THE RELATIONSHIP BETWEEN PRINT LAYER HEIGHT OF 3D-PRINTED DENTAL MODELS AND THERMOPLASTIC RETAINER FIT: AN IN VIVO STUDY

by

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Dedication

I dedicate this project to the people without whom it would not be possible.

To my parents Linda and Charles, your love and support has known no bounds and is the reason I have grown into the person I am today. I'll never be able to describe my gratitude to you.

To my siblings, Alex, Hannah, and Everett I continue to learn so much about how to live from each of one of you. You may be across the country but your love always makes you feel near.

To my loving girlfriend Alex, you inspire me with everything you do and your limitless ability to care. You are the highlight of every one of my days.

All of my accomplishments are in part because of them

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Abstract

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Introduction: Past studies have investigated the effect of various print layer heights on the accuracy of three-dimensional (3D) printed models as well as for several clinical uses. The purpose of this study was to compare the effect of 100µm and 170µm print layer height on the accuracy of the 3D printed models as well as on the fit of vacuum-formed retainers (VFR) from those models in vivo.

Methods: Intra-Oral (IO) scans of fifteen patients no longer in active treatment were used to 3D print dental models at 100µm and 170µm print layer heights. The models were scanned using the same IO scanner and then VFRs were fabricated from each model. Patients returned, placed and removed each retainer and rated its fit. An ABO certified orthodontist also placed and removed the retainers and rated

their fit. Scans from each model were digitally superimposed on the original corresponding IO scan for analysis of deviations.

Results: The mean standard deviation and data within tolerance (±0.25mm) did not significantly differ between models of 100µm and 170µm print layer height. There were not any differences in evaluator ratings, but there was a statistically significant difference of patient ratings between the retainers from the 100µm and 170µm print layer height models.

Conclusion:

1. Models printed at 100µm and 170µm print layer heights do not significantly differ inside of the threshold of ±0.25mm when compared to original IO scans.
2. A clinical evaluator was unable to determine the difference in fit of retainers made from either print layer height.
3. Patient's reported both retainers had a clinically ideal fit, however had a slight preference for retainers made from 170µm models over those made from 100µm models.

Review of Literature

Orthodontic Retention

The idea of retaining teeth following treatment is by no means a novel one, nor even one of this century. The concept of orthodontic retention dates back to as early as 1860 when Emerson Angell proposed 'orthodontic retention is needed to stabilize the result of an orthodontic treatment'.[1] This was reinforced in 1880 by Norman Kingsley when he suggested teeth 'could only be retained in the new position by constantly wearing fixtures…nevertheless, the fruits of a skillful and successful effort in regulating teeth must not be lost by neglecting to retain'.[2] Over the decades that followed, additional pioneers of Orthodontics like Dr. Edward Angle, Dr. Calvin Case, and Dr. Charles Hawley built upon the notion of necessary mechanical retention as they invented and refined both fixed and removable retention appliances, the likeness of many can be seen today.[3] While in the beginning of the 1900s most retainers involved a combination of metal, and vulcanite or later, acrylic, it wasn't until 1940s when Dr. Harold Kesling introduced an elastoplastic positioner, a translucent appliance that while allowed for minor corrections, eventually could

act as a retainer as well.[4,5] Two decades later Dr. Henry Nahoun developed and introduced retainers made of clear thermoplastic material, vacuum formed on a patient's model – known as vacuum-formed retainers (VFRs).[6] As this plastic has been developed further it has been popularized and preferred by patient's and orthodontists for is aesthetics, ease of fabrication, and speech during wear.[7]

Thermoplastic Vacuum-Formed Retainers

Since the advent of VFRs the plastic used has been refined and this form of retention has become more popular among patients and orthodontists alike, in the United States as well as around the world. In a 2011 survey of orthodontists in the United States Pratt et al. noted a 'current shift away from Hawley retainers and toward vacuum-formed retainers.[8] In a 2022 cross-sectional survey Carneiro et al. found that among orthodontists practicing in Canada VFRs were the preferred form of removable retainer by a wide margin.[9] Additionally, Singh et al. found that even as early as 2009 VFRs were the most commonly used removable retainer in the NHS, hospitals, and private practices in the United Kingdom.[10] While reluctance to change and suspicion of

effectiveness of a new appliance is natural, Rowland et al. found in their randomized clinical trial (RCT) the VFRs appeared to be more effective than traditional Hawley retention in terms of maintaining correction of incisor irregularity in the mandibular arch 6 months following bracket removal.[11] This was supported by Demir et al. who in 2012 found VFR to be more efficient in retaining anterior teeth in the mandible.[12] While Kaya et al. found no significant difference between patients a 1 year after treatment using VFRs or Hawley retainers in terms of overjet, overbite, irregularity indexes, interdental widths and arch length.[13] When assessing the patient preference, in 2010 Nikolay et at. noted that patients in clear vacuum formed retainers are not only more satisfied with their current teeth, but were more likely to be wearing their retainers currently as well.[14] Rowland et al. additionally noted that patients with Hawley retainers were more embarrassed then the VFR group due to the metallic labial bow, as well as the effects of the retainer on their speech.[11] Saleh et al. supported this, finding VFRs were significantly more acceptable than Hawley retainers in speech, appearance, gingival irritation, swallowing, self-confidence, and comfort. However, they did note subjects in the Hawley retainer group believed that their retainers were significantly more durable than those in the VFR group at the final assessment. Both retainers were

equal regarding fitting of the appliance, biting, and hygiene perception.[15] Despite a growing body of research on the subject in the literature, systematic reviews still suggest further high-quality RCT research be conducted in the future for further investigation and confirmation.[16,17]

Intra-Oral Scanners

Difficulties and complications such as bubbles, tears, and distortions are all well known by any clinician that has taken alginate impressions. Likewise the susceptibility of the impressions and stone models to distortion due to time, temperature and mixtures are a further source of anguish associated with this classic method of fabricating dental models. In 2006, Cadent produced the iTero (Align, San Jose, Ca) digital impression system. In 2008 the system was capable of full arch digital impressions and in 2011 Align Technology purchased Cadent and its technology. Due to its convenience and growing applications its popularity among orthodontists rapidly grew as did the manufacturers of competing IO scanners.

An IO scanner is essentially a computer that compiles and processes the mass amount of data that is collected from the handheld camera wand as it scans the patient's teeth. The camera emits a laser through a filter that is cast onto the object which when at the correct distance reflects the focused light back to the camera and it is then able to re-enter through the filter and be recorded. With algorithms and hundreds of thousands of measurements taken per inch, through a process called "point-and-stitch reconstruction", a web of triangles is created resulting in the construction of a 3-D object. This object is then saved as a file type known as an STL, or Standard Triangulation Language file which can be manipulated on a computer through Computer Aided Design, or fed into a 3-D printer for fabrication. [18]

In 2012 Cuperus et al. aimed to determine the reproducibility of measurements on 3-D digital models made from dry human skulls. They validated using IO scanners to produce digital models for measuring distances of a dentition.[19] In 2013 Wiranto et al. aimed to measure the reliability of digital models made from an IO scanner by comparing tooth widths measured on digital models to the widths measured from plaster models made from the same patient. They found digital

models from IO scanning was a "valid, reliable, and reproducible method to obtain measurements for diagnostic purposes." [20]

In 2017, Mack et al. investigated the 3-D accuracy of the Cadent iTero specifically. They scanned 61 mandibles with the iTero IO scanner and produced 3-D models of each. Curvilinear measurements were taken on the digital models and compared to the same measurements taken on the corresponding physical mandibular teeth. They determined the measurements from the scanner to be comparatively accurate to the measurements made on the cast itself further supporting this as a means for creating dental models.[21] Burhardt et al. assessed perceptions and preferences of impression techniques in young orthodontic patients. Patients aged 10-17 years old participated and each had to digital scans taken as well as an alginate impression. They found while it increase chair time, the patients preferred the digital impression techniques over the alginate impressions.[22] Additionally, Mangano et al. found in 2018 that digital impressions were the most accepted and comfortable technique in young orthodontic patients, when compared to conventional techniques.[23]

Geomagic Control

Geomagic, the professional engineering software brand of 3D Systems was invented by Ping Fu and Herbert Edelsbrunner in 1997 and later acquired by 3D Systems in 2013. Geomagic Control X is a professional 3D quality control and dimensional inspection software produced by this company. Geomagic Control X allows you to load and process data from 3D scanners to virtually inspect, measure and compare objects.[24] It allows you to take objects and using a best fit algorithm, superimpose the two and analyze the similarities and differences between them. It then can color code the objects to indicate where the experimental object may have a positive or negative deviation from the master or reference object. Additionally, you can set threshold ranges that any deviations within that range are considered acceptable.

Gao et al. in 2014 measured the errors in surface accuracy by the Geomagic software. The 3D data of virtual models was compared and deviation values were generated. They deemed the limited amount of deviation to be acceptable, validating the accuracy of the

software as a viable 3D superimposition tool.[25] It has been referred to as the "gold standard" in the literature when attempting to investigate the accuracy of other softwares such as in a study by O'Toole et al.[26]

This software has been used by various studies when comparing the accuracy or similarity of dental models. Camardella et al. utilized this software as a means to compare plaster models and digital models from laser scanners, as they analyzed measurements from digital calipers and a virtual software.[27] Geomagic Control has also been prevalent in researching the accuracy of 3D printed models as in 2017 when Favero et al. investigated the effect of print layer height and orientation of models produced by SLA printers.[28] Similarly, Boyer et al. in 2021 utilized this software to quantify the dimensional deviation of 3D printed orthodontic aligners.[29]

3D Printing in Orthodontics

3D printing is a manufacturing approach that converts digital designs into three-dimensional objects by layering material one layer on top of another. Due to the nature in which objects are constructed,

3D printing is also referred to as additive manufacturing or rapid prototyping. 3D printing is by no means a new technology. Many of the 3D printing modalities that we are familiar with were first developed in the 1980s and 1990s.[30] There are three main types of commercial 3D printers:

- Stereolithography (SLA)

  This manufacturing technique is referred to as part of vat photopolymerization in that the object is constructed on the build platform in a vat of photosensitive resin and each layer is polymerized or hardened by means of a light source. In an SLA printer the light source is an Ultraviolet (UV) laser that will trace the entire object and build it layer by layer. Once constructed, post-processing must be done to wash off uncured resin from the object with alcohol and complete the final curing of the resin in a separate UV light box.

- Digital Light Processing (DLP)

  This is also a printer that constructs by vat photopolymerization. The major difference between Sla and DLP printers is the light source. A DLP printer's light source is a UV light projector that with a mirror or mirrors is reflected onto the build platform to polymerize the resin. Instead of tracing the object, the projector

will illuminate the shape of the entire layer and cure it at once. Like in an SLA printer, post processing must be done to wash away uncured resin and finalize the polymerization.

- Fused Deposition Modeling (FDM) / Fused Filament Fabrication (FFF) This method does not utilize vat photopolymerization as the resin comes in the form of a spool of filament and there is no polymerizing light source. The hard filament resin is fed into a heated nozzle that temporarily liquefies the filament so that it can be laid down to build the object layer by layer. Some additional processing and finishing may need to be done following the build.

SLA and FDM were two of the first widely used methods of 3D printing. Stereolithography was patented in 1986 by French engineer Charles Hull. One year later, he released the first ever 3D printer, the SLA-1. Fused Deposition Modeling was not far behind; its technology was patented in 1989 and the first FDM printer was released two years later in 1991.[32]

Since being released a little over thirty-five years ago, 3D printing technology has rapidly progressed. Initially, 3D printing was used for industrial prototyping. Today it is used in numerous fields, including

manufacturing, medicine, architecture, art, and dentistry. 3D printed anatomical study models are commonly used in oral and maxillofacial surgery; these models allow complex anatomy to be carefully reviewed and the surgical approach practiced before surgery. To improve surgical precision and predictability, surgical guides are fabricated using 3D technology with drilling or cutting guides.[33]

In Orthodontics, 3D printing can be used to make models in lieu of the traditional plaster or stone casts from alginate impressions. These models or series of models can be used to fabricate thermoplastic vacuum formed retainers or aligners. In 2018, Brown et al. investigated the accuracy of 3D printed models compared to traditional stone casts from alginate impressions. This study took tooth and arch measurements from DLP and polyjet printed models and compared those to the stone model measurements. They concluded that DLP and polyjet printers can produce clinically acceptable models and those models should be considered viable options for clinical applications.[34]

In 2018 Kim et al. studied the trueness and precision of models 3D printed by various types of printers including Polyjet, DLP, SLA and FFF. They noted that Polyjet and DLP printed models were more

precise than SLA and FFF printed models and PolyJet showed the highest degree of accuracy of them all. They also noted that the type of 3D printer should be determined with the clinical application and its precision and trueness requirements in mind.[35]

3D printers have settings on how thick each layer should be. The layer thickness, or as it is commonly referred to as the print layer height, in turn influences how many layers it will take to complete an object as well as how long the print job will last. These layers range from 20µm, 100µm, or can be even larger; the smaller the print layer height, the more layers to print an object, and the longer the print job will last. While one may think a smaller print height and more layers allows for a higher degree of detail, and this is true, there are other considerations that need to be taken into account. In addition to a longer print time, with each layer that it printed there is a possibility of an error in the curing and this error will either cause a distortion in the model or a complete failure in the printing.

In 2018, Favero et al investigated exactly how similar prints of varying print heights were to the STL file that the print job was based from using an. Using a single master STL file of a dental model they printed models at print layer heights of 25µm, 50µm and 100µm using 4

different commercially available printers. All the models were then rescanned and the respective STL was then superimposed onto the master STL to determine the amount of deviation each model had. They saw statistically significant deviations at each layer height with the 25µm models having the greatest amount of deviation and the 100µm having the least. They also found differences between each printer. While finding these differences, they noted all values fell within clinically acceptable limits. They advised that the envisioned application should drive the importance of the differences between the printer types and print layer heights.[26]

In 2019 Loflin et al. aimed to compare 3D printed models of varying print layer heights with the application of clinical study models in mind. They used 12 sets of stone models that had previously been submitted to and passed the ABO clinical exam and scanned each set. They then printed each set at 25, 50, 100µm print layer heights and submitted each to the same ABO grading system as the original stone models. They found that print layer height did not have a statistically significant effect on the grading of these models in any category, nor the score. The printed models were all positively correlated with the stone models for the total score, and the strongest correlation was found with models printed at the 100µm print layer height. They

determined that all layer heights may be acceptable for ABO grading, diagnosis, and treatment planning. They also recommended 100µm height models due to the decreased printing time. [36]

In 2021 Ko et al. generally confirmed the results of Favero et al. with a similarly styled study comparing the STL from the scan of 3D printed models of varying print layer heights to the initial STL the model with printed from. In addition, they investigated the effect of the angle at which the model is to the build platform because as you increase the angle at which the model is built at, you can fit more models on the build platform. They found a model printed at an oblique thirty or sixty-degree angle yielded the most accurate model when combined with 50µm print height, yet also observed there was a slight effect on the transverse of models. This transverse deviation was especially pronounced if the model was printed at ninety degrees and saw none of this effect when the model was printed at zero degrees, or the model base being parallel with the build platform. They likewise found that the smallest print height in this study, 20µm at zero degrees, produced the least accurate model. In final agreeance with Favero et al., concluded most models were within clinical acceptance and that the choice of layer height should be determined by the application, desired print time, and preferred efficiency of each print job.[37]

These aforementioned studies have noted statistically significant differences between print layer heights of 25µm, 50µm, 100µm of various printer types, they often highlight that the differences reside within a threshold of ±0.25mm. [26,36,37]

While research in the literature has expanded over the past decade, a consensus on the optimal print layer height as well as clinically acceptable accuracy has yet to be determined. Etemad-Shahidi Y et al noted in their 2020 systematic review that past studies have used thresholds ranging from ±0.1mm – ±0.5mm. Additionally, they mention that the requirements for accuracy of orthodontic models are more relaxed compared to the needs of restorative and prosthodontic dentistry. [38]

Some discuss what an acceptable threshold for error should be in terms of orthodontic movement performed by aligners made from 3D printed models. In 2018, Kim et al. considered that in Invisalign aligners (Align Technology, San Jose, Calif) the maximum tooth movement per aligner is 0.25mm to 0.3mm[39] so an acceptable threshold be lower than that.[35] In 2019 Zhang et al. noted that a minimum of 0.1mm difference in a tooth between two models is necessary to elicit movement from that aligner, thus a ±0.05mm

threshold is appropriate.[40] Both are interesting and valid propositions, however it is worth noting that in 2000 Santoro et al. found that a clinician using a boley gauge to measure inter-molar widths had an error coefficient as much as 0.20mm.[41] Additionally, in 2014 Hazeveld et al. measured the error of a plaster model is close to 0.20mm. [42]

The discussion over clinically acceptable thresholds and optimal print heights is ongoing but the principal idea is that the application should be the guiding factor in determining these settings. For example, a model for indirect bonding tray fabrication would need the upmost accuracy. Likewise, a series of models produced for the fabrication of aligners may also need higher accuracy to facilitate fine movements. It should be taken into consideration how many print jobs it will take to print the series of models and how long each job will take. Similarly, printing models for same day retainers may want the most time efficient print layer height so long as it will not significantly sacrifice accuracy. Lastly, printing diagnostic or study models may be on the other side of the spectrum from models for indirect bonding or aligners as they may not need the upmost accuracy and thus have more relaxed thresholds.

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Statement of Thesis

Objective: The purpose of this study was to compare the effect of 100µm and 170µm print layer height on the accuracy of the 3D printed models as well as on the fit of vacuum-formed retainers from those models in vivo.

Null Hypothesis:

- There is no clinically significant difference between 3D printed models of 100µm and 170µm layer height.
- There is no clinically detectable difference between retainers made from 3-D printed models of 100µm and 170µm layer height.

Alternative Hypothesis:

- There is a clinically significant difference between 3D printed models of 100µm and 170µm layer height.
- There is a clinically detectable difference between retainers made from 3-D printed models of 100µm and 170µm layer height.

Manuscript for Publication

THE RELATIONSHIP BETWEEN PRINT LAYER HEIGHT OF 3D-PRINTED DENTAL MODELS AND THERMOPLASTIC RETAINER FIT: AN IN VIVO STUDY

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Introduction

Three-dimensional (3D) printing is a manufacturing approach that converts digital designs into physical 3D objects by layering material one layer on top of another. Due to the nature in which objects are constructed, 3D printing is also referred to as additive manufacturing or rapid prototyping.

In orthodontics, 3D printing can be used to make models in lieu of the traditional plaster or stone casts from alginate impressions. These models or series of models can be used to fabricate thermoplastic vacuum formed retainers or aligners. In 2018, Brown et al investigated the accuracy of 3D printed models compared to traditional stone casts from alginate impressions. This study took tooth and arch measurement from digital light processing (DLP) and polyjet printed models and compared those to the stone model measurements. They concluded that DLP and polyjet printers can produce clinically acceptable models and those models should be considered viable options for clinical applications.[1]

In 2018 Kim et al. studied the trueness and precision of models 3D-printed by various types of printers including Polyjet, DLP, stereolithography (SLA) and Fused Filament Fabrication (FFF). They

noted that Poly Jet and DLP printed models were more precise than SLA and FFF printed models with PolyJet having highest degree of accuracy of them all. They also noted that the type of 3-D printer should be determined with the clinical application and its precision and trueness requirements in mind.[2]

3-D printer software can manipulate on how thick each layer should be. The layer thickness, or as it is commonly referred to as the print layer height, in turn influences how many layers it will take to complete an object as well as how long the print job will last. These layers can range from 20µm to 100µm, or even larger; the smaller the print layer height, the more layers to print an object, and the longer the print job will last. While a smaller print height and more layers allows for a higher degree of detail and surface smoothness, there are other considerations that need to be taken into account. In addition to a longer print time, with each layer that it printed there is a possibility of an error in the curing and this error will either cause a distortion in the model or a complete failure in the printing.

In 2019 Loflin et al. aimed to compare 3D printed models of varying print layer heights. They used 12 sets of stone models that had previously been submitted to and passed the ABO clinical exam and

scanned each set. They then printed each set at 25, 50, 100µm print layer heights and submitted each to the same ABO grading system as the original stone models. They found that print layer height did not have a statistically significant effect on the grading of these models in any category, nor the score. The printed models were all positively correlated with the stone models for the total score, and the strongest correlation was found with models printed at the 100µm print layer height. They determined that all layer heights may be acceptable for ABO grading, diagnosis, and treatment planning. They also recommended 100µm height models due to the decreased printing time.[3]

In 2018, Favero et al investigated using a SLA printer exactly how similar prints of varying print heights were to the STL file that the print job was based from. They saw statistically significant deviations at each layer height with the 25µm models having the greatest amount of deviation and the 100µm having the least. They found that the most accurate models were the ones of the largest print layer height. While finding these differences, they noted all values fell within clinically acceptable limits. They advised, the envisioned application should drive the importance of the differences between the printer types and print layer heights.[4]

In 2021 Ko et al. using a DLP printer compared the STL from the scan of 3D printed models of varying print layer heights and build angles to the initial STL the model was printed from. They likewise found that the smallest print height, 20µm in this study, produced the least accurate model. They too concluded most models were within clinical acceptance and that the choice of layer height should be determined by the application, desired print time, and preferred efficiency of each print job.[5]

As the prevalence of vacuum-formed retainers (VFRs) has risen over the years as noted by Pratt et al. in 2011, the application of making these retainers in house with a digital workflow has become more appealing.[6] In a clinical setting a faster print time will be paramount as long it will not sacrifice accuracy. While studies in the past have researched this up to 100µm print layer height we aimed to investigate if an even greater print layer height may be suitable as well as how the VFRs made from these models fit to a patient and to an ABO certified Orthodontist.

Materials and Methods

This study was approved by the Case Western Reserve University (CWRU) Institutional Review Board (IRB) (Appendix A). Patients between the ages of 14-60, who were previously treated at the CWRU orthodontics clinic, were in retention, and had none or minimal crowding, were eligible to be included in this study. Patients who had moderate-severe crowding or bone loss, attachments from past aligners, edentulous spaces, class II mobility or undergoing any active orthodontic movement were excluded from the study. There were 15 total subjects, 8 of whom were male and 7 were female. They ranged in age between 15.5 years old to 48.5 years old, the mean age being 27.5.

To begin, patients who had their active treatment completed in the past 6 months that satisfied the inclusion and exclusion criteria were identified. Patients were all already in full-time retention with either a VFR or Hawley. Either the intra-oral (IO) scan used for the patient's current retainer was used, or the IO scan was updated, and the STL files were saved as master files for each patient. The iTero Element 2 chairside IO scanner (Align Technology, San Jose, Ca) was used for all scanning in this study.

Using a Sprint Ray Pro 95 3-D printer with Sprint Ray Die and Model 2 resin (Sprint Ray, Los Angeles, CA), the STL files were printed at the recommended 100µm print layer height as well as the 170µm print layer height. For each patient only their upper and lower models were printed at a time with the base of the model parallel to the build platform, incisal edges facing away from the build platform, and the print time was recorded. After washing each model set in 90% isopropyl alcohol in the Sprint Ray Wash machine and a final cure in the Sprint Ray Cure box for the manufacturer's directed time, they were each scanned using the same iTero IO scanner as was used for the initial IO scan.

Following this, VFRs were fabricated from each model with a MiniSTAR S (Scheu-Dental, Iserlohn, Germany) thermoforming machine and Zendura (Straumann, Basel, Switzerland) retainer plastic discs (1.0mm (0.4") x125mm) following the manufacturer's instructions. If a patient had a fixed lingual retainer, block-out resin was conservatively placed to prevent any undercuts. When removed from the model the plastic was then trimmed to the zenith of gingival margins and the edges smoothed.

Once the retainers were fabricated, the patient returned for the retainer fit testing. Each set was either labeled A or B, and the sequence was randomized for blinding of the patient and the clinical evaluator. It was explained to the patient that the retainers were new and would likely be tighter than their current set they have been wearing full time. They were asked to score each individual upper and lower retainer of both sets, with a simple score between (worst) 1-5 (best) considering how well each retainer fit in terms of overall looseness/tightness, as well as their preference. Following their ratings, subjects were given the opportunity to elaborate on their ratings in the "comments" section of the scale. An American Board of Orthodontics certified orthodontist who remained the same for each patient throughout the study was used as a clinical evaluator to rate the retainers fit in addition to the patient ratings. After the patient had completed their evaluation, the clinical evaluator would see the patient and place, test, remove each retainer, and rate the fit on the exact same scale. They were also given an opportunity for further elaboration if they wished. After completion of both ratings, subjects were dismissed. (Appendix D)

Two 3-D superimpositions were created using the 3-D superimposition software Geomagic Control X (3-D Systems Rock Hill,

SC), the original IO scan as the reference data and either the 100µm model scan or the 170µm model scan as the measured data. The dentition was aligned using a bet fit surface alignment tool of the software. Once aligned, a selected area of the models was traced connecting the zenith of each tooth, replicating where the retainers were trimmed to during fabrication so that only the tooth surfaces and the interdental papilla were included in the measured data. A maximum range of ±0.5mm was set while the tolerance range for comparison was set to ±0.25mm. The largest negative and positive deviations, the average of all deviations, Root Mean Square (RMS), standard deviation, variance, and the percentage of points inside and outside the defined tolerance range were all recorded (Appendix C).

Statistical Analysis

All tests were conducted in statistical package for the social sciences (SPSS 26.0) software. For the data produced from the 3D superimpositions of the 100µm model to the original IO scan, and the 170µm model to the same original IO scan, mean standard deviation as well as percent of data in tolerance (±0.25mm) were compared. This data was determined to be parametric and one sided ANOVA

tests were performed for each. The data from the patient and evaluator ratings was determined to be non-parametric, and the Kuskal-Wallis one way analysis of variance was used to determine differentiation. For all tests, a P-value of ≤ 0.05 was considered statistically significant.

Results

The one sided ANOVA tests performed to compare the mean standard deviation as well as percent data within tolerance (±0.25mm) between the 100µm and 170µm model scans when compared to the original IO-scan demonstrated that this data did not significantly differ. (Appendix E) The Kruskal-Wallis test performed for the data yielded from the patient and evaluator ratings determined that while the evaluator ratings did not significantly differ between the print layer heights, the patient's ratings did have a statistically significant difference related to the print layer heights. (Appendix F)

Discussion

As the application of 3-D printing in an orthodontic practice has become more practical in recent years, its popularity has unsurprisingly grown. While research in the literature is also expanding, a consensus on the optimal print layer height as well as clinically acceptable accuracy has yet to be determined. Past studies have used thresholds ranging from ±0.1mm – ±0.5mm.[7] Some discuss what an acceptable threshold for error should be in terms of orthodontic movement performed by aligners made from 3-D printed models. Zhang et al. notes that a minimum of 0.1mm difference in a tooth between two models is necessary to elicit movement from that aligner, thus a ±0.05mm threshold is appropriate.[8] Kim et al. however considered that in Invisalign aligners (Align Technology, San Jose, Ca) the maximum tooth movement per aligner is 0.25mm to 0.3mm so an acceptable threshold should be lower than that.[9] Considering past studies have found a clinician with a boley gauge can vary as much as 0.20mm, and that the error of a plaster model is close to 0.20mm, for this study a threshold of ±0.25mm was determined to be reasonable as it is consistent with past studies and falls within previously reported limits.[10,11,12,13]

The discussion of optimal print layer height is related and equally ambiguous. While studies have noted statistically significant

differences between print layer heights of 25µm, 50µm, 100µm of various printer types, they often reside within a threshold of ±0.25mm.[14] We aimed to study the effect of an even larger print layer height than many past studies, and are the first to investigate the clinical fit, in vivo, of vacuum formed retainers made from these models. The initial hypothesis of the study was that the differences between models printed at 100µm and 170µm layer heights would not be significantly different and that there would be no clinically detectable differences in the fit of retainers made from the models. While our 3-D superimpositions of the printed models were in line with past studies and showed that both print layer height models had ~99% of points within ±0.25mm when compared to the original IO scan, our clinical testing detected a slight difference. When investigating the subjective fit of the retainers made from each model set, the fit rating scores from our clinical faculty did not yield any statistically significant differences. When analyzing the scores from our patient ratings however, we did detect a higher score for the retainers made from 170µm print layer height models than that of the 100µm print layer height models. Patient's often noted in the "comments" section, that while both fit ideally and were not loose, the retainers from the 100µm models were inconveniently difficult to seat and especially remove, leading to their

preference for the retainers made from the 170µm models. (Appendix D)

As it pertains to the time per print job, 100µm model print jobs on average printed in 42.2 minutes (std dev 4.6min) compared to 170µm model print jobs which on average printed in 32.4 minutes (std dev 3.5min). Overall, 170µm model jobs printed 9.2 minutes or 23% faster (std dev 2.7, 1%) than 100µm model print jobs. (Appendix D) Considering throughout a day there may be multiple print jobs, in addition to any in house aligner production that is done as well, this time difference could combine to a substantial amount of time saved.

We aimed to keep our fit rating scale simple, limited to patient/faculty's preference or which retainer they thought was best, as we did not want to confuse the patient on what they were to rate the retainers on. This lead to simple, yet consequently non-specific results. In the future, studies could make certain scoring categories for distinct qualities of the retainers and spend additional time training each patient on how to score or express what they are feeling. We chose to fabricate retainers from a 1mm thick plastic disc however a thinner plastic such as 0.5mm or 0.75mm is likely to have more flexibility during insertion and removal. In the same light, a different retainer

plastic will have its own special qualities that differ from that in which we used. A clinician will have to keep these variables in mind when they consider what our results could mean for their own clinical practices. Our results in terms of 3-D printing however are much more generalizable if you use the same or similarly performing DLP 3-D printer they show that 170µm, a more time efficient print layer height, can be used without sacrificing clinically relevant accuracy of that model for retainer fabrication in the short term.

In light of our detected differences we believe further investigation is necessary on various levels. The first of which would be to determine if this retainer fit difference remains consistent over the period of multiple months utilizing full time wear. This would give further insight into the retainers' fit during full time retention periods immediately following active treatment as the patient will be placing and removing the retainers multiple times per day. If the difficulty placing and removing the retainers were to persist over the course of months, might retainer breakage rates be higher in the more difficult to remove 100µm model retainer? Conversely, if the retainers from the 100µm models eventually became easier to place/remove, do the retainers from the 170µm models eventually become unsatisfactorily loose? Additionally, comparing the superimpositions at a tighter

threshold was outside the scope of this study, however conducting such a comparison may give additional understanding as to why patients are able to feel this difference. Investigation into the amount of play between the actual dentition and the retainers made from these different models could show that while there may be a perceived difference it does not indicate a clinically relevant lack of retention. These results ideally could be applied to fabricating models for in-house aligners, as this process could benefit most from using a faster print time. However further investigation involving superimpositions are needed to confirm there is no negative effect on shapes of attachments should they be used.

Conclusions

1. Models printed at 100µm and 170µm print layer heights do not significantly differ inside of the threshold of ±0.25mm when compared to original IO scans.

2. A clinical evaluator was unable to determine the difference in fit of retainers made from either print layer height.
3. Patient's reported both retainers had a clinically ideal fit, however had a slight preference for retainers made from 170µm models over those made from 100µm models.

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Appendices

Appendix A: IRB Approval

IRB Administration Offices
UH IRB Phone: 216.844.1529
CWRU IRB Phone: 216.368.6925

INITIAL APPROVAL

Principal Investigator:	Tarek ElShebiny
Title:	The relationship between print layer height of 3D-printed dental models and thermoplastic retainer fit: an in vivo study.
Submission Number:	STUDY20220125
IRB Office:	CWRU IRB
Approval Date:	6/29/2022
Effective Date:	7/1/2022
Approval End Date	6/29/2023
Type of Submission:	Initial Study
Type of Review:	Expedited
Documents Reviewed:	• Guide to 3D printing Retainer - SprintRay Inc..pdf, Category: Device Attachment; • Assent Script.pdf, Category: Consent Form; • Retainer Rating Scale.pdf, Category: Other; • Info Flyer.pdf, Category: Recruitment Materials; • Ian Canepa - Consent, Category: Consent Form; • Exemption, Category: Device Attachment; • SprintRay-ProS-Brochure_011121.pdf, Category: Device Attachment; • Protocol, Category: IRB Protocol; • HIPAA, Category: Other; • Resin Establishment Registration & Device Listing.pdf, Category: Device Attachment; • Safety Plan, Category: Other;

The IRB has reviewed this submission.

- Per Federal regulation, changes MAY NOT be made to any element of the current research without prior IRB approval, except to eliminate an immediate and apparent hazard to subjects enrolled in the study.
- Per Federal regulation, the research may not continue beyond the Approval End date. You must submit a continuing review form 6-8 weeks before this Approval End date in order to maintain IRB approval. Failure to maintain IRB approval is human subjects non-compliance. Please note that even if your study falls into a category that

The UH IRB operates under HHS Federalwide Assurance (FWA) number 00003937 and IRB registration numbers 00000684, 00001691 and 00008600. The CWRU IRB operates under DHHS FWA00004428 and IRB registration number 00000683.

Appendix B: Abbreviation Key

3D: Three-dimensional

VFR: Vacuum – formed retainer

IO: Intra-oral

RCT: Randomized Clinical Trial

SLA: Stereolithography

UV: Ultraviolet

DLP: Digital Light Processing

FFF: Fused Filament Fabrication

FDM: Fused Deposition Modeling

CWRU: Case Western Reserve University

IRB: Institutional Review Board

Appendix C: Raw Superimposition Data

100-io U

Name	Min.	Max.	Avg.	RMS	Std. Dev.	Var.	In Tol.(%)	Out Tol %
1	-0.270	0.247	-0.017	0.073	0.071	0.005	99.979	0.021
2	-0.310	0.341	-0.002	0.083	0.083	0.007	99.630	0.370
3	-0.211	0.191	-0.020	0.061	0.058	0.003	100.000	0.000
4	-0.295	0.213	-0.013	0.072	0.071	0.005	99.780	0.220
5	-0.279	0.345	-0.019	0.094	0.092	0.008	99.712	0.288
6	-0.265	0.266	-0.010	0.065	0.064	0.004	99.945	0.055
8	-0.231	0.260	0.000	0.065	0.065	0.004	99.992	0.008
9	-0.246	0.247	0.004	0.061	0.061	0.004	100.000	0.000
10	-0.387	0.401	-0.017	0.101	0.100	0.010	99.212	0.788
11	-0.279	0.279	-0.004	0.068	0.067	0.005	99.722	0.278
12	-0.235	0.235	-0.001	0.057	0.057	0.003	100.000	0.000
13	-0.453	0.410	-0.024	0.110	0.107	0.012	96.429	3.571
14	-0.377	0.352	-0.017	0.107	0.105	0.011	96.901	3.099
15	-0.298	0.316	-0.034	0.077	0.069	0.005	99.917	0.083
16	-0.187	0.196	-0.014	0.052	0.050	0.003	100.000	0.000
Average	-0.288	0.287	-0.012	0.076	0.075	0.006	99.415	0.585
STD	0.071	0.070	0.010	0.019	0.018	0.003	1.140	1.140

100-io L

Name	Min.	Max.	Avg.	RMS	Std. Dev.	Var.	In Tol.(%)	Out Tol %
1	-0.305	0.359	-0.001	0.102	0.102	0.011	98.918	1.082
2	-0.315	0.339	-0.009	0.082	0.082	0.007	99.811	0.189
3	-0.265	0.204	-0.016	0.061	0.058	0.003	99.809	0.191
4	-0.600	0.595	-0.013	0.068	0.067	0.005	99.407	0.593
5	-0.295	0.386	0.020	0.099	0.097	0.009	98.384	1.616
6	-0.355	0.389	-0.004	0.099	0.099	0.010	98.459	1.541
8	-0.226	0.327	0.010	0.081	0.081	0.007	99.988	0.013
9	-0.199	0.222	-0.002	0.060	0.060	0.004	100.000	0.000
10	-0.308	0.285	-0.004	0.077	0.077	0.006	99.670	0.330
11	-0.224	0.250	0.000	0.064	0.064	0.004	99.999	0.001
12	-0.171	0.242	0.002	0.061	0.061	0.004	100.000	0.000
13	-0.205	0.257	-0.004	0.064	0.063	0.004	99.999	0.001
14	-0.274	0.262	-0.025	0.066	0.061	0.004	99.756	0.244
15	-0.219	0.218	-0.009	0.052	0.051	0.003	100.000	0.000
16	-0.234	0.292	0.001	0.073	0.073	0.005	99.986	0.014
Average	-0.280	0.309	-0.004	0.074	0.073	0.006	99.612	0.388
STD	0.103	0.099	0.011	0.016	0.016	0.003	0.567	0.567

170-io U

Name	Min.	Max.	Avg.	RMS	Std. Dev.	Var.	In Tol.(%)	Out Tol %
1	-0.295	0.295	0.008	0.072	0.072	0.005	99.687	0.313
2	-0.268	0.358	0.025	0.086	0.082	0.007	99.756	0.244
3	-0.279	0.280	-0.007	0.068	0.068	0.005	99.858	0.142
4	-0.322	0.321	0.011	0.088	0.087	0.008	99.936	0.064
5	-0.263	0.254	-0.009	0.063	0.063	0.004	99.924	0.076
6	-0.244	0.235	-0.009	0.059	0.059	0.003	100.000	0.000
8	-0.231	0.261	0.000	0.065	0.065	0.004	99.991	0.009
9	-0.227	0.226	0.000	0.057	0.057	0.003	100.000	0.000
10	-0.260	0.326	-0.005	0.081	0.081	0.007	99.903	0.097
11	-0.301	0.308	-0.004	0.076	0.076	0.006	99.831	0.169
12	-0.276	0.275	0.003	0.065	0.065	0.004	99.930	0.070
13	-0.276	0.304	-0.012	0.085	0.085	0.007	99.862	0.138
14	-0.303	0.406	-0.005	0.100	0.099	0.010	98.990	1.010
15	-0.294	0.358	-0.024	0.104	0.101	0.010	99.476	0.524
16	-0.193	0.195	-0.004	0.048	0.048	0.002	100.000	0.000
Average	-0.269	0.293	-0.002	0.074	0.074	0.006	99.810	0.190
STD	0.034	0.056	0.011	0.016	0.015	0.002	0.267	0.267

170-io L

Name	Min.	Max.	Avg.	RMS	Std. Dev.	Var.	In Tol.(%)	Out Tol %
1	-0.203	0.281	0.002	0.073	0.073	0.005	99.989	0.011
2	-0.267	0.406	0.018	0.100	0.098	0.010	98.930	1.070
3	-0.290	0.336	-0.003	0.083	0.083	0.007	99.826	0.174
4	-0.309	0.325	0.013	0.085	0.084	0.007	99.893	0.107
5	-0.259	0.288	0.021	0.075	0.072	0.005	99.868	0.132
6	-0.408	0.509	0.013	0.132	0.132	0.017	93.929	6.071
8	-0.226	0.327	0.010	0.081	0.081	0.007	99.987	0.013
9	-0.279	0.388	0.011	0.117	0.117	0.014	97.903	2.097
10	-0.299	0.314	0.016	0.077	0.075	0.006	99.896	0.104
11	-0.324	0.454	0.011	0.111	0.111	0.012	97.426	2.574
12	-0.292	0.292	-0.001	0.067	0.067	0.005	99.625	0.375
13	-0.262	0.265	0.003	0.066	0.066	0.004	99.986	0.014
14	-0.235	0.233	0.001	0.057	0.057	0.003	100.000	
15	-0.271	0.384	0.017	0.094	0.093	0.009	99.621	0.379
16	-0.233	0.338	0.007	0.094	0.093	0.009	99.624	0.376
Average	-0.277	0.343	0.009	0.087	0.087	0.008	99.100	0.964
STD	0.049	0.074	0.007	0.021	0.021	0.004	1.634	1.676

Appendix D: Retainer Fit Ratings & Comments

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O	P
1	Patient	100 - U	100 - L	170 - U	170 - L	Dr. 100 - U	Dr. 100 - L	Dr. 170 - U	Dr. 170 - L	Age	Male	Female	100 Print time (min)	170 Print Time (min)	Time delta (min)	Average delta %
2	1	3	4	5	5	5	5	5	5	27	1		39	30	9	23%
3	2	4	4	4.5	4.5	5	5	5	5	29		1	47	36	11	23%
4	3	5	5	5	5	5	5	4	4	29		1	35	27	8	23%
5	4	4	4	4	3	5	5	5	5	20	1		49	38	11	22%
6	5	5	5	5	5	5	5	1	5	17.5	1		42	32	10	24%
7	6	5	3	5	5	5	5	5	5	22	1		38	30	8	21%
8															0	
9	8	3	2	3	5	5	5	5	5	15.5	1		47	36	11	23%
10	9	4	5	5	5	5	5	5	5	15.5	1		46	35	11	24%
11	10	4	5	5	4	5	5	5	5	25		1	42	32	10	24%
12	11	5	5	5	5	5	4	5	3	17.5	1		43	33	10	23%
13	12	5	4	4	3	5	4	5	5	29	1		48	37	11	23%
14	13	3	3	5	5	5	5	5	5	44		1	42	32	10	24%
15	14	5	5	5	5	5	5	5	5	48.5		1	34	26	8	24%
16	15	4	4	4	4	5	5	5	5	46.5		1	42	32	10	24%
17	16	4	4	5	5	5	5	5	5	26		1	39	30	9	23%
18																
19	Average	4.200	4.133	4.633	4.567	5.000	4.867	4.667	4.800	27.467	8.000	7.000	42.200	32.400	9.188	23%
20	STD	0.775	0.915	0.611	0.729	0.000	0.352	1.047	0.561	10.903			4.617	3.521	2.689	1%
21																
22	Patient Comments															
23	1	100 - tighter than A (170), Difficult to remove, lower as well but not as bad"														
24	2	100 - a bit too tight, upper more than lower 170 - material doesn't feel as thick, not loose but less tight														
25	3	Dr* - 100 feel a bit tighter, but 170 not loose														
26	4	170 - lower just a little loose														
27	5															
28	6	100 - bottom was tighest, mildly difficult to seat														
29																
30	8															
31	9															
32	10	would say (100) is tighter than (170)														
33	11															
34	12															
35	13	100 - snug; more difficult for removal (which can be awkward in public if removing) 170 - easy; feels like a perfect fit in/out														
36	14	100 - U - semi ok on, hard to get off L - easy on, semi ok off / 170 U easy on, semi hard to get off, L - easy on, easy off														
37	15	170 - feel like they fit well - went in fairly easily & came out likewise. They pretty much felt like putting in a new tray in for the week, starts a little tight then eases up.														
38		100 - Same as A(170), though they were a smidge more challenging to remove. They did however feel smoother in my mouth overall than the A(170) trays														
39	16	100 - harder to place & remove 170 - prefer														
40																

Appendix E: ANOVA Statistical Tables

Descriptives

Dev

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
1.00	30	.0739	.01696	.00310	.0675	.0802	.05	.11
2.00	30	.0803	.01911	.00349	.0732	.0875	.05	.13
Total	60	.0771	.01821	.00235	.0724	.0818	.05	.13

ANOVA

Dev

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.001	1	.001	1.922	.171
Within Groups	.019	58	.000		
Total	.020	59			

Descriptives

IntoIrance

	N	Mean	Std. Deviation	Std. Error	95% Confidence Interval for Mean		Minimum	Maximum
					Lower Bound	Upper Bound		
1.00	30	99.5135	.89021	.16253	99.1811	99.8459	96.43	100.00
2.00	30	99.4549	1.20561	.22011	99.0047	99.9051	93.93	100.00
Total	60	99.4842	1.05110	.13570	99.2127	99.7557	93.93	100.00

ANOVA

IntoIrance

	Sum of Squares	df	Mean Square	F	Sig.
Between Groups	.052	1	.052	.046	.831
Within Groups	65.133	58	1.123		
Total	65.184	59			

Appendix F: Kruskal-Wallis Statistical Results

Patient Ratings:

Independent-Samples Kruskal-Wallis Test Summary

Total N	60
Test Statistic	4.946[a,b]
Degree Of Freedom	1
Asymptotic Sig.(2-sided test)	.026

a. The test statistic is adjusted for ties.

b. Multiple comparisons are not performed because there are less than three test fields.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The distribution of Patientgrade is the same across categories of Layer.	Independent-Samples Kruskal-Wallis Test	.026	Reject the null hypothesis.

a. The significance level is .050.

b. Asymptotic significance is displayed.

Appendix F: Kruskal-Wallis Statistical Results

Doctor Ratings:

Independent-Samples Kruskal-Wallis Test Summary

Total N	60
Test Statistic	.827[a,b]
Degree Of Freedom	1
Asymptotic Sig.(2-sided test)	.363

a. The test statistic is adjusted for ties.

b. Multiple comparisons are not performed because there are less than three test fields.

Hypothesis Test Summary

	Null Hypothesis	Test	Sig.[a,b]	Decision
1	The distribution of docgrade is the same across categories of Layer.	Independent-Samples Kruskal-Wallis Test	.363	Retain the null hypothesis.

a. The significance level is .050.

b. Asymptotic significance is displayed.