THE EFFECT OF SIZE AND LOCATION OF COMPOSITE ATTACHMENTS ON THE EXTRUSIVE FORCE DELIVERED TO A MAXILLARY CENTRAL INCISOR BY A CLEAR ALIGNER

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Dedication

I would like to dedicate this work to:

My late father who taught me to value education, work hard and enjoy the simple parts of life. I would not be the person I am today without his guidance.

My family who has believed in and supported me throughout the years.

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Abstract

Introduction: One of the most challenging and least predictable tooth movements to achieve with clear aligner therapy is extrusion of maxillary central incisors. Composite attachments have been implemented to improve the biomechanical properties and make extrusion a more predictable tooth movement. Various attachment shapes have been investigated, but the effect of attachment size and location on the force delivered to a maxillary central incisor by a clear aligner has not been reported.

Aim: To evaluate the effect of composite attachment size and location on the extrusive force delivered to a maxillary central incisor with a Zendura FLX clear aligner.

Methods: Clear aligners designed to extrude a maxillary central incisor 0.25 mm using uLab software were fabricated using Zendura FLX .030 mil (0.75 mm) thickness clear aligner material. To evaluate the effect of attachment size, aligners were designed with three sizes of rectangular anterior extrusion attachments as well as no attachment. To evaluate the effect of attachment location, aligners were designed with a standard rectangular anterior extrusion attachment placed in the center of the facial surface of the crown, 2 mm apical, 2 mm incisal, in the center of the lingual surface of the crown and with no attachment. For each of the 9 groups, 5 aligners were fabricated with standardized margins trimmed 0.75 mm apical to the gingival margin. Extrusive force along the long axis of the crown was measured using a force gauge. Means and standard deviations were calculated and presented by group. The one-way analysis of variance (ANOVA) was conducted to compare the means between the groups and Tukey's method was used as a post-hoc procedure for pairwise comparisons. P-values less than 0.05 were considered statistically significant.

Results: Pairwise comparisons for all groups compared to No attachment were statistically significant ($p <.0001$). Pairwise comparisons for all attachment sizes were statistically significant ($p < .0001$). Although pairwise comparisons were statistically significant for the Incisal attachment group vs. Gingival attachment group ($p = 0.033$) and the Incisal attachment group vs. Mid-facial attachment group ($p = 0.002$), the observed differences may have been due to variation in aligner fabrication. No statistically significant differences were observed for pairwise comparisons of other attachment location groups.

Conclusions: This is the first study in which the effect of attachment size and location on the extrusion of a maxillary central incisor with a clear aligner has been reported. In a benchtop model, all attachment configurations generated greater initial extrusive compared to the No attachment control. Attachment size has a positive relationship with initial extrusive force with larger attachments producing greater force. Attachment location did not appear to be as critical as attachment size in producing extrusive force. Biomechanically, larger attachments can be recommended to help generate the force required to predictably extrude maxillary incisors.

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Introduction

In recent years, the orthodontic profession has experienced an increased demand for less conspicuous orthodontic treatment modalities. This may be in part due to the pronounced rise in the number of adults seeking orthodontic treatment.[1,2] A previous study has shown that 62% of potential adult orthodontic patients would reject treatment if it involved visible appliances.[3] Currently, there is a wide variety of esthetic alternatives to traditional braces including ceramic brackets, lingual braces and clear aligners (CAs) to help meet this need. Of the esthetic alternatives to traditional bonded brackets, clear aligner therapy (CAT) is the most well known and most popular. A recent study found that 83% of orthodontist utilize CAT to treat patients.[4]

Modern CAs were introduced to the orthodontic profession in 1998 when Align Technology obtained FDA approval for Invisalign and introduced computer-aided-design and computer-aided-manufacturing (CAD-CAM) technology that made large-scale production of clear aligners feasible.[5] The utility of this technology was promptly recognized by the private sector—a wide variety of companies emerged, producing thermoformed trays that progressively move teeth into alignment. Initially, the clinical application of CAT was limited primarily to minor tooth movements, but rapid advancements in aligner materials, manufacturing, computer programing and aligner auxiliaries have expanded the scope of what is achievable using CAT.

Regardless of the appliance used for orthodontic treatment, the biological principles of tooth movement are the same. Orthodontic tooth movement is the result of the orthodontist applying forces to the teeth, periodontium and bone. In conventional orthodontic treatment, the force system is comprised of two mechanical parts: brackets bonded to the teeth and a wire. As the wire engages the brackets, forces are transmitted to the teeth resulting in a mechanical-biological chain of events that results in orthodontic tooth movement. Conversely, CAT utilizes a mismatch between the aligner and the tooth surface to generate forces to push teeth into a predetermined position.[6] Irrespective of the appliance being used, it is prudent of the orthodontist to understand the forces being applied, and how to manipulate them to achieve the desired result. In recognition of this concept, Charles Burstone stated, “New appliances and treatment modalities will need a sound biomechanical foundation for their development and most efficient use.”[7]

Despite CAT’s technological advancements and increased popularity, questions remain regarding its effectiveness and limitations in orthodontic treatment. A study comparing treatment outcomes with CAs and fixed appliances concluded the use of CAs is not supported as an equally effective treatment modality to fixed appliances. In fact, orthodontic treatment with CAs was associated with worse treatment outcomes.[8] Currently, most orthodontic tooth movements are not predicable enough to achieve with a single set of CAs, necessitating additional sets of CAs to reach the desired result.[9] A systematic review assessing the reliability of CAs in producing various tooth movements found that CAs are not effective in controlling anterior tooth extrusion, and that extrusion of maxillary central incisors is the least predictable tooth movement in CAT.[10]

Composite resin attachments are used to improve CA retention and enable the aligner system to perform tooth movements that would otherwise be unpredictable. Composite attachments bonded to the tooth surface improve the biomechanical capabilities of CAs by facilitating the construction of more complex force systems.[6] While it is known that composite attachments bonded to the dental surface can improve the biomechanical properties in CAT, composite attachments can be perceived as unaesthetic. A recent study using eye tracking technology found that people perceive fewer and smaller attachments as more esthetic than multiple and larger attachments.[11] For this reason, clinicians may be reluctant to place attachments in the esthetic zone, particularly on the maxillary central incisors.

It is poorly documented in the literature how composite attachments affect the forces and moments applied to teeth during CAT. Evidence is available mainly from expert opinions and low-level, poorly designed studies.[5] Currently there is no scientific evidence to guide clinicians on appropriate attachment size and location to generate the force necessary to predictably extrude a maxillary central incisor, which has been demonstrated to be the least predictable tooth movement in CAT.[10] In order to improve the predictability of CAT and make it a viable alternative to fixed appliances, it is prudent to elucidate the effect of attachment size and location on the forces expressed during CAT.

Review of Literature

History of Clear Aligner Therapy

Removable appliances analogous to CAs date back to 1945 when Dr. H.D. Kesling introduced the tooth positioner—a flexible, removable, rubber appliance designed to achieve mild to moderate tooth movements during the finishing stages of orthodontic treatment.[12] The appliance was originally made of black rubber and fabricated on plaster models where teeth had been sectioned and repositioned with wax into the desired arch form, axial position and interdigitation. Forces required to move teeth into their predetermined positions were generated by biting into the appliance, which was primarily worn at night. Although the tooth positioner's application and ability to achieve complex tooth movements was limited, Kesling was the first to realize that more complex tooth movements could be achieved with a series of removable appliances.

Building upon Kesling's work, in 1959, Henry Isaac Nahoum introduced "The vacuum-formed dental contour appliance," the first documented clear thermoplastic appliance for the use in dentistry.[13] Similar to Kesling's tooth positioner, the vacuum-formed dental contour appliance was fabricated using an altered cast where teeth had been repositioned into the desired alignment. An industrial-grade vacuum former was used with thermoformed plastic sheets to create the retainers. The appliance was initially designed to maintain or change dental contours. However, it was later suggested that the appliance could be used to achieve orthodontic tooth movement with a series of thermoformed retainers designed to incrementally move teeth. Nahoum also suggested that buttons on the appliance could be added to allow the use of intermaxillary elastics.[13] Nahoum's auxiliaries and thermoforming technique set the groundwork for clear aligner therapy today.

Ponitz added to the body of work of his predecessors in 1971 with the introduction of "invisible retainers."[14] The invisible retainer was fabricated in a similar fashion to the tooth positioner and vacuum-formed dental contour appliance, using a master cast with teeth repositioned in baseplate wax. Retainers were formed by heating plastic sheets and adapting them to a master cast using a vacuum unit. Invisible retainers were designed to achieve mild tooth movements by placing pressure on teeth to guide them into the desired position. Ponitz also described prosthodontic applications for his retainers, incorporating denture teeth for the use as a partial denture, as well as surgical applications, using the retainers as a splint.[14] Ponitz encouraged clinicians to publish their techniques of aligner fabrication to further refine the method, and consequently in 1985 McNamara et al. published a modification of Ponitz's process. McNamara et al. reported a fabrication method using 1 mm thick Biocryl polymers and a Biostar forming machine. Rather than using vacuum pressure, the authors described the use of positive pressure to adapt the thermoplastic material to the cast.[15]

In 1993, Sheridan et al. introduced the Essix retainer, a new variation to the family of thermoformed appliances, which was designed to act both as a tooth positioner and a retainer.[16] The Essix retainer was fabricated using a 0.030 inch sheet of copolyester from Raintree Essix, Inc. Similar to the CAs previously described by McNamara et al., Sheridan et al. described the use of positive air pressure to adapt the material to the cast, which reduced the thickness of the material to 0.015 inches after fabrication.[16] If tooth movement was desired, a window was cut into the appliance in the direction of desired tooth movement, while a divot was placed in the aligner on the opposing surface to generate force.[17] Sheridan et al. later described a modification to the technique where instead of placing a dimple in the appliance, composite was placed directly on the tooth surface.[18] Composite could be progressively added or removed to modify the force applied to the tooth by the aligner. In contrast to the techniques that had been described previously,[12,14,15] this method could achieve up to 2-3 mm of tooth movement with a single appliance rather than fabricating a series of aligners to progressively move a tooth.[18] In addition to the contributions to CA design, Sheridan et al. were the first to describe using a CA with interproximal tooth reduction (IPR) to move teeth, a technique that is commonly used in CAT today.[19]

Soon after Sheridan et al. described the Essix retainer, CAT took a major step forward in 1998 when Align Technology (Santa Clara, CA, USA) obtained FDA approval for Invisalign. Invisalign took the work of Kesling,[20] Nahoum,[13] Ponitz,[14] Sheridan et al.[16–18] and others[15] further as Align Technology introduced computer-aided-design and computer-aided-manufacturing (CAD-CAM) technology into CAT. This innovation made large-scale production of clear aligners feasible and removed previously described barriers to CAT such as time-consuming laboratory steps and chairside time.[5]

Before the introduction of intraoral scanning, the Invisalign system required orthodontists to send a prescription, a set of polyvinyl siloxane impressions, a bite record, and radiographs to Align Technology. The impressions were poured up in dental plaster and scanned using a destructive scanning technique to generate a 3-dimensional (3D) model.[21] An Invisalign virtual orthodontic technician (VOT) would then use proprietary software to segment and individually move the teeth into alignment following the orthodontist's prescription. The data was then sent back to the orthodontist via the internet where he or she could view a virtual treatment simulation of the case, termed a ClinCheck, for modification and approval. This technology gave clinicians the capability to design a series of aligners with preprogrammed sequential tooth movements all from a single impression.[21] When the case was approved, the VOT would then print SLA models of the sequentially repositioned teeth and fabricate the aligners using a proprietary aligner material and a Biostar pressure-molding machine.[21] Align Technology uses proprietary algorithms to stage tooth movement based off an assumed center of resistance derived from G.V. Black's reference of the average length of roots. Based on the desired tooth movement, algorithms are used to populate attachments to optimize clinical efficiency and stage movements to 0.25 mm, 1° of torque and 2° of rotation per clear aligner.[22] In 2011, Align Technology acquired the intraoral scanning company Cadent and incorporated the use of intraoral scanning devices into its workflow, which obviated the needed to send polyvinyl siloxane impressions, and further streamlined the CA design process. As of September 30, 2021 Invisalign has been used to treat over 11 million people.[23]

For many years, Align Technology controlled the CA market and how patients were treated with CAs, but the utility of Invisalign was promptly recognized by the private sector. When Align Technology's proprietary patents began to expire in 2017, it catalyzed the emergence of CA manufactures entering the market and offering alternative options to CAT. In the early 2000's some aligner companies started advertising their products directly to consumers rather than to orthodontists, placing an emphasis on the appliance rather than the expertise of the clinician.[24] Taking this practice a step further, in 2014, Smile Direct Club (Nashville, TN, USA) began selling CAs directly to consumers, without the supervision of a treating orthodontist.[25]

Despite all of the groundbreaking technological advancements and advantages of commercial CAs such as Invisalign, clinicians have limited control over factors such as CA tray material type, thickness, and trim line, all of which may significantly influence the force systems delivered to the teeth. Information regarding material properties, design, and force systems of commercial CAs is scarce, as it is regarded by the manufacturers as proprietary information. In addition, there are high lab costs associated with third party CA manufacturers. Owing to this frustration, some clinicians have started to develop in-house or in-office CA options. Modern CAD-CAM technology has enabled orthodontists to combine the advantages of customization possible with earlier techniques[13,14,16–18,20] with the sophistication of fabricating an entire series of CAs from a single digital impression using in-house CA software. This allows the orthodontist to have control over the entire process. With 3D printers and thermoforming machines readily available, orthodontist have the option to print their own SLA models and manufacture CAs using in-house thermoforming machines. This permits the orthodontist to choose the CA material type, thickness, gingival margin design, as well as other variables to individualize the force systems for each patient.

Biomechanics of Tooth Movement

The goal of orthodontic treatment is to optimize orthodontic tooth movement (OTM), which requires the proper manipulation of the forces applied to teeth. In orthodontics, forces are typically described in Newtons (N) or in grams (gm), with 1.0 N being approximately 100 gm. Forces in orthodontics are also described as vectors with a point of application, direction, and magnitude.[7]

The point of application of a force vector is relevant as teeth are restrained bodies, held in periodontal structures. Teeth are not free to move in response to a force. A point exists in a restrained body, such as a tooth, called the center of resistance (COR). In theory, a force vector passing through the COR will produce pure translation of the tooth.[26] The precise location of the COR depends on factors such as root morphology, number of roots, alveolar crest level, and thickness and form of the periodontal ligament. In a single-rooted tooth, such as a central incisor, the center of resistance is on the long axis of the tooth, approximately one third to one half of the root length apical to the alveolar crest.[27] If a force is applied to a tooth that does not pass through the COR, the result will be some rotation. The potential for rotation is measured as a moment. The magnitude of the moment is equal to the magnitude of the applied force multiplied by the distance from the center of resistance.[26] The direction of a moment, and the tendency of a tooth to rotate, is determined by the resultant moment, or sum of all of the moments acting on the tooth.

The direction of a force vector affects the type of OTM that is observed. During orthodontic treatment, a tooth is often subjected to more than one singular force. Similar to moments, the direction of the force acting on a tooth is determined by the resultant force vector, or the sum of all of the forces acting on the tooth.[26] When pure, bodily extrusion of a tooth is desired, orthodontic forces must be applied very precisely. OTM is the result of the orthodontist applying forces to the teeth, which are transmitted to the periodontium and bone, resulting in a mechanical-biological chain of events that results in OTM.[6] When a prolonged force is applied to a tooth, there are areas of pressure and tension within the periodontal ligament causing an alteration in blood flow and the formation and release of chemical messengers. Osteoblasts and osteoclasts are activated causing resorption of bone on the pressure side, and formation of bone on the tension side, until a new equilibrium is reached.[28] If extrusion of a maxillary incisor is desired, ideally there would be no areas of compression within the periodontal ligament (PDL), only tension at the root apex. However, this concept is theoretical as any degree of tipping would result in some areas of compression within the PDL.[28] To avoid tipping or rotation, the resultant force vector applied to the central incisor would be directed apico-incisally, through the center of resistance, as to not produce a moment and unwanted tooth movement.

While the precise biological mechanisms that determine orthodontic tooth movement have yet to be fully elucidated, force magnitude plays an important role.[29] A force magnitude below the optimal threshold would produce a suboptimal response, whereas a force magnitude greater than optimal would result in increased hyalinization, patient discomfort, and delayed orthodontic tooth movement.[29] An optimal force magnitude, therefore, would be the lightest force possible to produce a maximum or near-maximum response.[28] Although at present there does not appear to be a consensus on the optimal force magnitude required for OTM, Proffit et al. suggested optimum force ranges for various types of tooth movement.[28] The authors proposed light forces of 35-60 gm be used for tipping, rotation, and extrusion, moderate force levels of 50-100 gm for torquing roots, and heavier forces of 70-120 gm be used for bodily tooth movement. Indeed, force magnitude is a critical factor in controlling OTM.

Incisor Extrusion With Clear Aligners

Since their introduction to orthodontics, the ability of CAs to extrude teeth has been debated. The level of available evidence is low with a limited number of studies on the topic. In 2009 Kravitz et al. conducted the first prospective study on the efficacy of CAs.[30] The authors evaluated the efficacy of Anterior Invisalign CAs in achieving predicted tooth movements in 37 adult patients. Predicted and achieved ClinCheck models were superimposed using ToothMeasure, a proprietary measuring software developed by Align Technology. Extrusion of maxillary central incisors was found to be the least accurate tooth movement with 18.3% accuracy.[30] In this study only anterior teeth were evaluated and Anterior Invisalign, the CA system used in the study, is a product that is no longer available.

In 2012, Krieger et al. evaluated the efficacy of Invisalign in achieving predicted tooth movements in the anterior region by comparing pre- and post-treatment casts of 50 patients treated with Invisalign.[31] Rather than studying individual tooth movements, the authors evaluated arch length, inter-canine distance, overbite, overjet, and midlines. They conclude that movements in the vertical plane resulted in larger deviations than movements in the sagittal or transverse dimension, but make no direct comment on extrusion of maxillary incisors.

In 2017, Grünheid et al. evaluated the efficacy of Invisalign in achieving predicted tooth movements for all teeth.[32] Post-treatment models of 30 patients were superimposed with their corresponding virtual treatment plan using best-fit surface based registration. Percent accuracy was not calculated, but the movements showing the greatest difference between predicted and achieved result were molar torque, mandibular incisor intrusion, and rotation of mandibular lateral incisors, canines and first premolars.[32]

Charalampakis et al. evaluated the efficacy of incisor, canine, and premolar movements with Invisalign in 2018.[33] Predicted and achieved models for 20 class I adult patients were superimposed on posterior teeth using Slicer CFM software (open-source, version 3.1; http://slicer.org). The authors reported that extrusion of maxillary incisors was accurate and in many cases achieved more extrusion than what was predicted. The authors noted that the method of superimposition used in the study may have contributed to this finding. In addition, measurements were taken from the incisal edge of the maxillary incisor and the authors failed to account for bucco-lingual tipping influencing linear measurements.[33]

A follow up study to the 2009 study by Kravitz et al.[30] was published in 2020 by Haouili et al.[34] The prospective study included 38 patients treated with Invisalign or Invisalign Teen. The accuracy of achieving predicted tooth movements was determined by superimposing the initial and final ClinCheck models with a best-fit analysis. They report a significant improvement in accuracy for all tooth movements compared to the 2009 study, with the most dramatic improvement for extrusion of maxillary incisors.[30] The authors attribute the improvement in extrusion accuracy to the use of extrusion attachments. A major limitation in this study, as with other studies,[30,32,33] is that ClinChecks were used for superimposition, which are a graphic depiction of force systems acting on the teeth, rather than a predictor of final tooth position.

A 2015 systematic review by Rossini et al. assessing the reliability of CAs in producing various tooth movements found that CAs are not effective in controlling anterior tooth extrusion. Specifically, extrusion of maxillary central incisors is the least predictable tooth movement in CAT.[10] Eleven relevant peer-reviewed articles published between January 2000 and June 2014 were included in the review. The primary evidence for the lack of efficacy of CAs in extrusion of maxillary central incisors is from the 2009 publication by Kravitz et al.[30] It is worth noting that there was significant heterogeneity in the studies included. Moreover, the data cited in this review is over seven years old and may not take into account more recent technological advancements.

More recently, in 2017 Rossini et al. published an updated systematic review evaluating the efficacy of CAT in controlling orthodontic tooth movements.[35] The updated review included 20 relevant articles, which was a significant improvement from the 11 articles evaluated in the 2015 publication. Despite the additional evidence and increased number of articles, the authors concluded that no significant data emerged regarding the efficiency of anterior extrusion in CAT, highlighting the need for additional research.[35]

A considerable portion of the maxillary incisor extrusion reported with CAT may be due to changes in the inclination and anterior-posterior position of anterior teeth rather than bodily extrusion of the incisors. Relative extrusion is a term that has been used to describe the geometric phenomenon of bite deepening as the buccal-lingual inclination of incisors is changed.[30] As incisors are retroclined and retracted, the position of the incisal edge of incisors changes. This creates the perception of extrusion, when there has been no change in the vertical position of the root apex (Figure 1). In the 2009 study by Kravitz et al., which highlights the difficulty of extruding maxillary incisors with CAs, the authors describe the use of retraction and retroclination of incisors as a more attainable, alternative method to absolute extrusion of maxillary anterior teeth. [30]

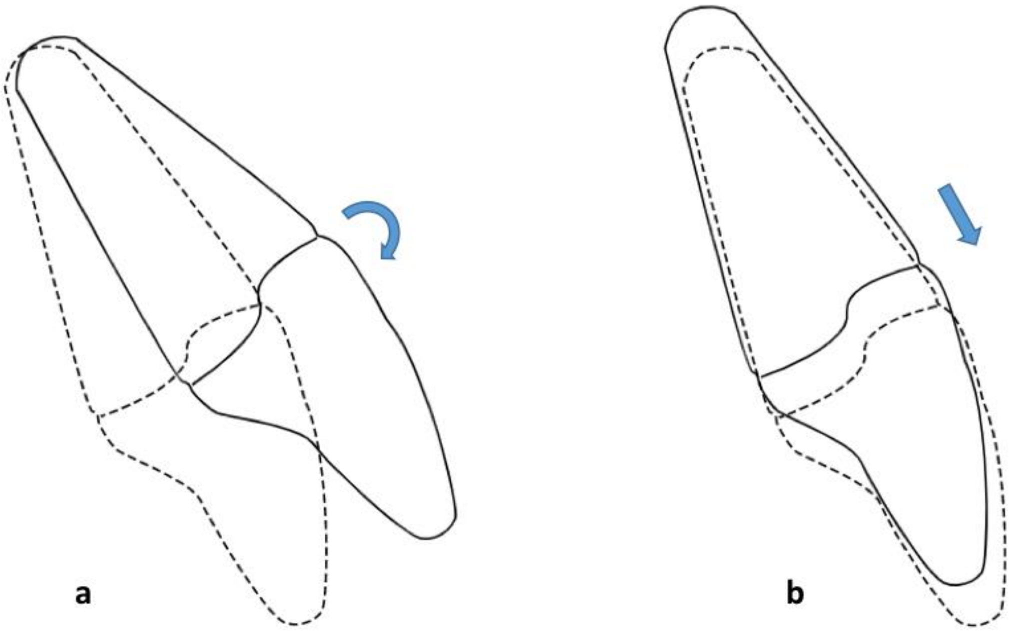

Figure 1: Graphic depiction of types of extrusion of a maxillary central incisor. a) Geometric extrusion; b) Absolute extrusion.

There have been three recent cephalometric studies evaluating open bite treatment with CAs.[36–38] Garnett et al. compared cephalometric outcomes of 36 adult patients treated with aligners to 17 adult patients treated with fixed appliances.[36] Apart from slightly more extrusion of lower incisors in the aligner group, the authors reported no significant difference between the two groups. Regarding the patients treated with CAs, the authors concluded "significant retroclination of upper and lower incisors, good vertical control, and no significant extrusion of posterior teeth appeared to be the main mechanisms of bite correction."[36] Harris et al. evaluated 45 adult patients treated with Invisalign to correct anterior open bites in a retrospective cephalometric study.[37] While the authors reported the effectiveness of Invisalign in treating anterior open-bite cases by a combination of anterior extrusion and posterior intrusion, they reported "significant retraction of maxillary and mandibular incisors," rather than absolute extrusion of the maxillary incisors.[37] Moshiri et al. retrospectively analyzed pre- and post-treatment cephalograms for 30 adult patients with anterior open-bites treated with Invisalign.[38] The authors of this study reported limited extrusion of maxillary incisors and concluded the open bites were successfully treated with a combination of counterclockwise rotation of the mandibular plane, lower molar intrusion and lower incisor extrusion. Further, they concluded increased extrusion of the lower incisors was observed compared to the maxillary incisors due to more interproximal reduction being prescribed in the lower arch allowing for more retraction and retroclination of the lower incisors.[38] These cephalometric studies[36–38] provide evidence that extrusion of maxillary incisors with CAs is achieved largely by retraction and retroclination of maxillary incisors rather than absolute extrusion.

Composite Attachments

Composite resin attachments have been introduced as a way to improve aligner retention and allow more predictable tooth movement. An attachment is a composite handle of well-defined geometry, protruding from the tooth surface. Attachments are placed to improve aligner retention and to help generate forces or moments.[39] After identifying extrusion of maxillary central incisors as a difficult tooth movement to achieve with CAs, the next logical step was to elucidate what makes it unpredictable and to identify strategies to improve efficacy. The shape of maxillary incisors and the lack of aligner retention have been proposed as reasons for the observed lack of efficacy. The shape of a maxillary central incisor predisposes the tooth to retention challenges. In the absence of an undercut, the aligner will slip off the flat surface of the tooth resulting in loss of aligner contact, which is referred to as aligner lag.[40] If a CA is not in contact with the tooth surface, it will be ineffective in applying an extrusive force. Jay Bowman described the shape related challenges of extruding a maxillary central incisor stating, "we cannot expect a blade-shaped tooth to track occlusally as if magically attracted to plastic above it."[40]

The first generation of CAs relied solely on a mismatch between the tooth and aligner to move teeth into a predetermined position and did not incorporate auxiliary features.[41] Attachments were introduced with the second generation of Invisalign CAs, as well as composite buttons for the use of intermaxillary elastics. The attachment configurations first introduced were ellipsoid, rectangular, and rectangular beveled (Figure 2) and were termed "conventional attachments."[42] Conventional attachments are still available and widely used today.

SmartForce features, which include optimized attachments, were introduced by Align Technology in 2009. Per the manufacturer, optimized attachments are designed to deliver optimal forces and moments based on individualized attachment shape and placement.[43] An important feature of the optimized attachments is that, unlike conventional attachments, the attachment recess in the aligner is not the same shape as the attachment. The aligner is designed to contact the optimized attachment on one surface with an intentional gap between the aligner and attachment on the opposing surface, to provide clearance for unimpeded tooth movement.[43] Currently, there are an abundance of attachment shapes and designs available, that are proposed by various CA manufactures to be tailored to specific tooth movements.

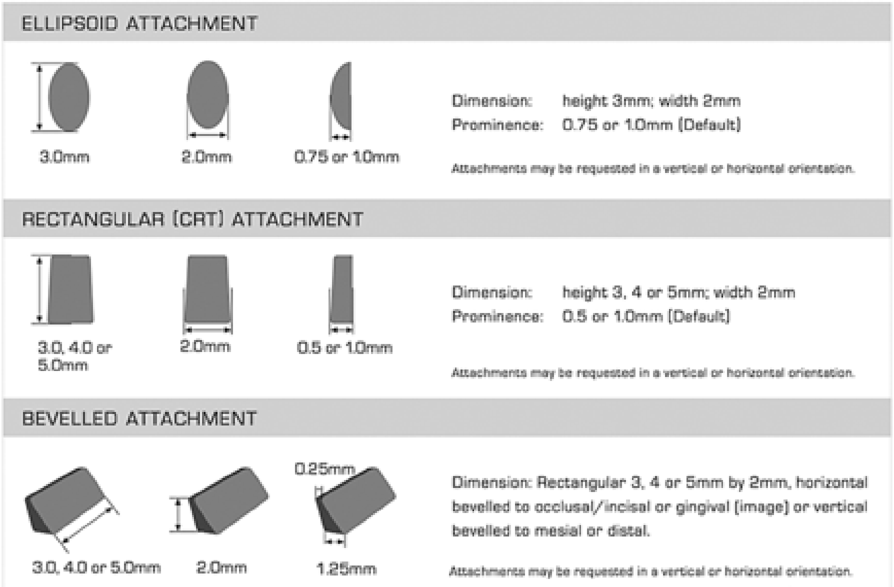

Figure 2: First generation of aligner attachments.[42]

Clear Aligner Material Properties and Stress Relaxation

The optimal CA material would be transparent, biocompatible, highly resilient, have a low degree of hardness, good elasticity, and resistant to enzymatic degradation from the saliva.[44] Thermoplastic sheets have been used to fabricate orthodontic CAs since their introduction to dentistry by Nahoum in 1959.[13] Thermoplastic materials are widely used in dentistry and orthodontics because of their unique physical properties.[45] Unlike traditional orthodontic appliances, the quality of the orthodontic force exerted by a thermoplastic CA is dependent on the mechanical properties of the fabrication material.[46] CA materials are composed of branched polymers, which determine the adaptability, flexibility, elasticity and clarity of the material. There are currently many different polymers being used to fabricate CAs, however Polyurethane (PUR), polyethylene terephthalate glycol (PET-G), polycarbonate (PC), thermoplastic polyurethanes (TPU) ethylene vinyl acetate, polyethylene terephthalate (PET) and copolyester are the most common materials used.[47]

The CAs initially introduced by Align technology were made of a single-layer rigid polyurethane. In 2012 this material was replaced by SmartTrack, a multilayer thermoplastic polyurethane, that was designed to have greater elasticity and produce lighter, constant forces making orthodontic treatment more predictable.[48] The proprietary multilayer design was able to combine the advantageous properties of multiple plastic layers into a single CA material. Since the release of SmartTrack in 2012, other manufacturers have developed multilayered CA materials. For example, Bay Materials recently developed a dual layer material called Zendura FLX, which, according to the manufacturer produces lower insertion forces, reduced pain, greater force production over time and more predictable tooth movement.[49]

While each thermoplastic aligner material is composed of a unique composition of polymers, the biomechanical properties continue, in many ways, to be comparable.[50] CAs, like other thermoformed materials, are viscoelastic in nature and are subject to deformation upon intraoral placement. When a thermoplastic material is subjected to a force, stress within the material, induced by initial deformation, causes deterioration of its mechanical properties over time.[45] At constant deflection, the load of viscoelastic materials decreases over time, which is referred to as stress relaxation.[48] Stress relaxation is a time-dependent material property of CAs defined as a steady reduction of stress when a material is held at a constant strain. Clinically, this means the CA loses its ability to impart orthodontic force on the teeth over time.

When a CA is inserted, forces immediately develop in specific areas of the aligner corresponding to the programmed tooth movement. The resultant force acting on the dentition is due to displacement of the aligner material. The initial magnitude of the force delivered by a CA to a tooth depends on material properties of the CA such as its thickness and stiffness, as well as the amount of displacement programmed into the CA. Stress relaxation begins to occur as soon as the aligner is inserted by the patient and the amount of force delivered by the CA immediately begins to decrease.[48] In CAT, each aligner is typically worn for 1-2 weeks. Thus, maintaining the appropriate magnitude of force for this duration is critical to achieve predictable OTM. [50]

Zhang et al. investigated stress relaxation properties in thermoplastic materials used for CAs.[46] The authors compared a PETG/PC/TPU polymer blend to Erkodur (Erkodent, Pfalzgrafenweiler, Germany) and Biolin (Dreve, Unna, Germany), two commercially available thermoplastic products. Rectangular samples measuring 5 mm x 40 mm of the thermoplastic aligner material were loaded and unloaded using a universal testing machine and stress within the material was recorded for one hour. The results of the study showed that when PETG was blended with PC, the stress relaxation rate increased with increasing blend ratio of PC. When PETG was blended with TPU, the stress relaxation rate decreased with increasing blend ratio of TPU. This study provides evidence that different polymers used to fabricate CAs have different rates of stress relaxation.[46] A limitation of this study was that it was not in vivo and the polymers may perform differently in the oral cavity. Additionally, raw materials were used rather than CAs and the thermoforming process may affect the material properties of the materials studied.

Two years later, Fang et al. conducted a similar study measuring stress relaxation of orthodontic materials in a simulated oral environment.[45] The authors tested five commercially available thermoplastic materials cut into dumbbell-shaped (115 mm long and 6 mm wide in the narrowest region) specimens. The materials tested were Erkodur (PET-G), Biolon (PET), Masel (Copolyester), and Duran (PET-G). The specimens were stretched to, and maintained at, 5% strain for three hours in an ElectroForce testing instrument (Bose, Farmington, MA, USA). Stress within the materials was measured over a three-hour period. Data was collected in a water bath set at 37 º Celsius to simulate the oral environment and compared to samples tested in ambient atmospheric conditions at 20 º Celsius. Results demonstrated significantly greater rates of stress relaxation obtained for samples tested at 37 º Celsius compared to those at room temperature. They found that the five thermoplastic aligner materials tested delivered only 42.29 % - 66.56 % of their initial force levels after immersion in the water bath for three hours.[45] This study provides evidence that the oral environment may significantly accelerate the stress relaxation of orthodontic thermoplastic materials. A limitation of this study is that while a water bath simulating the oral environment was used, this was not an in vivo study and the oral environment consists of other complexities and confounders than temperature alone.

More recently, improving upon the limitations of the study by Fang et al.,[45] Lombardo et al. investigated the stress relaxation properties of four orthodontic aligner materials in a 24 hour in vitro study.[48] Three 25 x 50 mm samples of each CA material were preconditioned in distilled water at 37 º Celsius for 24 hours prior to testing. Samples were placed in a hydraulic circuit with a constant load applied for twenty-four hours using an Instron 4467 dyanometer (Instron, Norwood, MA, USA). Similar to previous studies[45,46] rapid force decay was observed with total stress relaxation ranging between 19.9% and 62% for the four materials. In all four materials tested, stress decay was rapid during the first eight hours of testing and plateaued soon after. Interestingly, the aligner material with the highest initial force showed the greatest amount of decay and the material with the lowest initial force levels showed the smallest amount of force decay.[48] This study provides evidence that the force decay of CAs occurs rapidly until it plateaus upon reaching a critical point and that different aligner materials demonstrate different rates of stress relaxation. The authors suggested that future characterization of stress relaxation should be performed on materials of similar thickness, following the thermoforming process, and for a duration longer than 24 hours.[48]

A study conducted by Skaiik et al. in 2019 investigated the effect of time and frequency of removal on the force delivered by two thermoplastic CA materials.[51] A series of CAs with varying degrees of activation (0.0, 0.1, and 0.2 mm) at the maxillary central incisor, maxillary premolar, and maxillary molar were fabricated from PET-G and a modified PET-G material with a higher modulus of elasticity (Smartee Denti-Technology, Shanghai, China). Sensors measuring 0.2 mm thick (Yu Bo Intelligent Technology, Hangzhou, China) were placed on resin models. Aligners were seated on the resin models in room temperature as data was displayed in real time. The aligners were seated and removed 50 times with measurements collected every ten minutes. The authors found that as activation of the aligner increased, force decay also increased. Additionally, the force exerted by the CA decreased with increased removal frequency. This study provides evidence that increased aligner activation and frequency of removal contribute to increased stress relaxation in thermoplastic CA materials.

In 2020, a one-week long stress relaxation test on four orthodontic thermoplastic polymers was conducted by Jaggy et al.[50] The CA materials tested were CA-medium (Scheu-Dental, Iserlohn, Germany), Copolyester (Dentsply, Sarasota, FL, USA), Duran (Great Lakes Dental Technologies, Tonawanda, NY, USA), and Erkodur (Erkodent, Pfalzgrafenweiler, Germany). The aligner materials were thermoformed over a rectangular dental stone and prepared into strips (30 mm x 4 mm x 0.4 mm). Samples were then subjected to 2.1 MPa of constant force for seven days. The results of the study showed that the CA materials demonstrated an initial rapid decay in stress in the first two hours, followed by a slower release for the remainder of the seven days. While this study provides the longest stress relaxation data currently published on thermoplastic orthodontic materials, a limitation of the study is that the CA materials were tested dry and at room temperature.[50]

Stress relaxation properties of four CA materials following cyclic extension was recently investigated by Keller et al.[52] The aim of the study was to provide baseline information on the force change produced by repeated insertion and removal of CAs. The materials tested in the study were Essix Ace (Dentsply, Sarasota, FL, USA), Taglus (Allure Ortho, Whitinsville, MA, USA), Zendura, and Zendura FLX (Bay Materials, Fremont, CA, USA). Aligners were fabricated on resin blocks to simulate how the material is stretched during CA fabrication. The samples were cut into rectangular strips (76 mm x 18 mm) and loaded into a servohydraulic Instron Universal Testing Machine, submerged in a water chamber at 37° Celsius. Each sample was stretched and relaxed for fifty cycles. Force was measured after the first cycle, second, third, and fiftieth cycle, as well as one week after initial testing. The results showed that force levels decreased by 50% between the first and second cycle and decreased again by 50% between the third and fiftieth cycle. Interestingly, after one week of relaxation the force levels rebounded to slightly below the initial levels. A limitation of this study was the force level chosen to impart on the CA material. It was determined by the lowest yield strength of the material. A more appropriate force level may have been a force corresponding to the amount of deformation a CA undergoes when placed over a large attachment, simulating the force imparted on the CA during clinical use. Additionally, the materials were thermoformed over rectangular blocks, while CA geometry is significantly more complex.

Clear Aligner Therapy Force Measurement Techniques

A number of different methods have been described to measure CA force systems. The ideal method to measure forces delivered by a CA would be to measure the forces applied to teeth in vivo. However, presently, there are no in vivo studies in the orthodontic literature directly measuring the forces and moments applied to teeth by CAs. The first technique reported in literature to measure the force imparted by a CA was described by Barbagallo et al. and utilized a pressure sensitive film (Fuji Photo Film, Tokyo, Japan) placed between the CA and the maxillary first premolar.[53] The CA was programmed to perform 0.5 mm of buccal tipping of the maxillary first premolar. The force applied by the CA was transmitted to the film, resulting in pressure stain samples. The pressure stain samples were compared to stain samples of known pressures using a combination of digital imaging and spectrophotometry.[53] The authors calculated the mean initial force at aligner insertion to be 5.12 N, which rapidly decayed over a two-week period to -2.67 N at aligner retrieval. The authors concluded that the CAs used in the study produced high initial forces that rapidly diminished. Significant variation was noted during repeated measurements and 95% of the force measured was attributed to irrelevant pressures, demonstrating the shortcomings of this technique.

A method of indirectly measuring in vivo forces by measuring von Mises strain was described by Vardimon et al. in a prospective cohort study.[54] Two identical sets of Invisalign CAs were fabricated for three patients requiring incisor retraction with stationary anchored premolars. Strain gauge rosettes (Vishay Measurements Group, Raleigh, NC, USA) were bonded to the aligner on facial surface of the maxillary central incisor and the buccal surface of a maxillary premolar to measure von Mises strain during incisor retraction. Measurements were collected over a two-week period on the identical duplicate CA that was not exposed to the intraoral environment. The authors observed the von Mises strain peaked day 1, decreased significantly day 2 and plateaued from days 2-15. Based on the findings of the study, the authors recommended that each aligner be worn full time for the first 2 days and then wear time can be decreased during the following 12 days, corresponding to the plateau in von Mises strain. The authors also recommended a longer wear regimen at the final stages of treatment, or the use of a thicker and more rigid aligner material. The conclusions drawn by the authors were based on the premise that the strain on the aligner surface can be interpreted as force exerted by the CA on the tooth.

More recently, Cervinara et al. evaluated the precise points of pressure exertion by passive CAs and active CAs with 2 degrees of tipping of a maxillary central incisor.[55] Stereolithography (SLA) models were utilized and pressure was measured using a chemically treated PET film housed between the aligner and the SLA model. Pressure was recorded by the pressure sensor film as the F22 TPU aligners (Sweden and Martina Due Carrarae, Padua, Italy) were seated on the SLA models for fifteen seconds. Film samples were subsequently scanned, digitized and interpreted. The authors found that both passive and active aligners exerted a net force on the maxillary central incisor. While the net pressure across the entire tooth was similar between groups, the authors noted a statistically significant difference between identical passive and active aligners. The authors attributed this finding to the variability in the CA manufacturing process. Limitations of this study are the assumptions made during calculation of net force and the absence of a periodontal ligament in the SLA models. An additional limitation of this technique, as well as the other previously described techniques,[53,54] is the attachment of the measurement apparatus to the CA. It may have altered the mechanical properties of the aligner and the adaptation of the CA to the tooth surface. Ideally, force measurements would be collected without placing a measurement device between the tooth of interest and the CA.

A variety of techniques using force measuring devices have been developed in order to more thoroughly quantify the force systems of CAs. Hahn et al. described the use of a modular force-torque measuring device to measure forces with six degrees of freedom in a series of in-vitro studies.[56–58] A standard resin model of a maxillary arch (Frasaco, Tellnang, Germany) was used with a separated maxillary central incisor. The authors placed CAs on the model with artificial saliva in a chamber set to 37 ° Celsius to simulate the oral environment. A Nano 17 (ATI Industrial Automation, Apex, NC, USA) sensor was fixed to the central incisor with a clamp to measure forces and moments during tipping[56,58] and torque.[57] The authors found that the thickness of CA material and the thermoforming process influenced the force magnitude[56] as well as the material used and the shape of the tooth.[57]

A similar force measuring technique was described in a series of in vitro studies by Elkholy et al.[59–61] Like the studies by Hahn et al.,[56–58] the authors used a standard resin model of a maxillary arch (Frasaco, Tellnang, Germany) with a separated central incisor. The incisor was mounted with a Nano 17 force and moment sensor (ATI Industrial Automation, Apex, NC, USA) to record the forces and moments imparted by the CA during experimental tooth movement. Again, the oral environment was simulated using artificial saliva and aligners were stored in a climate chamber at 37° Celsius for at least 30 minutes prior to data collection. In a later study, Elkholy et al. described a similar force measuring device with a separated maxillary canine, evaluating the effectiveness of various attachment geometries during the rotation of a maxillary canine.[62] The authors noted the absence of a periodontal ligament (PDL) as a limitation of their technique, but concluded that it is the best available experimental method to achieve quantitative measurements when studying forces imparted by CAs.[62]

Costa et al. used a similar force measuring device to investigate the effect of three different attachment designs on the extrusive force imparted by CAs on a central incisor.[39] Meshmixer software (Autodesk, Mill City, CA, USA) was used to design a rectangular attachment (4 mm width x 2 mm height x 3 mm depth), a rectangular beveled attachment derived from a cuboid (4 mm width x 2 mm height x 3 mm depth) with a 45 degree bevel, and a rounded attachment of unknown dimensions. Three CAs were fabricated for each attachment geometry using Poyacetal DH aligner material (Dhpro, Parana, Brazil) with a thickness of 0.75 mm. Each aligner was programmed to extrude the central incisor 0.33 mm and the margins of each CA were trimmed with a standardized margin using an HM carbide cutter (Scheu, Iserlohn, Germany). Each CA was loaded onto a force gauge with three one-dimensional load cells (Diamond, Hong Kong, China) attached to the maxillary central incisor to record force measurements along the X, Y, and Z axis. The results of the study demonstrated that the varying attachment geometries generated variable forces in all three dimensions. The authors concluded that the rectangular attachment generated the greatest extrusive force but also generated unwanted forces in other planes of space. Notable disadvantage of these in-vitro studies utilizing a force measuring device is the lack of simulation of a PDL. Additionally, benchtop studies are unable to fully simulate the oral environment.

Another method of analyzing the force imparted by a CA is the Finite Element Method (FEM). Savignano et al. investigated the effect of four aligner auxiliary designs on the extrusive force applied to a maxillary central incisor using finite element analysis (FEA).[63] The authors compared an aligner with no attachment to aligners with a rectangular palatal attachment (4.0 mm width x 2.0 mm height x 2.5 mm depth), a rectangular buccal attachment (4.0 mm width x 2.0 mm height x 2.5 mm depth), and an ellipsoid buccal attachment (4.0 mm width x 2.5 mm height x 1.5 mm depth). Forces and moments were calculated for each configuration at the center of resistance of the tooth. The maximum tooth displacement on the z-axis was observed for the rectangular palatal attachment, while the least amount of extrusive force was noted for the aligner with no attachment. The ellipsoid attachment produced the most undesirable forces and moments. The authors concluded that a rectangular palatal attachment can improve the effectiveness of CAs in the extrusion of maxillary central incisors, and that extrusion of a maxillary central incisor cannot be achieved without an attachment.[63] A limitation of this study is that only four aligner auxiliaries were modeled, and the assumptions made in the FEA model.

A similar study using FEA to evaluate the effect of six attachment configurations on the extrusive force applied to a maxillary central incisor during CAT was competed by

Rossini et al.[64] Six models were produced using CAD software (SpaceClaim, Canonsburg, PA, USA) and imported into FEA software (ANSYS 18.2, Canonsburg, PA, USA). The authors compared force systems for an aligner with no attachments, rectangular attachments on the incisors only, rectangular attachments from second molar to canine only, optimized extrusion attachments on the incisors and rectangular attachments on the second molar to canine, rectangular buccal attachments on the incisors plus rectangular attachments second molar to canine, and rectangular palatal attachments on the incisors plus rectangular attachments from second molar to canine. All rectangular attachments measured 3.0 mm width x 2.0 mm depth x 1.0 mm height and the optimized extrusion attachments were the ones used in the ClinCheck software. The results of the study showed the most ideal force distribution with a horizontal attachment on the facial or lingual of the incisors and when horizontal attachments were placed on posterior teeth. For all simulations, significant retroclination of the maxillary incisors was observed, rather than pure bodily extrusion. The authors concluded that pure bodily extrusion of incisors is unpredictable and results in retroclination of central incisors.[64]

A limitation of these FEA techniques is that they are models and in vivo and in vitro results may differ. FEA is a valuable tool to analyze force systems in orthodontics; however, modeling the material properties of biological components such as the PDL remains an issue. Additionally, aligner material, friction, the thermoforming process and insertion and removal of the aligner are factors that affect the material properties of CAs. Many of these factors are considered proprietary information and are not disclosed by companies, thus cannot be used to increase the complexity of the FEA.[64]

Aims and Hypotheses

The general aim of this study was to evaluate the effect of attachment size and location on the extrusive force delivered by Zendura FLX clear aligners to a maxillary central incisor during extrusion along the long axis of the tooth.

The specific aims of this study were:

1. To compare the extrusive force applied to a central incisor by a Zendura FLX clear aligner when three sizes of rectangular extrusion attachments were utilized as well as in the absence of an attachment.
2. To compare the extrusive force applied to a central incisor by a Zendura FLX clear aligner when four locations of rectangular extrusion attachments were utilized as well as in the absence of an attachment.

The following hypotheses were tested:

1. H_0: There is no difference in the initial extrusive force when different sized horizontal extrusion attachments are utilized during the extrusion of a maxillary central incisor with a clear aligner.
2. H_0: There is no difference in the initial extrusive force when different locations of horizontal extrusion attachment are utilized during the extrusion of a maxillary central incisor with a clear aligner.
3. H_0: There is no difference in the initial extrusive force during the extrusion of a maxillary central incisor with a clear aligner in the presence or absence of an attachment.

Materials and Methods

Model Fabrication

A micro-CT scan was taken of an SLA model of a maxillary arch with a full complement of teeth excluding third molars. The DICOM file was then converted to an STL file and the scan was imported into uLab's uDesign software version 5.8.1 (uLab Systems, Memphis, TN, USA). Using uDesign, the maxillary arch was segmented and the right central incisor was removed, generating the target tooth and remaining maxillary arch. The remaining arch had a base added with a platform containing holes, placed to orient the model on the force measuring device. The STL files of the target tooth and the remaining arch were exported and uploaded to PreForm 3D Printing Software (Formlabs, Somerville, MA, USA). The central incisor target tooth and maxillary arch were printed in Formlabs Photopolymer Resin containing a mixture of (meth)acrylated monomers, (meth)acrylated oligomers, and photoinitiators. Manufacturing instructions were followed for the printing and post-curing process.[65] Models were removed from the platform with a spatula and pre-washed for 60 seconds in 99% Isopropyl Alcohol (Breen Laboratories, Carson, CA, USA). Models were then rinsed for 10 minutes in 99% Isopropyl Alcohol, in the Form Wash (Formlabs, Somerville, MA, USA) and allowed to air dry for twenty minutes. Dry models were placed in the Form Cure (Formlabs, Somerville, MA, USA) for 30 minutes following manufacturer recommended settings.[65] Models were visually evaluated for printing and processing errors and remade if errors were detected.

The target tooth and arch were reassembled on the uForce platform. Gaps between the target tooth and arch were temporarily filled with Play-Doh (Hasbro, Pawtucket, RI, USA) to facilitate the scanning of the assembled arch. The reassembled maxillary arch was scanned using an Itero Element Intraoral Scanner (Align Technology, Phoenix, AZ, USA) and an STL file was generated. The STL file was imported into uLab's uDesign software version 5.8.1. The teeth, occlusal grooves, incisal edges and the long axis of each tooth was identified (Figure 3a-c).

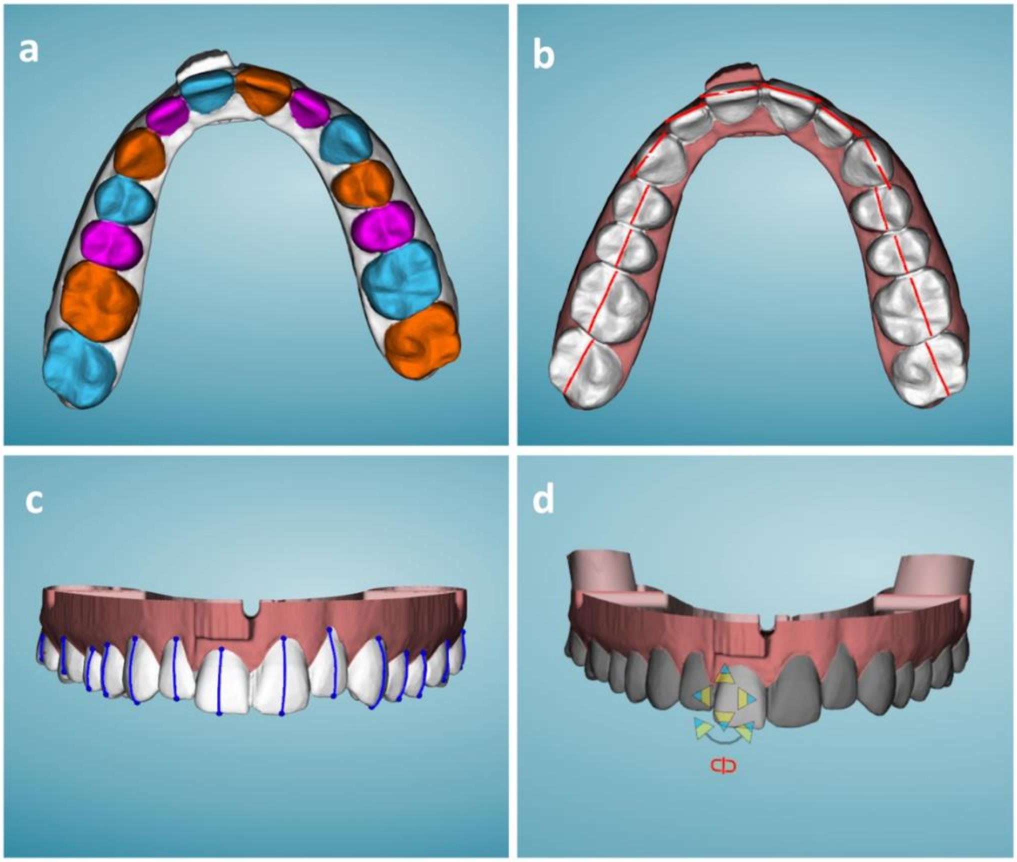

Figure 3: Maxillary arch in uDesign software. a) Identification of individual teeth. b) Identification of occlusal grooves and incisal edges. c) Identification of long axes of teeth. d) Extrusion programmed into maxillary right central incisor with all remaining teeth set as immovable.

Clear Aligner Design

Using uDesign, 0.25 mm of extrusion along the long axis of the maxillary right central incisor was programmed with all other teeth set as immovable (Figure 3d). The identified arch and programmed tooth movement was saved and used for all subsequent aligner designs so that each CA group was programmed to perform the same tooth movement. The STL file was exported as the No attachment control. Using the saved tooth movement setup, a standard, rectangular anterior extrusion attachment (4.1 mm width x 2.6 mm height x 2.5 mm depth) was placed on the midfacial surface of the crown to generate the Medium attachment design. The attachment was modified by increasing its width and height by 1 mm to generate the Large attachment design (5.1 mm width x 3.6 mm height x 2.5 mm depth). Width and height of the standard anterior extrusion attachment were decreased by 1 mm to generate the Small attachment design (3.1 mm width x 1.6 mm height x 2.5 mm depth), while all other variables were unchanged (Figure 4).

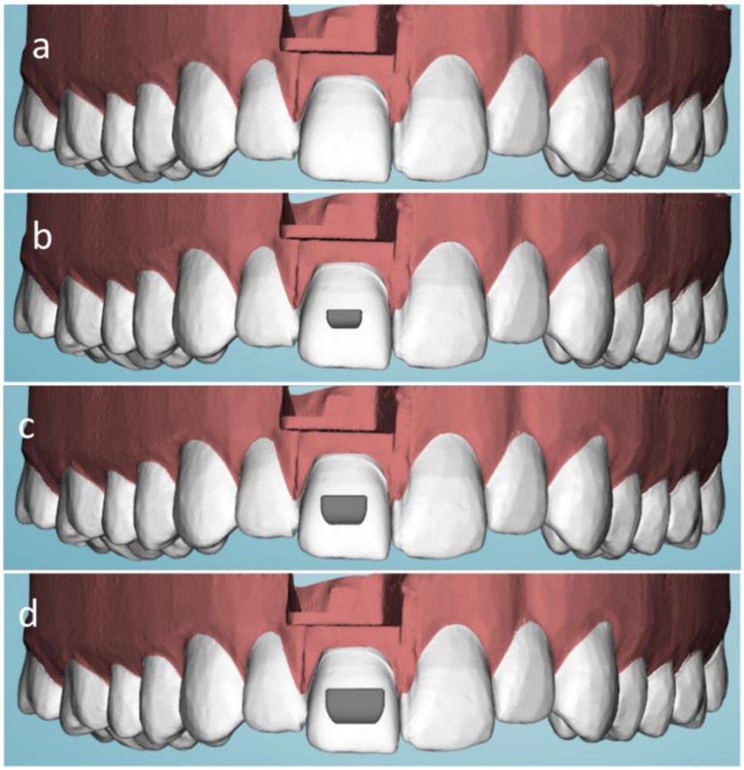

Figure 4: Attachment size design. a) No attachment. b) Small attachment. c) Medium attachment. d) Large attachment.

Using the same arrangement in uDesign as described previously, a standard, anterior extrusion attachment (4.1 mm width x 2.6 mm height x 2.5 mm depth) was placed on the mid-facial surface of the crown to generate the Mid-Facial attachment design. The attachment was moved 2 mm gingival to create the Gingival attachment design. The attachment was moved 2 mm incisal from the midfacial of the crown to create the Incisal attachment design. The attachment was then moved to the center of the lingual surface of the clinical crown to create the Lingual attachment design (Figure 5).

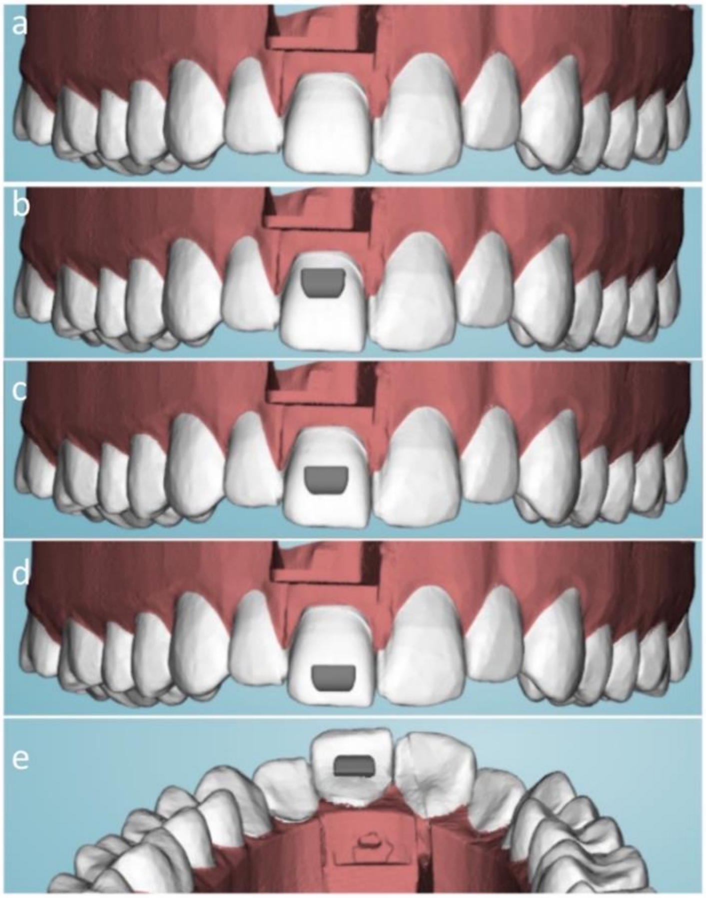

Figure 5: Attachment location design. a) No Attachment. b) Gingival attachment. c) Mid-Facial attachment. d) Incisal attachment. e) Lingual attachment.

The files for all attachment configurations were exported as STL files. Additionally, attachment transfer templates for each attachment design were exported as STL files. The SLA models for CA fabrication, the SLA models for attachment transfer templates and 9 target teeth were printed using the same printing process as described previously. All SLA models were closely evaluated for printing errors and discarded and refabricated if errors were observed.

Clear Aligner and Attachment Template Fabrication

In total, 45 SLA models to fabricate CAs, 7 SLA models to fabricate attachment templates, and 9 target teeth were printed. Prior to CA fabrication, the SLA models were sprayed with Trim-Rite releasing agent (Dentsply Sirona, York, PA, USA) and allowed to air dry. All CAs and attachment templates were fabricated using Zendura FLX (Bay Materials, Fremont, CA, USA) in 0.030 mil (0.75 mm) thickness CA material. A Biostar machine (Great Lakes Orthodontics, Tonawanda, NY, USA) was used for the thermoforming process. The SLA models were placed on a uContour model platform designed to fit the model, the Biostar machine, and orient the model in the uContour machine. The uContour model platform was placed in the Biostar machine with the SLA model oriented with the facial surface of the incisors facing the heating element (Figure 6a). Tray material was heated for 50 seconds at 427° Fahrenheit following manufacturer recommendations. After the thermoforming process, CAs were visually inspected for adequate adaptation of the CA material to the SLA model and rejected and remade if necessary.

The uCounter platform containing the SLA model and thermoformed aligner was placed in the uContour machine (uLab Systems, Memphis, TN, USA) to trim the aligners (Figure 6b). The trim line was set using uLab's uDesign software version 5.8.1. All CAs and attachment templates were trimmed with a straight margin, 0.75 mm apical to the gingival zenith (figure 6c). Trim lines were visually inspected and CAs were rejected and remade if necessary.

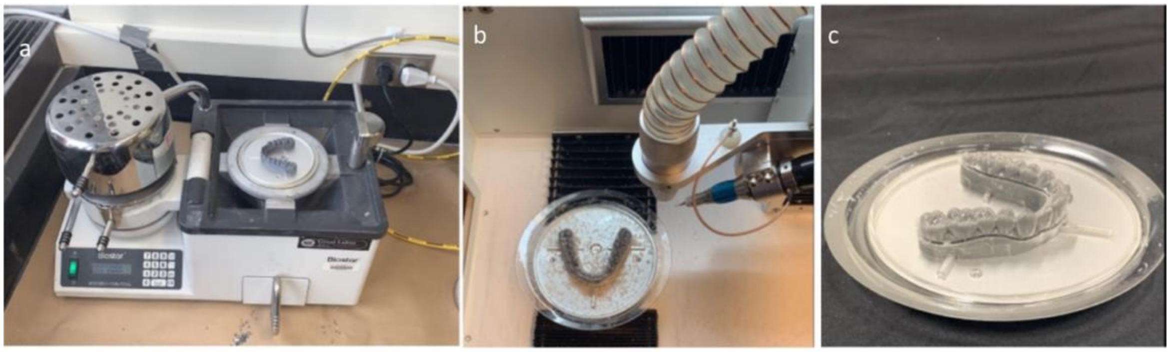

Figure 6: Clear aligner fabrication. a) Thermoforming with Biostar. b) Trimming model using uContour. c) Trimmed clear aligner and SLA model on uContour platform.

Attachment Placement

Bracepaste medium viscosity adhesive (American Orthodontics, Sheboygan, WI, USA) was placed in the attachment well of the attachment templates using a plastic instrument. To bond the attachments to the target teeth, Assure Plus primer bonding resin (Reliance Orthodontic Products Inc. 2021) was placed on the central incisor in the area of the planned attachment placement, air thinned and light cured. The attachment template was firmly placed on the target tooth and light cured. The attachment template was removed and composite attachments were visually inspected for accuracy. The procedure was repeated to produce target teeth with attachments corresponding to the three attachment size groups and the four attachment location groups. Attachment flash was carefully removed using a carbide finishing bur under magnification. No modifications were made to the central incisor target tooth for the two No attachment control groups.

Force Measurement using uForce Instrument

The uForce instrument used for force measurements was designed and fabricated by uLab Systems Inc. The device has the capability to measure force and moment load of an object with six degrees of freedom (Fx, Fy, Fz, Mx, My, Mz). Forces are measured in N and moments measured in Nmm. For each aligner group, the corresponding target tooth was secured to the sensor. Sensor control software was installed on a computer adjacent to the uForce instrument and force readings were displayed in real time.

After securing the target tooth to the sensor (Figure 7), offset data was collected in real time without CA engagement. As real time data was shown, the CA was seated on the model and secured with firm finger pressure. Measurements were taken after 30 seconds to allow the aligner to stabilize. The CA was carefully removed from the model and replaced after 30 seconds. To account for variability in seating the CA on the model, 3 measurements were taken for each CA. To account for fatigue of the uForce instrument and potential wear of the model, each CA was assigned an ID and a random number generator was used to randomize the order in which data was collected. Extrusive force measurements were taken following the same protocol until all 45 aligners had been measured 3 times. Force measurements were rounded to the hundredths place prior to statistical analysis.

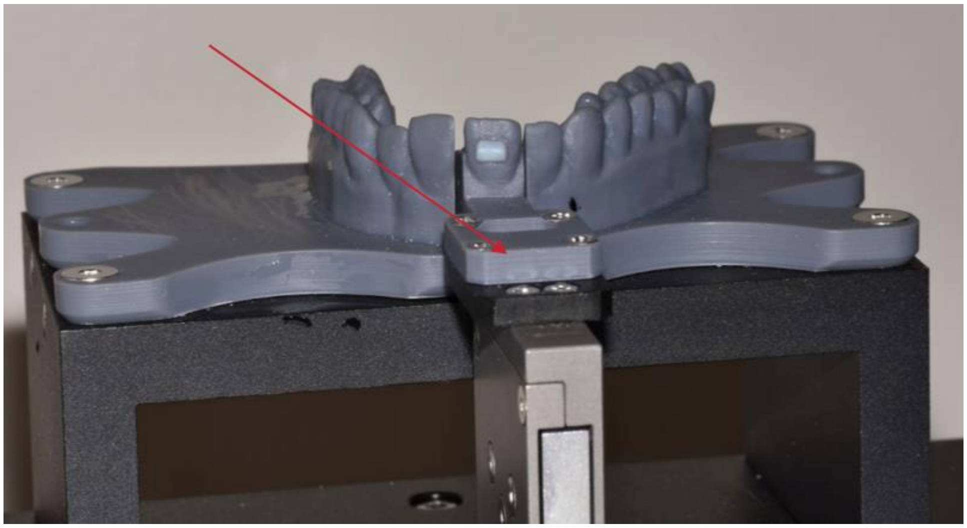

Figure 7: uForce assembly with Mid-Facial attachment target tooth. Arrow indicates interface of target tooth and sensor.

During initial data acquisition, in trials involving a composite attachment, it was observed that each time the CA was removed from the model and replaced, the force generated by the aligner decreased noticeably. This trend was not observed in the No attachment control groups. Owing to this observation, additional experiments were designed. Using the previously described protocol for SLA model and CA fabrication, 5 additional CAs with no attachment and 5 CAs with a standard anterior extrusion attachment were fabricated. For each CA, 30 measurements were acquired using the previously described force measurement acquisition protocol. Additionally, The second and third force measurements pertaining to attachment size and location were discarded.

Statistical Methods

Means and standard deviations (SD) were calculated and presented by group. Data were checked for normality using the Shapiro-Wilk test and homoscedasticity using the Bartlett's test. ANOVA was conducted to compare the means between groups. Tukey's method was used as a post-hoc procedure for pairwise comparisons. Analyses were performed in SAS software version 9.4 (SAS institute, Cary, NC, USA). P-values less than 0.05 were considered to be statistically significant.

Results

Attachment Size

The initial extrusive force levels are presented by group in Table 1. Raw data for all trials corresponding to attachment size is presented in Table 3 of the appendix. All pairwise comparisons for initial extrusive force were found to be statistically significant with p-value < .0001 for all pairwise comparisons and F test p-value < .0001. The largest initial extrusive force was observed in the Large attachment group. The attachment group with the smallest initial extrusive force was the Small attachment group. The smallest initial extrusive force was observed in the No attachment control. There was a positive relationship between attachment size and initial extrusive force and all groups with attachments generated greater initial extrusive force than the No attachment control.

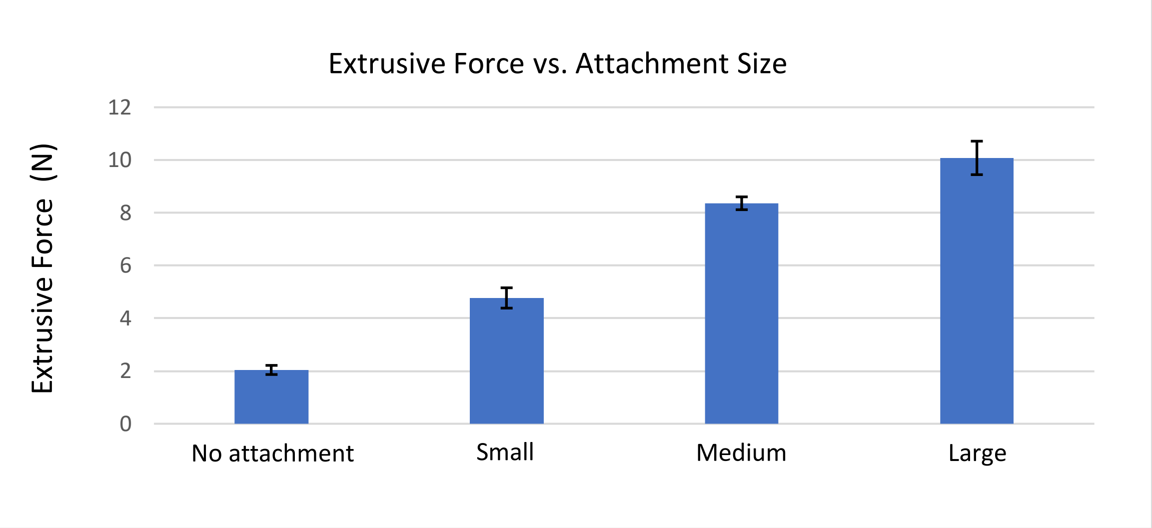

Figure 8: Extrusive force vs. attachment size. N indicates Newtons. Error bars represent standard deviation.

Attachment Location

Mean initial force levels are presented by group in Table 2. Raw data for all trials corresponding to attachment location is presented in Table 4 of the appendix. Pairwise comparisons for all attachment location groups were statistically significant compared to the No attachment control with p-values < .0001 for all pairwise comparisons and F test p-value < .0001. The largest mean extrusive force was observed in the Mid-Facial attachment group. Of all of the attachment locations, the Incisal attachment group had the lowest initial extrusive force, and also demonstrate the largest SD. Pairwise comparisons for the Incisal attachment group vs. the Gingival attachment group as well as the Incisal attachment group vs. the Mid-Facial attachment group were found to be statistically significant with p-values of 0.033 and 0.002, respectively. Mean initial extrusive force for attachment groups were comparable demonstrating differences that were not as robust as the differences observed related to attachment size.

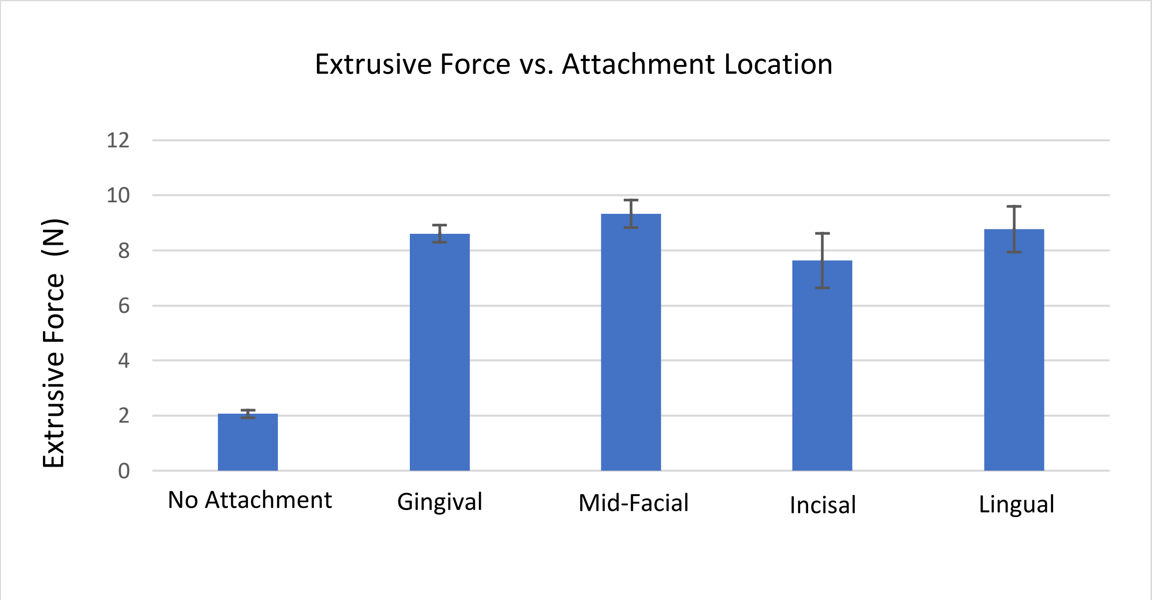

Figure 9: Extrusive force vs. attachment location. N indicates Newtons. Error bars represent standard deviation.

Stress Relaxation

The extrusive force values for 30 repetitions for the No attachment control group and the Standard attachment group are presented graphically in Figures 8 and Figure 9, respectively. Force values for each trial are presented in Table 5 and Table 6 of the appendix. Minimal to no force decay was observed when an aligner with No attachment was tested 30 times while an appreciable force reduction was observed in the group with a Standard attachment. The mean initial extrusive force for the 5 trials with No attachment was 2.05 N and the mean extrusive force after 30 repetitions was 2.0 N. In each of the trails, some variability in extrusive force was noted, but the initial force value was approximately maintained. In the Standard attachment group, the mean initial extrusive force of the 5 trials was 9.16 N. After 30 repetitions the mean extrusive force decreased over 50% to 4.47 N. There was slight variability in the measurements noted, however a decrease in force for the Standard attachment group was observed in all trials and demonstrated a linear relationship.

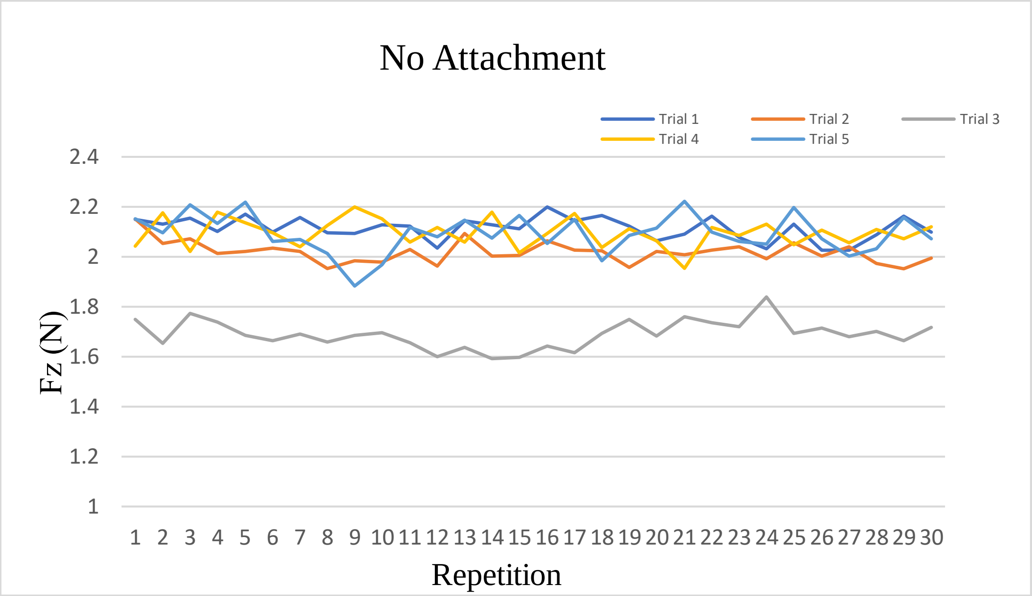

Figure 10: Extrusive force versus repetition: No attachment group. Fz indicates extrusive force. N indicates Newtons.

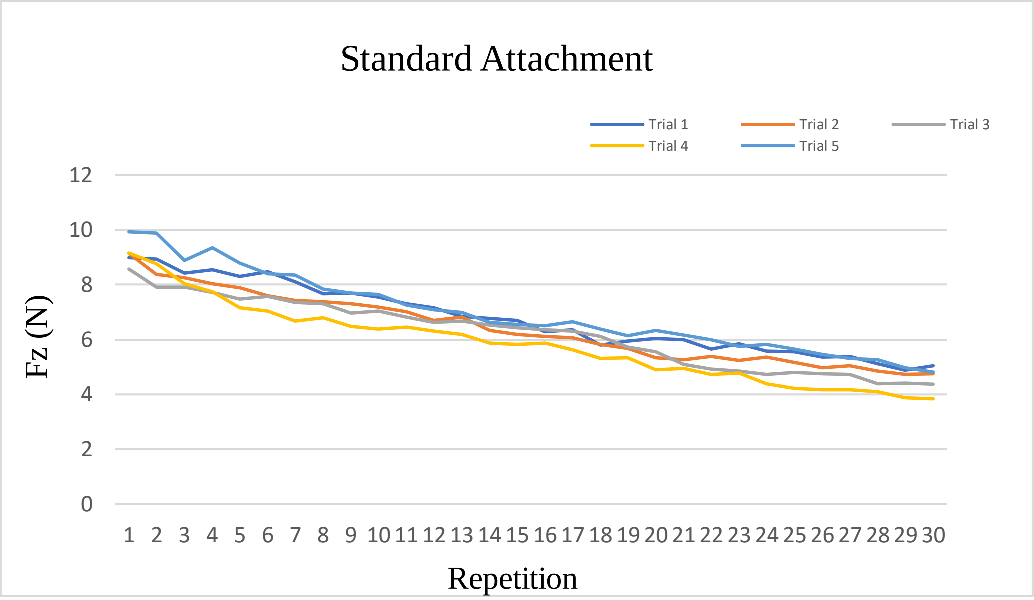

Figure 11: Extrusive force versus repetition: Standard attachment group. Fz indicates extrusive force. N indicates Newtons.

Discussion

Under the current study conditions, attachment size had a significant impact on the amount of extrusive force imparted by a CA on a maxillary central incisor. The mean initial extrusive force for the Large attachment group was 11.34 N, compared to an initial mean extrusive force of 5.32 N in the Small attachment group. This result provides evidence that larger attachments enable CAs to impart more extrusive force during extrusion of a maxillary central incisor. This finding is likely due to the increased surface area afforded by larger attachments. The force applied to teeth during CAT is the result of mismatch between the aligner and the tooth surface, resulting in a pushing force to move teeth into a predetermined position. With a more robust attachment, there is more surface area available for the aligner to contact to generate a pushing force. We Reject the null hypothesis that there is no difference in the initial extrusive force when different sized horizontal extrusion attachments are utilized during the extrusion of a maxillary central incisor with a CA.

When comparing the differences in initial extrusive force generated by a CA for the four attachment locations investigated in the present study, the results were comparable. Although the pairwise comparisons between the Incisal attachment group and the Gingival attachment group as well as the Incisal attachment group and the Mid-Facial attachment group showed statistically significant differences, the magnitude of these differences was of little clinical significance. The Incisal attachment group showed the greatest variability in initial mean force, demonstrated by the largest observed standard deviation calculated for this group. The differences observed could have been due to the degree of variability in the CAs or the variability in the attachment placement process. Taken together, the results of this study suggest that attachment location does not affect the extrusive force imparted by a CA on a maxillary central incisor to the same degree as attachment size. We accept the null hypothesis that there is no difference in the initial extrusive force when different locations of horizontal extrusion attachment are utilized during the extrusion of a maxillary central incisor with a CA.

Additionally, the results provide evidence that irrespective of attachment size and location, CAs exert more extrusive force with attachments compared to when no attachment is placed. The observed differences in force were statistically significant for all attachment configurations compared to the control. This finding, again, is likely due to the increased surface area available when attachments are placed. We reject the null hypothesis that here is no difference in the initial extrusive force during the extrusion of a maxillary central incisor with a clear aligner in the presence or absence of an attachment.

The results also demonstrate that when attachments are utilized for the extrusion of a maxillary central incisor, the rate of stress relaxation of the CA material increases. In the No attachment control group, little to no force decay was observed after 30 consecutive measurement. In the group with a Standard attachment, the force imparted by the CA decreased approximately 50% after 30 consecutive measurements. This observation could have been due to the increased amount of force imparted on the viscoelastic CA material for the Standard attachment group resulting in plastic deformation, or less likely, differences in the geometry of the two CA groups. These results should be interpreted with caution for several reasons. The mean initial force imparted by the Standard attachment CA group was 9.16 N or 934 gm of force, which is significantly more force than the optimal extrusive force range of 35-60 gm suggested by Proffit et al.[28] It is unreasonable to assume a force level of that magnitude would be desired in vivo. Additionally, only 30 measurements were taken for each CA and only one variation of attachment was investigated. Different attachments may have demonstrated different patterns of force decay, and the rate of decay may have proved to not be linear had more trials been completed.

As described previously, two studies using FEM[63,64] and one study using a force measuring device[39] have investigated the effect of composite attachments on the extrusive force imparted by a CA on a maxillary central incisor. However, no previous studies have evaluated the effect of composite attachment size, and only one study[63] investigated the effect of composite attachment location. Savignano et al.[63] compared the extrusive force delivered by a CA when a rectangular buccal attachment was utilized and when a rectangular palatal attachment was utilized. The authors used FEM rather than a force measuring device, therefore, it is difficult to directly compare their findings to the results of the present study. However, contrary to the findings in our study, the authors reported more extrusive force generated with a palatal attachment compared to a buccal attachment. In our study, the force difference between the two attachment locations were smaller, and not statistically significant. Taken together, these results suggest that the lingual surface of a maxillary central incisor may be a suitable location for attachments when extrusion is desired. Savignano et al. also compared the extrusive force generated by a CA when multiple attachment configurations were utilized to a CA without an attachment. Similar to the findings in the present study, the authors found the lowest extrusive force when no attachment was utilized. Together, these results emphasize that to extrude a maxillary central incisor with a CA, attachments are needed.

Currently, there is only one study in the orthodontic literature that examined the effect of repeated CA insertion and removal on the stress relaxation properties of a CA.[51] Similar to the present results, the study provides evidence that the force imparted by a CA decreases with the number of times the CA is inserted and removed. It also appears that with increased activation, there was a more pronounced decrease in force. These findings are consistent with those of the present study, which found with increased repetitions of removal and insertion, force exerted by a CA decreased significantly in the Standard attachment group, which generated more force initially, but not for the No attachment group, which exerted less force initially. Essentially, the the more often a CA is inserted and removed, the more the force generated by the CA will decrease. Additionally, the rate of reduction in force generated by the CA may be positively correlated to the initial force level generated by the CA. However, whether these findings are clinically significant is still in question.

Costa et al.[39] published a study in 2020 evaluating the effect of three attachment geometries on the extrusive force delivered to a central incisor. Different aligner material was used and attachment size and location were not investigated, but a force gauge and methodology similar to the current study was utilized. The authors found variation in measurements among identical aligners, even when standardized protocols were employed. These findings are similar to the findings of the current study and provide evidence that variation occurs in the CA fabrication process, further supporting the need for replication of CAs for this type of research study.

Attempts were made in this study to account for variation in CAs during the fabrication process. To best represent each of the 9 CA designs, five aligners were created for each group. Design of the CAs, printing of the STL models, post-curing processing, thermoforming, and the CA trimline were standardized for each aligner. Despite careful and standardized methodology, some degree of variability between CAs was expected. The amount of variation of the CAs and its exact impact on our results is unknown, however it may account for some of the variability observed between force measurements of CAs within the same group.

The force measurement device used in this study is similar to other devices previously described in the orthodontic literature.[56–61] Measuring forces imparted by a CA using this method involves limitations. The force measurement device used in this study was unable to simulate the PDL and the mobility of a tooth within the PDL space. The periodontal ligament space is a fluid filled chamber ranging from 0.15 mm to 0.28 mm wide and functions as a shock absorber.[66] Because the PDL space was not simulated, the central incisor target tooth measured in this study was likely much stiffer than a tooth with a PDL. Additionally, factors such as saliva and temperature present in vivo were not reproduced in this study. Recognizing these limitations, a greater emphasis was placed on the force measurements relative to one another rather than the magnitude of the individual measurements themselves.

It is important to consider that, with regard to attachment size and location, only initial force measurements delivered by CAs were evaluated. During initial data acquisition it was noted that force generated by some of the aligner groups decreased noticeably with repeated measurements. While three data points for each aligner were collected, only initial force values were considered. As discussed previously, and further demonstrated by our 30 trial results, the amount of force imparted by a CA changes rapidly over time due to stress relaxation of the material. It is also important to consider that only Fz was analyzed. It is expected that factors impacting extrusive force also impact forces and moments generated in other planes of space.

Future studies are needed to further elucidate the biomechanical effect of composite attachments used in CAT. A better understanding of the impact of attachments on forces imparted during CAT is needed to improve the predictability of CAT, and enable orthodontists to design force systems to more predictably move teeth. Future studies analyzing forces and moments imparted by CAs in all planes of space would be informative. Additional teeth and attachment configurations should be investigated, particularly those for which OTM has proved most challenging with CAs. As the sophistication of force measuring devices and techniques continue to improve, investigations with fewer limitations will be possible, offering a valuable addition to the current understanding of the biomechanical properties of CAs.

It is clear that CAT will be an integral part of orthodontics for the foreseeable future and that technological advancements will likely continue to expand the scope of what is achievable with CAs. Currently, questions remain regarding the effectiveness and limitations of CAs in orthodontic treatment. The ability of CAs to extrude teeth has been debated, with a degree of variability in the limited literature available on the topic. The most challenging and unpredictable tooth movement to achieve with CAs is reported to be the extrusion of maxillary central incisors.[10] While the exact biological mechanisms that determine OTM have yet to be fully elucidated, force magnitude plays an important role.[29] The findings of the current study show that composite attachment size has a significant effect on the amount of extrusive force imparted by a CA on a maxillary central incisor during extrusion, while location does not appear to be as critical. Additionally, the results of the current study show that during repeated insertion and removal of CAs, the presence of composite attachments increases the rate of stress relaxation in the aligner.

Conclusions

- When clear aligners are used for the extrusion of a maxillary central incisor, attachment size significantly influences the amount of force delivered by the clear aligner with larger attachments generating greater force.
- Attachment location does not influence the extrusive force delivered by a CA to a maxillary central incisor to the same extent as attachment size.
- CAs exert more extrusive force on a maxillary central incisor when a composite attachment, regardless of size and location, is utilized.
- CAs experience more stress relaxation when composite attachments are utilized compared to when no attachment is used.

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Appendix

Table 1: Raw Data Attachment Size

ID	Trial	Attachment Size	Fz (N)
1.1	1	No Attachment	2.15
1.2	1	No Attachment	2.13
1.3	1	No Attachment	2.16
2.1	2	No Attachment	2.15
2.2	2	No Attachment	2.05
2.3	2	No Attachment	2.07
3.1	3	No Attachment	1.75
3.2	3	No Attachment	1.65
3.3	3	No Attachment	1.77
4.1	4	No Attachment	2.04
4.2	4	No Attachment	2.17
4.3	4	No Attachment	2.02
5.1	5	No Attachment	2.15
5.2	5	No Attachment	2.10
5.3	5	No Attachment	2.21
6.1	1	Small	5.12
6.2	1	Small	4.49
6.3	1	Small	4.36
7.1	2	Small	4.75
7.2	2	Small	4.14
7.3	2	Small	4.02
8.1	3	Small	5.56
8.2	3	Small	5.05
8.3	3	Small	4.33
9.1	4	Small	5.72
9.2	4	Small	4.66
9.3	4	Small	4.27
10.1	5	Small	5.43
10.2	5	Small	5.25
10.3	5	Small	4.40
11.1	1	Standard	8.99
11.2	1	Standard	8.92
11.3	1	Standard	8.42
12.1	2	Standard	9.14
12.2	2	Standard	8.37
12.3	2	Standard	8.24
13.1	3	Standard	8.57

13.2	3	Standard	7.91
13.3	3	Standard	7.91
14.1	4	Standard	8.61
14.2	4	Standard	8.33
14.3	4	Standard	7.68
15.1	5	Standard	8.81
15.2	5	Standard	8.00
15.3	5	Standard	7.51
16.1	1	Large	10.71
16.2	1	Large	8.22
16.3	1	Large	7.33
17.1	2	Large	10.61
17.2	2	Large	10.11
17.3	2	Large	9.70
18.1	3	Large	11.65
18.2	3	Large	9.79
18.3	3	Large	8.43
19.1	4	Large	11.98
19.2	4	Large	10.86
19.3	4	Large	10.10
20.1	5	Large	11.76
20.2	5	Large	10.71
20.3	5	Large	9.24

Fz indicates extrusive force. N indicates Newtons

Table 2: Raw Data Attachment Location

ID	Trial	Attachment Location	Fz (N)
21.1	1	No Attachment	1.96
21.2	1	No Attachment	1.95
21.3	1	No Attachment	1.93
22.1	2	No Attachment	2.24
22.2	2	No Attachment	2.20
22.3	2	No Attachment	2.20
23.1	3	No Attachment	2.01
23.2	3	No Attachment	1.86
23.3	3	No Attachment	1.97
24.1	4	No Attachment	1.99
24.2	4	No Attachment	2.02
24.3	4	No Attachment	1.99
25.1	5	No Attachment	2.26
25.2	5	No Attachment	2.18
25.3	5	No Attachment	2.09
26.1	1	Gingival	9.64
26.2	1	Gingival	9.01
26.3	1	Gingival	8.75
27.1	2	Gingival	9.23
27.2	2	Gingival	8.26
27.3	2	Gingival	8.11
28.1	3	Gingival	9.78
28.2	3	Gingival	8.43
28.3	3	Gingival	7.52
29.1	4	Gingival	9.01
29.2	4	Gingival	8.29
29.3	4	Gingival	7.87
30.1	5	Gingival	9.33
30.2	5	Gingival	7.97
30.3	5	Gingival	7.91
31.1	1	Mid-Facial	9.15
31.2	1	Mid-Facial	8.77
31.3	1	Mid-Facial	8.04
32.1	2	Mid-Facial	9.93
32.2	2	Mid-Facial	9.87
32.3	2	Mid-Facial	8.88
33.1	3	Mid-Facial	9.78
33.2	3	Mid-Facial	9.21
33.3	3	Mid-Facial	8.11
34.1	4	Mid-Facial	10.33
34.2	4	Mid-Facial	9.74

34.3	4	Mid-Facial	8.51
35.1	5	Mid-Facial	10.40
35.2	5	Mid-Facial	9.88
35.3	5	Mid-Facial	9.40
36.1	1	Incisal	6.79
36.2	1	Incisal	6.26
36.3	1	Incisal	6.06
37.1	2	Incisal	8.90
37.2	2	Incisal	8.08
37.3	2	Incisal	7.86
38.1	3	Incisal	8.05
38.2	3	Incisal	7.39
38.3	3	Incisal	7.34
39.1	4	Incisal	7.60
39.2	4	Incisal	6.98
39.3	4	Incisal	6.76
40.1	5	Incisal	9.23
40.2	5	Incisal	8.84
40.3	5	Incisal	8.34
41.1	1	Mid-Lingual	8.48
41.2	1	Mid-Lingual	8.36
41.3	1	Mid-Lingual	6.94
42.1	2	Mid-Lingual	10.01
42.2	2	Mid-Lingual	9.14
42.3	2	Mid-Lingual	8.96
43.1	3	Mid-Lingual	8.91
43.2	3	Mid-Lingual	8.87
43.3	3	Mid-Lingual	8.63
44.1	4	Mid-Lingual	8.31
44.2	4	Mid-Lingual	7.86
44.3	4	Mid-Lingual	7.64
45.1	5	Mid-Lingual	10.03
45.2	5	Mid-Lingual	9.92
45.3	5	Mid-Lingual	9.44

Fz indicates extrusive force. N indicates Newtons

Table 3: Repeated Insertion No Attachment

Measurement	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5
1	2.15	2.15	1.75	2.04	2.15
2	2.13	2.05	1.65	2.17	2.1
3	2.16	2.07	1.77	2.02	2.21
4	2.1	2.01	1.74	2.18	2.13
5	2.17	2.02	1.69	2.14	2.22
6	2.1	2.03	1.66	2.1	2.06
7	2.16	2.02	1.69	2.04	2.07
8	2.1	1.95	1.66	2.13	2.01
9	2.09	1.99	1.69	2.2	1.88
10	2.13	1.98	1.7	2.15	1.97
11	2.12	2.03	1.66	2.06	2.12
12	2.03	1.96	1.6	2.12	2.08
13	2.15	2.09	1.64	2.06	2.15
14	2.13	2	1.59	2.18	2.07
15	2.11	2.01	1.6	2.02	2.17
16	2.2	2.06	1.64	2.09	2.05
17	2.15	2.03	1.62	2.17	2.15
18	2.16	2.02	1.69	2.04	1.98
19	2.12	1.96	1.75	2.11	2.09
20	2.06	2.02	1.68	2.06	2.11
21	2.09	2.01	1.76	1.95	2.22
22	2.16	2.03	1.74	2.12	2.1
23	2.08	2.04	1.72	2.09	2.06
24	2.03	1.99	1.84	2.13	2.05
25	2.13	2.06	1.69	2.05	2.2
26	2.03	2	1.72	2.11	2.07
27	2.03	2.04	1.68	2.06	2
28	2.09	1.97	1.7	2.11	2.03
29	2.16	1.95	1.66	2.07	2.16
30	2.1	1.99	1.72	2.12	2.07

Fz indicates extrusive force. N indicates Newtons

Table 4: Repeated Insertion Standard Attachment

Measurement	Trial 1	Trial 2	Trial 3	Trial 4	Trial 5
1	8.99	9.14	8.57	9.15	9.93
2	8.92	8.37	7.91	8.77	9.87
3	8.42	8.24	7.91	8.04	8.88
4	8.54	8.03	7.71	7.73	9.35
5	8.29	7.9	7.47	7.15	8.78
6	8.48	7.59	7.58	7.04	8.39
7	8.1	7.42	7.35	6.67	8.35
8	7.66	7.37	7.3	6.79	7.85
9	7.69	7.31	6.97	6.47	7.69
10	7.55	7.19	7.03	6.39	7.64
11	7.3	7.01	6.81	6.45	7.26
12	7.17	6.68	6.62	6.3	7.08
13	6.83	6.82	6.67	6.19	6.99
14	6.76	6.33	6.53	5.87	6.62
15	6.69	6.19	6.43	5.82	6.55
16	6.27	6.12	6.37	5.88	6.5
17	6.34	6.07	6.3	5.63	6.65
18	5.8	5.82	6.11	5.3	6.38
19	5.94	5.68	5.73	5.34	6.13
20	6.05	5.34	5.55	4.89	6.32
21	5.98	5.27	5.09	4.95	6.15
22	5.66	5.39	4.93	4.71	6
23	5.84	5.24	4.86	4.77	5.76
24	5.57	5.37	4.72	4.39	5.83
25	5.54	5.15	4.8	4.22	5.64
26	5.36	4.96	4.75	4.16	5.46
27	5.38	5.04	4.72	4.17	5.32
28	5.11	4.84	4.39	4.1	5.25
29	4.88	4.73	4.42	3.88	4.98
30	5.05	4.76	4.37	3.83	4.81

Fz indicates extrusive force. N indicates Newtons