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Effect of Gingival Margin Design on Retention of Thermoformed Orthodontic Aligners

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EFFECT OF GINGIVAL MARGIN DESIGN ON RETENTION OF THERMOFORMED ORTHODONTIC ALIGNERS

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ABSTRACT

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by

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Purpose: The aim of this study was evaluate the effect of gingival margin design (scalloped vs. straight cut at gingival zenith vs. straight cut 2mm above gingival zenith) on the retention of thermoformed aligners. Retention of aligners is a critical requirement for efficient tooth movement.

Methods: Two thermoform aligner materials were used, Invisacryl A and Invisacryl C, in 0.040 mil (1mm) thickness. Six aligner designs were fabricated for each of the two aligner materials (12 total aligner designs). Aligner designs are scalloped, straight cut at gingival zenith (0mm), and straight cut 2mm above gingival zenith on a model with attachments. These designs were tested with and without attachments. Three aligners were made for each of the 12 aligner designs for a total of 36 aligners. A Universal Testing Machine was used to pull each aligner off of a Kilgore dentoform in a direction perpendicular to the occlusal plane. The force needed to pull each aligner off of the dentoform was recorded as the retentive force of the aligner. A one way ANOVA with a Post Hoc Bonferroni test was completed on the average pull off force for each of the 12 aligner groups.

Results: Of the 66 comparisons made 57 had significant differences when comparing each aligner group's average retentive pull off force. The highest retentive force was Invisacryl A, 2mm straight margin, with attachments while the lowest retentive force was Invisacryl C, scalloped with attachments.

Conclusions: Invisacryl A material showed increased retention when compared to Invisacryl C material of the same aligner margin and attachment design. Straight line gingival margins (0 and 2mm) showed and increased retention when compared to scalloped margins for Invisacryl A and Invisacryl C with attachments. Aligners with attachments and scalloped margins had significantly less retention than aligners of the same material type with scalloped margins and no attachments. The 2mm straight gingival margin design had the highest retentive forces when compared to aligners of the same material and attachment type.

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CHAPTER 1

INTRODUCTION

Dental cosmetics have been promoted in human civilization throughout early recorded history. Cornelius Celsus wrote that finger pressure can be used to move teeth into alignment (Tuncay, 2006, p.166). A number of appliances and approaches have been developed to move teeth. One of the more recent approaches involves utilization of a series of thermoformed plastic shells, commonly referred to as aligners. Removable thermoformed aligners such as Invisalign® (Align Technology, Inc. Santa Clara, CA, USA), ClearSmile® (ClearSmile Pty Ltd. Keiraville, Australia), ClearCorrect® (Houston, TX) and Simpli5 (AOA Laboratories) are available treatment options in many orthodontic and general dental offices especially for an adult patient seeking an esthetic alternative to fixed orthodontic appliances.

Removable thermoformed appliances (RTA) initially appeared in the literature in 1945 when Kesling introduced a tooth positioning device created using a pliable rubber appliance fabricated on idealized wax set ups for patients whose basic orthodontic treatment was completed (Kesling, 1945). Since Kesling, the uses of a thermoformed appliance have expanded into other fields of dentistry. Thermoformed appliances are used in restorative dentistry to make temporary bridges, duplicate dentures or to serve as athletic mouth guards. Periodontists use these for splints, night guards, to deliver medicaments or cover tissue after periodontal surgery (Nahoum, 1964). One of the other common uses of thermoformed appliances in general dentistry is to serve as a surgical stent for implant placement. Overall, the most common use of RTAs is to align or retain aligned teeth.

Thermoformed appliances are fabricated using many types of thermoplastic materials. A thermoplastic material becomes pliable when heated and returns to a rigid state when the material is cooled. Acetate, butyrate, polyethylene, polypropylene, styrene and vinyl are common compounds that can be thermoformed into clear, translucent, opaque or colored films. Material thickness commonly varies in a range from .010 to 0.04 inches (0.04 inches = 1mm), but can even be used as thick as 0.08 inch (2mm) in selected applications. It is important that the material be inert, non-toxic, odorless, tasteless, remain unaffected by chemicals of the body, have minimal water absorption and resist warping. The overall process of thermoforming was first described by Nahoum in 1964. A plastic sheet or film is molded over a cast or die (stone models in the case of orthodontics or dental appliances) using a vacuum forming machine. The plastic is heated to a molding temperature (varies for individual plastics and thicknesses) and then draped over the model. A vacuum is turned on creating a negative pressure removing the air from between the plastic material and the model helping to mold the material to model (Fig. 1.1). Newer machines use a vacuum with simultaneous positive pressure to achieve greater adaptability. The plastic is removed from the model and trimmed to desired specifications and rinsed prior to delivery to the patient.

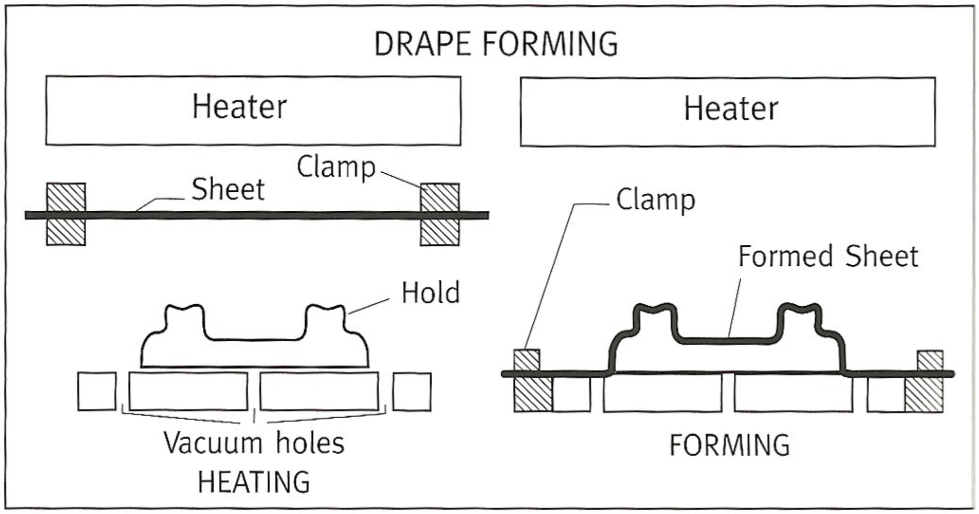


Figure 1.1 Thermoforming Process (from Tuncay, 2006, p. 4, Quintessence Publishing)

Thermoformed material can be used as a removable retainer to prevent tooth movement or as a removable aligner to move teeth. To obtain orthodontic movement, teeth on the plaster models are cut out using jewelers saw or fine fissure burr and reset to ideal positions in the model using wax. Programmed movement is typically less than 0.5mm. The plastic is vacuum formed over the new corrected model. Correction is obtained as a result of pressure exerted on the irregular teeth by the appliance fabricated on the corrected model. The plastic properties of the material flex over the teeth and exert pressure to move teeth into the corrected positions (Nahoum, 1964).

The flexibility or stiffness of a material is the material modulus. An appliance made from a material of lower modulus exhibits an increased flexibility; it is easier to place the appliance over the teeth, but there will have less control of tooth movement. Controlled tooth movement requires an aligner with a maximum amount of adaptability to the undercuts and a decrease in flexibility. As a tooth moves and the material fatigues, force levels will decrease (Barbagallo et al., 2007). Therefore, a two week replacement time was shown to have the most efficient tooth movement (Bollen et al., 2003). If the desired tooth movement is greater than 0.5mm, then a series of aligners is typically used to obtain the desired tooth movement. Resetting teeth on models for a sequence of aligners can become a tedious process. Initially, a dental technician resets teeth on a plaster model by hand for every step in a sequence of aligners.

Companies such as Align Technologies, Inc. have further developed this process and utilize digital technologies to help create a more commercial and practical method for sequential RTAs. Align Technologies, Inc. uses CAD CAM technology to plan tooth movements and positions and then fabricate a stereolithographic model of each position in the sequence. A thermoformed aligner is made on these models (Hahn, Fialka-Fricke et al., 2009). In an ideal situation, the aligners are progressed in sequence every two weeks to obtain maximum tooth movement prior to material fatigue (Bollen et al, 2003).

As with any new technologies and methods, there are several limitations and potential problems with the technique. One of the largest faults with RTAs is the excessive flexibility of the material next to the gingival margins. The area along the gingival margins will typically not have enough force to create movement (Tuncay, 2006). This results in a problem that influences the effectiveness of the appliance and in particular when orthodontic torque movements are attempted with aligners. In order to create torque, the aligner must place a force at both the incisal edge and at the gingival margin otherwise only a tipping movement will occur. Tooth movement with RTAs in a sequence has been shown to be only 80% of the expected movement generated by the computer models. This difference between obtained and expected tooth movement is referred to as tooth lag (Tuncay, 2006, p. 151). Tooth lag is a result of both limitations to the RTA material and inability to account for PDL adaptation. Another study has shown that the accuracy of predicted tooth movement is only 41% even with built in over corrections (Kravitz et al., 2009). Inability to obtain desired tooth movement leads to revisions and potential placement of traditional fixed orthodontic appliances to finish cases.

In fixed appliance therapy, wires are bent to sufficiently detail and finish tooth movements. This option is not available with RTAs. Therefore, understanding the abilities and limitations of RTAs and appropriate case selection by the dental practitioner is crucial to obtaining acceptable results. Many dental practitioners attempt dental corrections beyond the ability of aligner producing poor results and delays in treatment. Cases treated within the scope of aligners yield successful results (LeGravere and Flores-Mir, 2005). Lack of patient cooperation and compliance with aligner wear during treatment will also lead to increase tooth lag and poor results.

In order to produce desired and predictable tooth movement, practitioners must be able to not only produce forces but also control the forces that are produced. Clinicians using RTAs must do as much as possible to increase the accuracy of tooth movement and decrease tooth lag. Research into material properties and aligner design provide needed information to address some of the problems and limitations with using RTAs for orthodontic tooth movement. Increasing aligner thickness from 0.030 mil to 0.040 mil has been shown to help increase expected tooth movement by decreasing flexibility (Tuncay, 2006, p. 188). An assortment of material types and polymers with different material properties may help produce desired movements. Use of one material type with one thickness for all treatment modalities as is the case with several sequential RTA companies may be a considerable limitation. Research into material types and properties is sparse. Ideal treatment with RTAs may possibly include several aligner material types and fabrication of a sequence of aligners in subsets with new impressions taken between subsets. This could be a strategy to help control and prevent tooth lag. These options are currently not available. An understanding of material properties and aligner designs are needed to best produce the desired tooth movements and to help obtain the highest amount of control possible during force applications.

Purpose of the Study

To help increase the success of removable thermoformed aligners for orthodontic tooth movement, this study evaluated a flexible and a rigid thermoplastic material (Invisacryl A and Invisacryl C) and alternations in aligner design (scalloped gingival margins versus straight gingival margins) with a focus on increasing retentive strength of the aligner at the gingival third of the tooth. RTAs such as Invisalign and ClearCorrect use a 0.030 mil semi-rigid material with scalloped gingival borders cut along the free gingival margins of the tooth. As the material is thermoformed over the model, it becomes thinned to less than 0.030, particularly in the regions further away from the occlusal surface. Both the thickness of the material and the scalloped design of the free gingival margins may affect flexibility and retention of the RTA. The measurement of the force required to pull an aligner off of a dentiform model was used as a measure of material flexibility. The results of this study may help to better select materials and design RTAs for controlled tooth movement.

Definition of Terms

Aligner- an orthodontic appliance used to move teeth into a desired position

Thermoform- a method of shaping using heat, especially for thermoplastics

Thermoplastic- plastic polymer material that softens when heated and hardens when cooled

Removable Orthodontic Appliance- an orthodontic appliance that can be taken in and out of the mouth and is not rigidly fixed to the teeth

Free Gingival Margin- terminal edge of the gingiva surrounding the tooth in a collar like fashion

Gingival Zenith- apical most point of the free gingival as it crosses the facial surface of the tooth (Figure 1.2)

Scalloped Gingival Aligner Margin- design of the gingival margin of an aligner that follows the free gingival margin along each tooth (Figure 1.3)

Straight Gingival Aligner Margin- design of the gingival margin of an aligner that is cut straight and does not follow the contours of the free gingival margin. (Figure 1.4 and Figure 1.5)

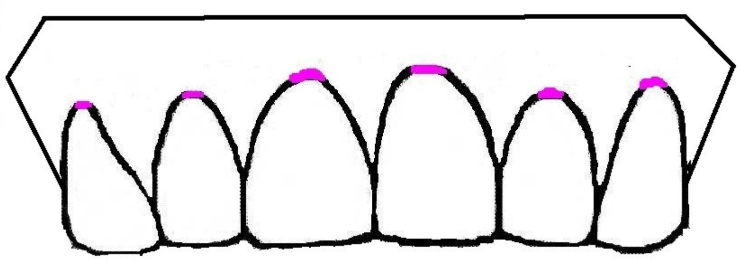


Figure 1.2 – Location of Gingival Zenith (indicated in pink)

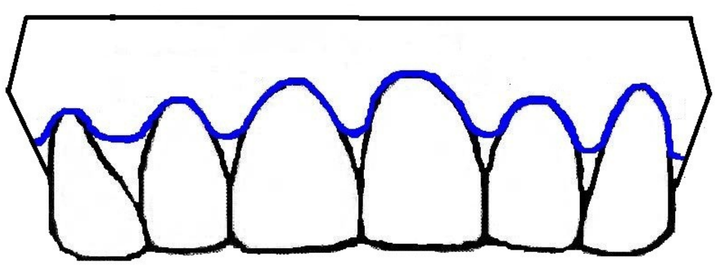


Figure 1.3- Scalloped Gingival Margin Design along Gingival Zenith

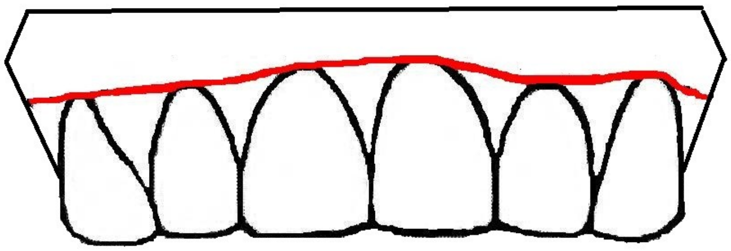


Figure 1.4 – Straight Line Gingival Margin along Gingival Zenith

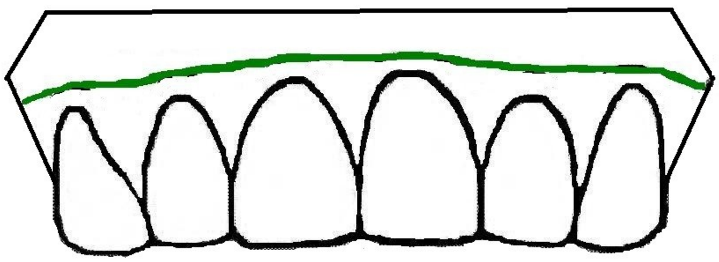


Figure 1.5- Straight Line Gingival Margin above Gingival Zenith

Research Questions

The overall research goal is as follows:

Comparison of the retention force properties of thermoformed aligners between scalloped gingival margin design and straight line gingival margin design using two types of material (Invisacryl A and Invisacryl C) with and without rectangular attachments on premolars.

The research goal can be addressed by evaluating the following specific questions.

1- How does the scalloped gingival margin design compare to the straight line gingival margin design cut at the level of the free gingival margin zenith during pull off tests without attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut at the free gingival margin zenith during pull off tests without attachments.

2- How does the scalloped gingival margin design compare to the straight line gingival margin design cut 2mm above free gingival margin during pull off tests without attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull off tests without attachments.

3- How does the straight line gingival margin design cut at the zenith compare to the straight line gingival margin design cut 2mm above the gingival zenith during pull off tests without attachments on first premolars?

Hypothesis:

The straight line gingival margin design cut at the gingival zenith will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull of tests without attachments.

4- How does the scalloped gingival margin design compare to the straight line gingival margin design cut at the free gingival margin zenith during pull off tests with attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut at the free gingival margin zenith during pull off tests with attachments.

5- How does the scalloped gingival margin design compare to the straight line gingival margin design cut 2mm above free gingival margin zenith during pull off tests with attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull off tests with attachments.

6- How does the straight line gingival margin design cut at the zenith compare to the straight line gingival margin design cut 2mm above the gingival zenith during pull off tests with attachments on first premolars?

Hypothesis:

The straight gingival margin design cut at the zenith will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith with attachments.

7- How does Invisacryl A material compare directly to Invisacryl C material on pull off tests (in the same margin design category) without attachments?

Hypothesis:

The Invisacryl C material will not have a higher retentive force when compared directly to the Invisacryl A material with the same margin type during pull of tests without attachments.

8- How does Invisacryl A material compare directly to Invisacryl C material on pull off tests (in the same margin design category) with attachments?

Hypothesis:

The Invisacryl C material will not have a higher retentive force when compared directly to the Invisacryl A material with the same margin type during pull of tests with attachments.

CHAPTER 2

REVIEW OF THE LITERATURE

Literature review of this topic encompassed both US and European published literature via online databases. Search terms included the following: thermoformed aligner, invisalign, thermoplastic aligner, thermoformed retainer, removable plastic aligner, and essix. Searchable databases included: Pubmed, Science Direct, Scopus, Academic Search Premier, Medline, Web of Knowledge, and Cochrane Library. A UNLV library search was also completed on the search terms to locate books regarding this topic. The search terms were also placed into several internet search engines including Google, Yahoo and MSN for further investigation. The literature search revealed 27 articles and three books related to forces and/or structure/design of RTAs.

History of RTAs

Movement of teeth without bands, brackets and wires using a thermoformed material was described in detail as early as 1945 by Kesling. He reported using a one piece flexible tooth positioning device made from vulcanite rubber for post orthodontic treatment to get minor finishing tooth movements (Kwon, Lim and Lim, 2008). The positioner was fabricated on idealized wax set-ups to help position the teeth in an artistic fashion and retain the alignment. Kesling also predicted that major tooth movements can be accomplished using a series of positioners fabricated from resetting teeth on models in a series of minor movements (Phan and Ling, 2007). Remensnyder was able to produce minor tooth movements while using the Flex-O-Tite gum-massaging appliance to treat pyorrhea in as early as 1926 (Tuncay, 2006, p.25).

Nahoum further promoted the use of removable thermoformed aligners in 1964. Nahoum listed several material types that can be used to fabricate aligners by thermoforming including: acetate, butyrate, polyethylene, styrene and vinyl. The list of materials has continued to grow and includes many other types of materials. Nahoum documented the use of a Tronomatic vacuum forming machine (Tronomatic Machine Co.) to fabricate thermoformed dental and orthodontic appliances as early as 1959. He mentioned that the ideal thermoformed material must be inert, non-toxic, odorless, tasteless, remain unaffected by chemical of the mouth, no warpage and have minimal water absorption. Nahoum invented and documented the basic process of heating and thermoforming the material and the system of cutting teeth from the model and adjusting their positions in the dental cast to produce orthodontic tooth movement. He rationalized that the alignment of teeth was a result of pressure exerted on the irregular teeth by the appliance which was made on the corrected model. For mass movements, Nahoum proposed using elastics attached to a hook bonded to the appliance. Nahoum went further to explain the application of thermoformed appliances in other fields of dentistry. Thermoformed appliances can be used in periodontics as a splint for mobile teeth, as a night guard, to carry medicaments to the gingival or hold a surgical pack following periodontal surgery. These appliances can be used in restorative dentistry as a matrix for temporary bridges or crowns, protection of teeth from trauma, or for duplication of dentures. They can be used in oral surgery as a splint, stent, or as a method to hold medicaments in the oral cavity. Nahoum believed RTA appliances can be worn at all times over the teeth, (including during mastication) and only be removed to clean like a denture (Nahoum, 1964). Plastic materials wear more than porcelain and enamel during mastication, but most alignment processes using thermoformed appliances require that they be changed within a two to three week period of time.

In 1971, Ponitz introduced an appliance called an "invisible retainer". This appliance was fabricated on a model with teeth prepositioned in base-plate wax to help create minor tooth movements (Ponitz, 1971).

The next large step in using RTA's for orthodontic purposes was accomplished when Sheridan took Kesling's proposal regarding sequential RTA's and developed a technique using Essix retainer material (Raintree Essix, New Orleans, La.) to obtain larger tooth movements. Sheridan used composite mounds placed on the tooth or dimples placed into the aligner to localize force to a desired area on the tooth (see Fig. 2.1). This method would allow for 2-3mm of movement without resetting the teeth (Sheridan, LeDoux and McMinn, 1993).

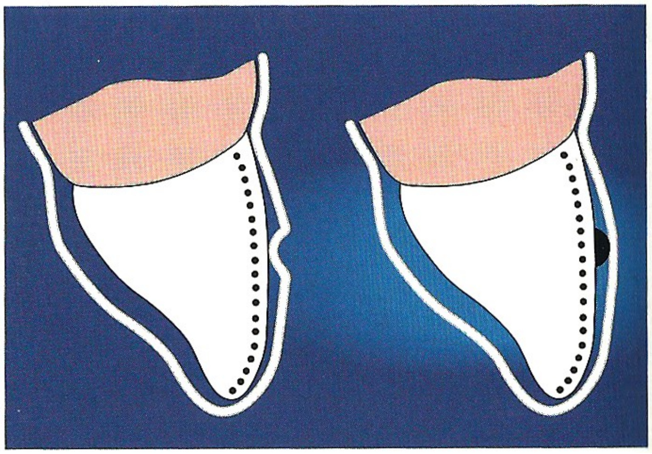


Figure 2.1 Dimples placed in Aligner on left, Right is a composite mound on a tooth (from Tuncay, 2006, p.16, Quintessence Publishing).

Two types of space must be available to move teeth with a RTA. Space is required within the appliance and space is required within the dentition. In the former, Sheridan described an approach of cutting windows into the aligner or placing a material on the tooth in the desired direction of movement to block out space for movement when the aligner is fabricated. In the latter, creation of space within the dental arch may involve expansion, extraction or reduction of tooth size. Perhaps due to the difficulty in closing extraction spaces or expanding arches using RTAs, Sheridan documented several approaches to interproximal reduction (IPR). These include the use of hand-pulled strips which can be laborious, hand piece mounted reducing disks which can accidentally cut adjacent tissue or the lip, and air-rotor stripping using an air turbine handpiece which is generally thought to be safer and may be easier to more precisely gauge the amount of tooth reduction. Sheridan also documented the types of movements that can be completed using Essix mechanics. Labial and lingual tipping, and rotation can be created using force-inducing projections and either windows or blockouts. Lateral movement can be created by adjusting tooth position on the aligner prior to thermoforming (Sheridan, Armbruster, Nguyen and Pulitzer, 2004). Torque requires a force to be placed on the tooth at the incisal edge on one side and at the gingival margin on the other to create a couple. The force placed at the gingival margin must exceed the force placed at the incisal edge due to location of force in relation to center of resistance. Torque movement is very difficult to achieve using aligners due to the increased flexibility at the gingival margins (Tuncay, 2006, pp. 12-24). Hilliard worked with Sheridan's Essix principles and created a thermoplier system for placing dimples, enhancing undercuts or removing undercuts which increased the versatility and longevity of a RTA. His plier system is also used to enhance Essix retainers for movement or to increase fit. Extrusion and intrusion movements require the use of elastics and the RTAs serve as a base to complete the movements. Buttons to serve as attachments for elastics are created in the plastic using Hilliard thermopliers (Hilliard and Sheridan, 2000, pp. 236-238).

In 1997, Align Technologies Inc. (Santa Clara, Ca.) commercialized a sequential removable thermoformed aligners by creating the Invisalign® system. Align Technologies uses a CAD-CAM system to anticipate tooth movements and create sequential models for larger tooth movements without using a lab technician to reset teeth (Hahn, Dathe, et al., 2009). The invisalign process begins with an initial impression of the patient using a polyvinylsiloxane (PVS) impression material. The impressions are sent to Align Tech where they are scanned into the computer system and sequential orthodontic tooth movements are created on the computer following a prescription provided by the clinician. The dental practitioner can review the tooth movements using Invisalign's ClinCheck software and approve the proposed orthodontic movements. The three dimensional CAD-CAM images are produced into models for each stage in the sequence using a process of laser stereolithography. From these models, thermoformed aligners are fabricated in a sequential order for the desired tooth movement using a Biostar (Scheu-Dental, Iserlohn, Germany) pressure molding machine. Align Technologies trims the aligners using a robotically controlled five-axis milling machine (Tuncay, 2006, pp. 28-29).

Other companies have progressed to offer sequential RTA fabrication. ClearSmile® (ClearSmile Pty Ltd. Keiraville, Australia) is Australia's version of sequential RTAs. ClearSmile offers a complete aligner system with an average of 12-34 aligners per case. ClearSmile technicians manually reset teeth into the sequential stages. Their preferred material type is a polyurethane thermoplastic of 0.8mm thickness (Barbagallo, et al., 2008). AOA Laboratories offers two types of sequential aligner systems. Red, White and Blue® is a sequential three tray system usually used to treat one arch only and Simpli5® is a five tray system that can be used for either a single or dual arch case (AOA Laboratories, Sturtevant, WI, USA). Companies have only made minor advancements into material properties, material types and their respective clinical applications.

One area of advancement deals with ways to complete the thermoforming process. The initial thermoforming machine was created using an iron for a heat source, a large metal drum and a household vacuum. This progressed into an all-in-one machine such as the Tronomatic vacuum forming machine, which uses negative air pressure to form the plastic material onto the model. New thermoforming machines such as the Biostar® and Ministar S® (Scheu-Dental, Iserlohn, Germany) use positive air pressure to form the plastic material to the model. The positive pressure enables an increased adaptation and an overall better result from the aligner.

Advantages of RTAs

Corporate marketing of the advantages of RTAs has lead to a vast increase in demand for RTAs by the consumer. For patients with the suitable type of malocclusion, the advantages of using RTAs can outweigh the disadvantages and an excellent orthodontic result may be achieved. The Invisalign appliance provides the patient an esthetic, comfortable, easy and clean alternative to conventional orthodontic appliances (Phan and Ling, 2007, p. 266). The most significant advantage is the overall esthetic appearance of the appliance. On average, RTAs are undetectable to anyone further than 2 feet away. Adults are a growing population of orthodontic patients and they seek treatment with minimal esthetic and comfort compromises. The esthetics associated with thermoformed aligners have a high appeal to these patients. Since RTAs are both clear and removable, they are preferable for many patients when compared to other esthetic options for fixed appliances such as ceramic or plastic brackets. The undetectable and removable properties of RTAs allow the patient to either wear or remove the appliance during important personal or business situations (Tuncay, 2006, p 217).

A second advantage to thermoformed aligners is the removable nature of the appliance. This allows increased versatility with the appliance for patients that have important engagements where optimal natural esthetics is indicated. Removability of the appliance also allows for maintenance of good oral hygiene. Patients are able to brush and floss normally without interference from brackets or wires. There is no need for proxy brushes or other flossing devices to assist with flossing under wires. The increase in oral hygiene is a benefit to patients with a history of periodontal disease, decalcification or high caries risk. Since these appliances are removable, patients do not necessarily need to change diet habits.

Overall comfort of the appliance is another advantage. Aligners have minimal cheek and gingival irritation. This eliminates a need for plastic sleeves, wax and bracket removal due to trauma. Many adults that have had fixed orthodontics as adolescents followed by RTA treatment as adults reported a decrease in pain and an increase in overall comfort with RTAs. Since there are no metal components in thermoformed plastics, these appliances may be suitable for patients with nickel or other hard metal allergy. With no bonding necessary, thermoformed aligners can be used on patients with enamel defects such as amelogenesis imperfect and hypocalcified enamel or teeth with amalgam or porcelain restorations that inhibit bonding (Tuncay, 2006, p 217).

Tuncay (2006) reported evidence in studies that show no root resorption on patients treated with RTAs, but more long term studies need to be completed to fully support this theory. RTAs may also have advantages in a decrease of overall patient chairtime, but more of the clinician's time is needed in early diagnosis and treatment planning. It has been suggested that aligners are effective at controlling anterior open bite cases since they cover the entire coronal surface of all teeth and may have a bite block intrusion effect on posterior teeth allowing for closure of an anterior open bite. Treatment with deep bite patients also has a benefit with RTAs. With both occlusal surfaces covered, there is not a need for bite plates or treatment of one arch before the other due to the patient hitting on brackets. This has potential to decrease treatment time, but in most cases does not. Without the use of brackets and wires, there are fewer emergencies with RTA treatment. Situations arise where a patient loses and aligner or an aligner breaks, but neither of these demands immediate emergency attention (Tuncay, 2006, p 221).

RTAs can benefit professional populations where conventional braces are not an option. Patients with high risk of root resorption may benefit from thermoformed aligners due to the documented lower prevalence of root resorption in RTA cases (Brezniak and Wasserstein, 2008). Brackets and wires are not safe for athletes and can interfere with the ability of musicians to perform. If an aligner is left in the mouth of an athlete by accident, it can serve as a mouth guard and protect his/her teeth. RTAs can serve as bleaching trays and allow the patient an option of bleaching his or her teeth during the course of treatment, and/or protect the patient's teeth if they have a bruxism or clenching habit (Tuncay, 2006, p 222). In cases where increased retention and force control is needed, clear composite attachments can be bonded to selected teeth allowing for an increase in control with minimal compromises to esthetics (Jones, 2009, p. 113).

Disadvantages of RTAs

Removable thermoformed aligner treatment offers patients several advantages over conventional braces. In deciding treatment options, the disadvantages of every treatment option must be considered and RTAs have several disadvantages. Difficulty in finishing cases with RTAs is the biggest disadvantage. In the study completed by Bollen, et al. (2003), only 15 of 51 patients (29%) were able to complete the initial series of aligners and all 51 test subjects required either an additional series of case refinement aligners or conventional fixed orthodontic appliances to finish treatment. The inability of RTAs to finish treatment is multifactoral and all are disadvantages to RTAs. Many instances are a result of patient non-compliance. Appliances that are not worn correctly will not produce the anticipated amount of correction. Patient non-compliance can be due to burn out from extended treatment times, pain associated with tooth movement or an overall lack of motivation. The reliance of RTAs on patient compliance is the primary reason why treatment with aligners should only be completed on adults. Many children and teens are not compliant with this type of treatment modality (pp 496-500).

Another disadvantage to RTAs and a cause of their inability to finish treatment is tooth lag. Tooth lag results when biologic tooth movement is less than the anticipated tooth movement determined by CAD CAM systems. Tooth position on average is no better than 80% of the position expected by computer software programs (Tuncay, 2006, p 131). This poses several problems when dealing with sequential aligners and will limit the overall control of tooth movement making the system less predictable.

Lost appliances pose a disadvantage to a sequential aligner system. If an appliance is lost, the patient is required to step back to a previous aligner while a new aligner for the next step is fabricated. Patients that do not return to the office for fabrication of a new aligner within a reasonable time frame may need to step back several aligners in order to get an ideal fit due to relapse. This slows down treatment time and potentially influence treatment results.

A final disadvantage is the difficulty to accurately predict tooth movement. RTAs are more successful with anterior movements than posterior movements, mandibular alignment easier than maxillary, and incisor space closure has greater success than posterior space closure (Clements, et al., 2003, p. 506-508). Correction of rotations is very difficult to predict. Kravitz, Kusnoto, Agran and Viana (2008) noted that the mean accuracy of canine rotation to the rotation placed in the aligner is 35.8% and 15 out of 53 canines obtained rotational accuracy greater than 50%. Cylindrical shaped crowns are a mechanical challenge to rotate due to a lack of interproximal undercuts allowing the aligner to slip (pp. 682-686). RTAs can not accurately close spaces by tooth translation bodily movement. A force and a moment are needed to move teeth bodily. Most of the force on an RTA is exerted on the occlusal portion of the crown and the force is minimal at the gingival. The difference in forces prevents the force couple needed for bodily movement is very difficult (Brenzniak, 2008, p. 381). Material thickness with RTAs acts like a posterior bite plate and leading to a posterior open bite during treatment. Posterior contact is increased during retention when RTAs are worn night time only (Dincer and Aslan, 2009, p. 6).

Several techniques may be used to increase the predictability of tooth movement. These techniques include: auxiliaries, overcorrection, interproximal reduction, and attachments. Nahoum (1964) used five material types of varying thicknesses to obtain the desired amount of movement. The length of time the appliance is in use and the desired purpose of the appliance dictated the material type and thickness. Nahoum took new impressions and reset teeth manually whenever a new aligner was needed providing the opportunity to change material type or thickness as needed during treatment if needed (Nahoum, 1964, p. 385). This technique removes tooth lag associated in CAD CAM produced sequential aligners.

Thermoplastic Material Properties

Thermoplastic materials are linear to slightly branched polymers with strong covalent and weak Van der Waals bonds. Increased temperatures allow molecular chains to move allowing the plastic to become pliable. When cooled, the molecular chains solidify into new shapes. The type of polymer and arrangement of bonds dictate flexibility, adaptability, elasticity, and clarity of the material. Materials used in the oral cavity must be biocompatible. Biocompatibility incorporates the following: inert, non-toxic, odorless, tasteless, remain unaffected by body chemicals and have minimal water absorption (Tuncay, 2006). Along with biocompatibility, an ideal orthodontic material will also contain the following desirable properties: large spring back, low stiffness, good formability, thermostability, high stored energy and environmentally stable (Kwon, Lee, Lim and Lim, 2008, p. 231). At the current time, there is no known material with all of the ideal properties. Clarity of RTAs is a valuable property for optimal esthetics. The crystalline structure of the thermoplastic dictates the clarity. Amorphous plastics are clear and allow visible light to pass through the polymer chains. Crystalline plastics contain a mixture of both amorphous and crystalline polymers each with different refractive indexes making the material opaque (Ryokawa, et al., 2006, p. 69). The mechanical properties of thermoplastic materials may also be influenced by environmental factors such as temperature, humidity, and pressure.

Clinicians must decide the appropriate thermoplastic to use for each type of tooth movement. Difficulty moving teeth occurs when the aligner cannot grasp the tooth either due to poor adaptability, excess flexibility or decay of mechanical properties over time. Research must still be conducted to determine which material types are indicated for particular tooth movements. Several common thermoplastic materials and properties are listed in the following table.

Table 2.1

Material Name	Polymer	Thicknesses	Manufacturer	Translucency
Invisacryl A	Copolyester	0.75 and 1mm	Great Lakes Orthodontics	Clear
Invisacryl C	Polypropylene	0.75 and 1mm	Great Lakes Orthodontics	Opaque
Essix A+	Copolyester	1mm(0.040)	Raintree Essix	Clear
Essix C+	Polypropylene/ethylene	1mm(0.040)	Raintree Essix	Opaque
Bioplast	Ethylene-Vinyl Acetate	0.75 and 1mm	Scheu-Dental	Opaque
Copyplast	Polyethylene	1mm	Scheu-Dental	Opaque
Hardcast	Polypropylene	0.8mm	Scheu-Dental	Opaque
Duran	Polyethylene terepthalate glycol	1mm	Scheu-Dental	Clear
Imprelon "S"	Polycarbonate	0.75mm	Scheu-Dental	Clear
Invisalign	Polyurethane from Methylene dipheynl diisocyanate	0.75mm (0.030 in.)	Align Technology Inc.	Clear

Material Name	Water Absorption	Thickness change	Elastic Modulus	Tensile Yield Stress
Invisacryl A	Similar to A+	Similar to A+	Similar to A+	Similar to A+
Invisacryl C	Similar to C+	Similar to C+	Similar to C+	Similar to C+
Essix A+	0.8 wt%	0.2mm	550 MPa	45 MPa
Essix C+	0.1 wt%	0.1mm	450 MPa	27 MPa
Bioplast	0.22 wt %	0.1mm	25 MPa	5 MPa
Copyplast	Lowest (0.03 wt %)	0.2mm	175 MPa	10 MPa
Hardcast	0.1 wt%	0.05mm	425 MPa	25 MPa
Duran	0.8 wt%	0.15mm	500 MPa	45 MPa
Imprelon "S"	0.35 wt%	0.1mm	625 MPa	55 MPa
Invisalign	Highest (1.5 wt%)	0.1mm	425 MPa	48 MPa

Material in this table from Ryokawa et.al, 2006 and Gardner,Dunn and Taloumis, 2003

Thickness changes, Elastic modulus and tensile yeild strength are post thermoformed

Due to same material polymer the numbers for Invisacryl A will be similar to Essix A+ and those for Invisacryl C will be similar to Essix C+

Stress-Strain Properties of Thermoplastics

Thermoplastics must generate and retain force through material deflection in order to create tooth movement. The extent of aligner deflection or displacement depends upon the intrinsic material stiffness and may be defined by the stress-strain property of the material. The stress-strain properties of a material determine the force levels, deformation, yield strength and elasticity (stiffness) of a material. Stress of a material in a given direction is determined by the load (force) divided by the area (S = Load/Area). Strain is a measure of how far apart the atoms in a solid are being pulled apart through the stretching of bonds. Strain on thermoplastic materials occurs under tension, bending and torsion. A stress-strain curve for each thermoplastic material plots the reaction of the material under one type of deformation. Figure 2.2 shows a typical stress-strain curve for a thermoplastic under tension.

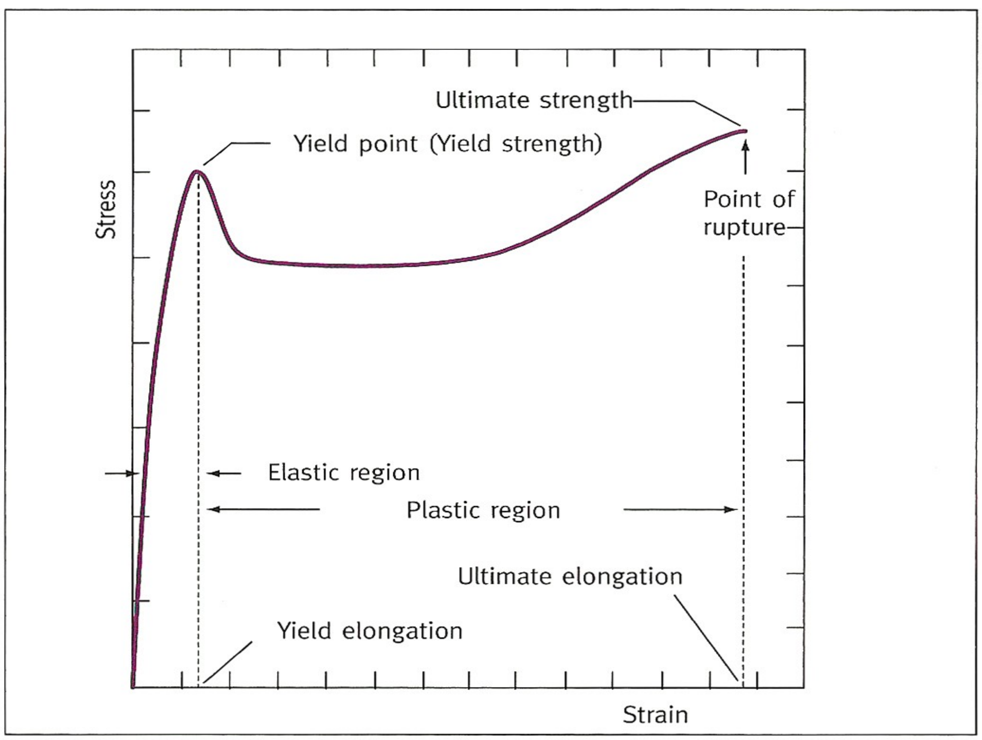


Figure 2.2 Stress-Strain Curve for Thermoplastic Material
(from Tuncay, 2006, p. 179, Quintessence Publishing)

The elastic region represents where the material exhibits linear behavior. The material will deflect and return to original size and shape upon removal of the stress. Once the material deformation reaches the yeild strength, plastic (permanent) deformation begins to occur and the material will not return to its original size and shape. Going beyond the elastic limit of the RTA will have an adverse effect on obtaining the prescribed amount of tooth movement. The modulus (modulus of elasticity or Young's modulus) is the most important characteristics of thermoformed plastics. Elastic modulus (E) is the measure of stiffness for a material. The formula for E is as follows: stress = E(strain). In reference to the figure 2.2, E is the slope of line bewteen zero and the yield point. Higher modulus (increased stiffness) will have a steeper slope. RTA stiffness provides aligner retention and force. A high modulus thermoplastic will have increased potential for tooth movement but may be difficult for the patient to insert and remove. Conversely, a material with a low modulus will be easy to remove and place, but will not have enough force to provide accurate tooth movement.

The ultimate tensile strength is the point on the stress-strain plot where the material can not withstand further deformation resulting in fracture. Aligner placement and intrinsic programmed tooth movement should not force an RTA past the yeild strength and never reach the tensile strength of a material. In cases where a patient has a history of bruxism or the properties of the aligner material have been altered, these limits may be reached and aligers may fracture.

Figure 2.3 compares the stress-strain curve for Invisalign's EX30 material to those stainless steel and Nitinol archwires. Both types of wires have a larger E value and as a result are stiffer than thermoplastics (Tuncay, 2006, pp. 179-190).

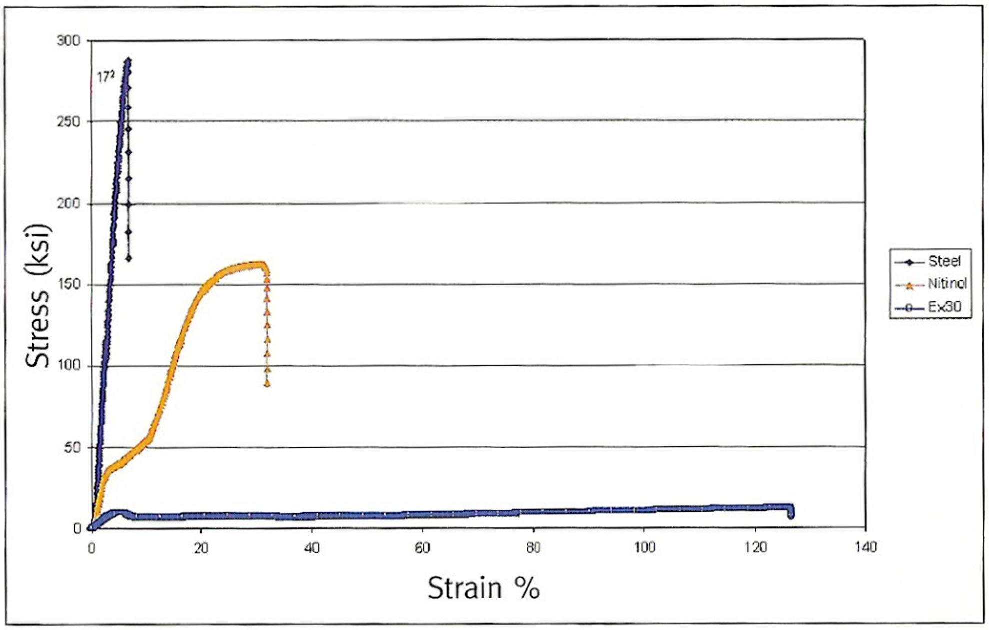


Figure 2.3 Comparison of Thermoplastic to Stainless Steel and Nitinol
(from Tuncay, 2006, p. 189, Quintessence Publishing)

Alteration of Thermoplastic Material Properties

Thermoplastic material propertied may be altered by: changing thickness, material decay in an oral environment, and material wear over time.

A change in thickness of a thermoplastic material will alter the stress-strain properties of the material. Hahn, Dathe, et al. (2009) used two thermoplastic materials and found that increasing the thickness of the material increased the amount of force placed by the aligner (p. 12.e7). Increasing the thickness of Invisalign's polyurethane materal from EX30 (0.030 mil, about 0.75mm) to EX40 (0.040 mil, about 1mm) increased the stiffness by 1/3. The increase in stiffness of a polyurethane material translated into an approximate force increase of 1/3. Figure 2.4 shows the stress-strain curve for EX30 and EX40. (Tuncay, 2006, p. 190).

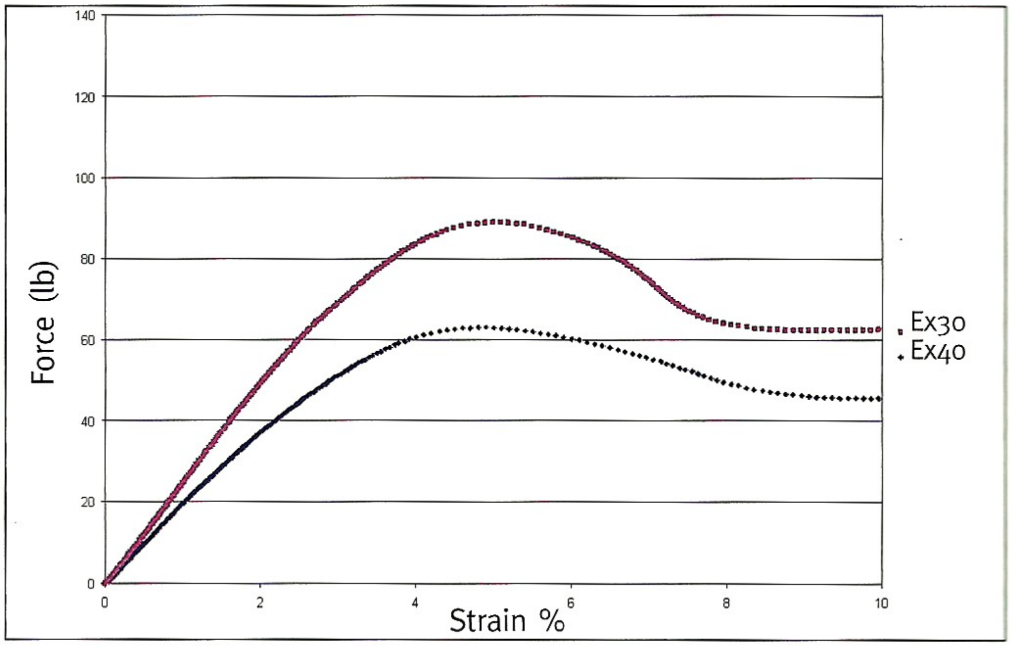


Figure 2.4 Stress-Strain Comparison due to Thickness Change
(from Tuncay, 2006, p.190, Quintessence Publishing)

Flexibility of the material affects both the local deformation where the tooth and aligner touch and allows bowing of the aligner body away from the natural undercuts of the teeth. Increasing material thickness decreases local and bodily aligner deformation increasing tooth to aligner contact areas. Several studies evaluated effectiveness of aligner thickness on case finish and found minor improvement in case control. These studies used a thicker material as every fifth aligner, as the final five aligners only or as retention only. Studies have not been conducted using a stiffer material throughout treatment to evaluate final results (Tuncay, 2006, p. 190).

Jones, Mah and O'Toole (2009) noted that as the thermoforming process drapes over the model the material thins especially in the gingival regions (p.116). Zhang, Zhang, Ren, Zhou, and Qi (2010) also noted the same changes in thickness due to thermoforming process (p. 91). The change in thickness results in increased flexiblity near the gingival margins. Decreasing the thickness of a thermoplastic material decreases the yeild strength and tensile strength allowing for easier deformation and increased risk of fracture. Aligner thickness and material properties need to be adjusted over the course of treatment to obtain a desired and predictable outcome.

Intraoral environmental changes can alter the certain properties of thermoplastic materials. Thermoplastics may be sensitive to changes in tempertature and absorption of water. Ryokawa, et al. (2006) found that amorphous (clear) plastics had an increased elastic modulus and increased water absorption when exposed to the oral environment. They also noted that temperature changes from room temp to body temperature had minimal influence on the mechanical properties or amorphous thermoplastics. Alterations in dimesion due to water aborbed expansion decrease the fit and adaptation of an aligner. These changes result in decreased control of forces and tooth movement. Polyurethane (EX30) has the highest amount of water absorption while Essix C+ and Invisacryl C had the least. Rykawa, et al. also noted that crystalline (cloudy) plastics had a lower elastic modulus (more flexible), decreased amount of water absorption and changes in temperature from extra to intraoral have an increased effect on mechanical properties. Understanding the resultant changes in an oral enviroment is key to deciding the correct material type for each application.

Material wear during fabrication and use alters the mechanical properties of the aligner. The thermoforming process alters the polymer organization resulting in a shrinkage of the material. Shrinkage rates after thermoforming vary between materials and are not directly correlated to initial thickness. Post thermoforming thickness is directly related to heating temperature, melting temperature, heating time and molecular weight of the polymer. Crystalline plastics (except Essix C+) exhibit a decrease in yield strength and elastic modulus after thermoforming. Amorphous plastics (except polyurethane) exhibit a reduction in tensile yield stress, but an increase in elastic modulus. The reduction of yield strength for both plastic types is the result of polymer reorganization. The new polymer arrangement stores residual bond distention after a load is placed promoting fatigue and stress upon relaxation lowering the tensile strength. Essix C+ contains a stabilizer in the composition of the plastic preventing polymer reorganization during heating. Stabilization minimizes changes in material properties (shrinkage, reduction in molecular weight, polymer reorganization) observed from pre to post thermoforming (Ryokawa, et al., 2006, p. 70) . Conversely, Kwon, Lee, Lim and Lim (2008) found that thermoforming had no statistically significant effect on the influence of delivered forces when the deflection was between 0.25 to 0.75mm. But at higher ranges of deflection, the differences in force between pre and post thermocycling tests was statistically significant.

Material wear as a result of daily use can occur in three ways: sliding/adhesive wear, fatigue/age wear and wear due to corrosion. Most sliding wear occurs during initial placement and removal of the aligner. Aligner/tooth contact occurs at high points (projections) between the surfaces. As the materials slide along each other, the high areas wear altering the size and location of the tooth/aligner contact points. Changes in contact points alter location and direction of forces. Sliding/adhesive wear also occurs if aligners are worn during mastication or nocturnal bruxing events. Displacement and warping of aligners allows intraoral particles between the aligner and tooth structure. The particles move when the aligner material is repetitively displaced abraiding the tooth/aligner contact areas.

Fatigue/age wear of a RTA is the result of repeated stress near the elastic limit of a thermoplastic material. The natural bonds within the material begin to fail and the material weakens. (Gardner, Dunn and Taloumis, 2003, p. 296). Eliades and Bourauel (2005) noted an age-induced increase in hardness of RTA material. This hardness can be attributed to surface modification of intraorally deposited material and cold working of the material during mastication (p.410). A pressure film study showed the age/fatigue and intraoral use for two weeks lead to an exponential decrease in force from intial placement to last wear of the RTA. Microscopic evaluation of the tested aligners revealed distortion, cracking, wear of contact points and a calcified protein biofilm on the aligners. These changes in the material directly affect the material's stress-strain properties (Barbagallo, et.al, 2005, pp. 335-341).

Corrosion induced from cleansers (except oral rinses and peroxide) and ingested fluids chemically wear thermoplastic materials. Oral rinses and peroxide have no effect on the overall tensile strength of aligner materials (Pascual, et al. 2010). Abrasive particles in toothpastes used to clean aligners abrade the aligner surface altering the thickness. Acidic or basic beverages ingested while aligners are in place may also corrode surfaces of the aligners resulting in thinning of the material. Alcohol plasticizers, certain polymers, and water cause leaching of filler and degradation of the plastic. Microorganisms that produce esterases degrade polymers reducing the durability of the material (Gardner, Dunn and Taloumis, 2003, p. 296). The exact mechanism and overall effects on aligners from ingested fluids and food remnants has not been directly evaluated, but possible alternation of aligner properties may exist.

Understanding the advantages and disadvantages of each individual material is a key factor in the effective use of RTAs. Knowing alterations in material structure due to the oral environment and the resultant effects on the forces placed can be used to increase the accuracy of predicted tooth movement and provide the basis for case limitation for successful orthodontic treatment with RTAs.

Tooth Movement and Forces with RTAs

The essential elements required for orthodontic tooth movement are force, space and time. An orthodontic system needs adequate force to move the teeth without inducing a pathological response, adequate space to accomplish the desired tooth movement and enough time for the force to be effective. Tooth movement will not occur without all three of these elements. Prior to understanding tooth movement limitations of aligners a knowledge of orthodontic movement is required.

Orthodontic Tooth Movement

There are several types of tooth movements. The following is a list of orthodontic tooth movements: tipping, bodily (translation), rotational, torque, extrusive and intrusive. Uncontrolled tipping occurs when a single force is placed against the crown of a tooth causing the crown of the tooth to rotate in the direction of the force and the root to rotate in the opposite direction (Figure 2.5). This is the simplest orthodontic tooth movement. Controlled tipping occurs when the crown rotates in the direction of the force but the root apex does not move (Nanda, 2005, p. 6) (Figure 2.6). Tipping can occur in a buccal-lingual or mesial-distal directions. Uncontrolled tipping is the easiest tooth movement to achieve with RTAs. Tipping movement is programmed into the aligner by resetting teeth into a better position prior to aligner fabrication. This allows both space for movement and force for movement. The Hilliard thermoforming plier can be used to create a dimple in the aligner to place a tipping force or a composite mound can be placed on the tooth to create force without resetting the teeth, but a window must be cut into the aligner to allow space for tooth movement.

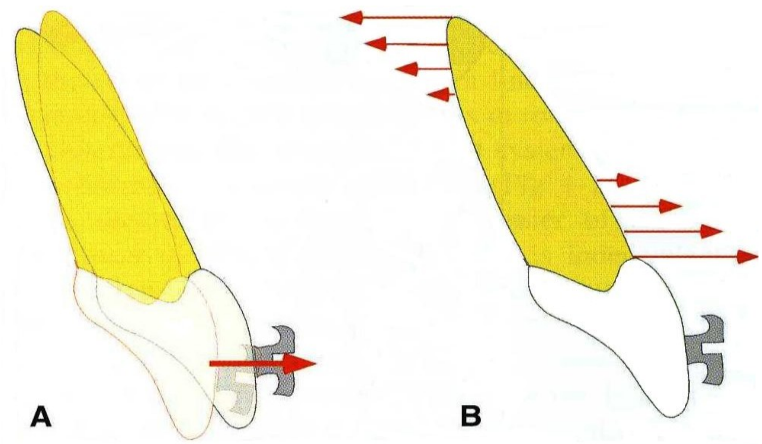


Figure 2.5 Uncontrolled Tipping; A- Force direction and location; B- Movement direction and amount (from Nanda, 2005, p. 6, Elsevier Publishing)

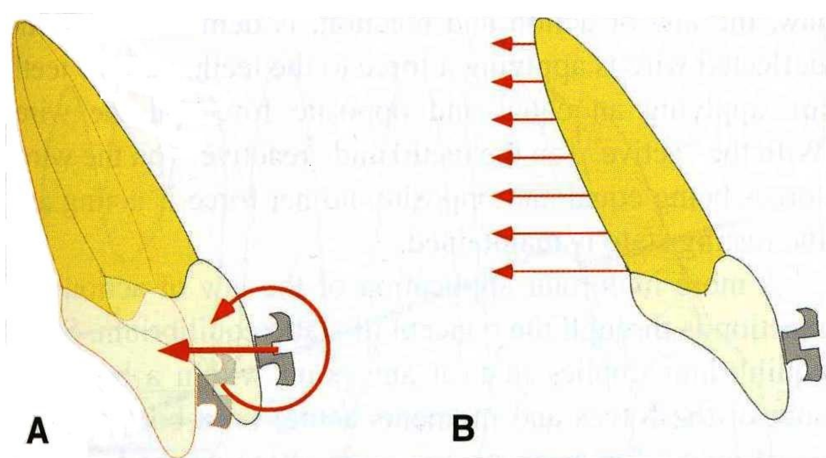


Figure 2.6 Controlled Tipping; A- Force direction and location with couple; B- Movement direction and amount (from Nanda , 2005, p. 7, Elsevier Publishing)

Bodily (translation) movement occurs when the crown and root apex of a tooth move the same distance in the same horizontal direction (Nanda, 2005, p. 7). Translation allows a tooth to slide into a space without tipping. Translation requires equal amounts of force at the incisal and apical portions of the tooth (Figure 2.7). Pure translational movement is impossible to accomplish using RTAs due to the variation in force levels going from incisal to gingival. Physical gradient properties of aligners allow for increased force at the incisal and less near gingival resulting in tipping not translation (Brezniak, 2008, p. 381). Closing large spaces such as extraction spaces requires translation and/or controlled tipping and is very difficult to complete with RTAs even with utilization of auxilliaries and elastics.

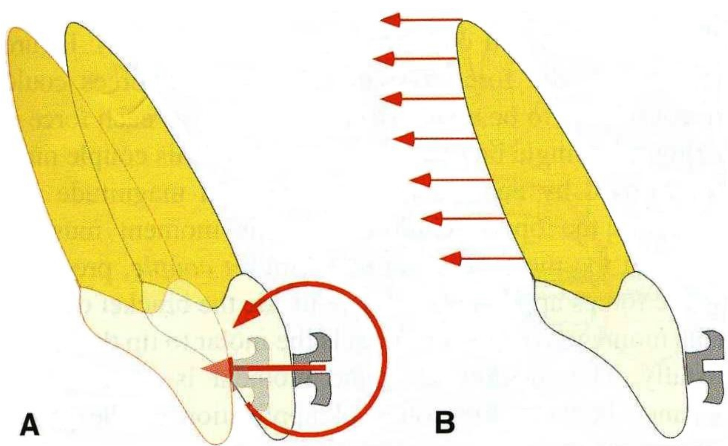


Figure 2.7 Translational Movement; A- Force direction and location; B- Movement direction and amount (from Nanda , 2005, p. 7, Elsevier Publishing)

Torque (root movement) is created by changing the axial inclination of a tooth by moving the root apex and holding the crown stationary (Nanda, 2005, p.7) (Figure 2.8). Torque is created in fixed appliances by creating a couple within the bracket. RTAs require a force to be placed in one direction at the incisal edge and a stronger force placed at the gingival margin in the opposite direction to create the couple (Figure 2.9). The force gradient in aligners makes this movement impossible and uncontrolled tipping is result from attempted torque movements (Tuncay, 2006, p. 17).

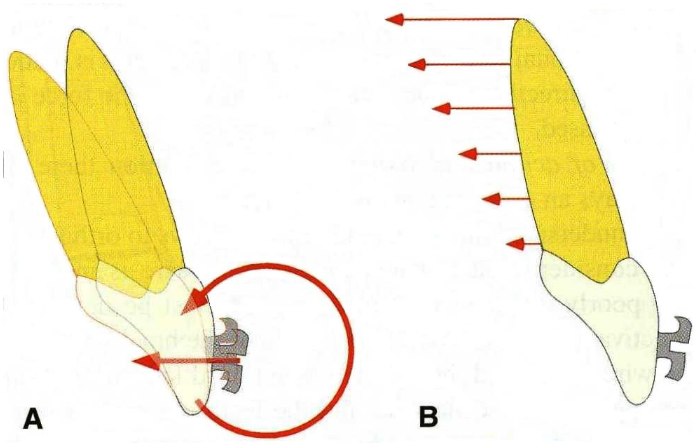


Figure 2.8 Torque (Root Movement); A- Force direction and location with couple; B- Movement direction and amount (from Nanda , 2005, p. 7, Elsevier Publishing)

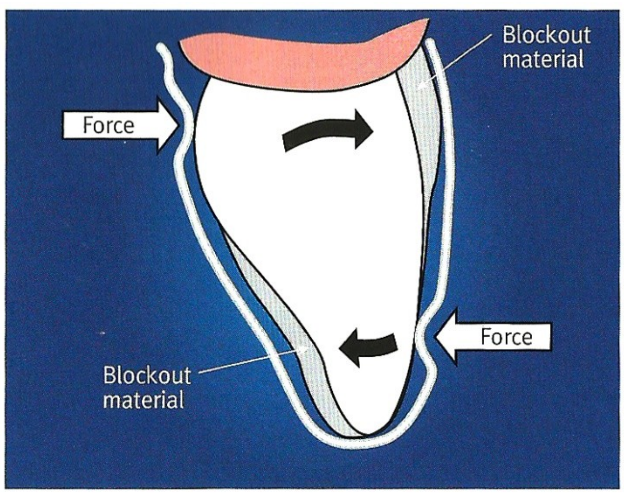


Figure 2.9 Aligner set up using block out material and dimple to create torque (from Tuncay, 2006, p.18, Quintessence Publishing)

Orthodontic rotational movement is referenced from an occlusal perspective and occurs along the long axis of the tooth. Rotation requires placement of forces of equal value at both the mesial and distal with one force directed to the buccal and another directed toward the lingual (Nanda, 2005, pp. 7-8) (Figure 2.10). Rotational movements are common with RTAs. In most cases, space must be created prior to attempting rotational movements. Ipsilateral rotational movements can also be achived with RTAs. This requires a unilateral force to be placed on one side while the other side is held motionless.

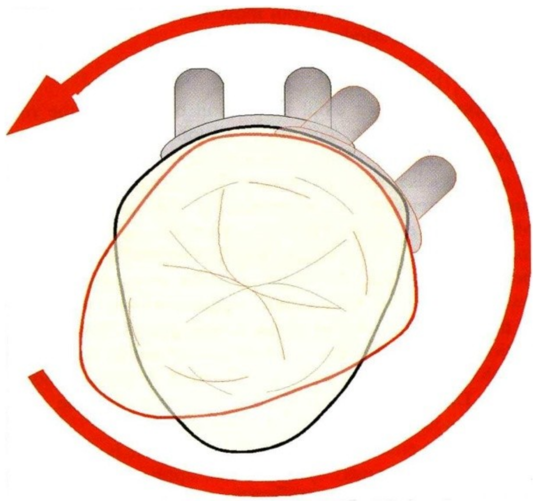


Figure 2.10 Rotational Movement (from Nanda, 2005, p. 8, Elsevier Publishing)

Extrusion is forced eruption of the tooth out of the socket toward the occlusal plane. Extrusion movements are difficult with RTAs due to excess flexibility near the gingival margins. Extrusion by natural eruption may occur with RTAs if space is blocked out on the model. Extrusion can also be accomplished using RTAs as a base for an elastic attachment to the tooth and the elastic provides the extrusive force. Material deformation of the aligner due to forces from elastics may result in unwanted/unpredicted tooth movements. A thick aligner, with maximum ginigval adaptation, minimial flexibility and maximum retention on the arch is needed.

Orthodontic intrusion is forced impaction of the tooth into the bony socket away from the occlusal plane. Pure intrusive movements are nearly impossible and highly unpredicatable with RTAs unless an auxillary elastic is used with the RTA serving as a base (Tuncay, 2006, pp 18-21).

The biological response of orthodontic movement begins when force displaces the tooth within the socket constricting blood vessels inside the periodontal ligament. The constriction of vessels triggers an inflammatory response to initiate bone remodeling. Complete occlusion of the blood vessels results in a hyalinization of the periodontal ligament and an undermining resorption of the bone due to the lack of blood flow. Both of these events can slow down tooth movement. Forces that intiate tooth movement need to be strong enough to collapse the blood vessels but remain light enough to minimize hyalinzation of the periodontal lingament. Ideal orthodontic forces vary among individuals and among teeth within an individual. As a result, some hyalinization and undermining resorption occurs in every case. Aligner must create and maintain enough force to promote tooth movement. Initial aligner forces will be higher but as tooth movement occurs and the aligner wears and fatigues the force levels will drop.

Forces with Removable Thermoformed Aligners

Orthodontic appliances can create three types of force: continuous, interrupted and intermittent. Continuous force is a force that is maintained over the entire duration. The force level may decrease over time but a force is constantly present. Interrupted force levels drop to zero between activations. Intermittent forces occur with removable appliances. Force levels drop to zero when the appliance is removed but return when the appliance is replaced (Tuncay, 2006, p. 209). Interrupted forces pose problems for tooth movement. When the force levels approach zero, there will not be enough force to initiate tooth movement. The exact amount of time no tooth movement occurs is unknown, will vary among individuals and may last for several days. Force levels not strong enough to oppose periodontal ligament fibers can allow these fibers to pull the tooth back towards its intial position resulting in relapse. Therefore, ideal orthodontic forces are described as light continous forces. Light cyclic (intermittent) forces for 16-20 hours per day has been shown to be as effective in obtaining tooth movement as light continous forces (Tuncay, 2006, p.208). 4-8 hours without force is not enough of a duration to allow cessation of the inflammatory response and bone remodeling can still occur when the appliance is not in place. In cases with optimal patient compliance, the appliance is not inactive for one 4-8 hour span per day, but rather a one hour span six to eight times during the day. This short duration is definitely not long enough to allow the bone remodeling process to stop. Aligners must have a continuous force when in place to ensure tooth movement.

Forces are generated in a removable thermoformed aligner when the resilient thermoplastic returns to its original state after distention. Aligners exhibit a local deformation at the contact point with the tooth, and friction in the molars causes vertical distention bowing the aligner away from the teeth (Hahn, et al., 2009, p. 12.e6). Most aligners can have 0.25-0.75mm of local distention before permanent deformation begins. Force response of a displaced aligner depends on the internal properties of the material and aligner geometry (thickness and design) which allow for increased bowing and flexibility. Thin flexible aligners have increased local and vertical distention (Tuncay, 2006, p.82).

Prediction of forces generated by aligners is difficult. Complex aligner shapes make the exact aligner-tooth contact points differ from expected locations. Variations in tooth shape, slipping motions created by vertical distention, and alteration of aligner shape change the location of aligner-tooth contacts. Aligner variations created during thermoforming process also change how the aligner engages the tooth. Variations in the biological response toward tooth movement and the amount of force absorbed by the periodontal ligment will vary between patients and among individual teeth. All of the above combine to make predicting force direction and magnitude of RTAs difficult.

Proffit (2007) noted that the optimal force needed for the individual tooth movements are as follows: tipping 35-60 grams (approx. 0.35-0.60 Newtons); translation 70-120 gms (0.70-1.20 N); rotational 35-60 gms (0.35-0.60 N); torque (root uprighting) 50-100 gms (0.50-1.0 N); extrusion 35-60 gms (0.35-0.60 N); and intrusion 10-20 gms (0.10-0.20 N) (p. 340). Kwon, et al. (2008) found that Essix A+ 1mm in thickness could generate 129 grams (1.2 N) of force with 0.25mm deflection and 336 gms (3.3 N) at 0.50mm deflection. Essix A+ with a thickness of 0.75mm produced 72 gms (0.7 N) of force at 0.25mm deflection and 169 gms (1.6 N) at 0.50mm. They also noted that Essix C+ with 1mm thickness had 16 gms (0.16 N) at 0.25mm and 118 gms (1.1 N) at 0.50mm deflection (p.231). Upon immediate inspection, Essix A+ at 1 and 0.75mm and Essix C+ at 1mm generate forces in the ideal range for tooth movement and Essix A+ in both sizes would generate more than ideal force. The problem is this study did not take into account thickness changes and property changes that occur during thermoforming and also force absorbed by the periodontal ligment and bone. Align Technology only allows for 0.25 to 0.33mm of tooth movement during each resetting (Kwon, Lee, Lim and Lim, 2008, p.228). Maximal deflection in these cases is 0.33mm and after 0.1mm of tooth movement deflection is now 0.20 mm and force levels on Essix C+ drop below those needed for tooth movement. Kwon, Lee, Lim and Lim (2008). also found in their study that Essix A+ at 0.75mm thickness with 0.20mm deflection had a force of 55 gms (0.5 N) with a standard deviation of 26.8 gms (p.231). At best, the force generated at 0.20 mm deflection with Essix A+ at 0.75mm thickness is 80 gms and may be as little as 20 gms, which is not enough for tooth movement. Once the material is thermoformed and the material modulus alters, the thickness decreases (especially at the gingival margin) and the tooth supporting structures absorb force, many thermoforming materials do not generate enough force to move teeth beyond 0.1 to 0.15mm if the initial reset/displacement is 0.25 to 0.33mm. With the properties of Invisalign's EX30 near those of 0.75mm thick Essix A+, in many cases there may not be enough force for continuous tooth movement once the teeth begin to move. Raintree Essix recommends tooth movement during resetting to be 0.5 to 1.0mm to account for displacement of force by periodontum and decay of force due to tooth movement and material fatigue (Kwon, Lee, Lim and Lim., 2008, p.228). Increasing the reset distance will increase displacement and force and help overcome the decreases in force created by thermoforming and the peridontum. More research needs to be completed to validate this theory.

Orthodontic Tooth Lag

Orthodontic tooth lag is the difference between actual tooth position and planned tooth position after an aligner is used. The combination of complex force loads and directions, variable periodontal responses, material insuffficency and material modulus result in orthodontic tooth lag. Each stage of tooth movement in a sequence of aligners will exhibit lag. Tuncay (2006) expects clinical tooth movement to be 80% of that expected by ClinCheck (p. 131). Aligners generated in a sequence from expected tooth positions will no correspond to the predetermined locations once tooth lag occurs. If a tooth is out of it's expected position when a new aligner is placed, this creates a new unpredicted force dynamic potentially causing unexpected tooth movement, further delay in desired tooth movement or the new aligner may not fit at all.

Several methods exhist for decreasing tooth lag. The first is to decrease material flexibility. Increased stiffness equates to an overall increase in force magnitude, less increased retetion and less material flex around the contact points. Increased thickness, material selection, and aligner design are all ways to help increase stiffness. A second method is to attempt to maintain material thickness from incisal to gingival and minimize the amount the material thins during thermoforming. Removing extra base from the model and heating only to the necessary temperature to ensure adequate model adaptation can help reduce thinning.

A third method involves taking new impressions after every aligner and reseting the teeth from the current positions. Tooth lag is not a concern since there is not an expected tooth position and the next aligner is fabricated from the current tooth positions. This method is time consuming and not practicle for most orthodontic practices. Advancements in digital impressions and stereolithographic carving of models from these digital images may make this the preferred method for thermoplastic treatment in the future. A fourth method is overcorrection. Some tooth lag can be accomodated for by overcorrection of tooth position during resetting. Overcorrection can be accomplished by resetting teeth beyond the ideal final position. This process is not predictable due to difficulty in predicting how much overcorrection is needed. Another method involves resetting teeth for a movement of 0.5 to 1.0mm but only expect movement to be 0.25-0.33mm. This method accounts for tooth lag and will help reduce observed tooth lag, but is not predictable. A sixth method alters aligners using Hilliard thermoforming pliers to create dimples in the aligner or placement bonded composite mounds on the teeth to create a local force on a tooth allowing for increased tooth movement from the current aligner in a sequence (Tuncay, 2006).

A final method currently used to help decrease tooth lag is the use of custom-formed composite attachments. Attachments are various geometric shapes of composite bonded to buccal or lingual surfaces of teeth for the purpose of increasing aligner retention and augmenting tooth movement (Tuncay, 2006, p. 92). The composite material varies in viscosity from flowable to dense/packable. Material viscosity is a preference of the clinician, but the attachment must retain its shape throughout treatment with the aligner being placed and removed thousands of times. Therefore, a composite with an increased density will have an increased hardness and resist wear.

There are three primary functions for attachments. Attachments can assist movement, augment retention and support auxiliary function. Bonded attachments increase retention and surface contact on teeth with short clinical crowns, no undercuts and/or a tooth size to shape discrepency (Tuncay, 2006, p. 80). Attachments allow for greater chance of movement on these teeth as well as help prevent vertical lifting (bowing) of the aligner. Bonded attachments on teeth can serve as anchors (hooks) for auxiliary elastics, springs or other appliances to help with tooth movement (such as extrusion, or anterior posterior correction). They assist movement by providing a predictable contact point and force direction. When attachments are used to augment movement, more local deformation is needed and the amount of desired tooth movement must be minimal. Attachments can indirectly assist movement by providing friction on adjacent teeth to prevent vertical lift.

Variations is attachment size, shape and position on the tooth can influence aligner retention. Jones, Mah and O'Toole (2009) found that a vertically oriented rectangular shape attachment placed in the gingival 1/3 of the tooth had the greatest retention during pull off tests (17 N). The least retentive is any shape or design of attachment that was placed in the incisal 1/3 (average force of 2.5-4 N). This is contradictory to initial thought regarding the force gradient decreasing on the aligner from occlusal to gingival. Under this theory, the most retentive should be near the incisal edge where the aligner is thicker and less flexible. Jones, Mah and O'Toole believe that as the aligner follows the contour of the tooth towards the gingival there is an increase in retentive undercuts resulting in an increase in overall retention (p.116). A well fit and well retained aligner will have an increased opportunity for tooth movement.

Creating Space for Tooth Movement with RTAs

The second crucial element for tooth movement is space. In order for a tooth to move, a space must exist for the tooth to move into. Space must be present both within the dental arch and within the aligner. Space within the appliance is created by blocking out the space on the cast, resetting teeth into the new position or by cutting a window in the thermoformed appliance where the tooth is predicted to move.

Space is created within a dental arch either by expanding the arch, extracting teeth or reducing tooth size. Extraction is not an advised approach for creating space when using RTAs. As described before, it is very difficult to get translative movement and root uprighting with RTAs. Both movements are needed to close extraction spaces.

Expansion of arches with RTAs is possible by flaring (tipping) the teeth buccally. Tipping movements are among the easiest movements achieved with RTAs. Achieving arch coordination and the liability of tipping the teeth buccally beyond the envelope of the aveolar ridge are two negative aspects to arch expansion. Both coordination and bone support are key components in maintaining orthodontic correction after active treatment is complete. Expansion is not indicated in cases where a patients chief complaint is centered around anterior crowding of one arch, since arch coordination can not be achieved.

Interproximal reduction (IPR) is the primary method to obtain space in RTA cases. IPR is the reduction of tooth size on a malaligned tooth and adjacent teeth to create space for alignment. IPR is completed by several methods. Minor amounts of reduction may be completed using abrasive strips. This method is very laborious and time consuming and should only be used for minor amounts of reduction or to smooth a tooth surface. Another method involves using handpiece mounted reduction disks. This method is effective for enamel removal but can easily induce trauma to the gingiva, tongue and cheeks. The most effective method includes the use of a handpiece and burr. Several systems are available with variances amoung burr shapes, sizes and types and differences in handpieces and available movements. IPR in anterior contacts should be limited to approximately 0.75mm between teeth (0.37mm on each tooth) and 1mm for posterior contact points. Estimations in enamel thickness range from 1.5 to 3mm, so a reduction of 0.5mm will leave acceptable enamel thickness. Reduction can be measured using finger gauges in 0.1mm increments (Tuncay, 2006, pp. 12-14). After IPR, recontouring of the surfaces to resemble natural morphology and polishing with a fluoride pumice or prescribing and fluoride gel or toothpaste is necessary to remineralize and strengthen reduced enamel. Most moderate to severe crowding RTA cases will use a combination of IPR and expansion to create needed space.

Time Needed for Tooth Movement with RTAs

The third critical element for tooth movement is time. Bollen, et al. (2003) found that two week activation times led to a higher degree of success for tooth movement when compared to a one week activation time. Success in this study is limited as only 15 of 51 subjects completed the initial series of aligners and all treatment subjects had either an additional series of refinement aligners or fixed appliances to finish treatment (p.500). Studies have not been conducted to evaluate two versus three or four week activation time per aligner. Affects on aligner material due to the oral enviroment, cleaning and repeated loading and unloading will limit the overall effective life expectancy of an aligner (Kwon, Lee, Lim and Lim, 2008). Variations in oral environment, cleaning habits and average times aligner is removed per day will vary with each patient. The biological responses associated with tooth movement vary among individuals and among individual teeth. In all cases, it is necessary for the clinician to determine ideal time for each aligner based on observed tooth movement, patient compliance and physical wear of aligners. Aligner activation times will be different for each patient and may vary during patient treatment. Typical activation times for an aligner ranges from 2 to 4 weeks.

When to Use RTAs: Case Selection

As stated before, Bollen, et al. (2003) found that only 29% of their cases completed the initial series of aligners and all of their cases needed refinement aligners or fixed appliances to finish treatment (p. 500). Many of the failures associated with removable thermoformed aligner treatment are due to clinical error in attempting to correct a malocclusion beyond the limits of RTAs. It is important to choose RTA cases with motivated and compliant patients. To help prevent failures with RTA treatment, limitations must be understood and cases must be selected accordingly. After evaluation of the literature, selection criteria is listed as the following.

1- Adult patients: motivated and compliant with instructions
2- Mild, non-skeletal malocclusions
3- Anterior-posterior discrepency of 2mm or less
4- Crowding or spacing of 5mm or less
5- Rotations less than 20 degrees
6- Tipping less than 45 degrees
7- Centric Relation = Centric Occlusion
8- Minor amounts of Intrusion
9- Mild amount of over bite (treat with simple intrusion or flaring of anterior teeth)

Avoid:

1- Arches with multiple missing teeth (difficult to close space, and there is decreased anchorage for aligner retention)
2- Anterior and Posterior open bite- difficult to extrude teeth and RTAs tend to introduce posterior open bites
3- Extrusive movements
4- Teeth with short clinical crowns- not have ideal undercuts
5- Extraction cases

(Lagravere, and Flores-Mir, 2005, p. 1727), (Phan and Ling, 2007, p. 264) (Kraviz, Kusnoto, BeGole, Obrez and Agran, 2007, p. 28)

RTAs for Post Treatment Retention

Kuncio, Maganzini, Shelton, and Freeman (2007) found that patients treated with Invisalign relapsed more than those treated with conventional fixed appliances after one year. Post treatment retention is a must for all RTA cases. RTA treatment allows for the last aligner in the sequence to serve as the patient's retainer. With Invisalign, post treatment retainers are made from a 1mm thick material and is an additional cost. Studies completed as early as 1993 have shown the effectiveness and versatility for Essix© (Raintree Essix Inc, New Orleans, LA) retainers. Thermoformed retainers are nearly invisible, inexpensive, and are uniquely effective for retention because they encompass all surfaces of the teeth. Full time (24 hour) wear of thermoformed retainers can result in posterior tooth intrusion due to material thickness result in deepening of the patient's bite in the anterior. Hilliard and Sheridan (2000) noted that night time only wear of the appliance during retention period allows for adequate settling of the posterior teeth and prevention of bite deepening (p. 236). Night time wear also removes many of the opportunities for the retainers to become damaged since the retainers are worn at night and placed directly into their protective cases during the daytime. This also limits the number of times the thermoplastic material is subjected to a load cycling of placement and removal increasing longevity of the material.

As with RTAs, thermoplastic retainers should be well adapting and have a decreased flexibility. Tuncay (2006) noted that the material thickness for the final retainer in the Invisalign sequence is 0.04 inch (1mm) to help decrease flexibilty and prevent tooth movement. A well fitting retainer will click onto the teeth when placed and can not be dislodged by the patient. Thermoformed retainers can be quickly adjusted chairside to help increase or decrease fit and also to incorporate minor tooth movements that may occur. Placement of dimples into the aligner or adjustments in the contact areas can be completed using Hilliard thermoforming pliers or acrylic burrs (Hilliard and Sheridan, 2000).

CHAPTER 3

METHODOLOGY

Six PVS impressions were taken of a Kilgore (Kilgore International Inc., Coldwater, MI) upper arch dentaform with no attachments on teeth. The upper first premolars without attachments were removed and replaced with identical premolars with buccal attachments. Attachments are 2mm incisal-cervical by 1.5mm mesial-distal and are located in the cervical third of the tooth. Six PVS impressions were then taken of the model with attachments.

All impressions were poured in Gibraltar® white labstone (Henry Schein, Melville, NY) and trimmed to allow access to margins and to a base thickness of 2mm in the palate. Each of the 12 impressions was poured in stone three times (total of 36 casts). Three RTAs were fabricated from Invisacryl A® (Great Lakes Orthodontics, Tonowanda, New York) for each category (scalloped margins with and without attachments, straight line gingival margin cut at gingival zenith, with attachments and without attachments and straight line gingival margin cut 2mm above gingival zenith, with and without attachments). Also, three aligners were fabricated from Invisacryl C® (Great Lakes

Orthodontics, Tonowanda, New York) using the same categories as Invisacryl A. This allowed for 12 aligner types with different designs and three aligners of each type (36 total aligners).

All models were trimmed flat on the bottom and excess material was trimmed from the buccal vestibule to match the shape of the original typodont. All models were trimmed to the following measurements to standardize model trim. Palatal thickness (thinnest point of palate (14-16mm), bottom to central incisor edge (34-36mm), bottom to MB cusp of second molar (34-36mm). (Figure 3.1 and 3.2).

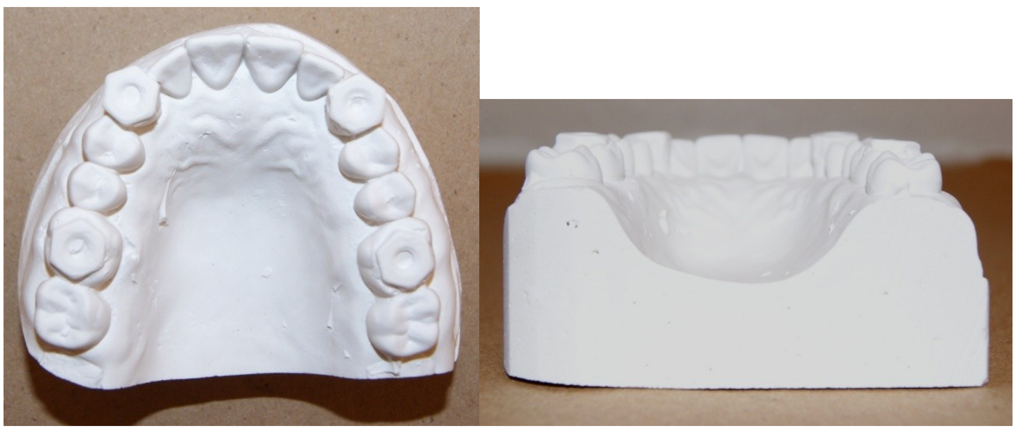


Figure 3.1 and 3.2- Occlusal and Posterior-Anterior view of trimmed model

Thermoforming was completed using a Ministar S® (Scheu-Dental, Iserlohn, Germany) thermoform machine according to manufacturer's specifications for each material type and to a minimum pressure of 3.2 Bar. Aligners were evaluated for adaptation after thermoforming and all aligners with questionable adaptation were discarded and a new aligner of the same specific type was fabricated. Aligner margins (both buccal and lingual) were measured and cut to specifications stated above and polished to remove any rough surfaces. (See flow chart I, Figure 3.3)

Retentive pull off tests were conducted on a Universal Testing Machine (United Calibration Corp. Huntington Beach, CA) with each aligner to evaluate the maximum force needed to remove the aligner from the Kilgore dentoform (Figure 3.4).

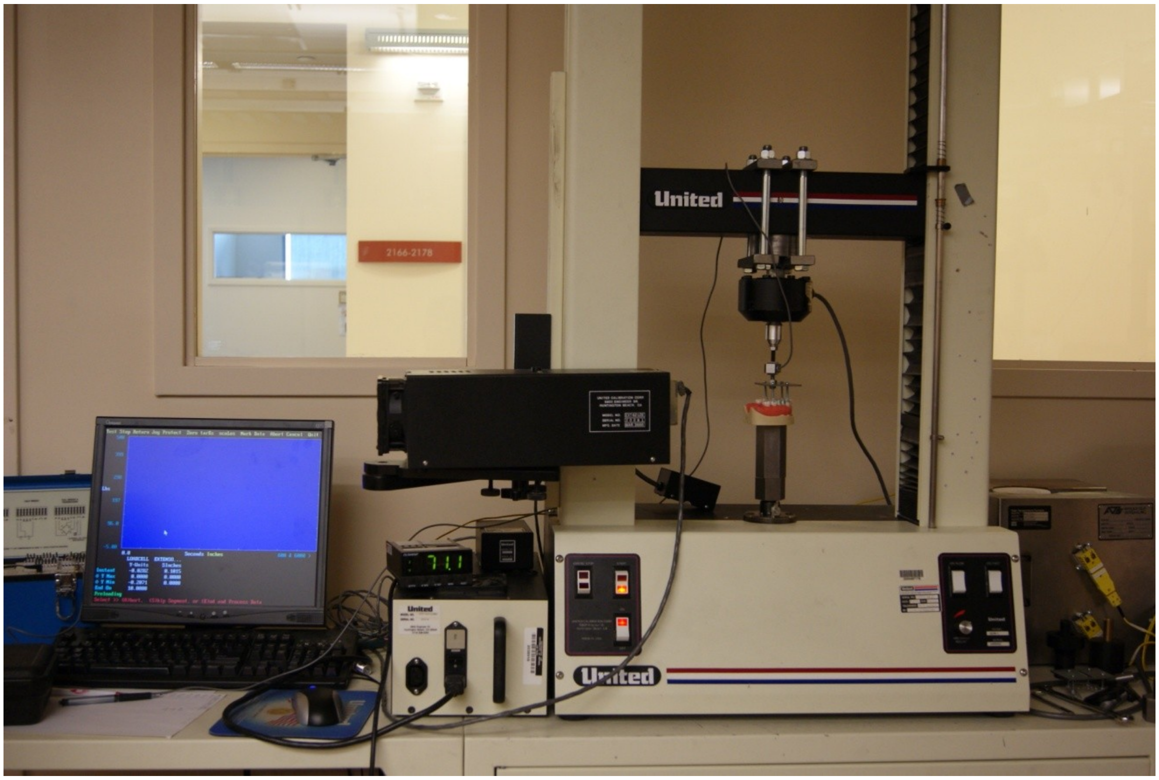


Figure 3.4- Experimental set up using Universal Testing Machine

Pull off direction was perpendicular to occlusal plane and occurred at a rate of 0.25in/minute (Figure 3.5 and 3.6). Aligners were evaluated during testing to ensure pull was constant in anterior and posterior portions of the aligner to standardized pull direction (Figure 3.7 and Figure 3.8).

Figure 3.5 and 3.6- Photos indicating pull off direction and seating of aligners

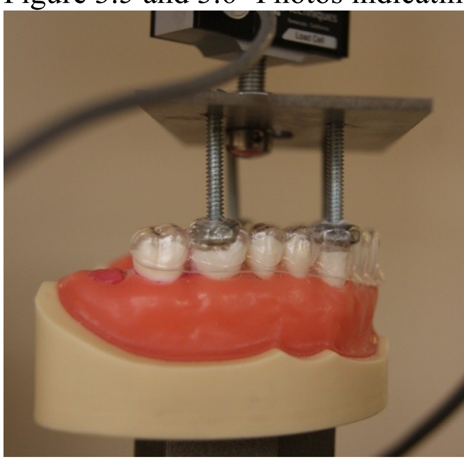
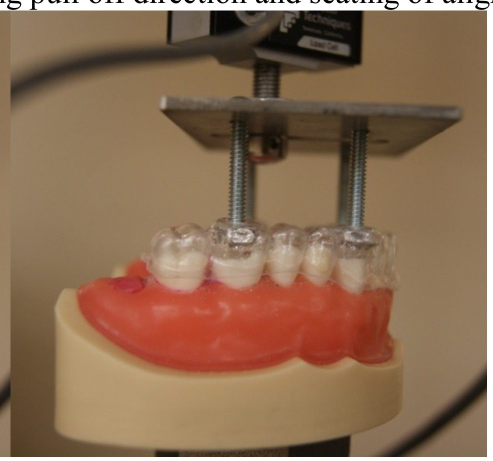



Figure 3.7 and 3.8- Photos indicating vertical pull off consistency in anterior and posterior

All force measurements were completed in pounds (lbs) and recorded into Table 3.1 and Table 3.2 respectively. A 25 lb force sensor (Transducer Techniques, Temecula, California) was used in all tests except for Invisacryl A, straight margins, 0mm and 2mm, with attachments where a 50 lb force sensor was used. The testing was performed 10 times for each of the 36 aligners (3 of each of the 12 types) for a total of 360 tests (Figure 3.9). Prior to testing aligners were rinsed with 70% isopropol alcohol and allowed to dry to remove any oils present inside the aligners from fabrication.

Treatment of the Data

Data was analyzed using a one way ANOVA with Post Hoc Bonferroni test to compare individual types. All 10 tests from each aligner type (ex. 1a, 1b, 1c) were combined yielding 30 total tests per aligner type. An average of these 30 tests was calculated and used to represent each group during statistical testing.

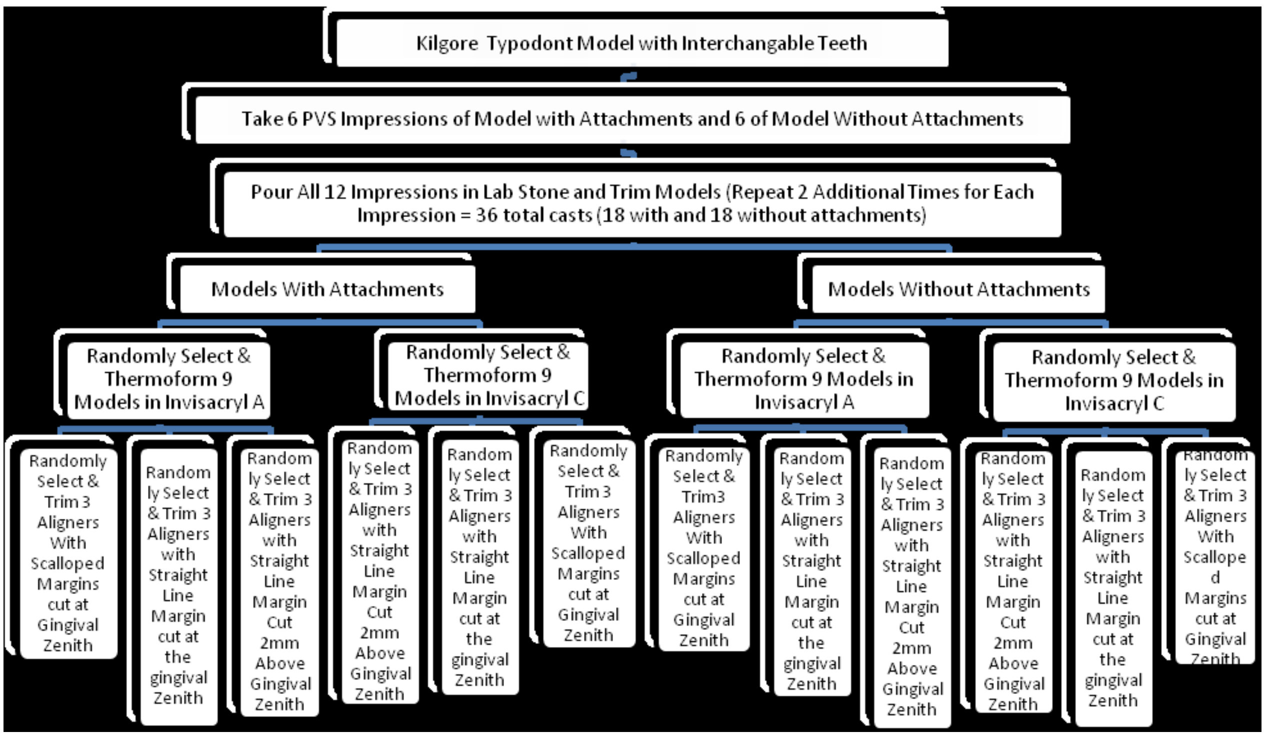


Figure 3.3- Flow Chart 1

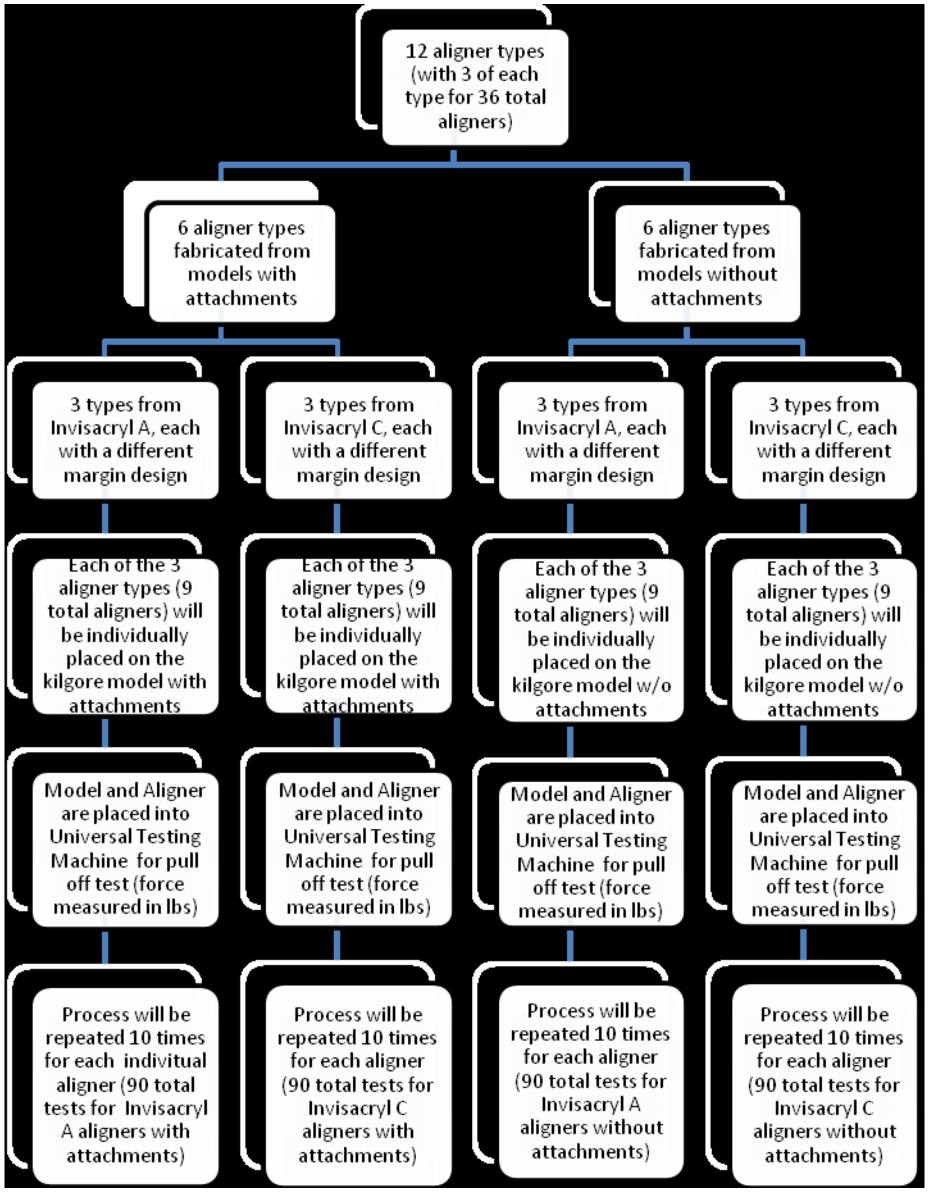


Figure 3.9 - Flow Chart 2

With Attachments

	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10
Group 1- Invisacryl A, Scalloped Margins										
1A										
1B										
1C										
Group 2- Invisacryl A, Straight Line, cut at Zenith										
2A										
2B										
2C										
Group 3- Invisacryl A, Straight Line, cut 2mm Above Zenith										
3A										
3B										
3C										
Group 4- Invisacryl C, Scalloped Margins										
4A										
4B										
4C										
Group 5- Invisacryl C, Straight Line, cut at Zenith										
5A										
5B										
5C										
Group 6- Invisacryl C, Straight Line, cut 2mm Above Zenith										
6A										
6B										
6C										

Table 3.1 - Aligners with Attachments Data

Without Attachments	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10
Group 7- Invisacryl A, Scalloped Margins										
7A										
7B										
7C										
Group 8- Invisacryl A, Straight Line, cut at Zenith										
8A										
8B										
8C										
Group 9- Invisacryl A, Straight Line, cut 2mm Above Zenith										
9A										
9B										
9C										
Group 10- Invisacryl C, Scalloped Margins										
10A										
10B										
10C										
Group 11- Invisacryl C, Straight Line, cut at Zenith										
11A										
11B										
11C										
Group 12- Invisacryl C, Straight Line, cut 2mm Above Zenith										
12A										
12B										
12C										

Table 3.2 - Aligners without Attachments Data

CHAPTER 4

RESULTS OF THE STUDY

The experimental results are listed in Table 4.1 (with attachments) and Table 4.2 (without attachments)

With Attachments

	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10	AVG	Group Avg	Std Error
Group 1- Invisacryl A, Scalloped Margins													
1A	8.353	8.065	8.25	8.325	6.242	7.718	6.205	5.066	6.819	5.528	7.0571		
1B	5.584	6.067	5.486	5.795	5.774	5.31	5.675	6.06	5.872	6.06	5.7683		
1C	5.727	5.336	4.966	5.619	5.273	4.94	5.144	4.98	4.528	4.797	5.131	5.985	0.981
Group 2- Invisacryl A, Straight Line, cut at Zenith													
2A	21.17	19.65	16.96	19.25	18.85	17.53	16.76	18.13	16.98	17.35	18.263		
2B	18.07	14.56	13.64	15.53	13.87	13.65	13.15	13.27	13.06	12.75	14.137		
2C	16.19	15.08	13.76	13.94	12.78	13.3	14.3	14.59	13.68	15.5	14.312	15.571	2.333
Group 3- Invisacryl A, Straight Line, cut 2mm Above Zenith													
3A	26.26	24	20.53	21.68	20.7	19.57	20.76	21.07	17.85	19.91	21.233		
3B	21.1	22.25	21.75	17.24	20.72	16.52	21.59	21.98	20.66	23.54	20.735		
3C	22.93	25.33	24.48	21.62	21.94	26.21	25.82	27.08	23.55	25.03	24.399	22.122	1.987
Group 4- Invisacryl C, Scalloped Margins													
4A	2.503	1.99	2.26	3.837	2.354	2.101	1.785	2.116	1.771	1.576	2.3959		
4B	1.227	1.031	1.71	1.773	2.212	1.46	2.156	2.447	1.745	1.03	1.6957		
4C	3.094	2.724	2.856	2.676	2.602	2.556	1.793	1.218	1.671	2.557	2.3747	2.155	0.398
Group 5- Invisacryl C, Straight Line, cut at Zenith													
5A	12.07	11.34	10.42	9.358	8.888	8.678	9.156	8.567	8.746	9.427	9.665		
5B	5.877	6.209	5.756	5.411	5.057	4.702	4.801	4.578	4.529	4.86	5.178		
5C	7.943	5.424	4.999	4.813	4.601	5.028	4.866	4.851	4.667	4.598	5.179	6.674	2.590
Group 6- Invisacryl C, Straight Line, cut 2mm Above Zenith													
6A	15.31	12.33	11.16	11.74	13.85	13.03	13	12.69	11.95	11.58	12.664		
6B	6.086	10.49	9.194	7.998	9.294	9.355	9.834	10.08	9.214	10.99	9.2535		
6C	16.62	22.36	13.06	20.21	18.15	19.31	20.19	20.24	17.67	20.69	18.85	13.589	4.865

Table 4.1- Table of Experimental Data of Aligners With Attachments. The red numbers are the high values for each aligner while blue numbers are the low values.

Without Attachments	Test 1	Test 2	Test 3	Test 4	Test 5	Test 6	Test 7	Test 8	Test 9	Test 10	AVG	Group Avg	Std. Error
Group 7- Invisacryl A, Scalloped Margins													
7A	7.544	6.218	7.161	6.232	6.035	5.789	7.424	6.296	6.017	7.403	6.6119		
7B	7.242	10.04	9.855	10.15	9.294	8.751	9.405	10.57	9.224	9.87	9.4401		
7C	7.897	11.57	11.69	11.27	10.25	10.4	10.42	10.21	11.18	10.38	10.5267	8.86	2.021
Group 8- Invisacryl A, Straight Line, cut at Zenith													
8A	9.351	11.17	10.85	10.94	11.36	11.08	10.79	10.6	10.55	10.32	10.7011		
8B	11.49	9.585	10.94	11.15	11.15	9.713	10.62	11.9	10.97	9.672	10.719		
8C	9.938	9.504	7.5	8.692	7.602	8.001	8.182	8.246	8.415	8.142	8.4222	9.947	1.321
Group 9- Invisacryl A, Straight Line, cut 2mm Above Zenith													
9A	16.31	14.57	13.1	13.2	12.55	11.13	11.01	12.91	11.31	12.21	12.83		
9B	18.92	21.9	13.99	15.96	18.16	18.93	17.09	14.15	20.54	17.74	17.738		
9C	21.44	18.61	18.45	17.77	18.01	17.99	17.41	17.36	17.39	18.17	18.26	16.276	2.996
Group 10- Invisacryl C, Scalloped Margins													
10A	2.697	2.567	2.744	2.258	2.48	2.333	2.399	2.63	2.506	2.337	2.4951		
10B	5.301	4.833	4.787	4.763	4.637	4.866	4.906	4.951	4.964	4.667	4.8675		
10C	6.191	5.665	5.371	5.169	4.919	4.993	5.124	5.089	4.263	4.975	5.1759	4.18	1.467
Group 11- Invisacryl C, Straight Line, cut at Zenith													
11A	4.987	4.692	4.604	4.637	4.6	4.472	4.552	4.289	4.381	4.388	4.5602		
11B	5.548	5.003	4.791	4.416	3.916	4.145	4.145	4.543	4.259	4.514	4.528		
11C	6.349	6.04	5.283	5.373	5.366	5.458	5.962	5.343	5.535	5.598	5.6307	4.906	0.628
Group 12- Invisacryl C, Straight Line, cut 2mm Above Zenith													
12A	11.11	10.41	9.675	10.18	9.989	9.498	9.515	7.81	9.818	9.373	9.7378		
12B	9.305	7.556	7.181	10.49	10.47	9.44	7.307	6.528	8.424	6.308	8.3009		
12C	9.862	9.62	5.872	11.14	9.587	10.7	9.618	8.732	9.453	9.251	9.335	9.125	0.741

Table 4.2- Experimental Data of Aligners Without Attachments

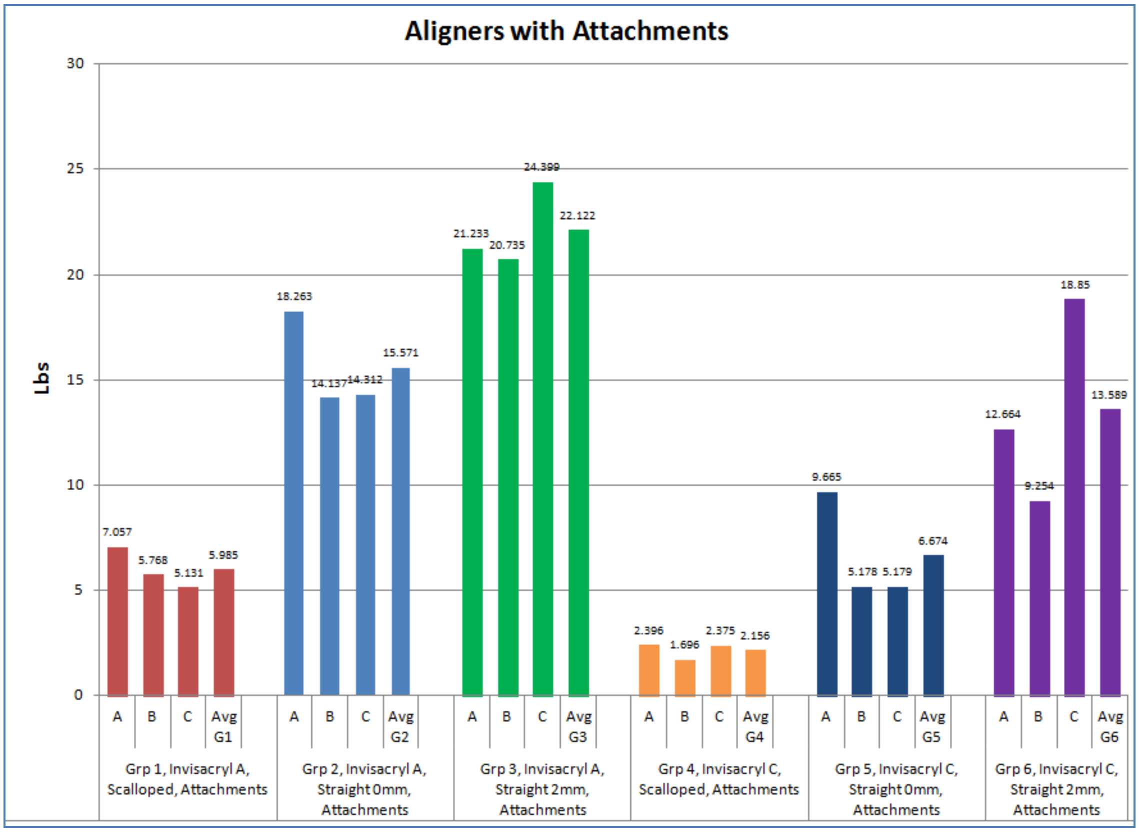
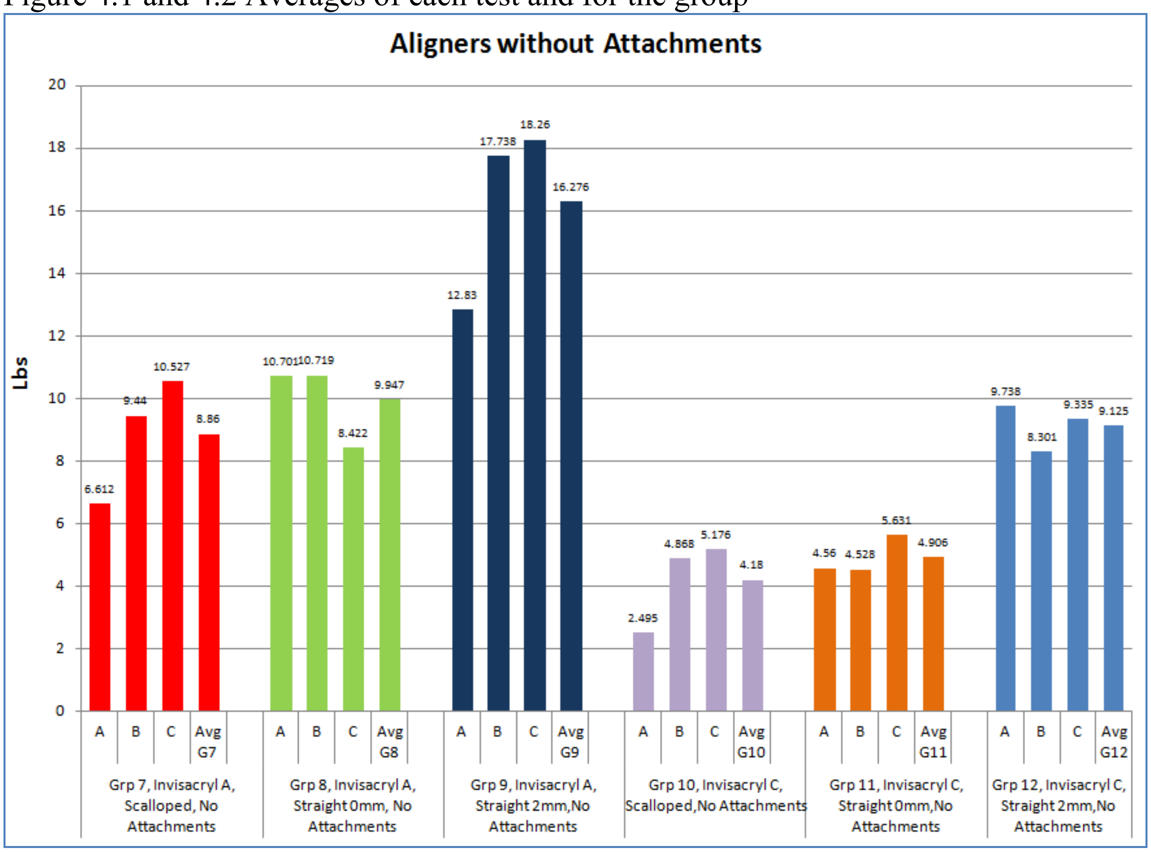


Figure 4.1 and 4.2 Averages of each test and for the group



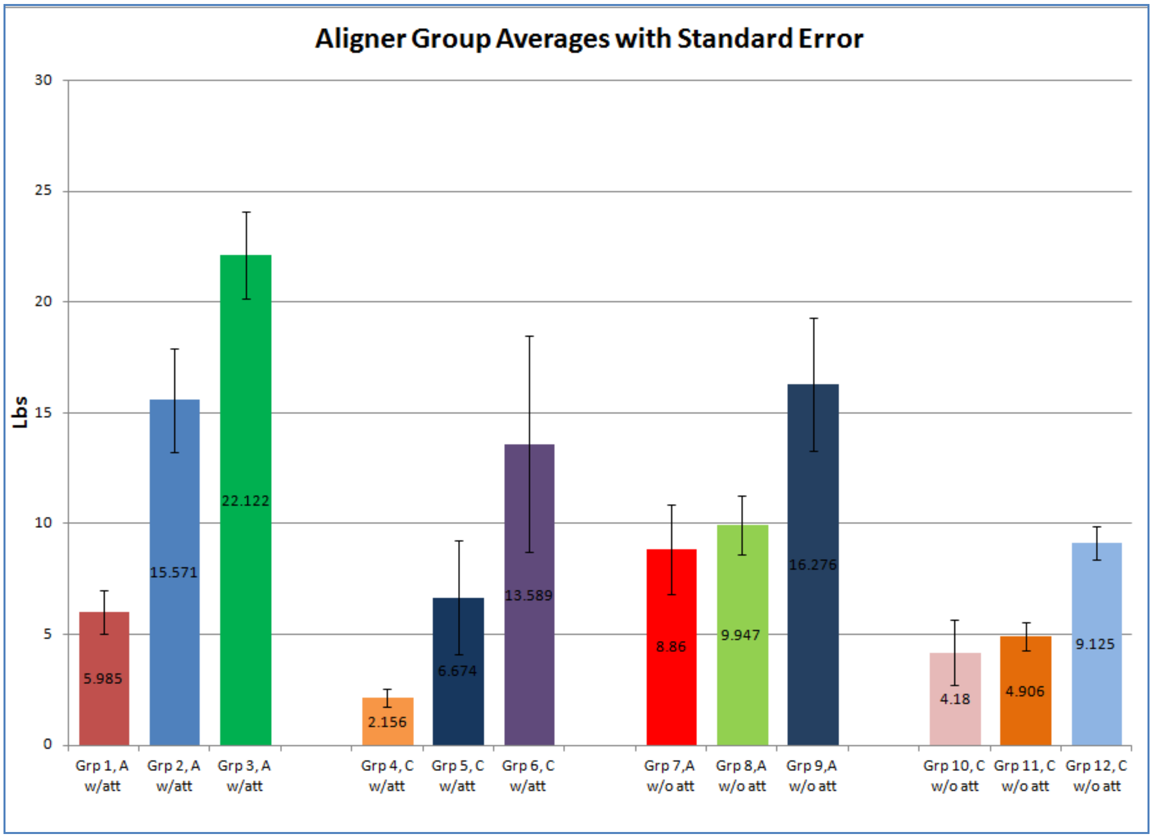
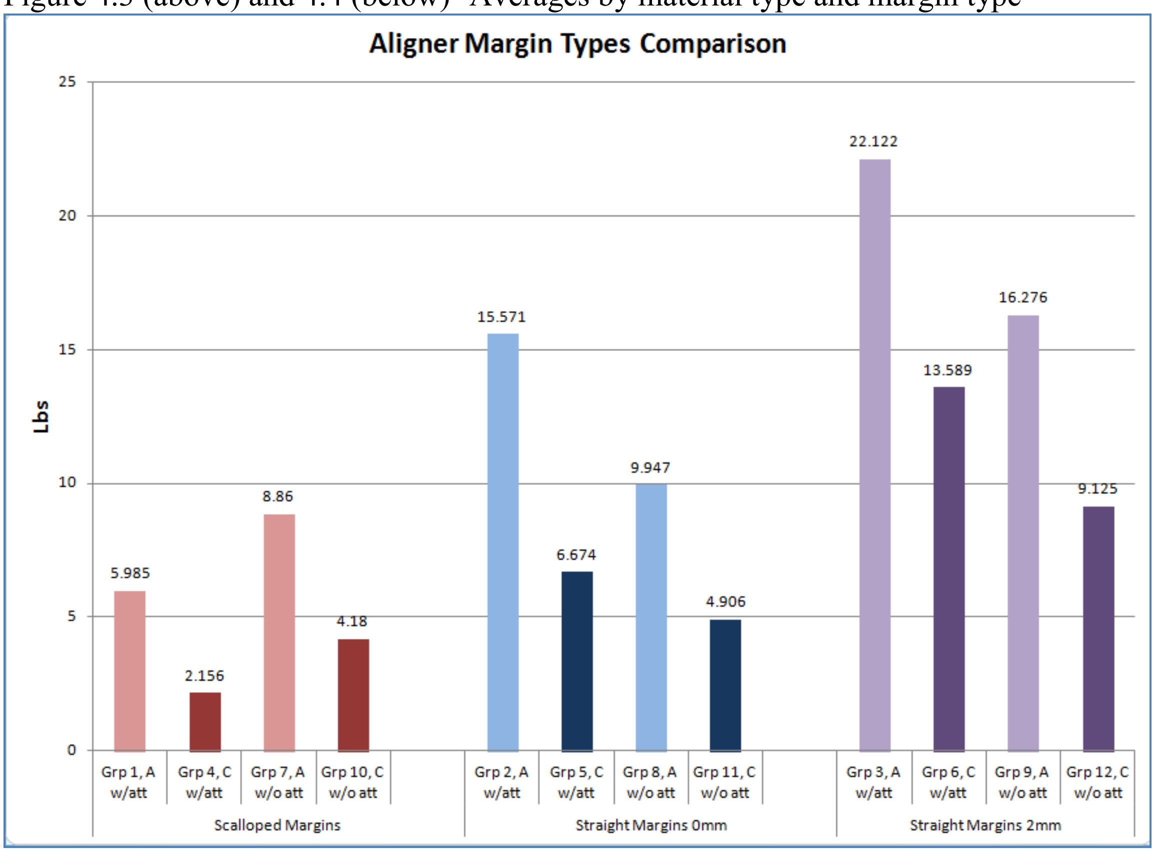


Figure 4.3 (above) and 4.4 (below)- Averages by material type and margin type



Statistical Analysis of The Data

The ANOVA Post Hoc Bonferroni test evaluated 66 comparisons. The results of the ANOVA test found significant findings (p value ≤ 0.05) in all group comparisons except the following nine comparisons.

- Group 1 Invisacryl A, scalloped margin, with attachments (5.985 Lbs/inch^2) to Group 5 Invisacryl C, 0mm, with attachments (6.674)
- Group 1 Invisacryl A, scalloped margin, with attachments (5.985) to Group 10 Invisacryl C, scalloped margin, without attachments (4.18)
- Group 1 Invisacryl A, scalloped margin, with attachments (5.985) to Group 11 Invisacryl C, 0mm, without attachments (4.906)
- Group 2 Invisacryl A, 0mm, with attachments (15.571) to Group 9 Invisacryl A, 2mm, without attachments (16.276)
- Group 5 Invisacryl C, 0mm, with attachments (6.674) to Group 11 Invisacryl C, 0mm, without attachments (4.906)
- Group 7 Invisacryl A, scalloped margin, without attachments (8.86) to Group 8 Invisacryl A, 0mm, without attachments (9.94)
- Group 7 Invisacryl A, scalloped margin, without attachments (8.86) to Group 12 Invisacryl C, 2mm, without attachments (9.125)
- Group 8 Invisacryl A, 0mm, without attachments (9.94) to Group 12 Invisacryl C, 2mm, without attachments (9.125)
- Group 10 Invisacryl C, scalloped margin, without attachments (4.18) to Group 11 Invisacryl C, 0mm, without attachments (4.906)

Of the 57 significant comparisons, Group 6 Invisacryl C, 2mm, with attachments (13.589) to Group 2 Invisacryl A, 0mm, with attachments (15.571) had a p value of 0.05 and was significant.

Group 4 Invisacryl C, scalloped, with attachments (2.155) to Group 10 Invisacryl C, scalloped margin, without attachments (4.18) had a p value of 0.019 and was significant to a 98% confidence level. The remaining comparisons were significant at a 99%+ confidence level when comparing the group averages.

CHAPTER 5

DISCUSSION, LIMITATIONS, CONCLUSIONS AND RECOMMENDATIONS

Discussion of Results

A primary concern for a study involving thermoformed aligners is accounting for natural variation in aligners due to the thermoforming process. For this study, we controlled the heating time (manufacturer's recommendations), standardized the size of the model bases, and followed identical protocol for trimming each of the aligners (cut aligner to size/shape and then polished smooth). Minimizing variables involved in the thermoforming process does not eliminate variation among aligners. Testing one aligner for each aligner type would not represent each group due to this variation. Therefore, three aligners from each aligner type were tested and then averaged to yield a better representation of each aligner group. The statistical analysis was completed using the group averages and the statistical significance or non-significance represents what will happen on average when comparing the aligner types.

Several conclusions can be drawn from the results of this experiment. When using attachments, straight margins (either 0mm or 2mm) had significantly higher retention than scalloped margins of the same Invisacryl material type (groups 2 and 3 were significantly higher than group 1 and groups 5 and 6 were significantly higher than group 4). The added rigidity created by straight margins maximizes the use of attachments for retention in both material types.

Comparing groups 3 to 9, groups 2 to 8, and groups 6 to 12 shows that the combination of straight margins and attachments yields significantly higher aligner retention when compared to aligners with the same margin type and material type without attachments.

When evaluating aligners without attachments the results vary (see figures 4.3 and 4.4). Only aligners with 2mm straight margins were significantly higher than scalloped margins of the same aligner material (group 9 compared to group 7 and group 12 compared to group 10). The averages of the straight 0mm aligner groups were higher than those of the scalloped with the same material, but the difference was not significant. There is also a difference when evaluating the attachment to non-attachment aligner groups with scalloped margins. The average of group 1 was significantly lower than group 7 and group 4 was significantly lower than group 10. Initial thought is that attachments increase retention, but with scalloped margins and first premolar attachments this does not appear to be the case. The decrease in retention of the attachment groups is a result of the increased flexibility of the aligner margins. The retention value recorded for the attachment groups is the force needed to flex the aligner over the attachment. As the aligner moves over the attachment the aligner bows away from the natural tooth undercuts. In the case of scalloped margins, on average the natural tooth undercuts provide higher retention than attachments on the first premolars. This is not the case with straight margins due to the increase in rigidity of the aligner. Based on the results of this experiment, attachments on first premolars provide increased retention when the aligner has a straight aligner margin cut 0mm or 2mm above the gingival zenith and first premolar attachments with scalloped aligners may result in a decrease in overall retention.

The statistical analysis of this experiment was completed using the averages of the groups. In several cases due to natural variation of aligners, the difference between the high value of one aligner group and the low value in another aligner group may not be statistically significant. For example, the low average in group 7 was aligner 7A with an average value of 6.6 lbs/square inch and the highest value for group 1 was aligner 1A with an average value of 7.057. While the averages of group 1 and group 7 were statistically significant, the high value of an aligner in group 1 (1A) and the low value of an aligner in group 7 (7A) were not statistically significantly different. The values for standard deviation for each group average can be found in table 4.1 and 4.2 and the error values can be seen in the graph for figure 4.3. This also occurs in the following 10 comparisons: group 2 when compared group 6, group 5 when compared to groups 6,7,8,10 and 12, and group 6 when compared to groups 7,8,9 and 12. Out of the 57 significant comparisons of group averages there were the 11 groups listed above that had range values that overlapped leaving 46 comparisons that are significant throughout the range averages of this study. The inverse of this is also true. Evaluation of the group averages between group 1 and group 5 was not statistically significant while evaluation of the low aligner in group 1 is 5.13 and the highest aligner in group 5 is 9.66 which would be statistically significant. Therefore, it is important to understand that due to natural variation in the thermoforming process there may be deviations higher or lower than the group averages making the retention of an aligner of one type similar or equal to the retention of an aligner of another type. From a clinical perspective, it is crucial to increase tooth movement and minimize tooth lag by increasing aligner retention. Selecting an aligner margin type and material type to maximize these principles favors the average for a group of aligners and not the variances of the groups. Therefore with current thermoforming techniques and materials, comparison of aligner group averages is the best way to determine the retentive ability of an aligner margin design.

Aligners with attachments tended to show highest pull off value in the beginning and the lowest pull off value near the end of the ten tests. Aligners without attachments had a greater diversity of time during testing where the aligner had the highest and lowest values. No analysis was used to evaluate this portion of the data. This is strictly a secondary observation, since an analysis of this information would require several hundred tests for each aligner to accurately determine decay rate of retention. This observation may be attributed to wear of the attachments after ten or less pull offs. Also, the aligners with 2mm margins and attachments had a pattern more similar to the aligners without attachments.

Limitations to this Study

As noted above a limitation to this study is control of material thickness during the thermoforming process to ensure each aligner is of the same thickness. Natural variations in thickness due to thermoforming will also be observed in aligners fabricated from commercial aligner companies. Another limitation is potential wear of attachments during testing. Composite material hardness is greater than that of thermoplastics and the attachments should not wear significantly, but the study is unable to control for attachment wear. Third, this study uses one direction of pull. This direction is perpendicular to the occlusal plane and is the common direction used when removing aligners, but the study does not evaluate retention in all directions of pull. In a clinical situation, there will be various types of forces from several different directions having an effect on the retention of an aligner. The fourth limitation is in the measurements of force. Force measuring sensors have not been developed in a small enough size to allow for an accurate measurement of force on one or several teeth and pressure film is not as accurate as we may need for this study. Therefore, we will use pull off retention to evaluate overall flexibility and adaptability of the aligner designs. Evaluating aligner retention over ten pull off tests limits our ability to estimate retention of the aligner as attachments begin to wear and the thermoplastic material begins to fatigue over an extended period of use. This study did not look at those changes. Minor limitations include the following: inability to accurately predict and model how the periodontal ligament would affect potential adaptation, and completion of the study in vitro without saliva. Saliva can act as either a lubricating agent to cause easier removal of RTAs or in well adapted aligners the bonding created by water between two surfaces could cause an increase in aligner retention.

Recommendations for Future Research

The primary goal of this project was to evaluate one method of reducing orthodontic tooth lag during treatment with thermoformed aligners. Evaluation of the effects of aligner thickness on tooth movement and force both in vitro and in vivo is one area for further study. Another area would be the evaluation of the above discussed margin types and their ability to move teeth and decrease tooth lag, decrease treatment time, decrease case refinements/midcourse corrections and provide superior American Board of Orthodontic quality results. Companies that use scalloped gingival margins do so to increase the esthetic appeal of the aligners. In most cases, patients have an upper lip drape while smiling that is ≤ 2mm above the gingival zenith of the upper central incisors. A study can be completed to evaluate the esthetics and comfort of straight line gingival margins (especially those trimmed 2mm above the gingival zenith) to see if the scalloped margins actually do have any esthetic difference since those trimmed 2mm above the zenith will not show in a majority of patients. Understanding the types of aligner materials, their properties, and the types of movements they can accomplish will be paramount in the future to creating a complement of aligners to address tooth movement needs while minimizing tooth lag. Research into thermoplastic materials and the types of movements they can complete is another recommended area for future study. Future studies may also include retentive tests involving aligners with several hundred cycles (simulating 2-3 weeks of normal wear) to evaluate decay of retentive force due to material fatigue and wear of attachments. Evaluation of several material types, thickness along with different attachment composite materials may determine which material and composite combination will display the greatest retention over time.

Hypothesis Evaluation

The eight null hypotheses of this study were derived from the secondary research questions. The research questions, hypothesis and evaluation of the hypotheses are listed below. Statistical significance for determination of rejection or acceptance of the hypothesis will be taken from the 57 accepted statistical comparisons.

1- How does the scalloped gingival margin design compare to the straight line gingival margin design cut at the level of the free gingival margin zenith during pull off tests without attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut at the free gingival margin zenith during pull off tests without attachments.

The hypothesis for question 1 was rejected for Invisacryl A and Invisacryl C with 0mm margins without attachments when compared to scalloped margins of the same material type without attachments since the 0mm margins and scalloped were not significantly different in force.

2- How does the scalloped gingival margin design compare to the straight line gingival margin design cut 2mm above free gingival margin during pull off tests without attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull off tests without attachments.

The hypothesis for question 2 is accepted for Invisacryl A and Invisacryl C with 2mm margins without attachments when compared to scalloped margins of the same material type without attachments since the 2mm margins were significantly higher in value than the scalloped margins of the same material type.

3- How does the straight line gingival margin design cut at the zenith compare to the straight line gingival margin design cut 2mm above the gingival zenith during pull off tests without attachments on first premolars?

Hypothesis:

The straight line gingival margin design cut at the gingival zenith will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull of tests without attachments.

The hypothesis for question 3 is accepted for Invisacryl A and Invisacryl C for 0mm straight margins when compared to 2mm of the same material type without attachments since the differences in force were significantly higher for 2mm margins.

4- How does the scalloped gingival margin design compare to the straight line gingival margin design cut at the free gingival margin zenith during pull off tests with attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut at the free gingival margin zenith during pull off tests with attachments.

The hypothesis for question 4 was accepted for Invisacryl A and Invisacryl C with 0mm margins with attachments when compared to scalloped margins of the same material type with attachments since the 0mm margin groups were significantly higher than scalloped groups of the same material.

5- How does the scalloped gingival margin design compare to the straight line gingival margin design cut 2mm above free gingival margin zenith during pull off tests with attachments on first premolars?

Hypothesis:

The scalloped gingival margin design will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith during pull off tests with attachments.

The hypothesis for question 5 is accepted for Invisacryl A and Invisacryl C with 2mm margins with attachments when compared to scalloped margins of the same material type with attachments since the 2mm margin groups were significantly higher in value than the scalloped margin groups of the same material type.

6- How does the straight line gingival margin design cut at the zenith compare to the straight line gingival margin design cut 2mm above the gingival zenith during pull off tests with attachments on first premolars?

Hypothesis:

The straight gingival margin design cut at the zenith will not have a higher retentive force than the straight line design cut 2mm above the free gingival margin zenith with attachments.

The hypothesis for question 6 is accepted for Invisacryl A and Invisacryl C for 0mm straight margins when compared to 2mm of the same material type with attachments since the differences in force were significantly higher for 2mm margin group when compared to 0mm margin group of the same material type.

7- How does Invisacryl A material compare directly to Invisacryl C material on pull off tests (in the same margin design category) without attachments?

Hypothesis:

The Invisacryl C material will not have a higher retentive force when compared directly to the Invisacryl A material with the same margin type during pull of tests without attachments.

The hypothesis for question 7 was accepted since there is a statistically significant difference between Invisacryl A when compared to Invisacryl C aligners of the same margin design without attachments.

8- How does Invisacryl A material compare directly to Invisacryl C material on pull off tests (in the same margin design category) with attachments?

Hypothesis:

The Invisacryl C material will not have a higher retentive force when compared directly to the Invisacryl A material with the same margin type during pull of tests with attachments.

The hypothesis for question 8 was accepted since there is a statistically significant difference between Invisacryl A when compared to Invisacryl C aligners of the same margin design with attachments.

Conclusions

Analysis of the results of this study yields the following conclusions:

- The most retentive aligner margin design is a straight line margin cut 2mm above the gingival zenith. This margin design had the highest retention with Invisacryl A material and first premolar attachments. This margin design was also significantly higher when compared to scalloped and straight line cut at the gingival zenith of the same attachment and material type.

- Straight line margins cut at the gingival zenith (0mm) had significantly higher retentive force when compared to scalloped margins of the same material type with attachments.
- Scalloped margins on aligners with attachments had significantly less retentive force when compared to scalloped margin of the same material type without attachments.
- Invisacryl A material had significantly higher retention values when compared to Invisacryl C material with the same margin and attachment design.
- Straight line gingival margin design (both 0mm and 2mm heights) with attachments had a significantly higher retentive value when compared to straight line margins of the same height and material type without attachments.
- Straight line gingival margins decrease the flexibility of an RTA at the gingival margin increasing retention, the probability of accomplishing more complex movements (such as torque), and expressing a greater amount of tooth movement.

APPENDIX 1

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