SHAPE MEMORY IN DIRECT-PRINTED 3D ALIGNERS AND EXPLORATION OF THE EFFECTS OF ATTACHMENTS AND TEMPERATURE

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“The important thing is not to stop questioning. Curiosity has its own reason for existence. One cannot help but be in awe when he contemplates the mysteries of eternity, of life, of the marvelous structure of reality. It is enough if one tries merely to comprehend a little of this mystery each day. Never lose a holy curiosity. Try not to become a man of success, but rather try to become a man of value. He is considered successful in our day who gets more out of life than he puts in. But a man of value will give more than he receives.”

- Albert Einstein

DEDICATION

To my wife, Leora Hertan, for her love, friendship, and partnership. Thank you for believing in me, encouraging me, and supporting me. Words cannot express the depth of my appreciation, it is an honor to have you by my side.

To my parents, Dr. Hilary and Sharon Hertan, and my sister, Lauren Hertan, who have always believed in me and supported me in this professional and educational journey.

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CHAPTER 1: INTRODUCTION

New technological developments and market demands have rapidly increased the availability and affordability of intraoral scanners and 3D printers. These technological advancements combined with the market demand for aesthetic treatment options have driven a surge in the use of clear aligners for orthodontic tooth movement. More specifically, this evolution has increased production and use of in-house 3D printed stents, splints, nightguards and models. Clear Aligner treatment utilizing 3D printing technology has been limited to printing 3D models with staged tooth movements and subsequently thermoforming plastic sheets to create the desired aligners. The prospect of direct 3D printing of aligners themselves offers to usher in an era of innovation. Specifically, the direct 3D printing of aligners offers the opportunity to more directly control material dimensions, structure, and properties. Precision control over these properties will afford the opportunity to control biomechanics in ways that were not readily imaginable nor possible with the conventional thermoforming process. Furthermore, direct 3D printing of aligners offers the promise of reduced waste, improved turnaround time, and an era of on-demand clear aligner treatment. Direct Print Aligners offer the promise of improved treatment techniques, modalities, and outcomes for the orthodontist and patient.

CHAPTER 2: REVIEW OF THE LITERATURE

Clear Aligners - A brief history

In 1945, Harold D. Kesling described the use of the positioner appliance to aid in "final artistic positioning and retention."[1] Kesling went on to found TP Orthodontics, an orthodontic company and lab still in existence to this day.[2] In an October 1970 article in the AJODO, Wells described the application of the positioner noting that "the degree of movement of improvement of tooth position was limited to 3 mm or less of tipping movement. Rotational correction of incisors, canines, and premolars was possible in certain instances. Virtually all types of correction of occlusion and tooth movement, with the exception of translation or bodily movement, were evidenced."[3] To summarize, as early as 1945 there was a rubber-based removable appliance capable of substantial tooth movement and by 1970 they had concluded that this appliance had the capability to improve interdigitation, correct cross-bites, improve overbite and overjet and close spaces, etc. To this effect, Graber attributes Kesling's discovery of the tooth positioner as the precursor to clear aligners. [4] In 1971, Ponitz published an article in the AJODO entitled Invisible Retainers in which he described the process for making vaccuformed clear retainers. He notes: "Teeth can be moved and repositioned in pink baseplate wax on the master model before the appliance is formed. The patient's teeth then can be moved to reasonable new positions by means of the retainer."[5] In the 1980s, thermoformed retainers became popular with the increased adoption of the vaccuform machine. According to Proffit, not long after the advent of thermoformed retainers did orthodontists realize that these same devices could be utilized to achieve tooth movement by altering the model to reflect the desired position of teeth in small increments.[6] In 1985, Sheridan would go on to write an article regarding air rotor stripping (ARS) and would subsequently produce update articles for its use with clear aligners.[7, 8, 9]

Clear Aligners - Tradition and Innovation

In the late 1990s and early 2000s, a host of companies including Cadent, Orametrix, Invisalign, etc. continued the digital disruptive innovation that would arguably create a paradigm shift in the industry of orthodontics. Appreciating the potential for integration of technology, 3D modeling, and orthodontics, these companies began using advanced scanning software and 3D imaging technology to move teeth and create set-ups for various wire and clear aligner orthodontic applications. The late 2010s has been marked by an emergence of companies focused on direct to consumer orthodontics as well as companies that place the orthodontist in the driver's seat of aligner creation and fabrication. Companies that enable clinicians to direct and control set-ups with an in-office flow include Archform, Maestro, and uLab to name a few. "There is nothing new under the sun…"[10] our developments are impressive, and simultaneously clear aligner treatment is remarkably similar to the innovation of Kesling in 1945. The next generation of innovation is here, and it is an innovation of engineering and materials science, specifically the ability to directly print clear aligners. Presumably the success and impact of this nascent technology will be dependent on the properties that can be achieved with direct print aligner (DPA) materials. In light of this, it is essential to explore and understand how Direct Print Aligners compare with Traditional Thermoformed Aligners in respect to their material properties and unique capabilities.

The Force Profile of Aligners

There are a number of studies in the literature that attempt to describe the forces of clear aligners on the dentition. Unlike traditional fixed appliances, clear aligners are an indeterminate force system, thereby making delivered forces extremely challenging to predict and measure. A variety of innovative techniques have been established to measure, estimate, and discover the underlying biomechanical principles of clear aligner therapy. In 2008, a study by Barbagallo et al. utilized a novel pressure-sensitive film to determine the force applied by an aligner in vivo. The study determined that the force of an 0.80 mm-thick aligner on a maxillary premolar programmed with 0.5 mm of buccal tipping at time of delivery was 5.12 N. While the benefits of capturing in vivo data are quite significant, one drawback of the pressure film is that the measurement represents an instanteous maximum reading which includes the forces of insertion and removal and is not dynamic.[11]

A 2009 study by Hahn et al. utilized a 3-axis Nano 17 sensor attached to an upper right central incisor (UR1) on a typodont in order to determine forces and motions along the X and Z axes. A benefit of the digital dynamometer approach was the ability to measure force over time; however, unlike the Barbagallo study, the results were not in-vivo. Hahn et. al. noted that the forces induced with 0.15 mm tipping were significantly higher than those forces recommended by Proffit (approximately 0.35 – 0.60 N). The mean Fx forces ranged from -2.82 N to 5.42 N, and the mean Fz Forces ranged from -0.14 N to -2.3 N. Hahn et al. postulate that due to the small activation range of the aligner, 0.15 mm, this higher force level may be acceptable. Finally, Hahn et al. analyzed the difference between vaccuformed clear aligners and high-pressure thermoformed clear aligners. The researchers concluded that “In general, high-pressure thermoformed appliances deliver significantly higher ($P < 0.01$) forces than those produced by vacuum forming”.[12]

In 2013, Khoda et al. developed an epoxy model with a digital pressure sensor embedded in the left maxillary central incisor flush with the labial surface. The researchers investigated the effects of material type, material thickness, and displacement (0.5 mm vs 1.0 mm). The authors obtained a force range of 0.18 - 2.91 N. The study concluded that material thickness and amount of activation were statistically significant factors. The finding that thicker material correlated to stronger forces in Newtons was expected and an important confirmation. Interestingly and probably one of the most important yet under-emphasized findings of the paper was: “appliances with the greater amount of activation showed significantly lower orthodontic force than those with the smaller amount of activation.” The authors attributed this phenomenon in the discussion to suspected deformation during insertion for aligners with excessive activation. The authors additionally note in their discussion a concern that though the aligners were fabricated with high-pressure thermoforming, there exists a possibility that the permanent deformation was introduced when the aligner was placed on the epoxy model.[13]

In 2017, Gao and Wichelhaus took the literature one step forwards by investigating the effect of aligner trim height and thickness. Using a Nano 17 connected to an incisor, they measured the effects of 0.5 mm intrusion or 0.5 mm palatal tipping of a cental incisor. Looking at a total of 18 groups (3 trim heights, 3 thicknesses, 2 movement types), they determined that aligner trim height was significantly correlated to the force delivered to a tooth during palatal tipping & intrusion. Importantly, while aligner trim height increased forces up to 4 mm, for trim heights greater than 4 mm past the gingival margin, there was not a statistically significant increase in forces. Additionally, they validated the findings of Khoda et al. that aligner thickness was significantly correlated with force delivered during tooth movement, with increased thickness delivering increased forces. The authors recommend against movements greater than 0.5 mm in a clinical set-up. Finally, the Gao et al. study concluded that the difference in thickness between 0.50 mm and 0.625 mm was not significant nor was the difference between 0.625 mm and 0.75 mm significant. Thus, the authors recommend to eliminate the 0.625 mm thickness from future research.[14]

Liu and Hu in 2018 examined the effects of different intrusion patterns on the force system delivered by an aligner. Liu and Hu created a dental model from tooth LR7 to LL7 attached to a 14 sensor Nano-17 array. They then recorded the force patterns exhibited by various intrusion patterns on a dentoform with rectangular attachments on teeth 4,5,6. Utilizing 0.80 mm Duran thermoforming material, they intruded mandibular teeth L1-3 in increments from 0.0 mm to 0.2 mm. Forces ranged from 0.92 N to 0.86 N. Importantly, a review of the force patterns reveals that as a general principle, adjacent teeth served as anchorage for any individual tooth movement. Nevertheless, this did also extend to non-adjacent teeth that were retained with attachments. A key and easy to overlook component of the study was the fact that the "passive" G0 aligners exhibited significant forces in the vertical dimension (z-axis) ranging from >0.75 N to <-0.65 N. The Liu and Hu attributed these forces to printing error during the printing of the teeth and installation error in the placement of the teeth. Liu and Hu used this data as "background error" and zeroed the model, removing it from all subsequent measurements. The author of this thesis questions whether the forces measured on the G0 as "background noise" from error was in fact the active forces that are exhibited by what is commonly percieved to be a "passive" aligner.[15]

Key Factors in Aligner Forces

The factors that influence the forces delivered by aligners are numerous. A 2009 study by Jones et. al. found that attachments were more retentive against aligner removal as they moved closer to the free gingival margin (FGM) and less retentive as they moved closer to the incisal edge. These results were counterintuitive in that most would assume that the thinner portion of the aligner towards the FGM would be weaker and prone to flexion; in contrast, attachments towards the cervical appeared to have the least resistance to displacement. Additionally, it should be noted that the shape of the attachments also appeared to have a significant impact on the force required to remove an aligner.[16] The question raised by this study is simply: Why should an engaged attachment in the cervical third be more retentive than one in the incisal third?

A 2012 study by Cowley et. al. published in the Journal of Clinical Orthodontics examined the effects of gingival margin design on retention of clear aligners. Specifically, they examined the difference between retention of straight cut vs scalloped aligners for aligners with and without attachments. With attachments, straight cut was superior to scalloped and 2 mm straight cut was superior to both. Without attachments, 2 mm straight cut was superior to scalloped or straight cut 0 mm. However, the scalloped and straight cut 0 mm were not significantly different. Interestingly, the authors note in the discussion that with scalloped margins, the undercuts on the tooth retain the aligner better than the attachments, while with a 0 mm straight cut, the attachments hold the aligner better than the undercuts. One of the author's conclusions is that "scalloped margins on aligners with attachments are significantly less retentive than scalloped margins are without attachments."[17]

In addition to the type of gingival margin (eg. scalloped vs flush cut), gingival trim height, aligner thickness, and attachment type and location, and other variables play important roles in the force delivered by aligners in the in-vivo environment. A 2006 study by Ryokawa et al. examined the effects of water absorption and temperature on material properties, noting material expansion and change in elastomeric properities.[18] A 2021 study by Xiang et al. utilized a thin film pressure sensor and a variety of other techniques to examine the effects of artificial saliva on PETG aligners and determined that properties significantly diminished after storage in artificial saliva.[19] A study by Vardimon et al. published in the AJODO examined Van Mises Strain in clear aligners specifically looking at IVM (Incisor Van Mises strain) and PVM (Premolar Van Mises strain). The unique nature of the design allowed for measurement of in-vivo force. The authors concluded that the strongest force was on the first day, followed by decreased force on day 2 which plateued for the remainder of treatment with each aligner. Additionally, the authors found that PVM typically had less of a decrease between the first day and subsequent days. Finally, the authors noted that there was an increase in IVM and PVM as the aligner sequence progressed from the intial aligners towards the final aligners.[20] The author of this thesis questions whether or not the authors considered the peak in IVM and PVM on day 1 represents a permanent deformation that occurred and is therefore not repeated on future days of the same aligner and appears stabilized. In summary, there are a multitude of factors that affect the forces delivered by aligners in the oral environment ranging from material type, thickness, and trim design, to temperature, saliva exposure, and permanent deformation.

Direct Print Aligners

A 2019 study by Jindal et al. examined the precision of 3D printed aligners (DPA) as well as their mechanical properties under load.[21] Specifically, the authors compared the 3D printed aligners fabricated to 0.75 mm thickness from Form Labs Dental LT resin with Thermoformed Duran Aligners. The study subjected the aligners to an Instron compression test between two flat metal plates to assess the properties of the aligners. The authors concluded that the uncured direct printed aligners displayed properties similar to thermoformed aligners. However, the authors noted that the cured DPA aligners displayed “superior dimensional accuracy and compressive mechanical strength” in comparison with the thermoformed aligners. The authors concluded that “a high yielding, higher load resisting, and lower deforming clear dental aligners obtained from 3D printing could provide a superior alternative” [to conventional thermoformed aligners].

This conclusion of Jindal et al. is counterintuitive to the traditional philosophy regarding tooth movement. Burstone and Mortensen in 1985 published a seminal paper introducing NiTi wire with the important note that “it is highly useful in clinical situations which require a low-stiffness wire with an extremely large springback.”[22]

The utility of the NiTi wire is undisputable, evinced today over 35 years later by its prevalence and ubiquity. The primary features that make NiTi so popular are its high deformation with high springback. The key features of moving teeth are the provision of continuous gentle forces. The manufacturers of the Dental LT resin advertise that it is a Class IIa long-term biocompatible resin ideal for hard splints, occlusal guards, and other direct-printed long-term orthodontic appliances.[23] The sample uses are suggestive of a highly rigid material that does not deform nor adapt to its patients. Clinically, there are reports of using it for retainers, splints, and even expanders; however, it does not appear to be used for the convential clear aligner style of orthodontic tooth movement.

Another note regarding this study is the fact that the Instron two-plate crush test provides insight into the material properties; however, it is not clear that this would translate to the clinical properties of the aligners. Ultimately, we can conclude that DPAs present dimensional accuracy and hold promise for the future, but the dental LT resin when cured does not deliver the properities needed for conventional clear aligner methods of orthodontic tooth movement.

A 2020 thesis by Koenig et al. examined the novel Tera Harz Direct Print Resin by Graphy. This resin is claimed by the manufacturer to deliver increased deformation and elasticity, with improved elasticity at intra-oral temperatures.[24] Koenig et al. utilized 3D Printing, CAD-CAM Scanning, and advanced engineering-grade metrology software to compare the accuracy of DPAs as compared with traditional thermoformed aligners. Koenig demonstrated that the accuracy of fit of DPAs was greater than that of traditional aligners. There were two points worth noting in the thesis: First, the aligners were completely cured before the printing scaffolding was removed; second, one potential reason for increased accuracy in the thermoformed group may reflect deformation of the thermoformed aligners when removed from their respective models after pressure thermoforming.[25] Ultimately, the new resin reviewed by Koenig offers promise of delivering the properties needed for the biological movement of teeth, combined with the accuracy to achieve these feats efficiently and effectively. Further research is necessary to determine if this resin can deliver the force profile necessary to move teeth with gentle continuous forces.

Statement of the Thesis

The aim of this study was tri-fold: one, to investigate the force delivery profile of thermoplastic aligners as compared with direct print aligners; two, to explore the effect of surface patterns such as attachments on the material properties of thermoplastic aligners and direct print aligners; three, to explore the effect of group extrusion vs single tooth extrusion on the force delivery profile of the respective aligner types. The collected data represent the force system produced by the aligner to the point of compression. The analysis will give us insight into the force properties of direct print aligners and how they compare with traditional aligners. The analysis will also yield insight into the effects of surface patterns on the material properties of an aligners. Improved understanding of the force profiles produced by surface patterns, aligner types, and group vs single tooth extrusion will aid in our knowledge of aligner biomechanics, thereby promoting efficient and effective treatment and improved clinical outcomes.

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CHAPTER 3: JOURNAL ARTICLE

Abstract

Objective: 1) To measure the forces delivered by Direct Print Aligners in the vertical dimension and compare the force profile with traditional thermoformed aligners; 2) To investigate the impact of non-engaged surface patterns (attachments) to the properties of Direct Print Aligners (DPA) and Thermoformed Aligners (TFM). **Methods:** A custom force-measuring appliance was fabricated capable of displacing the aligner in 0.10 mm increments and measuring the resultant force. 3D printed models were fabricated to simulate the supporting teeth. ATMOS 0.030" Thermoplastic Material (American Orthodontics) and Tera Harz Direct Print Resin (Graphy) were used to create the thermoformed and direct printed aligners respectively. Aligners were temperature-controlled prior to and during testing to simulate the oral environment. The resultant forces from displacements ranging from 0.10 mm to 0.50 mm were measured across the various conditions. **Results:** At intra-oral temperatures, the Direct Print Aligner groups demonstrated significantly less force than the Thermoformed Aligner groups. The Thermoformed Aligner groups demonstrated a substantial statistically significant increase in force with each 0.10 mm increase in vertical displacement. The Direct Print Aligner groups demonstrated a much more consistent force profile across the range of displacements. The effects of surface patterns in both the DPA group and the TFM group were generally a decrease in force. Statistical significance of surface patterns was detected for TFM at displacements of 0.30 mm and greater, and significant for DPA only at a displacement of 0.10 mm. **Conclusions:** Forces delivered by aligners in the vertical dimension by DPA are more consistent and of lower magnitude than those of TFM aligners. Surface patterns were capable of altering the force properties of both DPA and TFM aligners for larger spans.

Introduction

New technological developments and market demands have rapidly increased the availability and affordability of intraoral scanners and 3D printers. These technological advancements combined with the market demand for aesthetic treatment options have driven a surge in the use of clear aligners for orthodontic tooth movement. More specifically, this evolution has increased production and use of in-house 3D printed stents, splints, nightguards and models. Clear Aligner treatment utilizing 3D printing technology has been limited to printing 3D models with staged tooth movements and subsequently thermoforming plastic sheets to create the desired aligners. The prospect of direct 3D printing of aligners themselves offers to usher in an era of innovation. Specifically, the direct 3D printing of aligners offers the opportunity to more directly control material dimensions, structure, and properties. Precision control over these properties will afford the opportunity to control biomechanics in ways that were not readily imaginable nor possible with the conventional thermoforming process. Furthermore, direct 3D printing of aligners offers the promise of reduced waste, improved turnaround time, and an era of on-demand clear aligner treatment. Direct Print Aligners offer the promise of improved treatment techniques, modalities, and outcomes for the orthodontist and patient.

Recent advances in CAD-CAM scanning, Digital Modeling, and 3D Printing have resulted in ubiquity of the technology necessary for in-house clear aligner fabrication across North America. A number of novel software are available which enable the rapid segmentation of STL digital models, modification of dental positions, and staging of movements. Furthermore, this software is now readily available and affordable with some companies offering use-based subscription models. Novel developments such as LED 3D printers have brought the price of reliable, quality, 3D printing down to new lows. These advancements are begging to usher in the new age of clear aligner treatment. A subtle yet dramatic shift from 3D printing models and thermoforming aligners to the direct printing of clear aligners is poised to happen in the coming years. In light of this, it is essential we understand the abilities, advantages, and limitations of Direct Print Aligners (DPAs) in comparison to Thermoformed Aligners (TFMs).

Thermoformed aligners are the workhorse of clear aligner therapy. Following in the footsteps of Kesling's 1945 positioner, the first vaccuformed retainer was developed by Nahoum in 1964 over 55 years ago. Since that time, a variety of innovations and advancements have been investigated and incorporated. Specifically, materials science is a focus of the clear aligner movement - there is a tremendous body of research surrounding the properties of the aligner sheets used for thermoforming with an aim of capturing maximum elasticity, minimum deformation, and minimal water absorption. Other research has investigated how to maximize the biomechanical properties of aligners through attachment location, trim height, aligner thickness, etc. Thermoformed aligners have become the tried and true, time-tested modality for clear aligner orthodontic tooth movement.

Thermoformed aligners have inherent challenges and limitations. The essential nature of their fabrication - heating a sheet of plastic and vaccu-forming or pressure-forming it over a model of the desired staged tooth movement - results in a limited number of strategies to improve the biomechanics from a displacement-driven system to a force-driven system. Options to control the biomechanics may include: 1) changing material sheet thickness; 2) altering trim-height or style, scalloped vs flush cut, 1 mm from FGM vs 3 mm past FGM, etc.; 3) altering the cast in an acceptable way to create features in the aligner such as Invisalign's bite ramps or power ridges, which presumably involve a digital cut-out in the 3D printed model to achieve the ridge; 4) utilizing attachments to target a directed push force; 5) utilizing pressure points on the occlusal surface of teeth to change a force vector; 6) creating active attachments through an attachment template that is larger than the aligners in order to generate a greater active or directed force; 7) improving plastic wrap around teeth through IPR or deliberate spacing to improve retention and handling of the tooth; 8) careful control and staging of movement types such as synergistic and antagonist movements utilized by SureSmile for improved control over certain movements.

Direct Print Aligners, in contrast to thermoformed aligners, offer to usher in a new world of opportunities and possibilities to control tooth movements through novel techniques. Specifically, the creation of different thicknesses throughout the appliance or utilization of discrete pressure points or other patterns and surface textures or shapes may be able to generate a couple or improved biomechanics thereby removing or minimizing the need for attachments. The potential promise of 3D surface patterns, shapes, and techniques may be able to fundamentally modify the elasticity or rigidity of aligners in order to deliver improved biomechanics and expedite treatment. There were three essential questions that the current research seeks to examine: 1) How do DPA properties compare with those of TFM? 2) What is the relationship between number of teeth moved/edentulous space and the force properties of the aligner, and 3) What is the impact of unfilled attachments on an aligner?

Materials and Methods

Sample Preparation

A master CAD-CAM scan of a maxillary arch was captured utilizing a Trios 3Shape Scanner, post processed by Trios 3Shape software, and exported into Standard Tessellation Language (STL) file. The file was subsequently imported into uLab 6.0 software (uLab Systems Inc., San Mateo, CA, USA). Two digital master models were produced from the uLab software: one had no Attachments (NA), just the trimmed maxillary model while the other had attachments (Yes Attachments -YA) on all maxillary teeth 7-7 rectangular, gingivally beveled horizontal attachments with a depth of 2.7 mm, a height of 4.2 mm, and a width of 4.0 mm. NA and YA master models were trimmed and based and exported into STL file format utilizing the uLab 6.0 software. Four master models (2 NA & 2 YA) were printed with Sprint Ray Pro DLP Printer (SprintRay, Los Angeles, CA, USA) at 100 µm-layer thickness. SprintRay Die and Model Gray II photo-initiated methacrylate resin with a flexural modulus of 2650 MPa and a Flexural strength of 91.5 MPA was used for master model 3D printing fabrication.

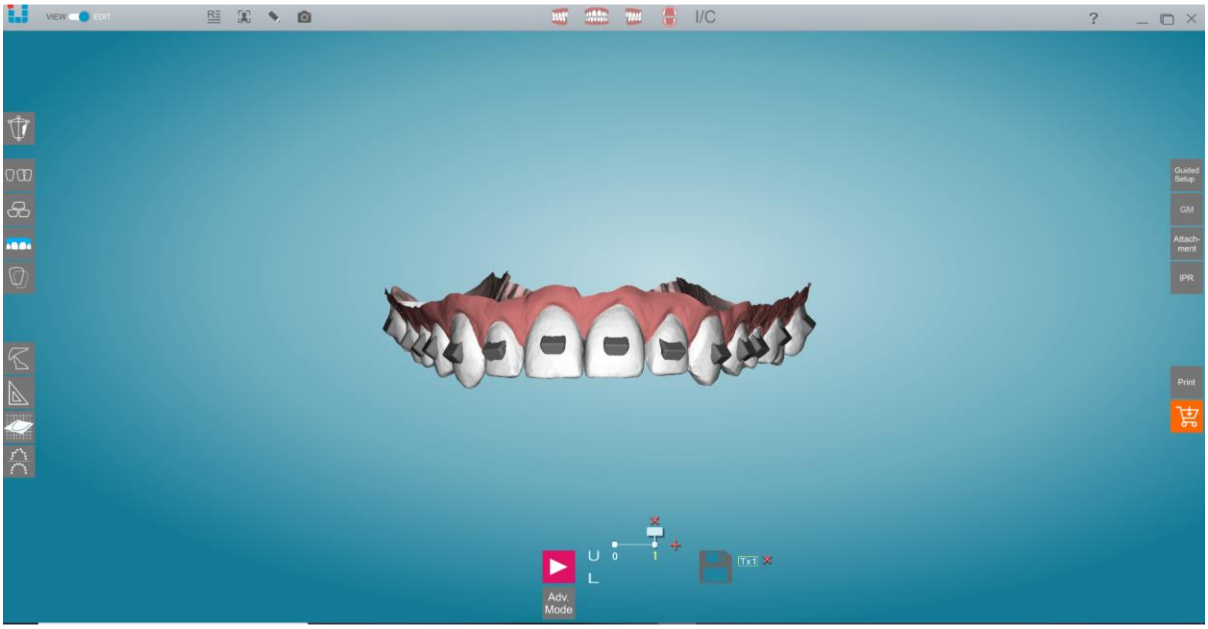

Figure 2.1: Design of the YA Master Model with attachments as designed in uLab. (frontal view)

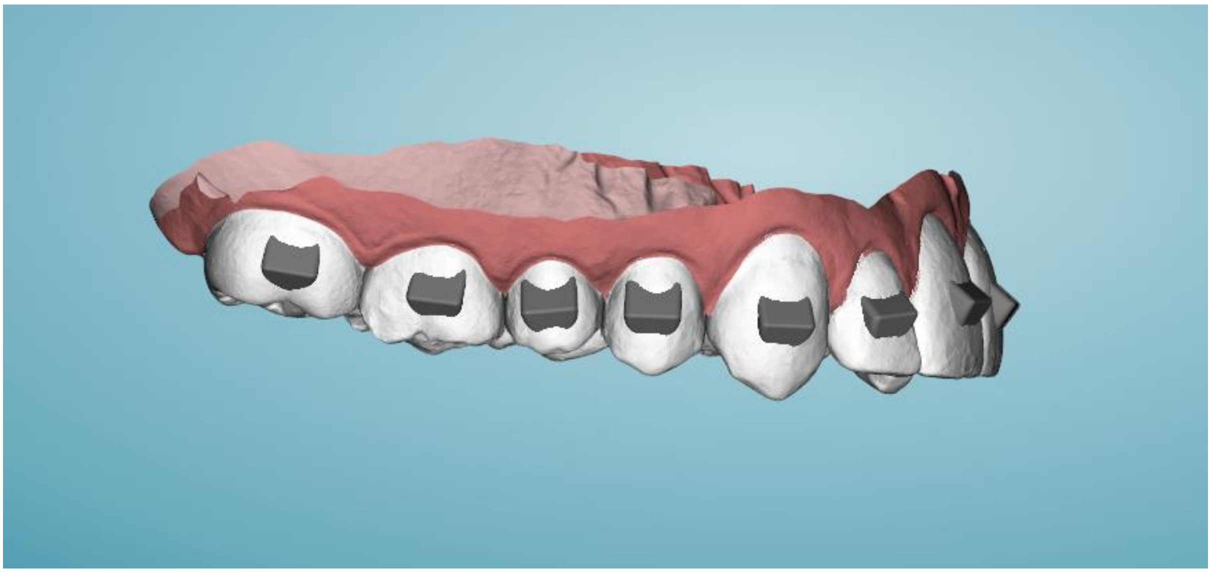

Figure 2.2: Design of the YA Master Model with attachments as designed in uLab. (right buccal view)

Thermoformed Aligner Fabrication

Models were processed following the resin manufacturer recommendations; excess uncured resin was removed in a mechanically agitated bath of 99.5% isopropyl alcohol for 5 minutes. Models were then transferred to a second mechanically agitated “clean bath” of 99.5% isopropyl alcohol for an additional 5 minutes. Models were then dried with compressed air and inspected for uncured resin. Models were subsequently cured using the SprintRay Pro Cure (SprintRay, Los Angeles, CA, USA) with the Die and Model II setting. ATMOS Thermoforming Plastic 125 mm round sheets with 0.030” thickness (American Orthodontics, Sheboygan, WI, USA) were thermoformed over the master models utilizing a Biostar (Scheu-Dental GmbH, Iserlohn, Germany) pressurized thermoforming machine per manufacturer recommendations. A total of 20 thermoformed aligners were created, 10 of the NA condition and 10 of the YA condition.

Direct Print Aligner Fabrication

The Direct Print Aligners (DPA) sample was fabricated utilizing the same digital NA and YA master models. DPAs were fabricated according to the latest SLU 3D Lab protocols which are described below. Specialized uLab 6.0 beta software was utilized to digitally thermoform and trim the DPA aligners over the master cast. Aligners were digitally trimmed to approximately 1 mm past the gingival margin. 0.50 mm thickness of DPA digital aligner and 0.05 mm offset of aligner from model were utilized. Two master aligner files were created with this method DPA No Attachments (DPA NA) and DPA Yes Attachments (DPA YA) were fabricated and exported as STL Files. The DPA master files were then imported into Uniz Software (Uniz, San Diego, CA, USA), rotated to -110 degrees and supports generated. Supports were designed to maximize support and minimize residue on removal. Supports were limited to the external structure of the aligner and were not placed on the intaglio surface to ensure appropriate fit on models. Files were exported from Uniz in STL format and imported into Rayware software (SprintRay, Los Angeles, CA, USA) for printing. DPA Aligners were printed on Sprint Ray Pro printers at 100 µm-layer thickness and splint material settings for printing. Graphy Tera Harz TC-85DAC resin was used for printing (Graphy, Seoul, Republic of Korea). The properties of the printed resin are described by the company as Shore Hardness (D) >,85, Flexural strength >, 65MPa, Flexural Modulus >,1500MPa.

DPA aligners with intact supports were removed from the printer build plate and placed in a centrifuge for 3 min. to remove excess structure. The aligner was then removed from the supportive scaffolding with finger pressure. Aligners were allowed to regain original shape with their inherent shape memory, and were subsequently placed in a specialized CureM machine with integrated nitrogen production. Aligners were cured for 35 min with nitrogen gas. Aligners were then removed and submerged in glycerin and cured without nitrogen gas for an additional 35 min. Aligners were then rinsed in room temperature water followed by boiling water to remove any residual glycerin and or resin and regain their shape memory. The DPA aligners were then briefly immersed in boiling water for 1-5 sec and immediately placed on the Master Model NA to simulate the normal intra-oral insertion process. They were then allowed to cool and labelled appropriately.

Test Model Preparation & Fabrication

Two test models were created to serve as supports for mechanical testing of the thermoformed and direct-print aligners (TFM & DPA). Two test models were created: Test Model UR1 was created with a missing UR1; and Test model U2-2 was created missing teeth U2-2. Both test model UR1 and test model U2-2 were created without attachments.

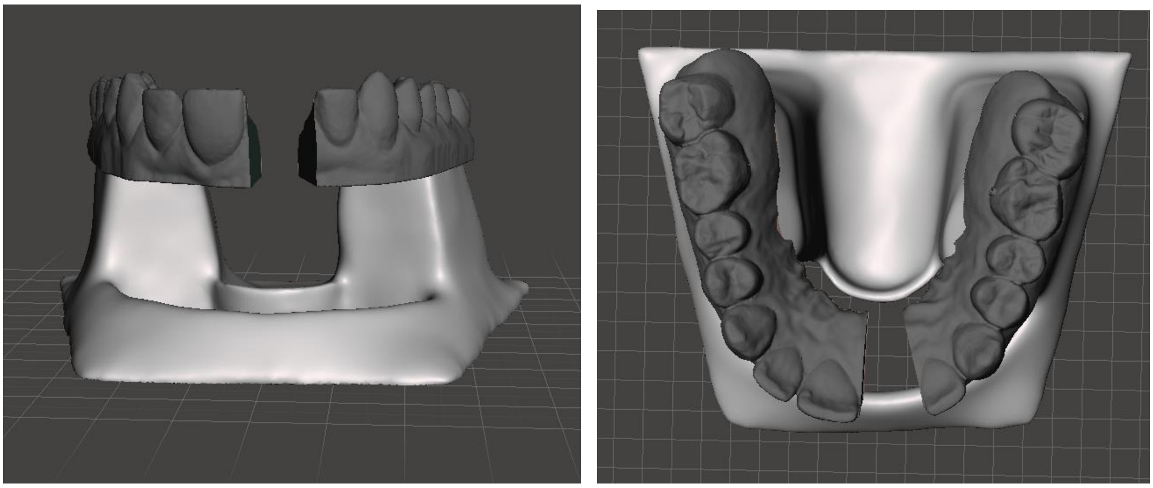

Figure 2.3: Design of the UR1 Test Model, note no attachments are present on the model.

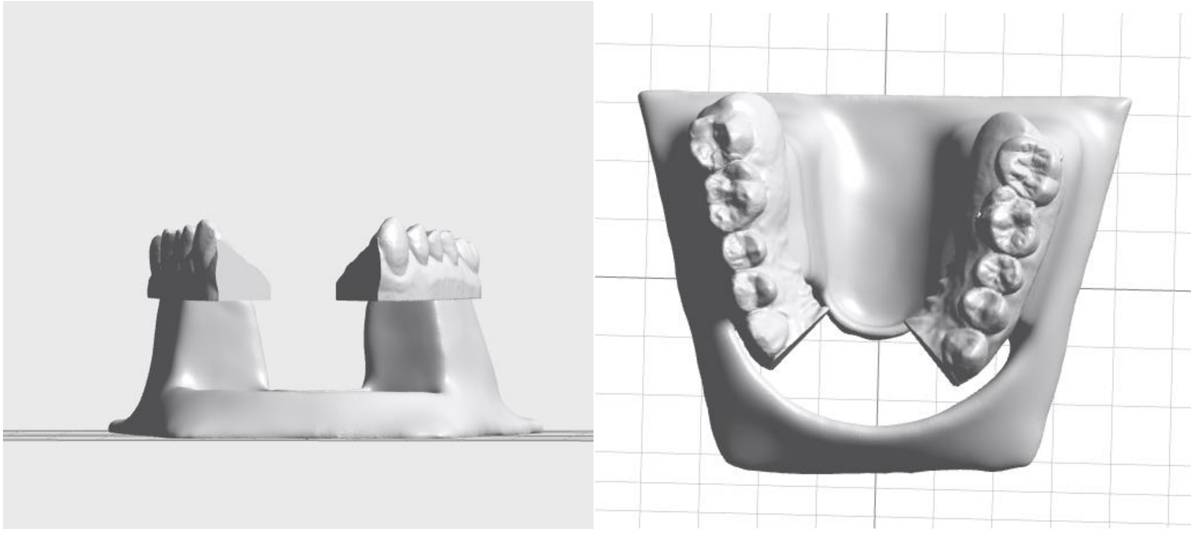

Figure 2.4: Design of the U2-2 Test Model, note no attachments are present on the model.

Test models were created by importing the trimmed master digital NA file exported from uLab into MeshMixer (Autodesk, San Rafael, CA, USA) where the model was segmented to remove the appropriate teeth. Digital superimposition of the original model was utilized to ensure that dimensionality was preserved after the digital modifications. The model was also supported vertically to provide strength and clearance for materials testing. The files were exported from MeshMixer as STLs and imported into Uniz for addition of supports for proper printing and optimal rigidity for mechanical testing.

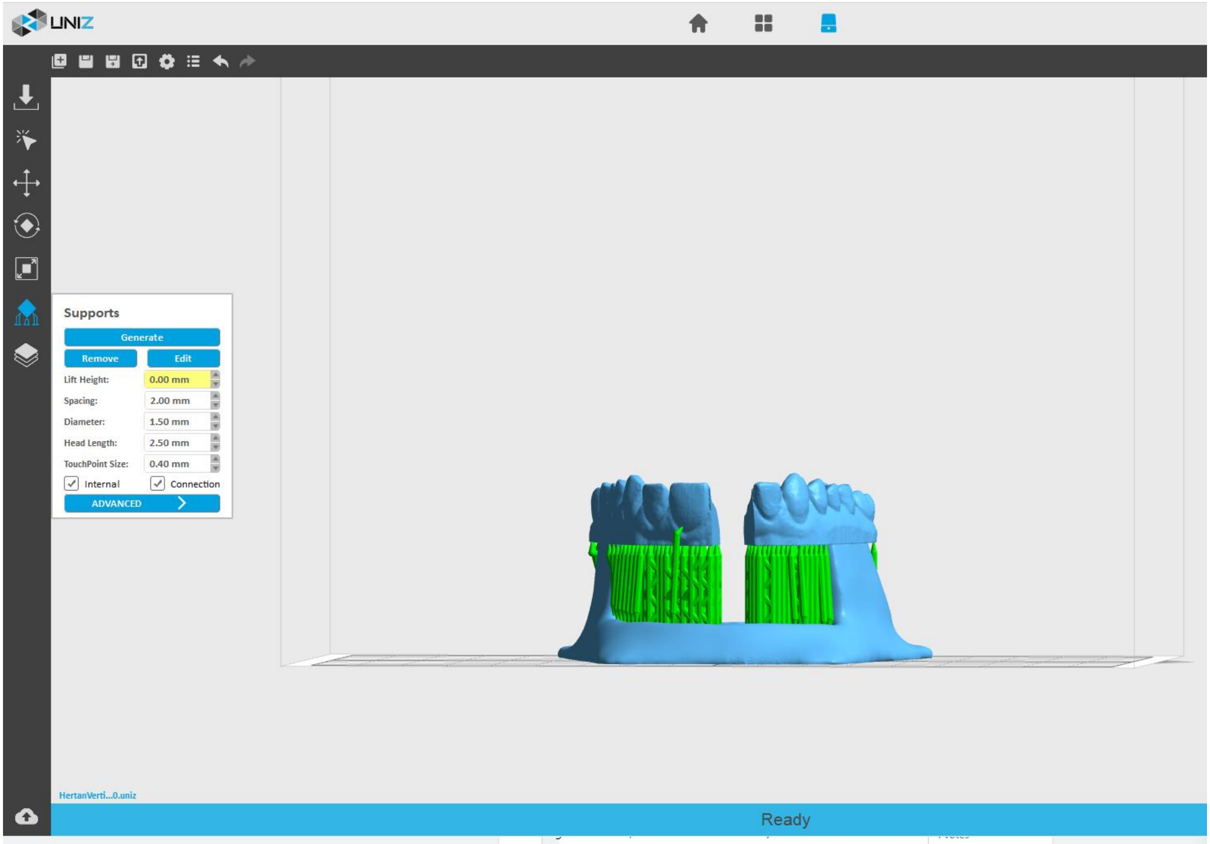

Figure 2.5: Design of the UR1 Test Model, addition of structural supports in Uniz software.

Test models were printed with a Uniz Slash-C LCD 3D printer (Uniz, San Diego, CA, USA) utilizing AnyCubic Clear 3D Resin (AnyCubic, Shenzhen, China). The manufacturer reported resin properties are a Shore Hardness (D) of 79, Tensile Strength of 23.4 MPa and Elongation of 14.2%. Test models were removed from the build plate and placed in a mechanically agitated bath of 99.5% isopropyl alcohol for 5 min. Models were then transferred to a second mechanically agitated "clean bath" of 99.5% isopropyl alcohol for an additional 5 min. Models were then dried with compressed air and inspected for uncured resin. Models were subsequently cured using the SprintRay Pro Cure (SprintRay, Los Angeles, CA, USA) with the Die and Model II setting.

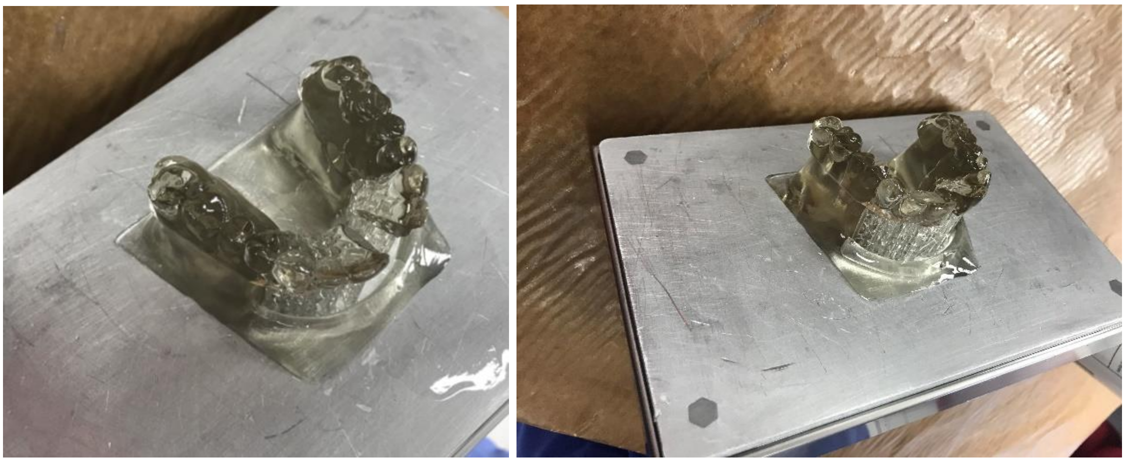

Figure 2.6: UR1 Test model on printer build plate prior to post processing.

Measurement Method

A hand wheel operated manual force test stand with integrated digital caliper with mm resolution to 0.01mm was paired with a ZP-50 digital force gauge with resolution to 0.01 N (Baoshishan, Shenzhen, China). Calibration of the ZP-50 dynamometer was verified with a hand-held Correx dynamometer (Haag-Streit Diagnostics, Köniz, Switzerland). The ZP-50 dynamometer was secured to the test stand in compression test mode. The selected test model was secured to the baseplate of the test stand utilizing a standard mini c-clamp.

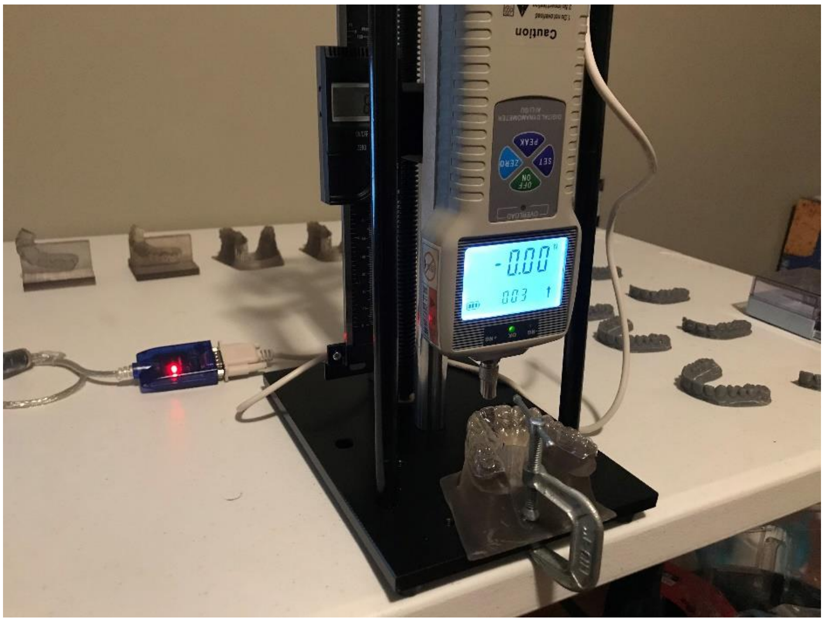

Figure 2.7: Experimental Test Stand with dynamometer and integrated caliper prior to initializing displacement test of TFM aligner on the UR1 test model.

Given the temperature-sensitive shape memory properties of the Direct Print Aligners, it was necessary to simulate the oral environment. Aligners were heated to 97.5 degrees F for a minimum of 5 minutes prior to testing by placement of each aligner in an individual water-filled bag (30 - 60 ml) in a warm water bath. The temperature was maintained by an Anova Precision Nano and monitored by Bluetooth. Temperature was verified with an instant-read thermometer and found to remain within 0.5 degrees F of the Bluetooth temperature reading. Pressure generated by submersion of the aligner in a warm water bath ensured that the aligner was totally covered in temperature-controlled liquid during its submersion without exposing it to excessive volumes of water. To further maintain the intra-oral simulated temperature environment, a ceramic positive thermal coefficient heater was used. An instant read thermometer was placed adjacent to the test model and target readings were 97 degrees. The range of temperature during the experiment was 88 deg F to 100.4 degree F; over 95% of the time, the temperature was within the 94 - 99 degree Fahrenheit range.

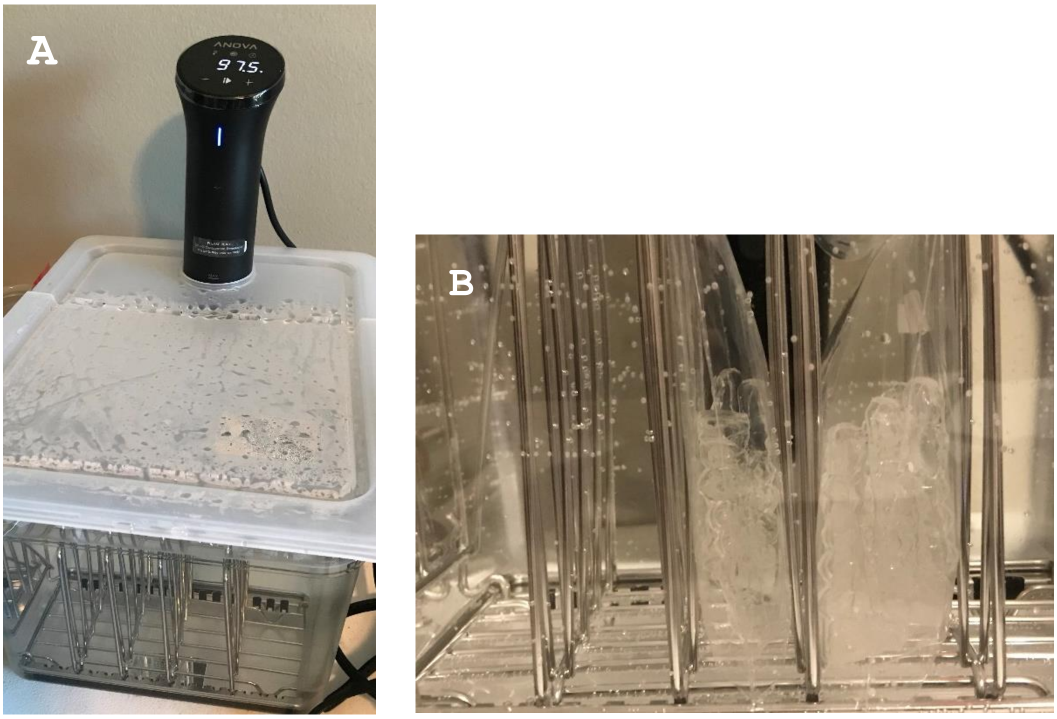

Figure 2.8: A) Temperature controlled water bath set to 97.5 degrees. B) Zoomed in view showing aligners in bags containing 30-60ml water, a metal rack system ensures proper circulation of warm water for optimal temperature.

Aligners were subject to testing on the UR1 Test Model first, with the rational that should there be a permanent deformation, this should have minimal impact on the 2-2 Test Model. Aligners were removed, gently shaken, and immediately placed on the heated test model. Liquid was allowed to remain on the aligner to maintain the test temperature. The newtometer was lowered incrementally until a force was read on the digital force meter. The meter was then raised until the force equaled zero. This process was repeated three times for each sample. The digital caliper was then zeroed and the aligner was compressed with vertical compression on external incisal edge of the missing UR1. Compression occurred until a displacement of 0.10 mm in the gingival direction and then peak N reading was recorded, a timer was then set and at 20 seconds, the N reading was recorded, compression then continued to 0.20 mm displacement with a subsequent peak N recording and a further N recording after 20 sec of force stabilization. This process continued until 0.50 mm displacement. It should be noted that TFM aligners were only tested to 0.30 mm displacement on the UR1 Test Model due to the high forces generated by the test and concerns regarding permanent deformation of the model. A total of 40 aligners were tested in this manner on the UR1 test model, 10 DPA NA, 10 DPA YA, 10 TFM NA, 10 TFM YA. Aligners were replaced in labeled bags such that results of individual aligners could be compared on the U2-2 model.

Following identical protocol, aligners were tested on the U2-2 Test Model. Aligners were removed, gently shaken, and immediately placed on the heated test model. Liquid was allowed to remain on the aligner to maintain the test temperature. The newtometer was lowered incrementally until a force was read on the digital force meter. The meter was then raised until the force equaled zero. The digital caliper was then zeroed and the aligner was compressed with vertical compression on external incisal edge at the contact of the missing UR1 and UL1. Compression occurred until a displacement of 0.10 mm in the gingival direction and then peak N reading was recorded, a timer was then set and at 20 sec, the N reading was recorded, compression then continued to 0.20 mm displacement with a subsequent peak N recording and a further N recording after 20 sec of force stabilization. This process continued until 0.50 mm displacement. A total of 40 aligners were tested in this manner on the U2-2 test model, 10 DPA NA, 10 DPA YA, 10 TFM NA, 10 TFM YA. All recorded data indicated the tested aligner number for quality assurance and appropriate statistical analysis.

Following initial testing, the ZP-50 meter was connected to Baoshishan Torque Meter Monitoring Software was utilized to capture pilot graphs of a single aligner of each condition on the U2-2 Model. Additional compression release testing was performed following the previous protocol in which each aligner was compressed to a total 0.50 mm in 0.10 mm increments with a 20 second rest period. Aligners were then decompressed in 0.10 mm increments with a 20 second rest period. Data was recorded in excel spreadsheet and graph formats.

Statistical Methodology

Dynamometer readings were captured at each respective displacement. Readings were captured for Peak Force (N), Stabilized Force (N). Force Decay (N) was calculated as the difference between peak force and stabilized force. Force Decay (%) was calculated as Force Decay (N) / Peak Force (N).

All analyses were conducted using SAS version 9.3 (SAS Inc, Cary, NC) and the level of significance (α) was set to 0.05. Wilcoxon rank-sum test (Non-parametric) was performed to compare the Peak Force, Stabilized Force and Force Decay among DPA and TFM groups with and without attachments in the UR1 and U2-2. Similarly, DPA and TFM among Missing U2-2, DPA in UR1 and U2-2, DPA without attachments in UR1 and U2-2, DPA with attachments in UR1 and U2-2, TFM in UR1 and U2-2, TFM without attachments in UR1 and U2-2, TFM with attachments in UR1 and U2-2 comparison were also made for the Peak Force, Stabilized Force and Force Decay using Wilcoxon rank-sum test. Force Decay (N) / Peak Force was also evaluated by degree of displacement among the various groups. Finally, Linear regression equations were calculated for each of these groups by displacement.

Results

DPA vs TFM in the UR1 Model

The median stabilized forces demonstrated by TFM in the missing UR1 model in response to 0.10 mm-0.30 mm displacements ranged from 4.70 N to 15.09 N. The median peak force demonstrated by TFM in the missing UR1 model in response to 0.10 mm - 0.30 mm displacements ranged from 5.23 N to 16.17 N. The median force decay demonstrated by TFM in the missing UR1 model in response to 0.10 mm - 0.30 mm displacements ranged from 0.57 N to 1.1 N. Note that testing of the UR1 TFM model was halted at 0.30 mm displacement due to concerns of possible permanent deformation of the test model due to high forces exhibited.

Median stabilized forces that were demonstrated by DPA in the missing UR1 model in response to 0.10 - 0.30 mm displacements ranged from 0.73 - 1.61 N. The median peak force demonstrated by DPA in the missing UR1 model in response to 0.10 - 0.30 mm displacements ranged from 2.46 - 3.75 N. The median force decay demonstrated by DPA in the missing UR1 model in response to 0.10 - 0.30 mm displacements ranged from 1.76 - 2.07 N.

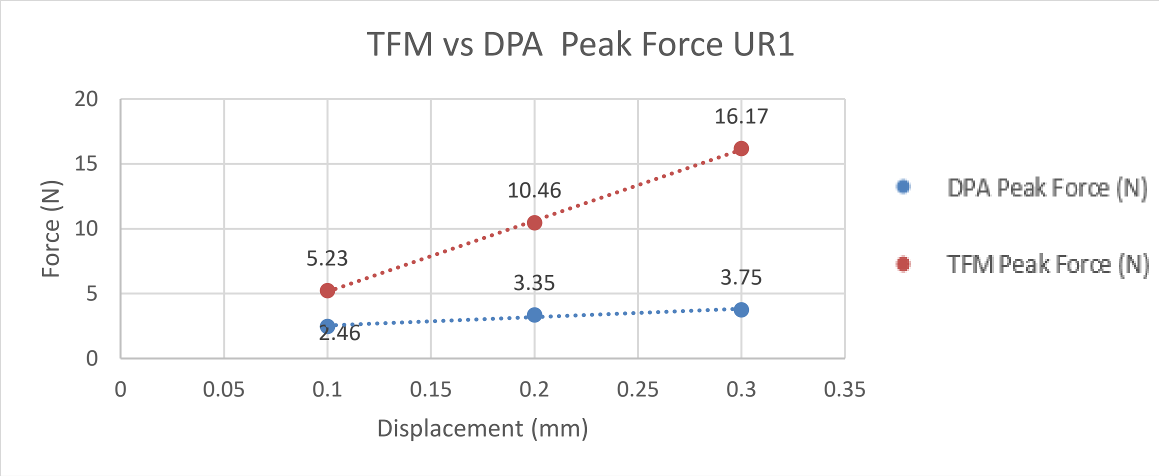

Figure 3.1 Comparison of Peak Forces of TFM vs DPA on the UR1 Model

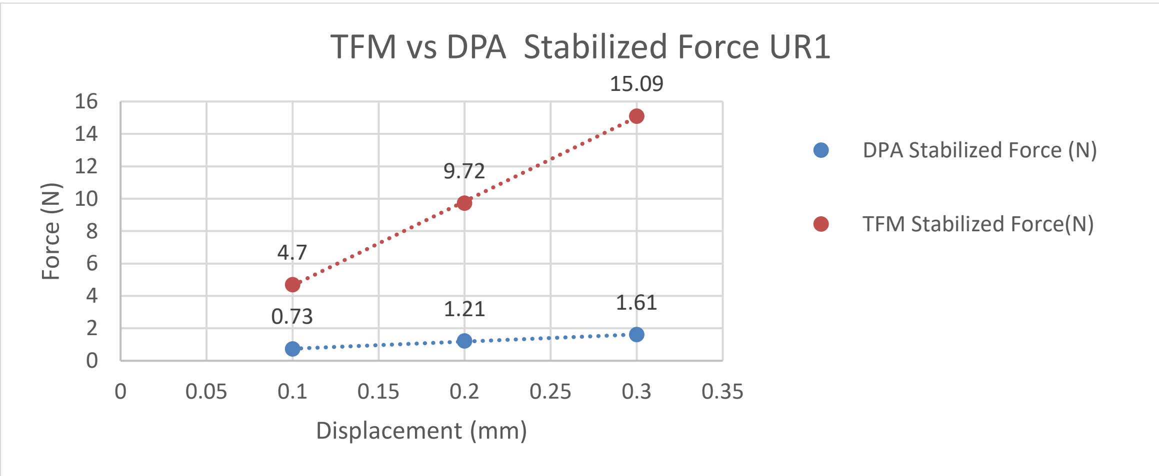

Figure 3.2 Comparison of Stabilized Forces of TFM vs DPA on the UR1 Model

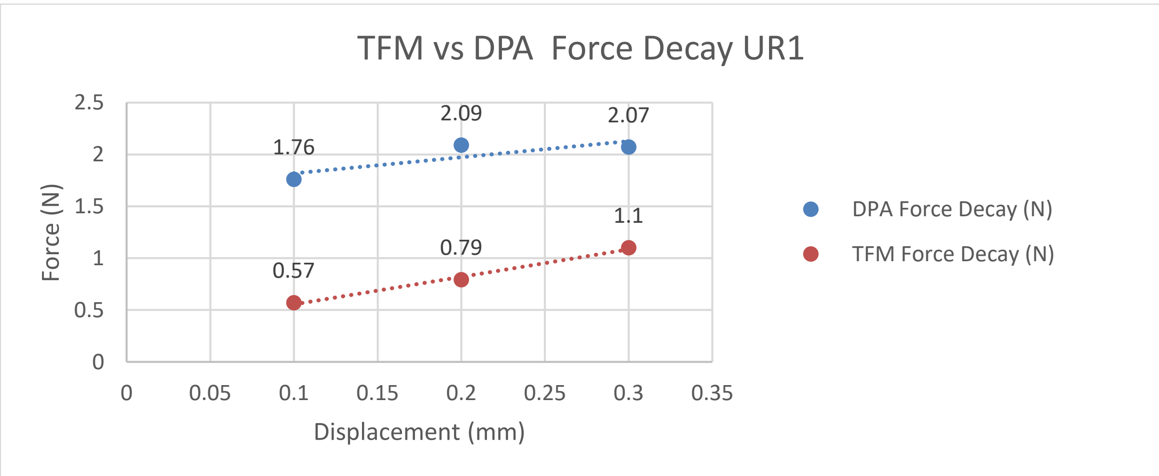

Figure 3.3 Comparison of Force Decay of TFM vs DPA on the UR1 Model

DPA vs TFM in the U2-2 Model

The median stabilized forces demonstrated by TFM in the missing U2-2 model in response to 0.10 - 0.50 mm displacements ranged from 3.52 - 12.55 N. The median peak force demonstrated by TFM in the missing U2-2 model in response to 0.10 -0.50 mm displacements ranged from 3.77 N - 12.99 N. The median force decay demonstrated by TFM in the missing U2-2 model in response to 0.10 - 0.50 mm displacements ranged from 0.25N - 0.52 N.

Median stabilized forces demonstrated by DPA in the missing U2-2 model in response to 0.10 - 0.50 mm displacements ranged from 0.13N - 0.31 N. The median peak force demonstrated by DPA in the missing U2-2 model in response to 0.10 - 0.50 mm displacements ranged from 0.43 - 0.60 N. The median force decay demonstrated by DPA in the missing U2-2 model in response to 0.10 - 0.50 mm displacements ranged from 0.36 - 0.32N.

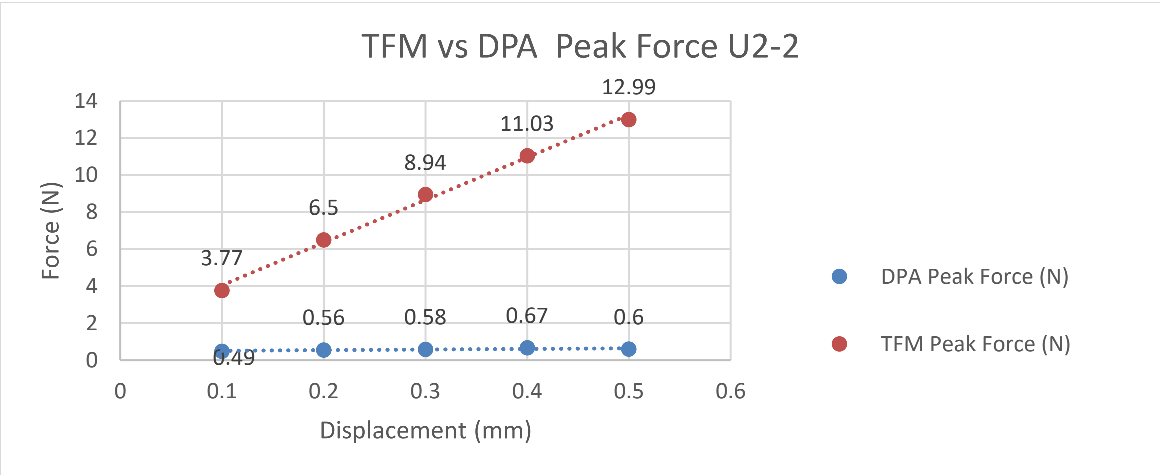

Figure 4.1 Comparison of Peak Forces of TFM vs DPA on the U2-2 Model

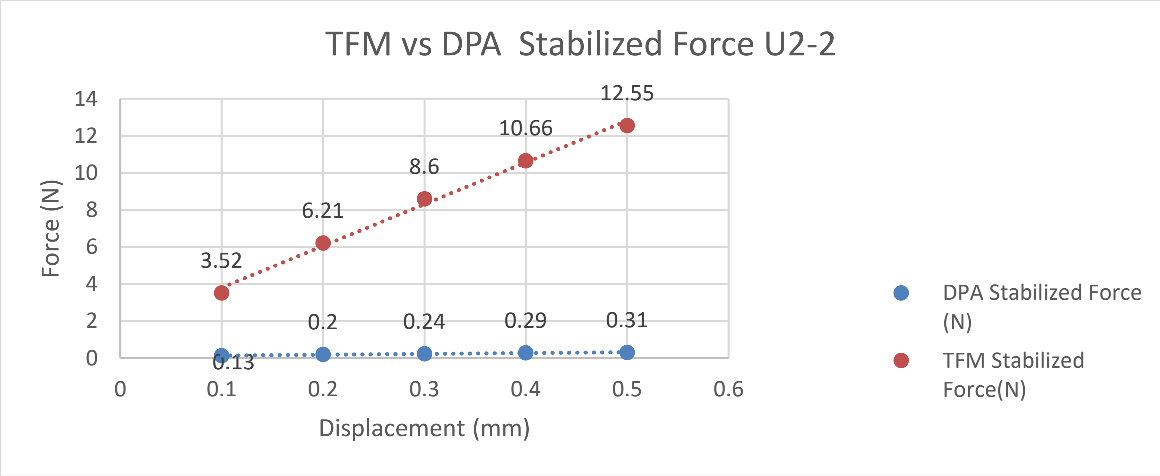

Figure 4.2 Comparison of Stabilized Forces of TFM vs DPA on the U2-2 Model

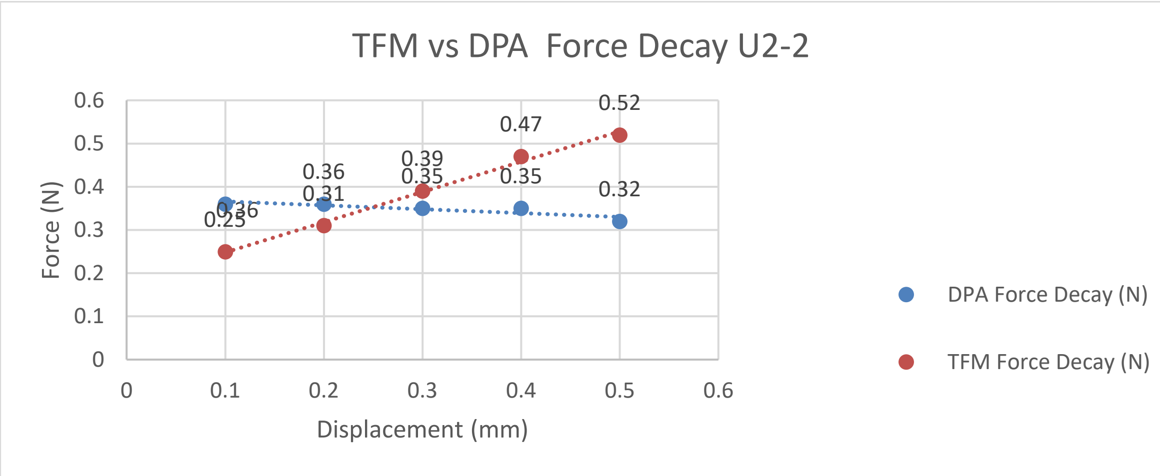

Figure 4.3 Comparison of Peak Forces of TFM vs DPA on the UR1 Model

<u>The Effect of Unsupported Attachments UR1 Model</u>

TFM aligners with attachments that were not engaged by the UR1 testing model did not show any statistically significant differences in comparison with TFM aligners without attachments in peak force (P-values for peak force ranged from 0.82-0.94). There were no statistically significant differences in Stabilized Force between the attachment and no-attachment condition (p-values=0.55 - 0.97). Force decay additionally did not display statistical significance (p-values=0.13 - 0.85). There were no obvious trends or differences between TFM aligners with and without attachments for 0.10 mm – 0.50 mm displacement. There exists a possibility that at increased power, there may be statistical significance for force decay at larger displacements.

Table 1. Comparing TFM with and without attachments in UR1

	No attachments			Attachments			P-value
	Mean	Std Dev	Median	Mean	Std Dev	Median	
Peak Force (N) 0.10mm	5.26	0.51	5.11	5.13	0.89	5.34	0.94
Stabilized Force (N) 0.10mm	4.73	0.5	4.6	4.6	0.84	4.74	0.97
Peak Force (N) 0.20mm	10.52	0.69	10.52	10.37	1.21	10.39	0.821
Stabilized Force (N) 0.20mm	9.77	0.76	9.68	9.6	1.18	9.75	0.94
Peak Force (N) 0.30mm	16.16	0.71	16.1	15.85	1.36	16.26	0.94
Stabilized Force (N) 0.30mm	15.04	0.8	14.89	14.84	1.48	15.3	0.545

DPA aligners with attachments that were not engaged by the UR1 testing model did not show any statistically significant differences in comparison with DPA aligners without attachments in peak force (p-values=0.45 - 0.08). There were no statistically significant differences in Stabilized Force between the attachment and no-attachment condition (p-values=0.65 - 0.09). Force decay additionally only displayed statistical significance for 0.40 mm displacement (P-values =0.03 - 0.32). DPA aligners with attachments generally delivered a stronger median force than those without attachments for the missing UR1 condition, though this finding was not statistically significant. There exists a substantial possibility that at increased power there may be statistical significance for force decay at larger displacements.

Table 2. Comparing DPA with and without attachments in UR1

	No attachments			Attachments			P-value
	Mean	Std Dev	Median	Mean	Std Dev	Median	
Peak Force (N) 0.10mm	2.59	0.62	2.44	2.77	0.6	2.65	0.45
Stabilized Force (N) 0.10mm	0.76	0.18	0.73	0.81	0.21	0.79	0.65
Peak Force (N) 0.20mm	3.15	0.65	3.18	3.58	0.51	3.52	0.14
Stabilized Force (N) 0.20mm	1.18	0.27	1.19	1.33	0.23	1.26	0.151
Peak Force (N) 0.30mm	3.49	0.71	3.48	4.04	0.67	3.87	0.076
Stabilized Force (N) 0.30mm	1.57	0.37	1.52	1.78	0.39	1.69	0.241
Peak Force (N) 0.40mm	3.84	0.71	4.12	4.47	0.8	4.26	0.162
Stabilized Force (N) 0.40mm	1.86	0.46	1.9	2.09	0.45	1.92	0.496
Peak Force (N) 0.50mm	4.14	1.04	4.32	5.06	0.87	4.93	0.131
Stabilized Force (N) 0.50mm	1.93	0.5	1.72	2.36	0.56	2.16	0.094

The Effect of Unsupported Attachments U2-2 Model

TFM aligners with attachments that were not engaged by the U2-2 testing model demonstrated statistically significant differences in comparison with TFM aligners without attachments in peak force beginning at 0.30 mm (for displacements of 0.30 mm - 0.50 mm p-values=0.013 - 0.028). There were statistically significant differences in stabilized force between the attachment and no-attachment condition for displacements of 0.30 mm - 0.50 mm (p-values=0.023 - 0.041). Force decay additionally did display statistical significance for displacements of 0.30 mm - 0.50 mm (P-values=0.06 - 0.041). The data demonstrated a trend that peak force, stabilized force, and force decay were lower for TFM aligners with unsupported attachments as compared to those without attachments.

Table 3. Comparing TFM with and without attachments in Missing U2-2

	No attachments			Attachments			P-value
	Mean	Std Dev	Median	Mean	Std Dev	Median	
Peak Force (N) 0.10mm	3.97	0.61	3.75	3.87	0.25	3.79	0.65
Stabilized Force (N) 0.10mm	3.71	0.59	3.48	3.63	0.25	3.56	0.427
Peak Force (N) 0.20mm	6.71	0.55	6.59	6.34	0.34	6.24	0.08
Stabilized Force (N) 0.20mm	6.38	0.55	6.29	6.04	0.37	5.93	0.151
Peak Force (N) 0.30mm	9.21	0.62	9.33	8.55	0.44	8.63	0.013*
Stabilized Force (N) 0.30mm	8.77	0.61	8.84	8.18	0.47	8.23	0.023*
Peak Force (N) 0.40mm	11.38	0.79	11.55	10.57	0.56	10.7	0.013*
Stabilized Force (N) 0.40mm	10.86	0.82	11.05	10.15	0.59	10.25	0.031*
Peak Force (N) 0.50mm	13.32	0.95	13.41	12.46	0.75	12.7	0.028*
Stabilized Force (N) 0.50mm	12.71	0.97	12.86	11.96	0.76	12.11	0.041*

DPA aligners with attachments that were not engaged by the U2-2 testing model demonstrated statistically significant differences in comparison with DPA aligners without attachments for a displacement of 0.10 mm in peak force, stabilized force, and force decay.

Of note, once displacement exceeded 0.10 mm there were no statistically significant differences between DPA Aligners with attachments and those without attachments. Median peak force values at 0.10 mm displacement were 0.52 N for no attachments and 0.32 N for DPA with attachments. There were statistically significant differences at 0.10 mm displacement in stabilized force between the attachment and no-attachment condition (p-value=0.025). Median stabilized force for DPA without attachments was 0.15 N, median stabilized force for DPA with attachments was 0.10 N. Median force decay for the no attachments group was 0.38 N whereas median force decay for the yes attachment group was 0.22 N (P-value=0.014). Displacements of 0.20 mm and beyond did not exhibit statistically significant differences between the groups the data does suggest that with a larger sample the results may be significant.

Table 4. Comparing DPA with and without attachments in Missing U2-2

	No attachments			Attachments			P-value
	Mean	Std Dev	Median	Mean	Std Dev	Median	
Peak Force (N) 0.10mm	0.57	0.15	0.54	0.37	0.18	0.32	0.008*
Stabilized Force (N) 0.10mm	0.16	0.04	0.15	0.11	0.05	0.1	0.025*
Peak Force (N) 0.20mm	0.58	0.12	0.59	0.53	0.15	0.55	0.571
Stabilized Force (N) 0.20mm	0.22	0.04	0.25	0.18	0.05	0.16	0.085
Peak Force (N) 0.30mm	0.65	0.14	0.62	0.58	0.11	0.56	0.289
Stabilized Force (N) 0.30mm	0.27	0.05	0.29	0.23	0.04	0.22	0.129
Peak Force (N) 0.40mm	0.7	0.16	0.75	0.58	0.15	0.52	0.104
Stabilized Force (N) 0.40mm	0.31	0.06	0.34	0.27	0.06	0.25	0.129
Peak Force (N) 0.50mm	0.69	0.15	0.71	0.6	0.17	0.55	0.185
Stabilized Force (N) 0.50mm	0.34	0.07	0.37	0.29	0.06	0.27	0.137

The Effect of UR1 vs U2-2 Model

The edentulous span was a major influence on the force exhibited by aligners. For TFM without attachments peak force, stabilized force, and force decay were all significantly lower in the U2-2 model. For TFM with attachments the results were similar peak force, stabilized force, and force decay were all significantly lower in the U2-2 model. Table 11 lists the various linear equations for the aligners as well as their respective p values.

Direct Print Aligners demonstrated significant differences in peak force, stabilized force, and force decay between the models, with all forces being significantly lower in the U2-2 model.

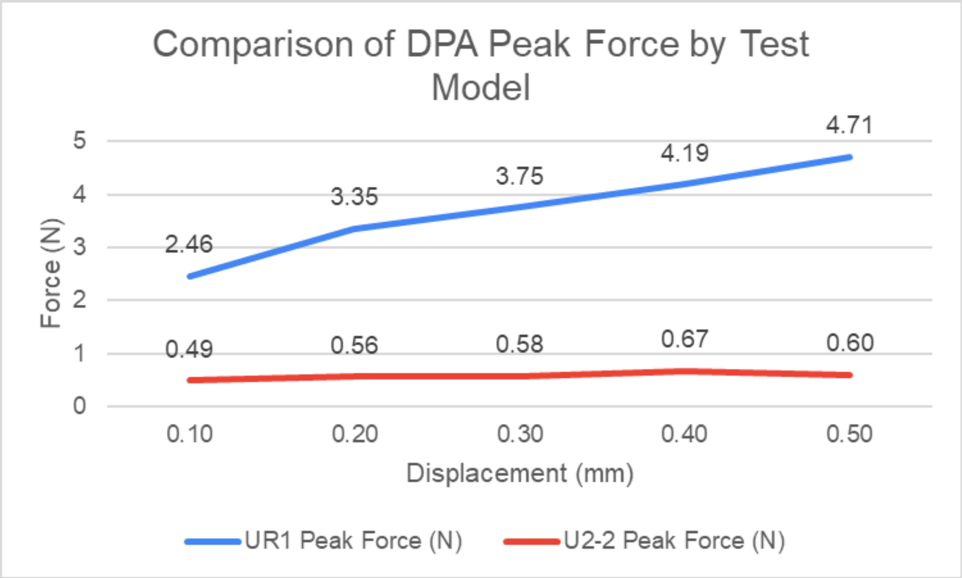

Figure 5.1 Comparison of DPA Peak Forces on UR1 vs U2-2 Model

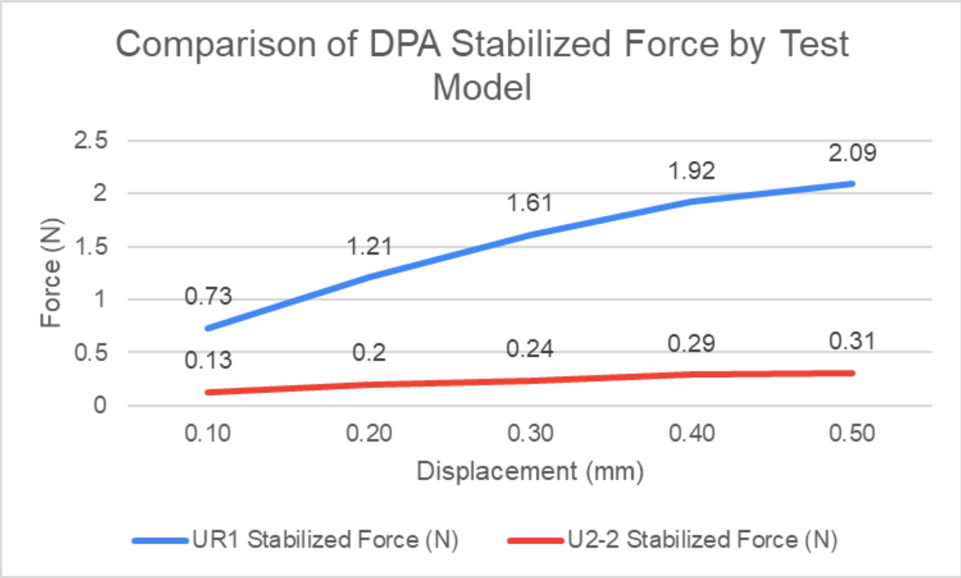

Figure 5.2 Comparison of Peak Forces of DPA by UR1 vs U2-2 Model

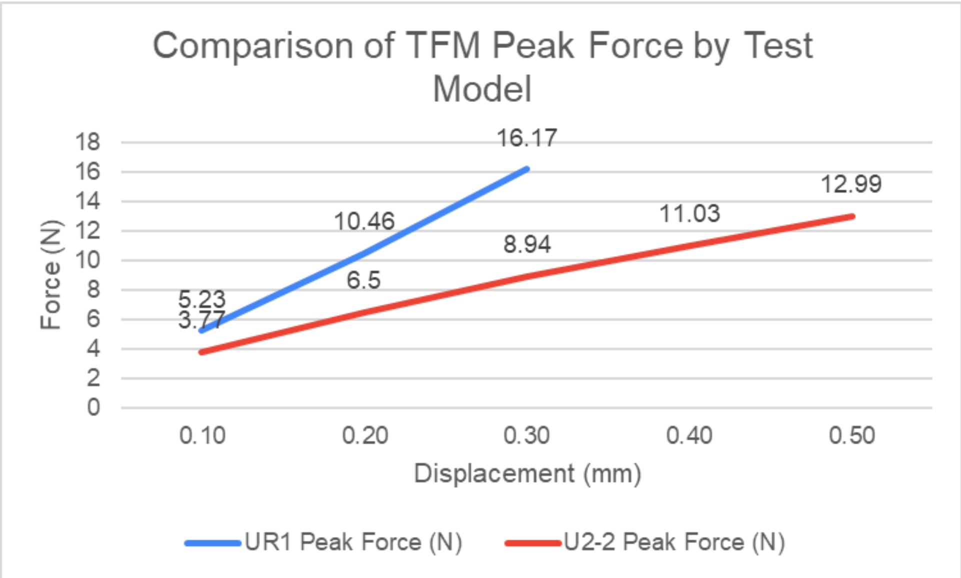

Figure 5.3 Comparison of Peak Forces of TFM by UR1 vs U2-2 Model

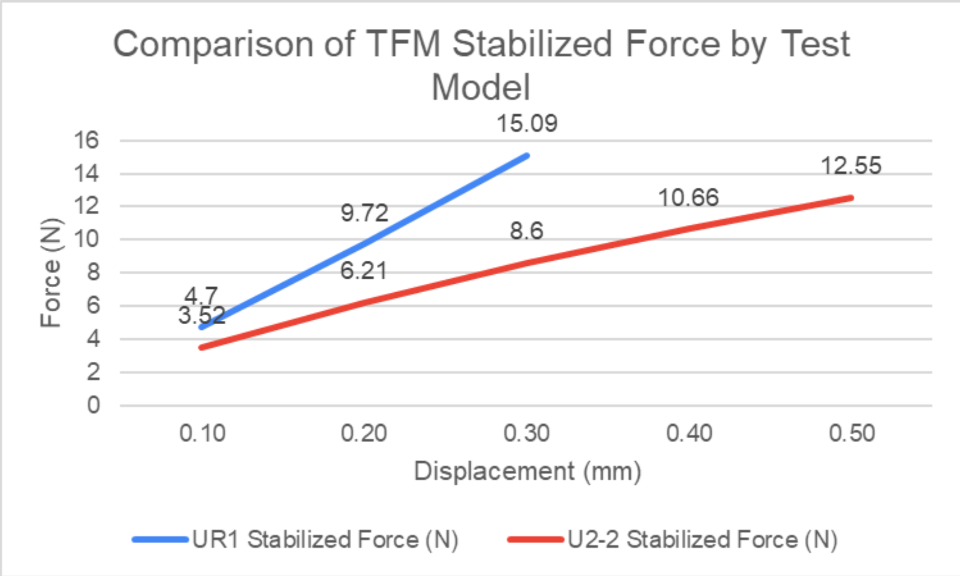

Figure 5.4 Comparison of Stabilized Forces of TFM by UR1 vs U2-2 Model

Discussion

Methodology

The approach utilized in this study may be considered analogous to measuring the extrusive force programmed into a tooth. Generally, when programming 0.1 mm extrusion on a central incisor with clear aligners, a 3D model is created with the extrusion built in. A thermoformed aligner is then created with this excess extrusion present in the aligner; the aligner is then placed and presumably compressed to engage the central incisor and thereby achieve extrusion. When compressing a central incisor 0.1 mm in the experiment, this compression may be analogous to the aforementioned extrusion case. Similarly, in the case of extrusion of all upper central and lateral incisors by 0.2 mm, a similar phenomenon occurs in which the aligner is printed with this movement built in and the aligner is subsequently compressed to engage the teeth. While certainly there are many limitations to this conceptual framework, it is a simplification that may aid in interpreting and contextualizing the results.

Benefits to this methodology include the ability to test the force of a variety of aligners without the need for passive calibration aligners. Previous research utilizing Nano17 sensors required passive calibration aligners. This system accurately captures the differences between groups; however, previous research by Heo et al.[26] and Hillam et al.[27] have revealed that passive aligners may apply a variety of unintended forces throughout the arch. Thus, removing these forces as background noise in calibration may create inaccurate force readings. An additional benefit of this methodology was the ability to accurately measure the properties of the plastic regardless of the tooth morphology. Due to natural variations in tooth structure, such as clinical crown height, embrasure sizes, spacing between teeth, etc. (Hillam et al) there can be varying retentiveness of the aligner on dentitions of different morphology. These variables can substantially affect tooth movement and can vary between experimental designs. By eliminating the impact of the aligner's ability to grip the tooth in question, it allows for the focus on the material properties of the aligners themselves prior to determining the optimal strategy for tooth retention in the aligner. In comparison to previous tests utilizing Van Mises Strain or Pressure Sensitive film, those studies only captured peak forces and could not isolate the direction of those forces. In contrast, the force over time was known and accurately measured in this experiment. Finally, this experiment examined aligners while simulating intra-oral moisture and temperatures, which may help provide more physiologically relevant results.

Limitations to this methodology include the lack of PDL in the experimental teeth; thus, the force generated may be of higher magnitude as compared with what would normally be expected in a system where all teeth have degrees of freedom corresponding to the PDL space. Additionally, when the aligner is compressed onto the teeth clinically, there may be over-compression followed by a release. For example, the aligner may be compressed to 0.2 mm displacement and then retain the target tooth at 0.1 mm displacement, this release of force will likely have a different stabilized force and overall force profile than a tooth with "perfect retention" which the aligner is displaced 0.2 mm and retains perfect anchorage at that displacement. Additional limitations include the ability of the aligner to retain a tooth in question and the effect of this on the force profile.

Delivered forces of DPA vs TFM

A critical provider goal in orthodontic treatment is to deliver treatment within the biomechanically acceptable therapeutic range. Proffit reports that ideal tooth movement forces range from 10 to 120 grams.[28] A 2003 systematic literature review in the Angle Orthodontist concluded that "no evidence about the optimal force level in orthodontics could be extracted from literature." Nevertheless, the accepted clinical practice in orthodontics remains the utilization of light forces as recommended by Proffit to minimize excessive hyalinization. The median stabilized force delivered by DPAs in the UR1 model (Table 7) ranged from 0.73 N at 0.10 mm displacement to 1.61 N at 0.30 mm displacement. The median stabilized force delivered by TFM aligners in the UR1 ranged from 4.70 N to 15.09 N. The data clearly suggests that the forces delivered by DPAs appear to be more aligned to the biomechanically desired force levels recommended by Proffit.

Comparing forces for the U2-2 model, the median stabilized force delivered by DPAs (Table 8) ranged from 0.13 N at 0.10 mm displacement to 0.31 N at 0.50 mm displacement. The median stabilized force delivered by TFM aligners in the U2-2 model ranged from 3.52 N to 12.55 N. The data clearly suggest that the forces delivered by DPAs appeared to deliver a more consistent force profile. In a sense, DPAs could be considered analogous to NiTi wires delivering gentle consistent forces over a range of displacements. However, there are concerns in the case of group extrusion (such as extrusion of teeth U2-2 0.2 mm) that the force may be below therapeutic levels on a per-tooth basis. Thus, further research on an individual tooth level is necessary to determine the actual forces delivered per tooth in a group extrusion or similar setting. These results may prompt manufacturers to investigate making the resin deliver a marginally higher force profile for increased therapeutic effect in cases where group movements are desired. One of the promises delivered by DPAs is the opportunity to create pressure points, undercuts, and other surface modifications and textures to improve treatment properties. A question raised by the study is whether the shape memory of DPAs results in an aligner that is too gentle to effectively use these features, and this is an intriguing area for future research.

The Effect of Attachments

The effects of attachments on the force delivered by aligners and retention of aligners have been extensively studied. However, the effects of attachments on the rigidity, flexibility, elasticity of aligners are not reported in the literature. One goal of the present study was to investigate how surface patterns of the aligner effect the forces of both TFM and DPA aligners. Despite the presence of attachments on some aligners, all test models had no attachments. For clarity, the test was similar to a clear aligner therapy patient with attachments on all maxillary teeth wearing their aligner after the attachments fell off. The aligners fit well; however, there were spaces of no contact in the location of the attachments.

The hypothesized impact of attachments was dichotomous prior to the experiment. On the one hand, a stress-breaking effect similar to that of bends in a wire could be anticipated. In contrast, others expected the attachments to serve in a similar fashion to increasing trim height or folding a piece of cardboard. In plastics, a similar technique is commonly referred to as ribbing. Due to the inability to achieve ribbing in a thermoformed aligner, attachments were placed to achieve a ribbing-like-effect that could be accurately compared across both DPAs and thermoformed aligners.

DPAs in the UR1 model displayed a tendency for increased median stabilized force at displacements of 0.30 mm and greater for the attachment condition (Table 1). This finding was not statistically significant; the data suggest that a larger sample with greater power may find significance. DPAs in the U2-2 model displayed a tendency for lower median peak forces and stabilized forces in the attachment group. These findings were only statistically significant at 0.10 mm displacement; however, there exists a strong trend in the data and a significant likelihood that with a larger sample, this finding could achieve statistical significance. The findings appear somewhat contradictory, suggesting that the attachments serve as a stress break, increasing the flexibility of the aligner in the U2-2 model, while seemingly serving to strengthen the model in the UR1 condition.

The effect of attachments in TFM aligners revealed a similar trend. TFM aligners in the UR1 model displayed higher median stabilized forces in the yes attachment condition, however, these results were not statistically significant (Table 2). TFM aligners in the U2-2 Model displayed weaker stabilized force, peak force, and force decay in the presence of attachments. These findings were statistically significant at a displacement of 0.10 mm (P values=0.008 - 0.025, Table 3). The data displayed a trend at displacements greater than 0.10 mm, suggesting that a larger sample with greater power may find statistical significance.

The findings were intriguing in that the trends remained consistent across DPA and TFM. Attachments in the UR1 model resulted in stronger forces, while attachments in the U2-2 model weakened forces. Notably, statistical significance was seen only in the U2-2 model, with statistical significance for TFM being seen at displacements of 0.30 mm and greater. In contrast, statistical significance for the U2-2 model for DPA was only seen at 0.10

mm. The fundamental underlying cause of these findings remains unknown but may be related to the elasticity of each polymer.

An important note relevant to the experiment methodology is the fact that the spaces between the aligner and the tooth could serve as a stress break to increase flexibility, and that a measured increase or decrease in flexibility with attachments, while meaningful in a materials science aspect, may not translate to clinical significance.

The Effect of Span UR1 vs U2-2

The test models UR1 and U2-2 were predicated on the desire to better understand the impact of group extrusion vs single tooth extrusion in relation to aligner properties. Anecdotally, some seasoned clear aligner clinicians report being more comfortable in the extrusion of U2-2 as a unit as compared with a single anterior tooth such as UR1, when no attachments are used. Inspired by the research of Khoda et al. which discovered that excessive activation decreased the force delivered, which the authors attributed to deformation, this experiment sought to investigate the effect of span on force for specific displacements. The hypothesized outcome was that larger spans of movement would allow for increased flexibility with decreased deformation. Thus, for the U2-2 model, a lower stabilized force with decreased percent force decay was hypothesized. The experiment clearly determined that U2-2 exhibited lower forces than the UR1 model. However, the differences in percent force decay were not statistically significant. Regarding the stabilized forces, Table 9 and Table 10 display a comparison of DPAs and TFM aligner performance in the UR1 and U2-2 models. Figure X shows a chart representing percentage force in U2-2 compared to UR1. For TFM aligners the force on the U2-2 model represented 57 - 75% of the same displacement force on the UR1 model, decreasing with each successive 0.01 mm displacement (Table 10). DPAs exhibited a similar trend of decreased force in the U2-2 condition with median stabilized force representing 15 - 18% of the stabilized force in the UR1 model. Traditional thermoformed aligners did a better job of maintaining the same stabilized force level in the U2-2 model as compared to the UR1 model. In contrast, DPAs were more forgiving, losing up to 85% of the force they would deliver in the UR1 model when tested in the larger span U2-2 model.

Discussion Summary

Force Levels

DPA aligners displayed a more consistent force profile regardless of displacement. In contrast, the forces delivered by thermoformed aligners were highly sensitive to displacement. DPA aligners in the group-extrusion use-case may deliver insufficient forces for ideal tooth movement. The force profile delivered by DPA aligners was more consistent with the target force range that is traditionally considered biocompatible for orthodontic tooth movement.

Group Extrusion vs Single Tooth Extrusion

The impact of Group extrusion vs single tooth extrusion as represented by test models U2-2 and UR1 predictably demonstrated that a larger span delivers decreased forces. Further research is necessary to better understand how this influences other properties such as elastic spring back, ability to engage target teeth, etc.

Surface Patterns

Surface patterns such as unfilled attachments demonstrated the ability to modify the mechanical force properties of aligners. In this experiment the effect of attachments was dependent on the test model. For the U2-2 model, attachments resulted in weaker stabilized forces. In contrast for the UR1 model attachments resulted in stronger forces (though this finding was not statistically significant). Further research is needed to better understand the effects of attachments and surface patterns on the properties of aligners. The surface patterning of aligners has the potential to create a significant impact on material properties and force profiles. Further research is necessary to explore surface pattern options with a focus on Direct Print Aligners and better harness their full potential.

Temperature Effects

The effect of temperature on DPA was substantial and significant. The force exhibited by DPAs at room temperature was over 10x the force level of DPAs when tested at intraoral temperatures. Intraoral temperatures significantly increased the flexibility of the material and decreased the forces exerted by the aligners in response to displacement.

Conclusions

Direct Print Aligners can deliver biologically compatible forces for orthodontic tooth movement in an in-vitro setting. In contrast to thermoformed aligners, the forces delivered by direct print aligners may demonstrate improved ability to deliver forces within traditionally accepted range of optimum forces for tooth movement. The temperature sensitivity of the Tera Hartz resin is very significant and may offer a variety of applications and opportunities in optimizing clear aligner orthodontic tooth movement. The study demonstrates that surface pattern techniques can alter the force profile of aligners. Specifically, surface patterns change the mechanical properties of a clear aligner, and thus the magnitude of forces exerted by the aligner. Further investigation of surface patterns, ribbing, and other features in direct print aligners offers an exciting new realm of opportunity in clear aligner research.

APPENDIX

Table A.1 Comparing DPA with and without attachments in UR1

	No attachments					**Attachments**					**P-value**
	Mean	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	
Peak Force (N) 0.10mm	2.59	0.62	2.44	2.22	2.7	2.77	0.6	2.65	2.36	3.25	0.45
Stabilized Force (N) 0.10mm	0.76	0.18	0.73	0.67	0.84	0.81	0.21	0.79	0.67	0.93	0.65
Force Decay (N) 0.10mm	1.83	0.54	1.72	1.54	2.03	1.96	0.43	1.86	1.69	2.23	0.326
Peak Force (N) 0.20mm	3.15	0.65	3.18	2.6	3.56	3.58	0.51	3.52	3.17	3.96	0.14
Stabilized Force (N) 0.20mm	1.18	0.27	1.19	0.93	1.28	1.33	0.23	1.26	1.17	1.45	0.151
Force Decay (N) 0.20mm	1.97	0.44	1.98	1.72	2.23	2.26	0.37	2.25	2	2.57	0.131
Peak Force (N) 0.30mm	3.49	0.71	3.48	3.03	3.82	4.04	0.67	3.87	3.56	4.7	0.076
Stabilized Force (N) 0.30mm	1.57	0.37	1.52	1.36	1.89	1.78	0.39	1.69	1.49	1.9	0.241
Force Decay (N) 0.30mm	1.92	0.36	1.89	1.67	2.09	2.25	0.35	2.28	2.05	2.42	0.059
Peak Force (N) 0.40mm	3.84	0.71	4.12	3.3	4.37	4.47	0.8	4.26	4.05	5.2	0.162
Stabilized Force (N) 0.40mm	1.86	0.46	1.9	1.44	2.24	2.09	0.45	1.92	1.79	2.31	0.496
Force Decay (N) 0.40mm	1.98	0.37	1.92	1.72	2.27	2.39	0.42	2.42	2.14	2.67	**0.034**
Peak Force (N) 0.50mm	4.14	1.04	4.32	3.24	5.06	5.06	0.87	4.93	4.23	5.38	0.131
Stabilized Force (N) 0.50mm	1.93	0.5	1.72	1.62	2.37	2.36	0.56	2.16	1.96	2.42	0.094
Force Decay (N) 0.50mm	2.14	0.63	2.49	1.59	2.55	2.7	0.36	2.77	2.44	2.95	0.056

Table A.2 Comparing TFM with and without attachments in UR1

	No attachments					Attachments					P-value
	Mean	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	
Peak Force (N) 0.10mm	5.26	0.51	5.11	4.9	5.64	5.13	0.89	5.34	4.73	5.52	0.94
Stabilized Force (N) 0.10mm	4.73	0.5	4.6	4.32	5.27	4.6	0.84	4.74	4.22	4.99	0.97
Force Decay (N) 0.10mm	0.53	0.16	0.58	0.37	0.66	0.54	0.1	0.55	0.5	0.59	0.571
Peak Force (N) 0.20mm	10.52	0.69	10.52	10.02	11.03	10.37	1.21	10.39	9.8	11.03	0.821
Stabilized Force (N) 0.20mm	9.77	0.76	9.68	9.21	10.23	9.6	1.18	9.75	9.01	10.18	0.94
Force Decay (N) 0.20mm	0.75	0.15	0.77	0.72	0.84	0.76	0.1	0.79	0.74	0.83	0.85
Peak Force (N) 0.30mm	16.16	0.71	16.1	15.93	16.56	15.85	1.36	16.26	14.96	16.46	0.94
Stabilized Force (N) 0.30mm	15.04	0.8	14.89	14.6	15.39	14.84	1.48	15.3	14.13	15.55	0.545
Force Decay (N) 0.30mm	1.12	0.23	1.17	1.1	1.21	1.01	0.21	0.94	0.9	1.1	0.131

Table A.3 Comparing DPA with and without attachments in Missing U2-2

	No attachments					**Attachments**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	0.57	0.15	0.54	0.49	0.62	0.37	0.18	0.32	0.27	0.48	**0.008**
Stabilized Force (N) 0.10mm	0.16	0.04	0.15	0.13	0.19	0.11	0.05	0.1	0.08	0.13	**0.025**
Force Decay (N) 0.10mm	0.41	0.12	0.38	0.36	0.46	0.26	0.13	0.22	0.17	0.35	**0.014**
Peak Force (N) 0.20mm	0.58	0.12	0.59	0.52	0.67	0.53	0.15	0.55	0.42	0.63	0.571
Stabilized Force (N) 0.20mm	0.22	0.04	0.25	0.18	0.25	0.18	0.05	0.16	0.15	0.2	0.085
Force Decay (N) 0.20mm	0.37	0.1	0.35	0.28	0.44	0.35	0.12	0.38	0.27	0.44	0.821
Peak Force (N) 0.30mm	0.65	0.14	0.62	0.54	0.79	0.58	0.11	0.56	0.49	0.68	0.289
Stabilized Force (N) 0.30mm	0.27	0.05	0.29	0.21	0.3	0.23	0.04	0.22	0.2	0.26	0.129
Force Decay (N) 0.30mm	0.39	0.11	0.35	0.31	0.46	0.35	0.08	0.35	0.29	0.42	0.45
Peak Force (N) 0.40mm	0.7	0.16	0.75	0.56	0.82	0.58	0.15	0.52	0.46	0.74	0.104
Stabilized Force (N) 0.40mm	0.31	0.06	0.34	0.24	0.36	0.27	0.06	0.25	0.23	0.33	0.129
Force Decay (N) 0.40mm	0.39	0.11	0.4	0.32	0.48	0.32	0.11	0.28	0.23	0.41	0.14
Peak Force (N) 0.50mm	0.69	0.15	0.71	0.56	0.79	0.6	0.17	0.55	0.46	0.73	0.185
Stabilized Force (N) 0.50mm	0.34	0.07	0.37	0.25	0.38	0.29	0.06	0.27	0.25	0.34	0.137
Force Decay (N) 0.50mm	0.35	0.1	0.34	0.26	0.42	0.31	0.12	0.3	0.2	0.42	0.289

Table A.4 Comparing TFM with and without attachments in Missing U2-2

	No attachments					**Attachments**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	3.97	0.61	3.75	3.58	4.61	3.87	0.25	3.79	3.69	4.01	0.65
Stabilized Force (N) 0.10mm	3.71	0.59	3.48	3.33	4.34	3.63	0.25	3.56	3.47	3.68	0.427
Force Decay (N) 0.10mm	0.26	0.03	0.26	0.23	0.28	0.24	0.05	0.22	0.2	0.26	0.13
Peak Force (N) 0.20mm	6.71	0.55	6.59	6.17	7.11	6.34	0.34	6.24	6.1	6.52	0.08
Stabilized Force (N) 0.20mm	6.38	0.55	6.29	5.89	6.84	6.04	0.37	5.93	5.78	6.23	0.151
Force Decay (N) 0.20mm	0.33	0.05	0.31	0.28	0.38	0.3	0.05	0.3	0.28	0.33	0.289
Peak Force (N) 0.30mm	9.21	0.62	9.33	9.03	9.51	8.55	0.44	8.63	8.31	8.85	**0.013**
Stabilized Force (N) 0.30mm	8.77	0.61	8.84	8.68	9.06	8.18	0.47	8.23	7.87	8.52	**0.023**
Force Decay (N) 0.30mm	0.43	0.05	0.45	0.38	0.46	0.38	0.05	0.38	0.33	0.4	**0.041**
Peak Force (N) 0.40mm	11.38	0.79	11.55	11.36	11.75	10.57	0.56	10.7	10.1	10.82	**0.013**
Stabilized Force (N) 0.40mm	10.86	0.82	11.05	10.86	11.22	10.15	0.59	10.25	9.62	10.46	**0.031**
Force Decay (N) 0.40mm	0.52	0.06	0.53	0.5	0.57	0.42	0.06	0.44	0.41	0.46	**0.006**
Peak Force (N) 0.50mm	13.32	0.95	13.41	13.08	13.94	12.46	0.75	12.7	11.72	12.89	**0.028**
Stabilized Force (N) 0.50mm	12.71	0.97	12.86	12.59	13.36	11.96	0.76	12.11	11.27	12.5	**0.041**
Force Decay (N) 0.50mm	0.61	0.12	0.6	0.5	0.68	0.5	0.08	0.49	0.45	0.54	**0.038**

Table A.5 Comparing UR1 with and without attachments

	No attachments					**Attachments**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	3.93	1.48	4.25	2.44	5.11	3.95	1.42	3.67	2.65	5.34	0.85
Stabilized Force (N) 0.10mm	2.75	2.07	2.66	0.73	4.6	2.7	2.03	2.16	0.79	4.74	0.86
Force Decay (N) 0.10mm	1.18	0.77	0.95	0.58	1.72	1.25	0.79	1	0.55	1.86	0.882
Peak Force (N) 0.20mm	6.83	3.84	6.78	3.18	10.52	6.97	3.59	6.29	3.52	10.39	0.655
Stabilized Force (N) 0.20mm	5.47	4.44	5.29	1.19	9.68	5.46	4.33	4.65	1.26	9.75	0.626
Force Decay (N) 0.20mm	1.36	0.7	1.15	0.77	1.98	1.51	0.81	1.28	0.79	2.25	0.543
Peak Force (N) 0.30mm	9.83	6.54	9.91	3.48	16.1	9.94	6.15	9.3	3.87	16.26	0.543
Stabilized Force (N) 0.30mm	8.31	6.94	8.21	1.52	14.89	8.31	6.78	7.24	1.69	15.3	0.525
Force Decay (N) 0.30mm	1.52	0.51	1.45	1.17	1.89	1.63	0.69	1.59	0.94	2.28	0.871
Peak Force (N) 0.40mm	3.84	0.71	4.12	3.3	4.37	4.47	0.8	4.26	4.05	5.2	0.162
Stabilized Force (N) 0.40mm	1.86	0.46	1.9	1.44	2.24	2.09	0.45	1.92	1.79	2.31	0.496
Force Decay (N) 0.40mm	1.98	0.37	1.92	1.72	2.27	2.39	0.42	2.42	2.14	2.67	**0.034**
Peak Force (N) 0.50mm	4.14	1.04	4.32	3.24	5.06	5.06	0.87	4.93	4.23	5.38	0.131
Stabilized Force (N) 0.50mm	1.93	0.5	1.72	1.62	2.37	2.36	0.56	2.16	1.96	2.42	0.094
Force Decay (N) 0.50mm	2.14	0.63	2.49	1.59	2.55	2.7	0.36	2.77	2.44	2.95	0.056

Table A.6 Comparing Missing U2-2 with and without attachments

	No attachments					Attachments					P-value
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	2.27	1.8	2.12	0.54	3.75	2.12	1.8	2.16	0.32	3.79	0.433
Stabilized Force (N) 0.10mm	1.93	1.87	1.66	0.15	3.48	1.87	1.81	1.76	0.1	3.56	0.607
Force Decay (N) 0.10mm	0.34	0.12	0.31	0.25	0.38	0.25	0.1	0.22	0.19	0.27	**0.002**
Peak Force (N) 0.20mm	3.64	3.16	3.47	0.59	6.59	3.43	2.99	3.33	0.55	6.24	0.409
Stabilized Force (N) 0.20mm	3.3	3.18	3	0.25	6.29	3.11	3.02	2.92	0.16	5.93	0.261
Force Decay (N) 0.20mm	0.35	0.08	0.32	0.28	0.4	0.33	0.09	0.32	0.27	0.39	0.552
Peak Force (N) 0.30mm	4.93	4.41	4.47	0.62	9.33	4.57	4.1	4.26	0.56	8.63	0.204
Stabilized Force (N) 0.30mm	4.52	4.38	3.99	0.29	8.84	4.2	4.09	3.88	0.22	8.23	0.176
Force Decay (N) 0.30mm	0.41	0.09	0.42	0.34	0.46	0.36	0.07	0.37	0.32	0.41	0.076
Peak Force (N) 0.40mm	6.04	5.5	5.44	0.75	11.55	5.58	5.14	5.3	0.52	10.7	0.14
Stabilized Force (N) 0.40mm	5.58	5.44	4.9	0.34	11.05	5.21	5.09	4.83	0.25	10.25	0.189
Force Decay (N) 0.40mm	0.46	0.11	0.49	0.4	0.53	0.37	0.1	0.41	0.25	0.46	**0.011**
Peak Force (N) 0.50mm	7	6.51	6.26	0.71	13.41	6.53	6.11	6.16	0.55	12.7	0.208
Stabilized Force (N) 0.50mm	6.52	6.38	5.68	0.37	12.86	6.13	6.01	5.62	0.27	12.11	0.208
Force Decay (N) 0.50mm	0.48	0.17	0.49	0.34	0.6	0.4	0.14	0.43	0.3	0.51	0.172

Table A.7 Comparing DPA and TFM among UR1

	DPA					TFM					P-value
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	2.68	0.6	2.46	2.25	3.12	5.2	0.71	5.23	4.88	5.58	**<.0001**
Stabilized Force (N) 0.10mm	0.78	0.2	0.73	0.67	0.88	4.67	0.68	4.7	4.3	5.13	**<.0001**
Force Decay (N) 0.10mm	1.89	0.48	1.76	1.58	2.09	0.53	0.13	0.57	0.47	0.62	**<.0001**
Peak Force (N) 0.20mm	3.36	0.61	3.35	3.01	3.82	10.44	0.96	10.46	9.91	11.03	**<.0001**
Stabilized Force (N) 0.20mm	1.25	0.26	1.21	1.1	1.35	9.69	0.97	9.72	9.14	10.21	**<.0001**
Force Decay (N) 0.20mm	2.11	0.42	2.09	1.79	2.43	0.76	0.13	0.79	0.73	0.84	**<.0001**
Peak Force (N) 0.30mm	3.76	0.73	3.75	3.29	4.18	16.01	1.07	16.17	15.64	16.51	**<.0001**
Stabilized Force (N) 0.30mm	1.68	0.38	1.61	1.42	1.9	14.94	1.16	15.09	14.41	15.54	**<.0001**
Force Decay (N) 0.30mm	2.09	0.38	2.07	1.78	2.35	1.07	0.22	1.1	0.9	1.18	**<.0001**
Peak Force (N) 0.40mm	4.16	0.81	4.19	3.68	4.54						
Stabilized Force (N) 0.40mm	1.97	0.46	1.92	1.67	2.28						
Force Decay (N) 0.40mm	2.18	0.44	2.21	1.89	2.54						
Peak Force (N) 0.50mm	4.65	1.03	4.71	4.22	5.28						
Stabilized Force (N) 0.50mm	2.15	0.56	2.09	1.72	2.42						
Force Decay (N) 0.50mm	2.45	0.56	2.54	2.32	2.85						

Table A.8 Comparing DPA and TFM among Missing U2-2

	DPA					**TFM**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	0.47	0.19	0.49	0.32	0.57	3.92	0.46	3.77	3.69	4.14	**<.0001**
Stabilized Force (N) 0.10mm	0.14	0.05	0.13	0.09	0.17	3.67	0.44	3.52	3.46	3.83	**<.0001**
Force Decay (N) 0.10mm	0.33	0.15	0.36	0.22	0.4	0.25	0.04	0.25	0.22	0.28	0.055
Peak Force (N) 0.20mm	0.56	0.14	0.56	0.46	0.65	6.52	0.48	6.5	6.15	6.75	**<.0001**
Stabilized Force (N) 0.20mm	0.2	0.05	0.2	0.16	0.25	6.21	0.48	6.21	5.79	6.45	**<.0001**
Force Decay (N) 0.20mm	0.36	0.11	0.36	0.28	0.44	0.32	0.05	0.31	0.28	0.36	0.144
Peak Force (N) 0.30mm	0.62	0.13	0.58	0.53	0.69	8.88	0.62	8.94	8.32	9.33	**<.0001**
Stabilized Force (N) 0.30mm	0.25	0.05	0.24	0.21	0.3	8.48	0.61	8.6	7.9	8.84	**<.0001**
Force Decay (N) 0.30mm	0.37	0.09	0.35	0.31	0.43	0.4	0.06	0.39	0.36	0.45	0.091
Peak Force (N) 0.40mm	0.64	0.17	0.67	0.49	0.79	10.97	0.78	11.03	10.21	11.55	**<.0001**
Stabilized Force (N) 0.40mm	0.29	0.06	0.29	0.23	0.34	10.5	0.78	10.66	9.76	11.07	**<.0001**
Force Decay (N) 0.40mm	0.35	0.11	0.35	0.24	0.47	0.47	0.08	0.47	0.42	0.53	**0.001**
Peak Force (N) 0.50mm	0.64	0.16	0.6	0.51	0.77	12.89	0.94	12.99	12.07	13.46	**<.0001**
Stabilized Force (N) 0.50mm	0.31	0.07	0.31	0.25	0.37	12.34	0.93	12.55	11.51	13.05	**<.0001**
Force Decay (N) 0.50mm	0.33	0.11	0.32	0.26	0.42	0.55	0.12	0.52	0.46	0.63	**<.0001**

Table A.9 DPA in UR1 and U2-2

	DPA in UR1					**DPA in U2-2**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	2.68	0.6	2.46	2.25	3.12	0.47	0.19	0.49	0.32	0.57	**<.0001**
Stabilized Force (N) 0.10mm	0.78	0.2	0.73	0.67	0.88	0.14	0.05	0.13	0.09	0.17	**<.0001**
Force Decay (N) 0.10mm	1.89	0.48	1.76	1.58	2.09	0.33	0.15	0.36	0.22	0.4	**<.0001**
Peak Force (N) 0.20mm	3.36	0.61	3.35	3.01	3.82	0.56	0.14	0.56	0.46	0.65	**<.0001**
Stabilized Force (N) 0.20mm	1.25	0.26	1.21	1.1	1.35	0.2	0.05	0.2	0.16	0.25	**<.0001**
Force Decay (N) 0.20mm	2.11	0.42	2.09	1.79	2.43	0.36	0.11	0.36	0.28	0.44	**<.0001**
Peak Force (N) 0.30mm	3.76	0.73	3.75	3.29	4.18	0.62	0.13	0.58	0.53	0.69	**<.0001**
Stabilized Force (N) 0.30mm	1.68	0.38	1.61	1.42	1.9	0.25	0.05	0.24	0.21	0.3	**<.0001**
Force Decay (N) 0.30mm	2.09	0.38	2.07	1.78	2.35	0.37	0.09	0.35	0.31	0.43	**<.0001**
Peak Force (N) 0.40mm	4.16	0.81	4.19	3.68	4.54	0.64	0.17	0.67	0.49	0.79	**<.0001**
Stabilized Force (N) 0.40mm	1.97	0.46	1.92	1.67	2.28	0.29	0.06	0.29	0.23	0.34	**<.0001**
Force Decay (N) 0.40mm	2.18	0.44	2.21	1.89	2.54	0.35	0.11	0.35	0.24	0.47	**<.0001**
Peak Force (N) 0.50mm	4.65	1.03	4.71	4.22	5.28	0.64	0.16	0.6	0.51	0.77	**<.0001**
Stabilized Force (N) 0.50mm	2.15	0.56	2.09	1.72	2.42	0.31	0.07	0.31	0.25	0.37	**<.0001**
Force Decay (N) 0.50mm	2.45	0.56	2.54	2.32	2.85	0.33	0.11	0.32	0.26	0.42	**<.0001**

Table A.9a Comparing DPA without attachments in UR1 and U2-2

	DPA No attachments- UR1					**DPA No attachments- U2-2**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	2.59	0.62	2.44	2.22	2.7	0.57	0.15	0.54	0.49	0.62	**<.001**
Stabilized Force (N) 0.10mm	0.76	0.18	0.73	0.67	0.84	0.16	0.04	0.15	0.13	0.19	**<.001**
Force Decay (N) 0.10mm	1.83	0.54	1.72	1.54	2.03	0.41	0.12	0.38	0.36	0.46	**<.001**
Peak Force (N) 0.20mm	3.15	0.65	3.18	2.6	3.56	0.58	0.12	0.59	0.52	0.67	**<.001**
Stabilized Force (N) 0.20mm	1.18	0.27	1.19	0.93	1.28	0.22	0.04	0.25	0.18	0.25	**<.001**
Force Decay (N) 0.20mm	1.97	0.44	1.98	1.72	2.23	0.37	0.1	0.35	0.28	0.44	**<.001**
Peak Force (N) 0.30mm	3.49	0.71	3.48	3.03	3.82	0.65	0.14	0.62	0.54	0.79	**<.001**
Stabilized Force (N) 0.30mm	1.57	0.37	1.52	1.36	1.89	0.27	0.05	0.29	0.21	0.3	**<.001**
Force Decay (N) 0.30mm	1.92	0.36	1.89	1.67	2.09	0.39	0.11	0.35	0.31	0.46	**<.001**
Peak Force (N) 0.40mm	3.84	0.71	4.12	3.3	4.37	0.7	0.16	0.75	0.56	0.82	**<.001**
Stabilized Force (N) 0.40mm	1.86	0.46	1.9	1.44	2.24	0.31	0.06	0.34	0.24	0.36	**<.001**
Force Decay (N) 0.40mm	1.98	0.37	1.92	1.72	2.27	0.39	0.11	0.4	0.32	0.48	**<.001**
Peak Force (N) 0.50mm	4.14	1.04	4.32	3.24	5.06	0.69	0.15	0.71	0.56	0.79	**0.002**
Stabilized Force (N) 0.50mm	1.93	0.5	1.72	1.62	2.37	0.34	0.07	0.37	0.25	0.38	**<.001**
Force Decay (N) 0.50mm	2.14	0.63	2.49	1.59	2.55	0.35	0.1	0.34	0.26	0.42	**<.001**

Table A.9b Comparing DPA with attachments in UR1 and U2-2

	DPA attachments- UR1					DPA attachments- U2-2					P-value
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	2.77	0.6	2.65	2.36	3.25	0.37	0.18	0.32	0.27	0.48	**<.001**
Stabilized Force (N) 0.10mm	0.81	0.21	0.79	0.67	0.93	0.11	0.05	0.1	0.08	0.13	**<.001**
Force Decay (N) 0.10mm	1.96	0.43	1.86	1.69	2.23	0.26	0.13	0.22	0.17	0.35	**<.001**
Peak Force (N) 0.20mm	3.58	0.51	3.52	3.17	3.96	0.53	0.15	0.55	0.42	0.63	**<.001**
Stabilized Force (N) 0.20mm	1.33	0.23	1.26	1.17	1.45	0.18	0.05	0.16	0.15	0.2	**<.001**
Force Decay (N) 0.20mm	2.26	0.37	2.25	2	2.57	0.35	0.12	0.38	0.27	0.44	**<.001**
Peak Force (N) 0.30mm	4.04	0.67	3.87	3.56	4.7	0.58	0.11	0.56	0.49	0.68	**<.001**
Stabilized Force (N) 0.30mm	1.78	0.39	1.69	1.49	1.9	0.23	0.04	0.22	0.2	0.26	**<.001**
Force Decay (N) 0.30mm	2.25	0.35	2.28	2.05	2.42	0.35	0.08	0.35	0.29	0.42	**<.001**
Peak Force (N) 0.40mm	4.47	0.8	4.26	4.05	5.2	0.58	0.15	0.52	0.46	0.74	**<.001**
Stabilized Force (N) 0.40mm	2.09	0.45	1.92	1.79	2.31	0.27	0.06	0.25	0.23	0.33	**<.001**
Force Decay (N) 0.40mm	2.39	0.42	2.42	2.14	2.67	0.32	0.11	0.28	0.23	0.41	**<.001**
Peak Force (N) 0.50mm	5.06	0.87	4.93	4.23	5.38	0.6	0.17	0.55	0.46	0.73	**<.001**
Stabilized Force (N) 0.50mm	2.36	0.56	2.16	1.96	2.42	0.29	0.06	0.27	0.25	0.34	**<.001**
Force Decay (N) 0.50mm	2.7	0.36	2.77	2.44	2.95	0.31	0.12	0.3	0.2	0.42	**<.001**

Table A.10 Comparing TFM in UR1 and U2-2

	TFM in UR1					**TFM in U2-2**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	5.2	0.71	5.23	4.88	5.58	3.92	0.46	3.77	3.69	4.14	**<.0001**
Stabilized Force (N) 0.10mm	4.67	0.68	4.7	4.3	5.13	3.67	0.44	3.52	3.46	3.83	**<.0001**
Force Decay (N) 0.10mm	0.53	0.13	0.57	0.47	0.62	0.25	0.04	0.25	0.22	0.28	**<.0001**
Peak Force (N) 0.20mm	10.44	0.96	10.46	9.91	11.03	6.52	0.48	6.5	6.15	6.75	**<.0001**
Stabilized Force (N) 0.20mm	9.69	0.97	9.72	9.14	10.21	6.21	0.48	6.21	5.79	6.45	**<.0001**
Force Decay (N) 0.20mm	0.76	0.13	0.79	0.73	0.84	0.32	0.05	0.31	0.28	0.36	**<.0001**
Peak Force (N) 0.30mm	16.01	1.07	16.17	15.64	16.51	8.88	0.62	8.94	8.32	9.33	**<.0001**
Stabilized Force (N) 0.30mm	14.94	1.16	15.09	14.41	15.54	8.48	0.61	8.6	7.9	8.84	**<.0001**
Force Decay (N) 0.30mm	1.07	0.22	1.1	0.9	1.18	0.4	0.06	0.39	0.36	0.45	**<.0001**
Peak Force (N) 0.40mm						10.97	0.78	11.03	10.21	11.55	-
Stabilized Force (N) 0.40mm						10.5	0.78	10.66	9.76	11.07	-
Force Decay (N) 0.40mm						0.47	0.08	0.47	0.42	0.53	-
Peak Force (N) 0.50mm						12.89	0.94	12.99	12.07	13.46	-
Stabilized Force (N) 0.50mm						12.34	0.93	12.55	11.51	13.05	-
Force Decay (N) 0.50mm						0.55	0.12	0.52	0.46	0.63	-

Table A.10a. Comparing TFM without attachments in UR1 and U2-2

	TFM No attachments- UR1					TFM No attachments- U2-2					P-value
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	5.26	0.51	5.11	4.9	5.64	3.97	0.61	3.75	3.58	4.61	**0.001**
Stabilized Force (N) 0.10mm	4.73	0.5	4.6	4.32	5.27	3.71	0.59	3.48	3.33	4.34	**0.005**
Force Decay (N) 0.10mm	0.53	0.16	0.58	0.37	0.66	0.26	0.03	0.26	0.23	0.28	**0.001**
Peak Force (N) 0.20mm	10.52	0.69	10.52	10.02	11.03	6.71	0.55	6.59	6.17	7.11	**<.001**
Stabilized Force (N) 0.20mm	9.77	0.76	9.68	9.21	10.23	6.38	0.55	6.29	5.89	6.84	**<.001**
Force Decay (N) 0.20mm	0.75	0.15	0.77	0.72	0.84	0.33	0.05	0.31	0.28	0.38	**<.001**
Peak Force (N) 0.30mm	16.16	0.71	16.1	15.93	16.56	9.21	0.62	9.33	9.03	9.51	**<.001**
Stabilized Force (N) 0.30mm	15.04	0.8	14.89	14.6	15.39	8.77	0.61	8.84	8.68	9.06	**<.001**
Force Decay (N) 0.30mm	1.12	0.23	1.17	1.1	1.21	0.43	0.05	0.45	0.38	0.46	**<.001**
Peak Force (N) 0.40mm	-	-	-	-	-	11.38	0.79	11.55	11.36	11.75	**-**
Stabilized Force (N) 0.40mm	-	-	-	-	-	10.86	0.82	11.05	10.86	11.22	**-**
Force Decay (N) 0.40mm	-	-	-	-	-	0.52	0.06	0.53	0.5	0.57	**-**
Peak Force (N) 0.50mm	-	-	-	-	-	13.32	0.95	13.41	13.08	13.94	**-**
Stabilized Force (N) 0.50mm	-	-	-	-	-	12.71	0.97	12.86	12.59	13.36	**-**
Force Decay (N) 0.50mm	-	-	-	-	-	0.61	0.12	0.6	0.5	0.68	**-**

Table A.10b. Comparing TFM with attachments in UR1 and U2-2

	TFM attachments- UR1					**TFM attachments- U2-2**					**P-value**
	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	
Peak Force (N) 0.10mm	5.13	0.89	5.34	4.73	5.52	3.87	0.25	3.79	3.69	4.01	**0.005**
Stabilized Force (N) 0.10mm	4.6	0.84	4.74	4.22	4.99	3.63	0.25	3.56	3.47	3.68	**0.019**
Force Decay (N) 0.10mm	0.54	0.1	0.55	0.5	0.59	0.24	0.05	0.22	0.2	0.26	**<.001**
Peak Force (N) 0.20mm	10.37	1.21	10.39	9.8	11.03	6.34	0.34	6.24	6.1	6.52	**<.001**
Stabilized Force (N) 0.20mm	9.6	1.18	9.75	9.01	10.18	6.04	0.37	5.93	5.78	6.23	**<.001**
Force Decay (N) 0.20mm	0.76	0.1	0.79	0.74	0.83	0.3	0.05	0.3	0.28	0.33	**<.001**
Peak Force (N) 0.30mm	15.85	1.36	16.26	14.96	16.46	8.55	0.44	8.63	8.31	8.85	**<.001**
Stabilized Force (N) 0.30mm	14.84	1.48	15.3	14.13	15.55	8.18	0.47	8.23	7.87	8.52	**<.001**
Force Decay (N) 0.30mm	1.01	0.21	0.94	0.9	1.1	0.38	0.05	0.38	0.33	0.4	**<.001**
Peak Force (N) 0.40mm	-	-	-	-	-	10.57	0.56	10.7	10.1	10.82	-
Stabilized Force (N) 0.40mm	-	-	-	-	-	10.15	0.59	10.25	9.62	10.46	-
Force Decay (N) 0.40mm	-	-	-	-	-	0.42	0.06	0.44	0.41	0.46	-
Peak Force (N) 0.50mm	-	-	-	-	-	12.46	0.75	12.7	11.72	12.89	-
Stabilized Force (N) 0.50mm	-	-	-	-	-	11.96	0.76	12.11	11.27	12.5	-
Force Decay (N) 0.50mm	-	-	-	-	-	0.5	0.08	0.49	0.45	0.54	-

Table A.11. Linear Regression Equations for Respective Aligner Test Groups

Variable	Equation	P-value
DPA UR1	1.63+0.168 (displacement)	0.016
TFM UR1	0.29+0.265(displacement)	0.062
DPA UR1 NA	1.556+0.148 (displacement)	0.10
DPA UR1 YA	1.719+0.199 (displacement)	0.01
TFM UR1 NA	0.25+0.295(displacement)	0.129
TFM UR1 YA	0.37+0.195(displacement)	0.084
DPA U2_2	0.375-0.009(displacement)	0.058
TFM U22	0.178+0.07(displacement)	<0.001
DPA U22 NA	0.373-0.003(displacement)	0.761
DPA U22 YA	0.288+0.006(displacement)	0.807
TFM U22 NA	0.160+0.090(displacement)	0.001
TFM U22 YA	0.145+0.063(displacement)	<0.001

* based on linear regression equation $y=b_0+b_1(x)$

Additional Analysis

Table A.12. Percentage Force Decay DPA with and without attachments in UR1

	No attachments					Attachments					
Variable	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	P-value
PR1	0.70	0.06	0.70	0.67	0.71	0.71	0.04	0.71	0.69	0.74	0.496
PR2	0.62	0.04	0.62	0.60	0.64	0.63	0.04	0.62	0.59	0.66	0.88
PR3	0.55	0.03	0.55	0.53	0.56	0.56	0.04	0.57	0.53	0.59	0.597
PR4	0.52	0.05	0.54	0.46	0.55	0.53	0.03	0.53	0.50	0.56	0.821
PR5	0.51	0.06	0.52	0.47	0.55	0.54	0.03	0.55	0.51	0.56	0.248

PR1 = Force Decay (N) 0.10mm/ Peak Force (N) 0.10mm
PR2 = Force Decay (N) 0.20mm/ Peak Force (N) 0.20mm
PR3 = Force Decay (N) 0.30mm/ Peak Force (N) 0.30mm
PR4 = Force Decay (N) 0.40mm/ Peak Force (N) 0.40mm
PR5 = Force Decay (N) 0.50mm/ Peak Force (N) 0.50mm

Table A.13. Percentage Force Decay TFM with and without attachments in UR1

	No attachments					Attachments					
Variable	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	Mean	Std Dev	Median	Lower Quartile	Upper Quartile	P-value
PR1	0.10	0.03	0.10	0.08	0.12	0.11	0.02	0.11	0.10	0.12	0.94
PR2	0.07	0.02	0.07	0.07	0.08	0.07	0.01	0.07	0.07	0.08	0.94
PR3	0.07	0.01	0.07	0.07	0.08	0.07	0.02	0.06	0.06	0.06	0.227
PR4	.	.	.	.	.	.	.	.	.	.	
PR5	.	.	.	.	.	.	.	.	.	.	

PR1 = Force Decay (N) 0.10mm/ Peak Force (N) 0.10mm
PR2 = Force Decay (N) 0.20mm/ Peak Force (N) 0.20mm
PR3 = Force Decay (N) 0.30mm/ Peak Force (N) 0.30mm
PR4 = Force Decay (N) 0.40mm/ Peak Force (N) 0.40mm
PR5 = Force Decay (N) 0.50mm/ Peak Force (N) 0.50mm

Table A.14. Percentage Force Decay DPA with and without attachments in Missing U2-2

	No attachments					Attachments					
Variable	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**P-value**
PR1	0.72	0.05	0.73	0.72	0.74	0.68	0.06	0.70	0.64	0.73	0.053
PR2	0.62	0.07	0.63	0.56	0.67	0.65	0.07	0.66	0.61	0.71	0.346
PR3	0.59	0.06	0.62	0.56	0.63	0.60	0.04	0.60	0.58	0.62	1.00
PR4	0.55	0.04	0.56	0.53	0.58	0.54	0.05	0.53	0.48	0.58	0.29
PR5	0.50	0.06	0.50	0.49	0.56	0.51	0.07	0.52	0.46	0.55	1.00

PR1 = Force Decay (N) 0.10mm/ Peak Force (N) 0.10mm
PR2 = Force Decay (N) 0.20mm/ Peak Force (N) 0.20mm
PR3 = Force Decay (N) 0.30mm/ Peak Force (N) 0.30mm
PR4 = Force Decay (N) 0.40mm/ Peak Force (N) 0.40mm
PR5 = Force Decay (N) 0.50mm/ Peak Force (N) 0.50mm

Table A.15. Percentage Force Decay TFM with and without attachments in Missing U2-2

	No attachments					Attachments					
Variable	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**Mean**	**Std Dev**	**Median**	**Lower Quartile**	**Upper Quartile**	**P-value**
PR1	0.07	0.01	0.06	0.06	0.07	0.06	0.01	0.06	0.05	0.07	0.174
PR2	0.05	0.01	0.05	0.05	0.05	0.05	0.01	0.05	0.05	0.05	0.94
PR3	0.05	0.01	0.05	0.04	0.05	0.04	0.01	0.04	0.04	0.05	0.227
PR4	0.05	0.01	0.04	0.04	0.05	0.04	0.01	0.04	0.04	0.05	0.174
PR5	0.05	0.01	0.04	0.04	0.06	0.04	0.01	0.04	0.04	0.04	0.151

PR1 = Force Decay (N) 0.10mm/ Peak Force (N) 0.10mm
PR2 = Force Decay (N) 0.20mm/ Peak Force (N) 0.20mm
PR3 = Force Decay (N) 0.30mm/ Peak Force (N) 0.30mm
PR4 = Force Decay (N) 0.40mm/ Peak Force (N) 0.40mm
PR5 = Force Decay (N) 0.50mm/ Peak Force (N) 0.50mm

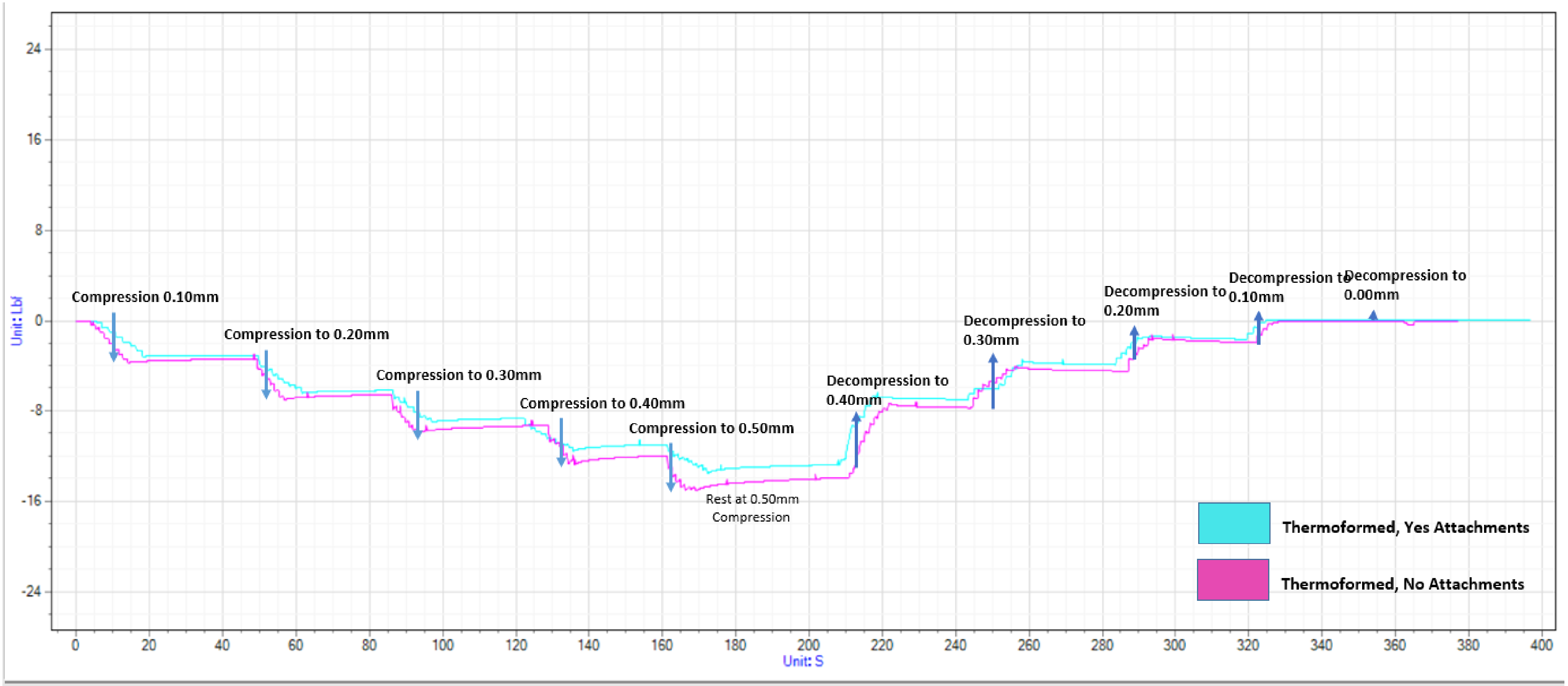

Figure A1. Compression Release test of Thermoformed Aligners in 0.10mm increments on U2-2 Model

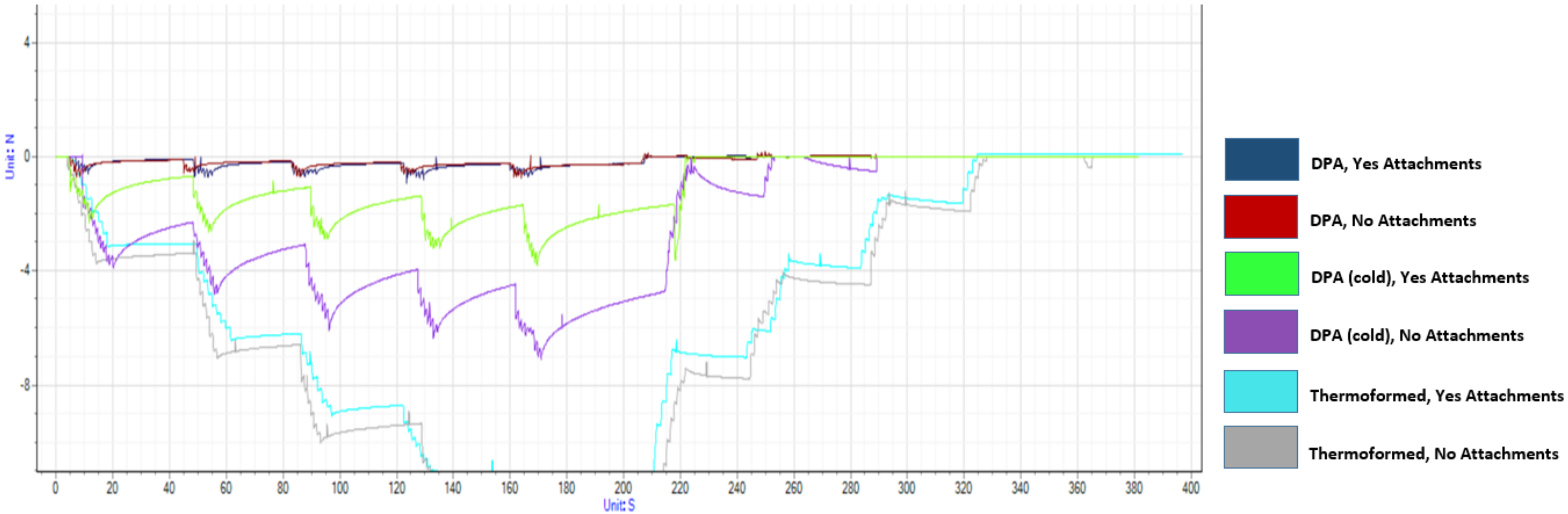

Figure A2. Compression Release test of DPA, TFM, and unheated DPA in 0.10mm increments on U2-2 Model Note: Unless (cold) indicated in legend, aligners were warmed to 97.5 degrees prior to testing.

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VITA AUCTORIS

Dr. Evan Hertan was born on August 27th, 1987 in Queens, New York. In 2003 and 2004, Evan spent summers engaged in research at the Garcia Center for Polymers at Engineered Interfaces at SUNY Stony Brook. In 2010 he graduated Summa Cum Laude from Yeshiva University with a major in Biology and minor in Psychology. Evan subsequently served as Robert M. Beren Presidential Fellow at Yeshiva University. In 2015, Dr. Hertan completed training at Columbia University College of Dental Medicine and received his Doctor of Dental Surgery degree. Dr. Hertan went on to complete a GPR residency and become chief resident at NYC HHC Bellevue and Gouverneur Hospitals with a focus on prosthodontics, implants, and cosmetic dentistry. He then practiced general dentistry at a private practice in New York City. In 2019, Dr. Hertan began the Saint Louis University Orthodontics Residency Program at the Center for Advanced Dental Education in St. Louis, Missouri. Dr. Hertan is currently a candidate for a Master of Science in Dentistry and Certificate in Orthodontics. Upon completion of his residency he plans to practice in New York and New Jersey.