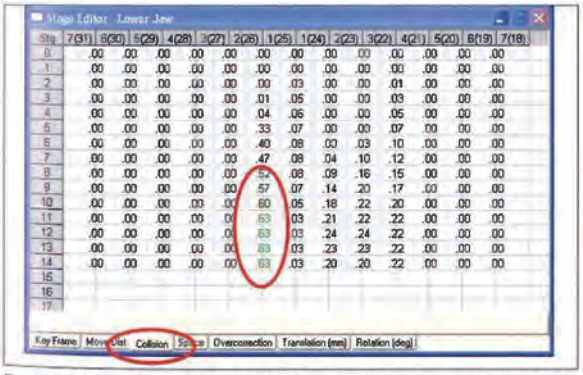


FIG 12-4b Collision window. High final collision in green (IPR > 0.5 mm would result).

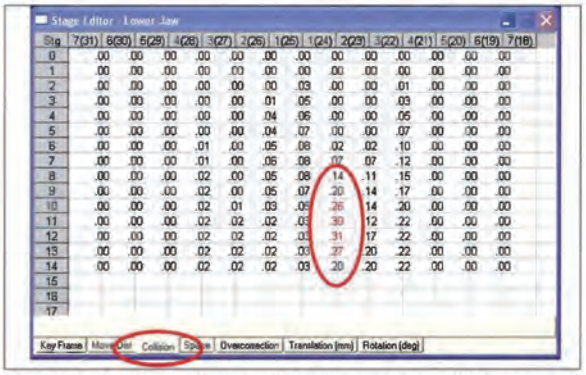


FIG 12-4c Collision window. High intermediate collisions are in red (requires intermediate key frames).

final overlap larger that 0.6 mm is highlighted in green so it is not inadvertently left unchanged by the technician (Fig 12-4b). To prevent intermediate collisions from being larger than the final overlap (which would either prevent the teeth from moving or, if IPR is performed, leave an open contact between the teeth at the end of the treatment), any overlap that is measured at 0.05 mm above the final one is highlighted in red to signal that it requires the technician's immediate attention (Fig 12-4c). Unless the clinician specifically requests that an IPR higher than 0.5 mm/contact be performed, all numbers should be black when the staging of the treatment is complete.

ClearCorrect Exhibit 1016, Page 121 of 335

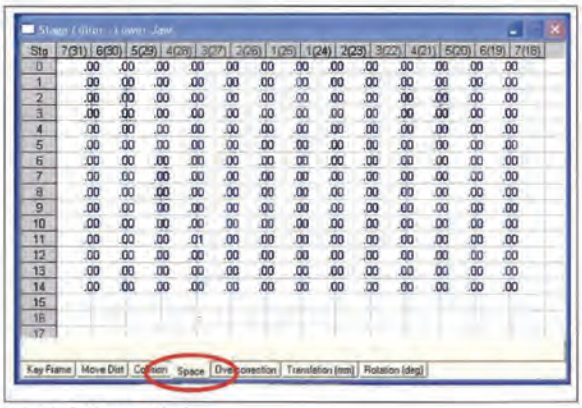


FIG 12-5 Space window.

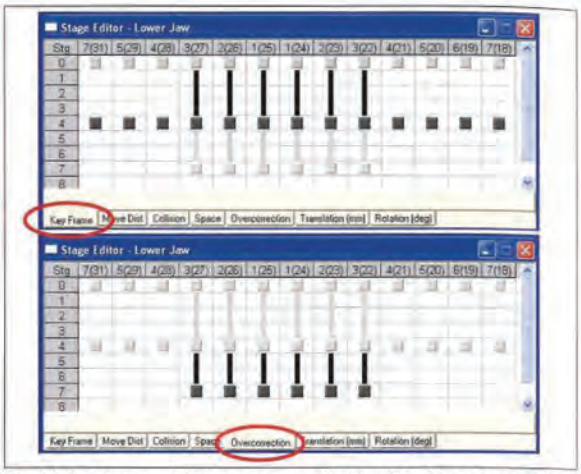


FIG 12-6 Overcorrection stages as displayed in Key Frame Editor (*top*) and the Overcorrection (*bottom*) windows.

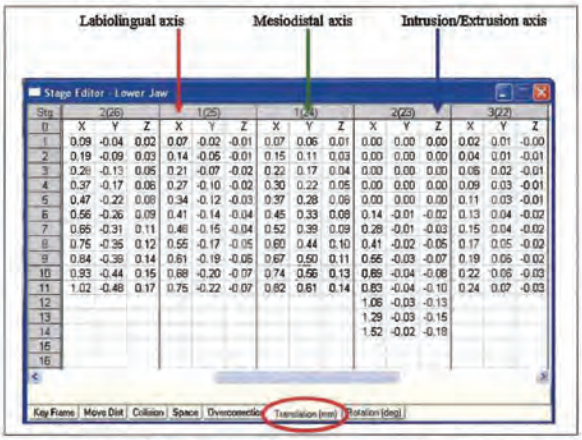


FIG 12-7 Translation window (linear movements and color correlation with widget axes).

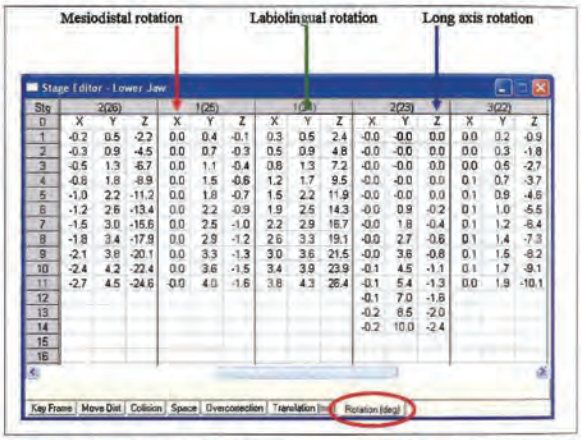


FIG 12-8 Rotation window (angular movements and color correlation with widget axes).

Space

The Space window is similar to the Collision window, except that it measures the interproximal space between the teeth (Fig 12-5). Once the teeth overlap, the space continues to read 0.00 mm. The numbers are always displayed in blue, to differentiate them at first glance from the collision numbers, which are black. Thus, an ideal contact would read "0.00" in both the Collision and Space windows. Realistically, it is not always possible to ensure good contacts at the end of the treatment. The Space window is usually used when the technician wants to make sure that the spaces required between the teeth in certain setups are equally distributed per the clinician's request.

Overcorrection

The Overcorrection window is used to stage overcorrection movements at the end of the regular treatment sequence (Fig 12-6). Overcorrection is usually performed in three stages and is designed to compensate for aligner lag and to ensure that the teeth can be moved to their final position as depicted in the virtual setup. Overcorrection is not performed in the initial setup unless it is requested and specific instructions are given by the clinician. It is always performed during case refinements (when it is clear which movements need refinement) to ensure that these movements get expressed clinically.

ClearCorrect Exhibit 1016, Page 122 of 335

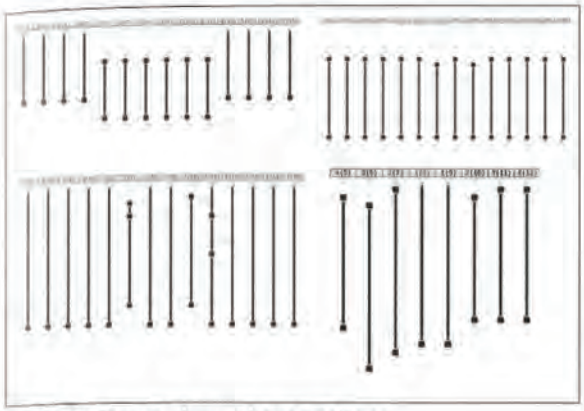


FIG 12-9a Common low-anchorage patterns.

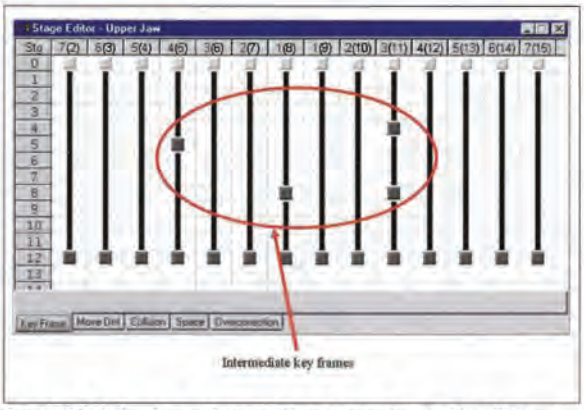


FIG 12-9b Adjusting at intermediate stages to avoid collisions.

Translation

The Translation window shows the distance that each tooth moves along the three linear axes depicted in the movement widget. These axes are the x-axis, which measures labiolingual movements along the red linear axis and is displayed under the X column; the y-axis, which measures mesiodistal movements along the green linear axis and is displayed under the Y column; and the z-axis, which measures intrusion and extrusion movements along the blue linear axis and is displayed under the Z column. The axes in the widget are shaped like arrows; if the movement is performed along the direction of the arrow's point, the number will be positive; if the movement is performed in the opposite direction, the number will be negative. A tooth can move in all three planes of space at the same time (Fig 12-7).

Rotation

The Rotation window shows the rotation that is applied to each tooth along the three rotation axes depicted in the movement widget. These rotation axes are the X rotational axis, which measures mesiodistal rotation along the red rotation axis and is displayed under the X column; the Y rotational axis, which measures labiolingual rotation along the green rotation axis and is displayed under the Y column; and the Z rotational axis, which measures rotation along the tooth's long axis along the blue rotation axis and is displayed under the Z column. If the direction of the movement is clockwise, the number will be negative; if the direction of movement is counterclockwise, the number will be positive. A tooth can rotate in all three planes of space at the same time (Fig 12-8).

Anchorage

Cases can be staged using a low-anchorage pattern or a high-anchorage pattern. This is determined based on the information contained in the doctor's prescription and diagnosis form, as well as the internal staging protocols that the technicians follow.

Low-anchorage pattern

A low-anchorage staging pattern, also known as an equal staging pattern or an "X" pattern, occurs when all the teeth move concurrently throughout the sequence (Figs 12-9a and 12-9b). The maximum velocity for tooth movement is 0.25 mm/stage, and usually all or most of the teeth are moving through all the stages at various speeds, depending on the total distance each tooth has to move. Low-anchorage patterns are usually used in Type I space closure cases, mandibular incisor extraction cases, and expansion and crowding cases where no distalization is needed. To avoid intra-arch collisions throughout the sequence of movements, intermediate key frame points can be used to manage any overlap between the teeth that may develop; these are usually added every five stages or so to ensure that the collisions remain within the protocol guidelines throughout the whole sequence. Rotations should be kept under 2 to 3 degrees per stage.

High-anchorage pattern

A high-anchorage pattern, sometimes referred to as a "V" pattern, is used when intra-arch anchorage needs to be

ClearCorrect Exhibit 1016, Page 123 of 335

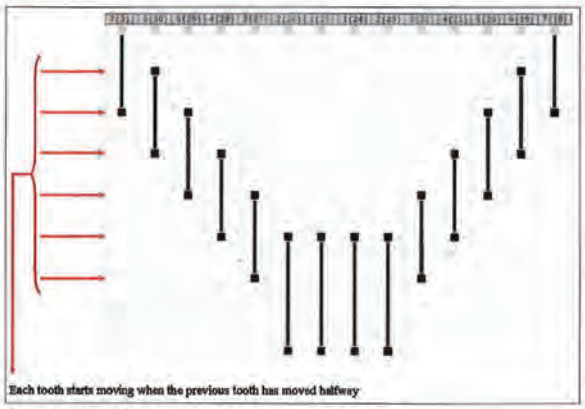


FIG 12-10a High-anchorage pattern overview.

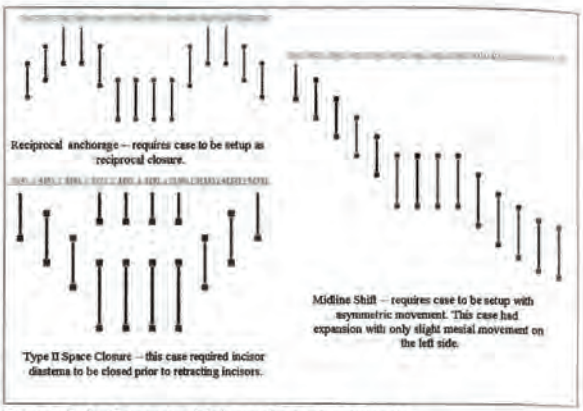


FIG 12-10b Common high-anchorage patterns.

maximized (Figs 12-10a). High-anchorage patterns are used in any case where the posterior teeth need to be distalized. It could be for Class II correction or when the relief of crowding on the anterior teeth requires that the space is created by the distal movement of the posterior teeth. This is also the case in Type II space closure cases where no mesial movement of the molars is desired. Additionally, reciprocal space closure cases where the space is closed by mesial movement of the posterior teeth (not to be confused with equal staging—minimal anchorage where no posterior mesialization is staged), and cases where a midline shift is desired, fall into this category (Fig 12-10b).

In high-anchorage patterns, only two posterior teeth can move concurrently, with the second one starting to move when the first one is halfway through its movement. The maximum speed is 0.33 mm/stage. In bilateral cases, both sides are staged symmetrically, with the number of stages determined by the teeth that are moving the most. The maximum speed for the anterior teeth remains 0.25 mm/stage.

Reproximation Calculation (Interproximal Reproximation Prescription)

Before saving the setup, or at any time during the staging, the reproximation calculation can be run to check the interproximal collisions during the staging of the case. Based on predefined parameters, the reproximation form can be created to show the clinician the interproximal contacts that will require IPR, the amount needed, and the timing of the reproximation. This information is viewed in Treat in the Reproximation Result window in a graphic manner that alerts the technicians to any potential errors. It is also sent to the clinician as an Adobe Acrobat (.pdf) file alongside the ClinCheck (Fig 12-11).

Enable Collisions

When Enable Collisions is selected, all areas where the teeth touch or overlap—both occlusally (interarch collisions) and interproximally (intra-arch collisions)—are highlighted in red. This allows the technician to visually adjust the occlusion and the contacts between the teeth, as well as visualize the areas where IPR is required in the setup. These areas can be visualized only in Treat, and are not sent to the ClinCheck (Fig 12-12).

Diagnostic Setup

A diagnostic setup is performed when the clinician checks the appropriate box in the prescription and diagnosis form. It is intended to allow the clinician and the patient to visualize in ClinCheck how one of the arches will look after the teeth are moved, but these movements are not staged in Treat so no aligners are produced. This is useful when one of the arches is being treated with fixed appliances, for example, and the clinician wants to try to match the finished result in the arch that is going to be treated with Invisalign to the intended final position of the teeth in the arch that is being treated with fixed appliances. It can also be used to show a patient how both arches will look after treatment, when the patient initially wants to treat only one arch.

ClearCorrect Exhibit 1016, Page 124 of 335

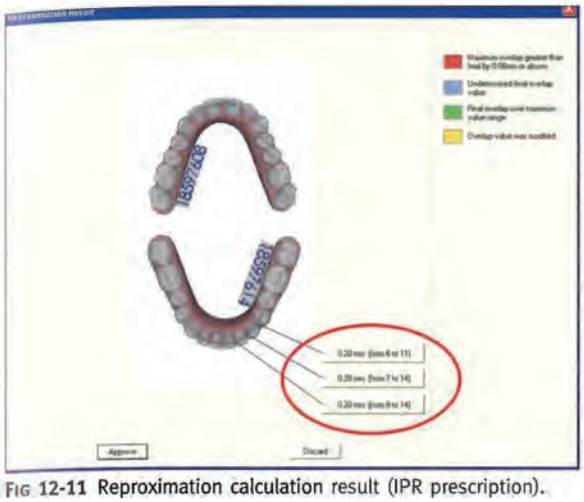


FIG 12-11 Reproximation calculation result (IPR prescription).

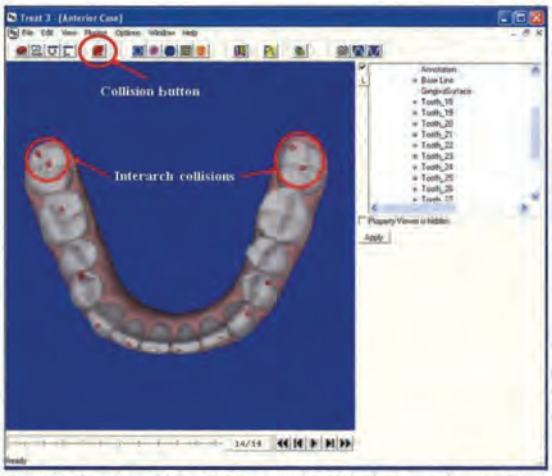
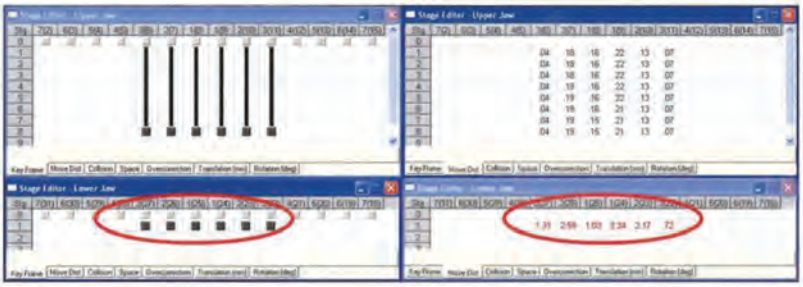


FIG 12-12 Interarch collisions enabled in Treat software (final collisions viewed).

FIG 12-13 Mandibular diagnostic setup. Key Frame Editor view (*left*) and Move Distance view (*right*). No aligners will be made for the mandibular arch.



A ClinCheck with a diagnostic setup shows one arch staged and the other arch as having only two stages: the initial stage 0 and the final stage 1 (Fig 12-13). No aligners are produced for this arch.

Surgical Setup

A surgical setup is performed in cases that require maxillofacial surgery, when the clinician wants to see that both arches are coordinated at the end of the treatment; of course, prior to actual surgery, they will not be related at occlusion. Each arch is set up and staged separately per the clinician's treatment prescription. At the end of the sequence, an additional stage is created in which both arches are occluded manually (simulating the proper occlusion that will be achieved after the surgery is performed). By doing this, the clinician can visualize the intended occlusion and confirm that both arches will be coordinated correctly (Fig 12-14).

Measuring Tools

The Treat software has several measuring tools that allow the technician to quantitatively apply the clinician's instructions. These tools also allow the technician to review the amount and type of movements being performed and determine if they are exceeding Align Technology's recommended parameters for predictable tooth movements.

Bolton Analysis Tool

The Bolton analysis tool calculates the tooth size discrepancy that is present in a case. The Bolton analysis is used to visualize the proportional relations between the maxillary and mandibular teeth in a clinically meaningful way. The Bolton analysis displays the anterior, or canine-to-canine, discrepancy and the full, or first molar–to–first molar, discrepancy (Fig 12-15).

ClearCorrect Exhibit 1016, Page 125 of 335

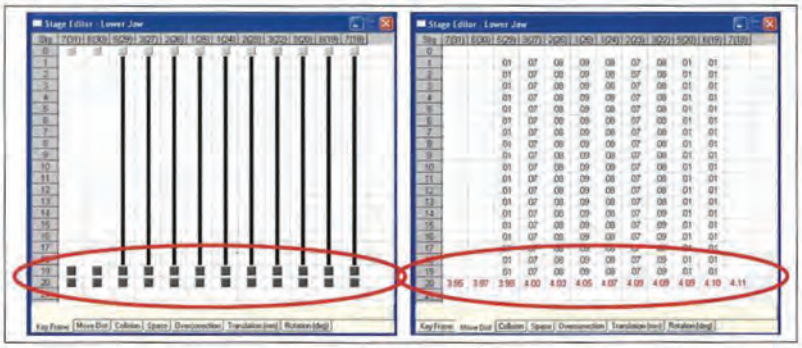


FIG 12-14 Surgical setup (mandibular repositioning). Key Frame Editor view (*left*) and Move Distance view (*right*). After stage 19, the mandible is being repositioned manually. No aligner will be made for stage 20.



FIG 12-15 Bolton analysis in Treat software.

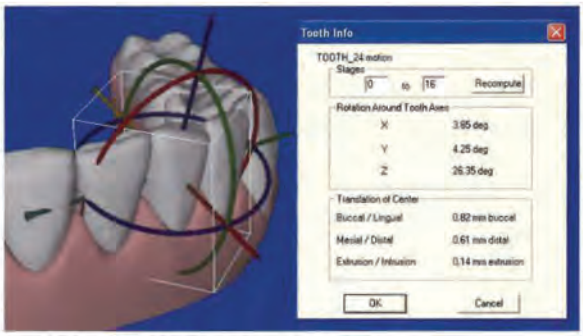


FIG 12-16 Tooth Motion Information window.



FIG 12-17 Arch Information window.

Tooth Motion Information

The Tooth Motion Information window provides a review of the clinical information on the linear movements that are being applied to the selected tooth, plus the rotation around its long axis. The measurements that are displayed include the amount of intrusion or extrusion movement, the amount of labial or lingual movement, and the amount of mesial or distal movement that are being performed, as well as the amount and direction of rotation that is being applied to the tooth around its long axis. These measurements are derived from the different axes of movement shown on the widget used to move each tooth in each particular axis (Fig 12-16).

Arch Information

When one of the arches is selected in the Treat software, the Arch Information tool allows the technician to visualize descriptive information such as arch length, perimeter, intercanine width, and intermolar width (Fig 12-17).

Attachments

Attachments are used to create a better hold for the aligner to move the teeth. They are used when the anatomy of the teeth does not provide enough undercuts for the aligner to grab the teeth solidly, to enhance the retention of the aligners to provide enough anchorage for certain movements to be expressed clinically, and to allow the aligners to apply forces in directions that they cannot otherwise achieve because of the biomechanics of the movement and the way they apply forces to the teeth. In both Treat and ClinCheck, the attachments are displayed as red

ClearCorrect Exhibit 1016, Page 126 of 335

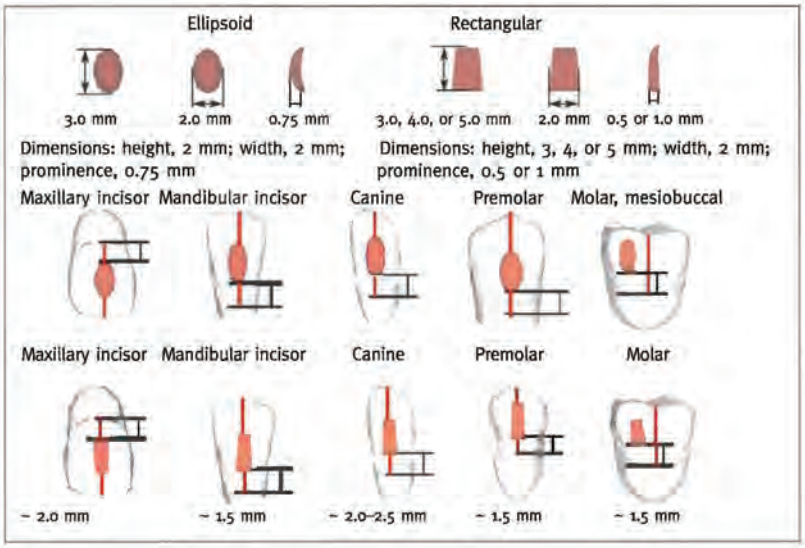


FIG 12-18 Attachment types and placement. Attachments may be requested in horizontal or vertical orientation.

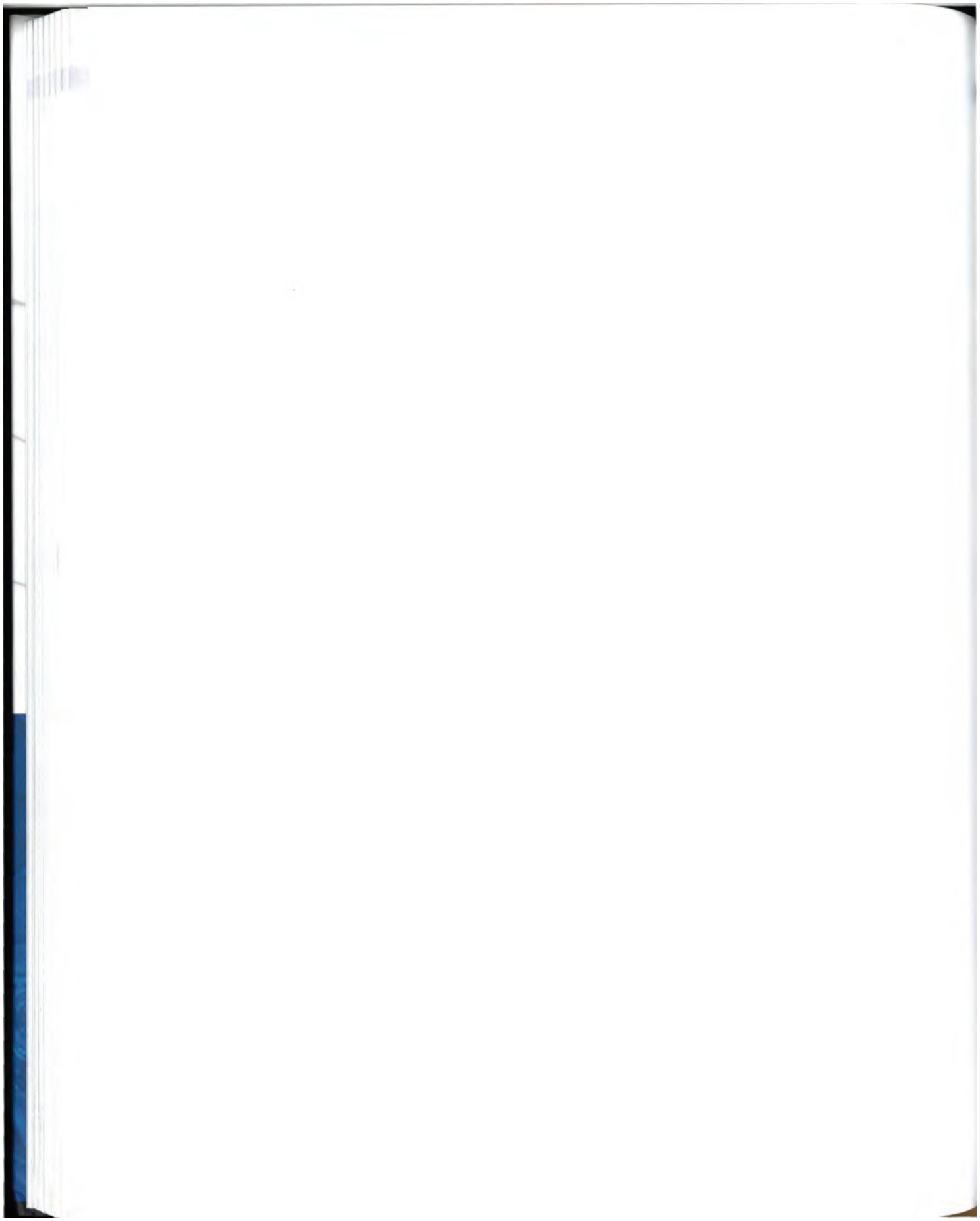
shapes. They can be placed manually or automatically, per the Invisalign attachment protocol.

Currently, ellipsoid and rectangular attachments are available (Fig 12-18). Other designs are being researched, but these are not yet available to treat regular commercial cases. Clinicians can request the type and placement of attachments and can override the aligner protocol. If no requests are made, Align will only place the attachments based on what the protocol calls for. More on attachments is covered in chapter 9.

Comments

The Notepad menu item allows the technicians to write individualized comments for the clinician to review in ClinCheck or for internal use while the case is being worked on. The Notepad window has two areas, an upper area titled Comments to Customers and a lower area called Notes. Anything typed in the Comments to Customers section will be uploaded via the ClinCheck for the clinician to review; comments typed in the Notes area do not get uploaded and are intended for internal use. These comments range from preset comments designed to alert the clinician about certain aspects of the treatment to clarifications about the treatment and explanations of the reasons certain decisions were made in the course of the setup.

ClearCorrect Exhibit 1016, Page 127 of 335



chapter 13

OVERCORRECTION: PRINCIPLES AND CONSIDERATIONS

by
Eric Kuo, DDS

ClearCorrect Exhibit 1016, Page 129 of 335



FIG 13-1a Distal-in rotation of the mandibular central incisors is needed.

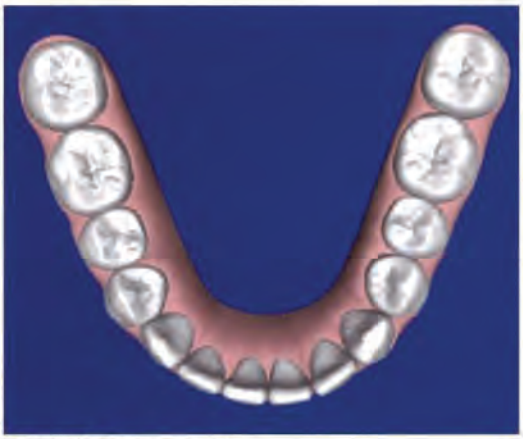


FIG 13-1b Treatment goal.

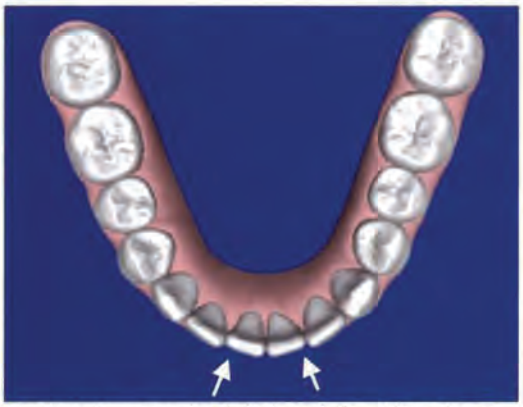


FIG 13-1c Overcorrection built in to help achieve the treatment goal.

When the final alignment of the teeth comes close to the goal but is not exactly as planned, it may be possible to program movement into additional aligners to create the extra force needed to achieve the desired outcome. Aligners built with overcorrection may be used to impart the forces needed to more effectively move the teeth to the target positions. An important point of clarification is that aligner overcorrection is not the same as "overcorrection" in fixed appliances whereby the teeth are set in an overcorrected position with the anticipation of relapse into the straight position at a later date. With aligner overcorrection, the aligner is built with tooth positions set past "ideal" so as to overcome any misalignment that would result if the teeth were to fall short of the goal.

For example, if a patient needed additional rotation of the mandibular central incisors after wearing the initial series of aligners (Fig 13-1a), additional orthodontic force on the distofacial surfaces would be needed to achieve the desired outcome (Fig 13-1b). Building overcorrection into the aligners (Fig 13-1c) may be used to improve alignment of the teeth.

Common Indications for Overcorrection

Overcorrection is most commonly used for minor incisor rotations, minor in-and-out discrepancies, minor residual spaces, and minor incisor deep bite.

The greatest challenge when planning for overcorrection is accurately predicting which teeth require overcorrection and which do not. For example, consider the mandibular incisor crowding shown in Fig 13-2a. The areas indicated by the white arrows are most likely to require additional correction to achieve the goal shown in Fig 13-2b. Consequently, adding 5 degrees of rotation beyond "ideal" may help ensure that the desired result is achieved by the last aligner. However, what if only two of the areas end up needing additional rotation, but overcorrection is built into all three areas? Building the last aligners with overcorrection in all three areas could result in making the areas with correct alignment incorrect as a result. Another possibility would be to build overcorrection into each area to account for the different combinations so that any correct areas could be omitted if the teeth are aligned correctly. Because the number of possible combinations that could result is rather large, however, this approach would not be cost-effective. In the above example, overcorrection aligners for 1 only, 2 only, 3 only,

ClearCorrect Exhibit 1016, Page 130 of 335



Fig 13-2a Overcorrection is likely to be needed in the three areas indicated by *arrows*.



Fig 13-2b Treatment goal.

1+2, 1+3, 2+3, and 1+2+3 would have to be made in order to capture all the different possible scenarios.

Because of the current inability to determine up front which teeth may require overcorrection and which will not, overcorrection is believed to be most effective when the overcorrection stages are created not at the onset of treatment but rather when the teeth are closer to the goal, such as at the time of case refinement. Near the end of treatment, it is more obvious which areas are not correcting according to plan. These are the areas most likely to require overcorrection to achieve the desired result, and it is much easier for the clinician to pinpoint the specific teeth that require overcorrection at the time of refinement than it is to speculate at the beginning which teeth may and which may not need it.

The exception to this recommendation is perhaps in generalized space closure cases, where an additional tightening of the interproximal contacts during the last three stages (sometimes referred to as *virtual c-chain* because the movements on ClinCheck appear similar to the movements of teeth when an elastic chain is placed) can be an effective way to help avoid minor interproximal spaces at the end of the initial aligner sequence. For example, the patient in Fig 13-3a is likely to have light contacts between the teeth where spaces are initially present if the teeth are moved to the setup in Fig 13-3b, where they are positioned so that they are lightly touching interproximally. Figure 13-3c shows the overcorrected position superimposed over the tooth position in Fig 13-3b, whereby the overcorrected position is designed to tighten any light interproximal contacts that may remain. The overcorrection occurs in three aligners, and the clinician can stop dispensing additional aligners once the contacts are adequately tightened.

Another important consideration is to plan overcorrection movements that are within the aligner's capabilities. For example, it would not be particularly useful to build extrusion overcorrection movements if the initial extrusion movements result in aligner disengagement from the tooth that is to be extruded. Having more extrusion built into the aligner will not make the tooth extrude any further if the aligner is already disconnected from the tooth to be extruded.

Alternative to Overcorrection: Detail Pliers

An alternative to overcorrection aligners for managing alignment discrepancies at the end of treatment is the use of Invisalign detail pliers (Fig 13-4) to generate additional orthodontic forces in the aligners. The plunger and recessed stop at the tip of the detail pliers create a permanent bump in the aligner, and unlike pliers that require heat to reshape the clear aligner appliances,[1] the detail pliers can be used at room temperature. Simply squeezing the pliers in the area of the aligner where additional force is needed creates a protrusion of 0.25 to 0.75 mm that can deliver additional force to the misaligned tooth for further correction. If reinforcement of the dimple is needed to prevent the plastic from collapsing, a filler material such as ClearLoc light-cure adhesive (Align Technology)

ClearCorrect Exhibit 1016, Page 131 of 335



Fig 13-3a Initial position.



Fig 13-3b Treatment goal.



Fig 13-3c Overcorrection (*dark blue*) required to achieve goal shown in Fig 13-3b.



Fig 13-4 Detail pliers.

may be used for support. In the event that a dimple is positioned in the wrong location of the aligner, an "eraser" pliers can be used to flatten out the formed dimple (Fig 13-5).

Detail pliers can be used to correct minor rotations, in-and-out discrepancies, and light interproximal contacts simply by varying the position in the aligner where they are placed (Figs 13-6 to 13-8). The assumption is that the pressure point will help conform the teeth to their intended position(s) already existing in the aligner; hence, so long as the aligner shape coincides with the desired position, the aligner does not need to be cut or altered to accommodate the new tooth position. In other words, if the desired goal is not the same as that approved in ClinCheck, the dimple pliers cannot be used to move the teeth beyond the tooth positions built into the aligner without first altering the aligner.

Preventive Strategies

A well-thought-out preventive strategy for avoiding overcorrection and detail pliers can lead to a more efficient treatment outcome and a more positive treatment experience. Three important considerations to help reduce the need for overcorrection are as follows:

1. **Set proper tooth-movement expectations.** Avoid aligner-incompatible tooth movements unless these movements are to be accomplished with ancillary orthodontic treatment in conjunction with aligners. Movements such as vertical extrusion and rotation of cylindrical-shaped teeth can be more effective when aligners are used in conjunction with auxiliaries such as elastics and sectional fixed appliances, respectively.
2. **Closely monitor any needed reproximation.** Any reproximation planned as part of the treatment should be performed in a timely and accurate manner. The aligner's

ClearCorrect Exhibit 1016, Page 132 of 335



FIG 13-5 Eraser pliers.



FIG 13-6 Distal-out, mesial-in forces (*arrows*) generated by the dimples for the purpose of rotating the mandibular right lateral incisor.

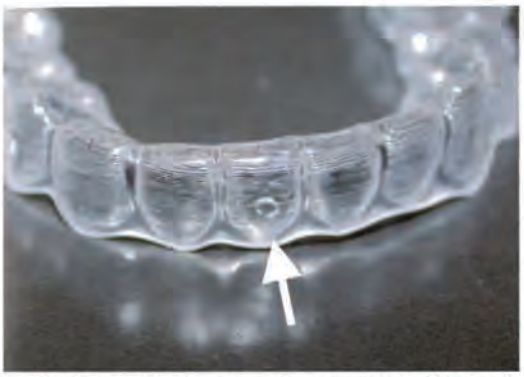


FIG 13-7 Lingual-in force (*arrow*) generated by the dimple for the purpose of moving the mandibular right central incisor lingually.

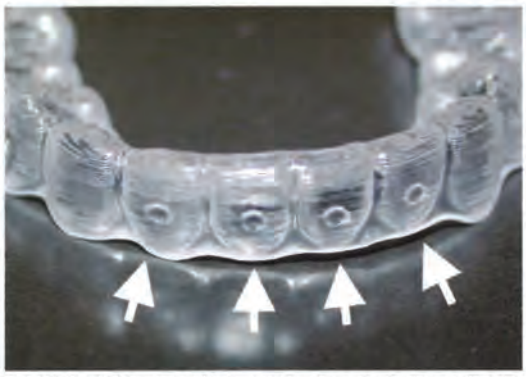


FIG 13-8 Tightening of interproximal contact of mandibular incisors through lingual-in forces (*arrows*) generated by dimples.

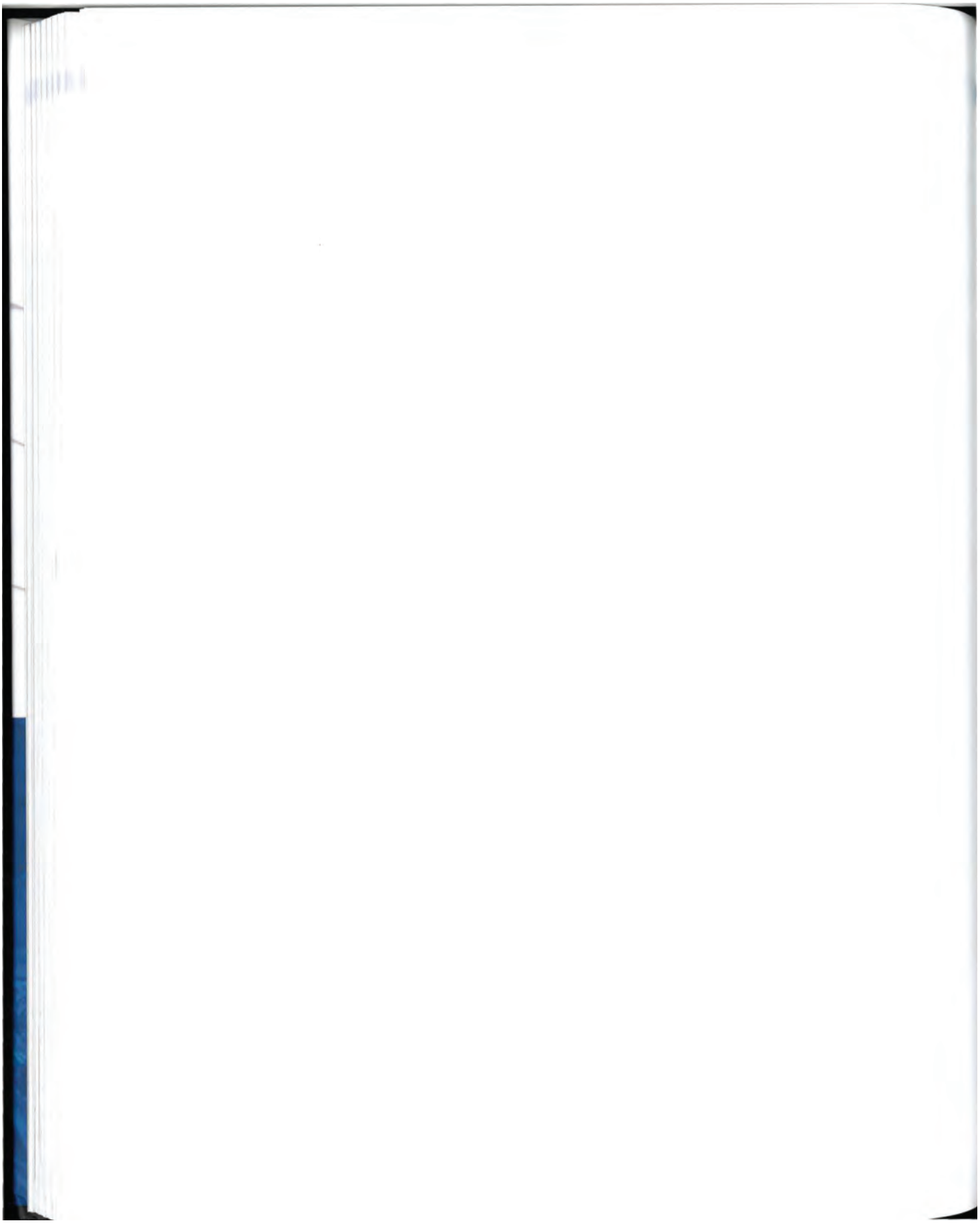
fit will be compromised if the teeth are not of the correct dimension, so the amounts of reproximation performed must be accurately determined. Proper timing of any needed reproximation is also important, as delaying reproximation beyond the time indicated in the patient's reproximation form (derived from the ClinCheck approved by the clinician) will prevent the teeth from moving correctly. The amount of reproximation performed can be confirmed using thickness gauges and can be documented in the patient's chart.

3. **Align first before closing spaces.** As with fixed appliances, aligners should be used first to align the teeth before retracting them to close any remaining interproximal spaces. If reproximation is needed, the teeth should also be aligned first to create more optimal access to interproximal surfaces. Unlike with fixed appliances, however, leveling should not be done initially, especially not if dental extrusion is desired, because if the aligner disengages from the tooth early on, any additional movements "downstream," such as rotation and inclination, may be compromised.

Reference

1. Hilliard K, Sheridan J. Adjusting Essix appliances at chairside. J Clin Orthod 2000;34:236–238.

ClearCorrect Exhibit 1016, Page 133 of 335



chapter 14

THREE-DIMENSIONAL SUPERIMPOSITION TOOL

by
C. Van Nguyen, DDS and Jihua Cheng, PhD

ClearCorrect Exhibit 1016, Page 135 of 335

What preceded the need for a three-dimensional (3-D) measuring tool for orthodontic treatment was a quest for the ideal representation of patient occlusion as it relates to the craniofacial complex. Unfortunately, the Invisalign System currently is a tooth-borne system. Thus, dental relationships are assessed with the aid of various intraoral landmarks. Assessment of orthodontic treatment outcomes has traditionally been based on two-dimensional (2-D) tracings of before-treatment and after-treatment lateral cephalometric radiographs. The initial departure from this traditional approach was the use of 3-D physical dental casts to evaluate treatment outcome.[1,2] Such effort was carried out with the understanding that certain parts of the palatal rugae are stable and identifiable during periods of growth in humans.[3] Because Invisalign is treatment in 3-D, Align Technology found it necessary to develop appropriate tools to measure treatment outcome.

Currently, Align's 3-D measurement tool used to evaluate treatment outcome matches crown surfaces tooth by tooth and then selects intraoral registration points, namely teeth, to relate the before- and after-treatment positions of teeth. The resultant registration reflects how relative tooth movements have been achieved. With this methodology, it is also possible to assess the efficiency of tooth movement.

In this section, we review 3-D mathematical algorithms associated with surface matching (superimposition) that are used for treatment outcome measurement.

Technology of 3-D Imaging in Orthodontics

The need to digitally store dental casts has been a driving force in orthodontic 3-D imaging. The digital storage of dental casts provides such benefits as reduced storage space and more efficient record retrieval.

There are many ways to acquire 3-D orthodontic images. Stereophotography uses two pictures taken in different views at the same time to produce a 3-D image. This method utilizes a triangulation technique that is analogous to how humans see objects stereoscopically. The disadvantage of creating stereophotographic images is the inherent error involved in the registration of the 2-D photographs together.

Surface laser scanning, which is also a triangulation technique, is widely used and based on projective imaging technique.[4] Volumetric images, such as those from computed tomography (CT) scans, are 3-D images obtained from axial slices of the object.

Free-Form Object Registration

Geometric matching is performed through both high-level and low-level approaches. The high-level method requires preprocessing: features and segmentation must be extracted from the data sets before registration. Low-level geometric matching uses raw data—like points and triangles—to match the data sets.

The advantage of the low-level approach is that it is not affected by unreliable features extracted from the free-form data sets. The disadvantage is, of course, that it disregards the work of experts who can enhance the registration by distinguishing important and unimportant features in the scanned objects.

Low-level approaches may include maximizing the correlation between the two data sets or using minimization of the distances between points of data sets in tooth alignment. The minimization of distances method is also known as *geometric point matching*. Geometric point matching starts out with a rough match. The corresponding points of the two objects can then be brought closer together by data transformation. Subsequently, through an iteration process, the distance between these points gets smaller, thereby making the match better. Many mathematical algorithms were developed to optimize this iteration process.[5,6] Among the algorithms used to achieve geometric matching is the iterative closest point (ICP).

For facial superimposition applications, for example, the technique of choice is a low-level approach (like ICP) to record and register using several landmarks. Although the task of identifying and acquiring landmarks is necessary for registration, the most critical issue is timely production of the best fit.[4]

One early attempt to superimpose 3-D images as free-form shapes was done by Faugeras and Hebert.[7] Algorithms used in shape registration can be derived from any of the following geometric data: point sets, line segment sets, curves (implicit or parametric), faceted surfaces (triangle sets), and surfaces (implicit or parametric).[5] The algorithm described by Faugeras and Hebert used least-squares computation in the registration of 3-D point sets. A different version of this registration methodology was derived by Horn.[8] The drawback of Horn's method, however, was its basis in the assumption that there are large

ClearCorrect Exhibit 1016, Page 136 of 335

planar regions in the free-form shapes.[9] Another approach to least-squares computation was adopted to match fairly homogeneous curve data but did not perform well against shapes with highly irregular curves.[10]

Method of Registration

Geometric matching utilizes the minimization of the mean square value of the difference between the registrations of the two data sets. As a requirement, the initial registration state is determined. After the initial matching is established, a convergence theorem is then proven. The method to find this initial state is critical because it has to be within a certain range of the correct matching state such that a convergence can occur. In other words, the difference between registrations must get smaller after a single iteration. According to Besl and McKay, "The least square registration generically reduces the average distance between corresponding points during each iteration."[5]

Several steps are involved in the process of ICP. First, computation of the closest points between two geometric objects is set up. The distance to be minimized can be euclidean (point-to-point) or a reference to the closest point from one surface to another point on the other surface and its normal plane (point-to-plane).[6] The euclidian distance is defined as the square root of the sum of the square of all 3-D distances.

In the second step, a mean squared error between the two data sets is defined. This error is subsequently minimized when computing for a rigid transformation. *Rigid transformation* is defined as translation, rotation, or both.

In the third step, registration is applied using the best rigid transformation. After this, a number of iterations (or any other criteria—eg, a matching error) is carried out to achieve the desired match.

Superimposition of 3-D Images in Orthodontics

There are four main methods of superimposing before- and after-treatment images to assess discrepancy and quantify the results of orthodontic treatment.

The first method involves the matching of tooth-by-tooth geometry via best surface match. The before- and after-treatment arches are registered by a number of points; this superimposition technique involves tooth-by-tooth matching and registration via least-moving teeth. As registration markings are not stationary, superimposition allows the clinicians to see the relative positions of each tooth during treatment. This method, therefore, only shows how much movement has been achieved between two moving objects. For example, Align's superimposition tool shows how much an anterior tooth retracts relative to a posterior tooth, but does not indicate how many millimeters a tooth moves anteroposteriorly relative to the craniofacial landmark sella. For any specific movements (eg, intrusion of anterior teeth), performance trends can also be obtained using the superimposition tool. It is not surprising that, "as teeth do not have simple geometric features, the comparison of tooth positions in two different impressions is not straightforward."[11]

The second method also attempts to measure tooth movements within either the maxillary or mandibular arch using intraoral landmarks. Unlike the previous method, this method uses soft tissues for registration. The basic premise for this approach is that palatal rugae—specifically, the medial aspects—are stable during the growth period.[3] The problem that Align Technology encountered is in determining how to locate these palatal rugae and consistently register maxillae without having difficulty with the vertical dimension (ie, the arches tend to register very well anteriorly, but posteriorly they become separated because of a lack of registering ruga points). Despite repeated efforts to overcome this drawback, the problem persists unless other registration points are identified in the posterior region of the maxilla. Superimposition of before and after images depends on the availability of rugae, which are present only on the palate. For the mandibular arch, the lack of stable intraoral features presents another problem. Currently, there is no good set of registration points identified. The effort of superimposition based on intraoral soft tissues is thus assumed to be an estimation only.

The third method involves alignment of the dental arches via 2-D extraoral landmarks that are stable during growth in the craniofacial structure. The relationship of the dentition can be intra-arch or extraoral. This approach is similar to cephalometric superimposition of tooth movements. There have been many attempts to register 2-D cephalometric radiographs taken from different angles to generate a 3-D image of the craniofacial structure. The tools used in this type of registration have their limitations, and the method of registering 2-D images into 3-D has some inherent error.[12,13] Nevertheless, this approach is useful in

ClearCorrect Exhibit 1016, Page 137 of 335

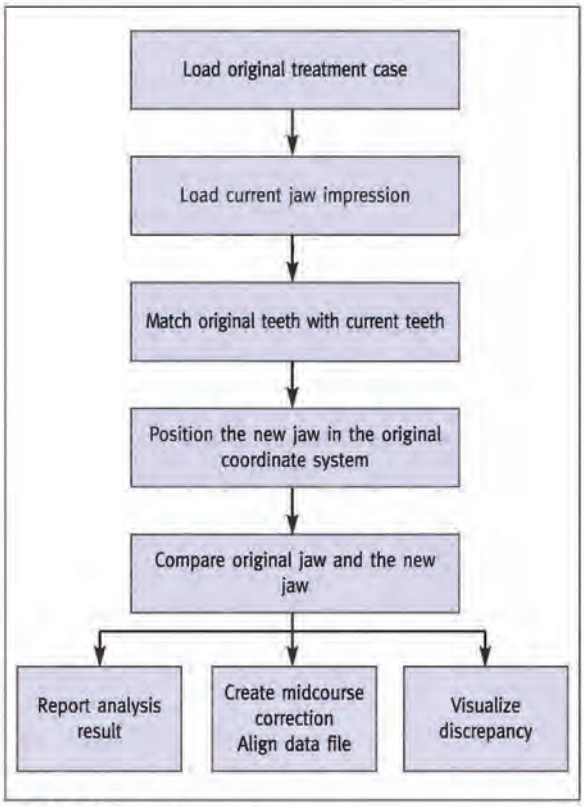


FIG 14-1 Process sequence.

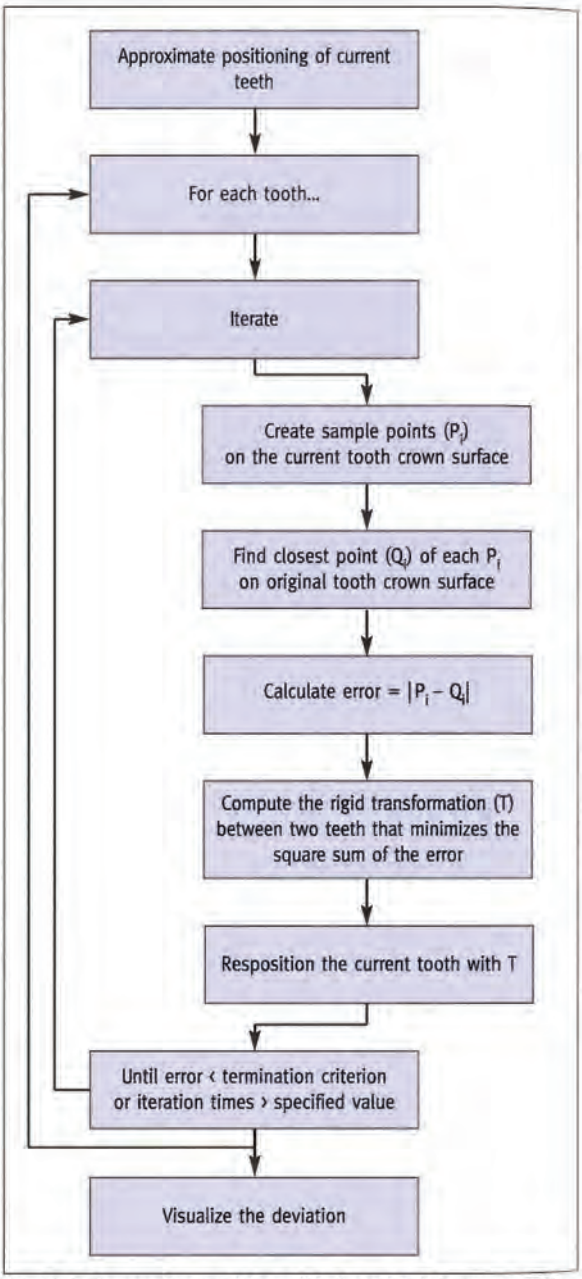


FIG 14-2 Process for matching original teeth with current teeth.

the development of a 3-D superimposition method to assess tooth movement because registration points can be selected from the cranial base, which is considered stable. Currently, researchers at the University of the Pacific (UOP) are assessing the accuracy of this methodology in treatment outcome analysis. A version of this technique that orients the 3-D dentition onto the lateral cephalometric radiograph is under development at UOP. This method was described as the manipulation of a virtual outline of the occlusal surface belonging to either the maxillary or mandibular cast so that it best fits the image of the teeth shown on the lateral cephalometric radiograph. A frame of reference was defined such that the x- and y-axes lie in the midsagittal plane of the head and the z-axis is perpendicular to both axes.[14]

The fourth method for assessing tooth movement involves volumetric 3-D images, which can be obtained by technologies developed by such companies as Hitachi, QR srl, Image Science International, and Morita. The NewTom 9000 (QR srl) scanner, for example, utilizes a cone-shaped beam approach that reduces the overall exposure dosage.[15] Limitation of the exposure dosage, however, diminishes the clarity and precision of the volumetric images.[14] The NewTom 9000 may need to be used in conjunction with panoramic or periapical radiographs, which suggests that this technology is not yet ready to replace other strategies for obtaining comprehensive 3-D images for the evaluation of tooth movement. It is safe to assume that other imaging devices (iCAT, Imaging

ClearCorrect Exhibit 1016, Page 138 of 335