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Evaluation of fit for 3D printed retainers as compared to thermoform retainers

David J. Cole

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Evaluation of fit for 3D printed retainers as compared to thermoform retainers

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University

by

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ABSTRACT

EVALUATION OF FIT FOR 3D PRINTED RETAINERS AS COMPARED TO THERMOFORM RETAINERS

By David Cole, D.M.D.

A thesis submitted in partial fulfillment of the requirements for the degree of Master of Science in Dentistry at Virginia Commonwealth University

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Introduction: Despite recent advances in three-dimensional (3D) printing, little information is available on 3D printed retainers

Methods: Three reference models were used to fabricate traditional vacuum formed, commercially-available vacuum formed, and 3D printed retainers. For each model, three retainers were made using the three methods (a total of 27 retainers). To determine the trueness, the distances between the intaglio surface of the retainers and the occlusal surface of the reference models were measured using an engineering software. A small difference was indicative of a good fit.

Results: Average differences of the traditional vacuum formed retainers ranged from 0.10 to 0.20mm. The commercially-available and 3D printed retainers had a range of 0.10 to 0.30mm and 0.10 to 0.40mm, respectively.

Conclusions: The traditional vacuum formed retainers showed the least amount of deviation from the original reference models while the 3D printed retainers showed the greatest deviation.
INTRODUCTION

Recent advances in digital dentistry have paved the way for the use of computer-aided design (CAD) technology in the modern orthodontic practice. Today, a three-dimensional (3D) digital model, produced with an intraoral scanner, can be easily manipulated to perform the necessary measurements to facilitate diagnosis and treatment planning. In addition, digital technology eliminates the need for storage space and makes the retrieval and transfer of the models easier. Because of these advantages, it is speculated that 3D models will soon replace conventional plaster models.\textsuperscript{1,2,3,4}

Traditionally, much of the work of an orthodontic office relied heavily upon alginate impressions which were turned into stone or plaster models of oral structures. These replicas were then used to fabricate orthodontic appliances such as retainers, mouth guards, space maintenance devices, and expanders. However, with the latest advancements in the digital manufacturing technologies, today, 3D printing makes it possible to directly fabricate dental and orthodontic appliances from 3D models.\textsuperscript{4,5,6,7}

3D printing is a manufacturing process to fabricate three-dimensional structures by joining material from a 3D model on a layer-by-layer basis.\textsuperscript{8} Currently, there are a number of different 3D printers available in the market. The oldest and most established 3D printing technology is stereolithography (SLA) which consists of a bath of photosensitive resin, a model-building platform, and an ultraviolet laser to cure the resin.\textsuperscript{9,10} While the underlying technology of the SLA has largely remained the same, recent innovations have led to the next generation of printers that are smaller, less expensive, and more efficient than the original SLA printers.\textsuperscript{11,12}
One of the most popular materials used for 3D printing technology is polymethylmethacrylate resin (PMMA). PMMA dental models fabricated with a 3D printer can shorten the lead time and facilitate the production of multiple copies without distortions of anatomy. Previous studies on the accuracy of printed models showed that 3D printed dental casts are suitable for diagnosis and treatment planning. Furthermore, Dietrich et al evaluated the accuracy of two different 3D printing techniques for the physical reproduction of dental resin casts by using a comparative assessment of the digital files. The dimensional errors in the replicas were a maximum of 127µm, far below the reported guidelines for accuracy for orthodontic casts, which are between 300-500µm. In a recent study, Kim et al also investigated dimensional differences between the 3D printed and digital reference models. They evaluated the “trueness” of the printed models and defined “trueness” as the closeness of a model to a true value. It was shown that even the least accurate 3D printing method produced replica casts within 260µm of the reference models, still below the reported guidelines.

While the increased accuracy of printed dental casts represents a large step forward in the advancement of 3D printing in dentistry, the “holy grail” of 3D printing for orthodontics is still a direct-printed clear retainer that is accurate, reproducible, and esthetic. To directly fabricate an appliance such as a retainer or clear aligner, the digital scan of patients’ dentition can be used without a physical dental model. The first attempt to fabricate a retainer directly from a digital model was in 2014. Nasef et al reported the successful fabrication of a retainer from an initial cone beam computed tomography (CBCT) image, with no physical model, using a selective laser sintering (SLS) 3D printer. Although the accuracy of the fabricated appliance was not evaluated, this study highlighted the potential uses of 3D printing in orthodontics. A recent study by the same investigators reported that the 3D printed retainers were as accurate and reliable as the
traditional, vacuum formed retainers. However, comparisons between the two retainers were made based on the linear measurements performed manually using digital calipers. Furthermore, the digital file used to fabricate the retainers was created from a CBCT. It has previously been shown that the intraoral digital images generated with an Itero scanner are slightly more accurate than the ones produced from CBCT scans. Also, 3D models produced from CBCT scans do not include gingival tissue. Finally, due to the use of an SLS printer, in the study by Nasef et al., the printed retainer was white and opaque which would be unacceptable to an orthodontic patient. Nevertheless, this investigation was one of the very first to show that it was possible to make retainers using the 3D printing technology. In the literature, there have been other reports of successfully 3D printed dental appliances such as orthognathic surgical splints, implant guides, and indirect bonding jigs; however, none of these studies evaluated the accuracy of the appliances made using this technology. To date, there is little information on the fit of 3D-printed orthodontic retainers that are directly produced from digital intraoral images. Therefore, the purpose of this study was to compare the trueness of 3D printed and conventionally fabricated clear retainers by comparing their fit to the original digital models. The null hypothesis was that there are no significant differences in the fit of 3D printed clear retainer versus conventionally fabricated clear retainers and their corresponding reference models.
MATERIALS AND METHODS

For this study, 3D digital scans of three different maxillary arches were selected from the digital orthodontic model archive at Virginia Commonwealth University Orthodontics clinic. All three arches had full complement of permanent teeth, except third molars. Scan 1 and Scan 2 were selected from the database of previously treated patients. Scan 3 was generated from a maxillary typodont. The study design is outlined in Figure 1.
Figure 1. Process for design and fabrication of retainers. A total of 27 retainers with each reference model used to fabricate 3 retainers of each of the 3 methods.

1. Design
2. Fabrication
3. Evaluation

Printed method

CT scanned model

Traditional vacuum formed

Plaster Mold

Printed model

CFRPM model

TJP model

Printed Reference 3

Printed Reference 2

Printed Reference 1

Reference models

 scanned (TJP, CT)

Vacuum formed (TJP, CT)

Commercially
The three digital scans were first converted into the standard tessellation language (.stl) file format, a data interface that is widely used in 3D printing and computer-aided manufacturing. The .stl files of the three scans were then 3D printed (Model 1, Model 2, Model 3) in an orthodontic lab (Accutech Orthodontic Lab, Inc.) with a polyjet style printer (Objet Eden 260VS, Stratasys; Eden Prairie, Minn). These 3D printed replicates (Model 1, Model 2, and Model 3) were used as reference models to ensure an equivalent starting point for the remainder of the study.

Model 1, Model 2, and Model 3 were used to fabricate clear retainers utilizing three different methods: 1) Traditional vacuum formed method (TVF) 2) Commercially-available vacuum formed method (CVF), and 3) 3D Printed (Printed) method. These three methods (TVF, CVF, and Printed) were completed three times for each of the three reference models (Model 1, 2, and 3) for a total of 27 retainers (Figure 1).

For the TVF group, alginate impressions (Fast Set Identic alginate, Kerr Corporation; Orange, CA) of Model 1, 2, and 3 were poured up in regular set plaster (Henry Schein; Melville, New York) and a 1mm plastic shell (Essix Plus, Dentsply International; York, PA) was vacuum-pressed over the plaster models using a thermoforming machine (MiniSTAR, Great Lakes Orthodontics, Tonawanda, New York). Since the TVF retainers were made using a standard technique according to the manufacturers’ instructions, they served as the gold standard.

For the CVF group, Model 1, 2, and 3 were digitally scanned with an intraoral scanner (IteroElement, Align Technology, Inc.; San Jose, California) and sent to Invisalign® (Align Technology, Inc.; San Jose, California) for the fabrication of Vivera® retainers. This process was completed by Invisalign who 3D printed a physical model from the digital scan and then thermoformed a retainer over the printed cast.
For the Printed group, Model 1, 2, and 3 were digitally scanned using the 3Shape Trios scanner (3Shape A/S; Copenhagen, Denmark) and exported to the 3Shape software (3Shape A/S; Copenhagen, Denmark). The digital scan was then used to fabricate a “splint” in 3Shape’s ApplianceDesigner™ (3Shape A/S; Copenhagen, Denmark) software. To limit any undercuts, a line of insertion was set and the retainer margin was drawn. The retainer thickness was set to 0.75mm and “offset” was set to 0.25mm to allow full seating of the printed retainer (Figure 2). The digital retainer was labeled with the model number and the file was saved (Figure 3). Once all of the digital retainers had been designed, the files were imported into PreForm™ (FormLabs Inc.; Somerville, MA), Formlabs’ software for preparing models for 3D printing. The retainers were oriented in the software to minimize cross-sectional peeling forces during printing and allow excess resin (Dental LT Clear, FormLabs Inc.; Somerville, MA) to drain. Support points were added to non-occlusal surfaces to maintain an accurate fit (Figure 4). The finalized retainer files were sent to the Form 2 3D printer (Formlabs Inc.; Somerville, MA) and printed with Dental LT Clear resin at 100µm resolution (Figure 5). After printing, the retainers were removed from the build platform and rinsed in two baths of 91% isopropyl alcohol for a total of 20 minutes and then allowed to air dry (Figure 6). Next, the retainers were fully post-cured in a cure chamber and the supports were removed (Figure 6).
Figure 2. Appliance design. Retainer was designed in 3Shape ApplianceDesigner™. Thickness was set to 0.75mm and offset to 0.25mm.

Figure 3. Completed design of “Printed” Model 1 retainer.
Figure 4. Layout of designed retainers before printing.

Figure 5. 3D printed retainers. Printed retainers for Models 1, 2, and 3 while still connected to the printing platform (A). Printed retainers for Models 1, 2, and 3 after removal of printing platform from the SLA printer (B).
Following fabrication, the intaglio surface of the retainers and the occlusal surface of the original master casts were scanned with the IteroElement scanner. In order to limit the light refraction from the clear retainers, an opaque CAD/CAM scanning spray (Henry Schein; Melville, New York) was applied to the intaglio surface of the retainers. Model 1, 2, and 3 were scanned, and the .stl files of the reference models and retainers were imported into engineering software (NetFabb, Autodesk; San Rafael, California) to analyze the fit of the 3D printed retainers. This was done by using a “compare” feature of the Netfabb software. Setting each model (Model 1, 2, 3) as the “reference” and each retainer as the “comparison” allowed for direct analysis of the differences in three dimensions. The comparison tool found the shortest available distance in millimeters between the surface of the reference and the surface of the comparison part, and displayed the result using a color gradient and numerical values. From this comparison output, specific measurements were made at the specific landmarks to find the exact difference.
The reference points chosen were similar to the ones used by Johal et al\textsuperscript{25} in a study evaluating the fit of different thermoform materials (Figure 7, Figure 8).

\textbf{Figure 7. Reference points used for measurement in the comparison software.} Each point was measured on the right and left sides for a total of 18 points for each comparison. Central incisor mid-facial: IF; Central incisor mid-incisal edge: IIE; Central incisor mid-lingual: IL; Canine cusp tip: CT; First molar mid-buccal: MB; First molar mesiobuccal cusp: MMBC; First molar distobuccal cusp: MDBC; First molar mid-palatal: MP; First molar mesiolingual cusp (MMLC)
Figure 8. Comparison in the NetFabb Autodesk software. Measurements were made at the right and left central incisors, canines, and first molars.

The primary investigator completed the measurements at each of the eighteen reference points for each retainer. An independent research assistant repeated the measures and reliability was high (ICC=0.888). The average absolute observed distances between the retainer and its digital model were calculated to evaluate fit for each of the fabrication methods (TVF, CVF, and Printed).
RESULTS

For each reference point, the average absolute observed distances between the retainer and its digital model are given in Table 1 and Figure 9. Average differences for the gold standard TVF ranged from 0.10mm-0.20mm. This was slightly smaller than the ranges for CVF and the 3D printed retainers which ranged from 0.10mm-0.30mm and 0.10mm-0.40mm, respectively. For all reference points, except the Central Incisor Mid-Facial (IF) and Central Incisor Mid-Incisal Edge (IIE), the TVF retainers had the smallest amount of deviation from the reference models, ranging from 0.10mm-0.20mm. The CVF retainer group, showed the least mean variance for the IF point (0.10mm) but showed the greatest variance, ranging from 0.13mm-0.25mm, at the Canine Cusp Tip (CT), Central Incisor Mid-Incisal Edge (IIE), First Molar Distobuccal Cusp (MDBC), First Molar Mesiobuccal Cusp (MMBC), and First Molar Mesiolingual Cusp (MMLC). In the Printed retainer group, less variation was seen at reference points located at the incisal edges and cusp tips (CT, IIE, MDBC, MMBC, MMLC) with mean variation between 0.10mm-0.19mm from the reference models. However, the Printed retainers had higher average differences, from 0.21-0.40mm, seen for the reference points found on the smooth surfaces of the teeth, such as the Central Incisor Mid-Facial (IF), Central Incisor Mid-Lingual (IL), First Molar Mid-Buccal (MB), First Molar Mid-Palatal (MP). Modified Bland-Altman plots demonstrate the actual differences (i.e. both positive and negative) from the reference model for each retainer and each reference point (Figure 10).
Figure 9. Average absolute differences.
<table>
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<th>Reference Point</th>
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<th>95% Confidence Interval</th>
<th>SD</th>
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<tr>
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<td>MB</td>
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<td></td>
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Figure 10. Modified Bland-Altman plots for differences between retainer and model. TVF (top), CVF (middle), 3D Printed (bottom)
DISCUSSION

A global industrial revolution is currently in motion, and much of that has to do with the evolution of 3D printing and its impact on different industries, such as orthodontics. To this point in time, the use of 3D printing in orthodontics has mostly been limited to the fabrication of physical models. In turn, research has focused primarily on the accuracy of these 3D printed models and shown them to be clinically accurate for orthodontics across a number of different 3D printers. However, little research has been done on the direct-fabrication of clear orthodontic retainers with 3D printers.

The first attempt to fabricate retainers using 3D printing technology was made by Nasef et al. in 2014. A few years later, the same authors evaluated the fit of the 3D printed retainers. In that study, digital calipers were used to measure the difference between the 3D printed retainer and vacuum formed retainer. In the current study, a software was used to superimpose the digital images of the printed retainers and their original models.

The TVF retainers were fabricated by an experienced technician and all the manufacturer’s instructions were carried out in detail. Therefore, these served as a gold standard to evaluate and compare the fit of the 3D printed retainers. For the TVF retainers, the average deviation from the reference model was 0.10-0.20mm with the least difference for all but two of the reference points measured (IF, IIE). The CVF retainers were the next closest to the reference models in average distance between 0.10-0.30mm. Finally, the Printed retainers showed the greatest deviation with as much as 0.40mm deviation from the reference model. However, the Printed retainer group showed less difference at the reference points for incisal edges and cusp
tips (CT, IIE, MDBC, MMBC, MMLC) but showed the most difference for the reference points located on the smooth surfaces of the teeth (IF, IL, MB, MP).

All 27 retainers were manually seated onto the reference models successfully and the fit was judged to be good and acceptable. In the literature, there is no information on the maximum acceptable distance between the clear retainers and their master casts to be accurate enough for clinical use. Therefore, in this study it was not possible to determine whether retainers fit accurately or not without a pre-specified clinical threshold value. Instead, the fit was reported in terms of distance between the retainer and its reference model at preselected reference points. Having two clinically accepted and widely used retainer types (TVF and CVF) served as a guideline when evaluating the fit of the Printed retainers.

The Printed retainers were fabricated from an ultraviolet (UV)-sensitive PMMA. It is very difficult to develop a clear and esthetic, curable resin that is biocompatible, stable at body temperature, strong enough to withstand the force of occlusion, and does not break down over time. In addition to these requirements, the 3D printing resin must have physical properties similar to the materials used for the fabrication of vacuum formed retainers. While the PMMA used in this study had some elasticity, it was anecdotally much more rigid than the thermoformed materials that make up the TVF and CVF retainers. The increased rigidity can cause issues when the retainer must flex over the heights of contours of teeth or adapt to undercuts in the dentition. In the design stage for the Printed method, a line of insertion was selected as the path with the least amount of undercuts, however, some undercuts still persisted, primarily at the midfacial and midlingual of the central incisors and at the molars. Therefore, the largest differences between the Printed retainers and their master models at these same locations may be attributed to the rigidity of the resin used in this study (Figure 9 and 10). It is reasonable to assume that as the
chemical makeup of the UV-cured resins improve, 3D printed retainers will acquire more flexibility. In the prototyping stages of this research, new PMMA resins were constantly being developed and a resin was eventually selected because of its compatibility with the 3D printer utilized in this study. A number of different companies claim that a clinically usable, printed retainer is being developed and that the new materials have been optimized to match thermoformed retainer materials. As new resins are developed, it may require special technology in the 3D printers themselves to leverage the advantages which may make it difficult for individual clinicians to afford the printer technology and make this technology more applicable for a clear aligner manufacturer.

Another factor specific to the Printed method was the offset. The term “offset” is not normally used in orthodontics but has applications in dentistry with the fabrication of full coverage fixed or removable prostheses. For instance, when a crown is made for an analogous crown prep, the intaglio, or inside surface, of the crown cannot be the exact accuracy of the tooth preparation or else the crown will not be able to fully seat. For this reason, there is some space added, offset, that is eventually filled with a dental cement. Initially, when prototyping the printed retainers the offset was set to ‘0’ and the resultant retainers could not be seated on the reference models. A pilot study to determine the minimum amount of offset to allow full seating of the retainers had indicated that 0.25mm would consistently allow for full seating. Therefore, an offset of 0.25mm could account for a larger deviation of the printed retainers from the reference models. It is possible that, as a result of appropriate seating, the printed appliances fit better than others in the incisal edges and cusp tips. This may also result in different clinical outcomes that will need future studies to determine the effectiveness of 3D printed appliances compared to conventional fabricated ones.
A general limitation in this study included the need to spray the intaglio surface of all retainers with a scanning powder in order for the scanner to read the surface. Previous research states that scanning spray can account for between 0.04-0.09mm of thickness.\(^{28}\) To eliminate the possible negative effect of the spray layer, all of the retainers were prepared by the same, well-trained operator under the standard conditions.

The fit was measured with software by superimposing the digital images of the retainers and their reference models. However, the alignment of the two images was done manually using the cusp tips and dental anatomy of the reference points. The operator error would have been improved with physical reference points added to the original reference models at the beginning of the study. These reference points may have aided in the alignment of the retainer and reference models scans, as well.

Since there is no information on how much deviation from the original model would be considered to be clinically acceptable, it was not possible to determine equivalence in terms of the accuracy of the fit of the groups tested. Instead, the difference between the intaglio surface of the retainers and the occlusal surface of the reference model was evaluated to determine “trueness.” In the literature, it has been previously denoted that measurements up to 0.50mm is generally considered clinically acceptable for the evaluation of a digital articulation.\(^{16,17}\) In this study, all of the retainers yielded measurements within 0.50mm. However, future studies are needed to evaluate the accuracy of retainers.

The technology surrounding digital dentistry and 3D printing is changing rapidly. An increasing number of orthodontists will adopt the technology, however, improvements in printing materials will be necessary to produce accurate 3D printed clear retainers that can be fabricated for clinical use.
CONCLUSIONS

- The traditional vacuum formed retainers showed the least amount of deviation from the original reference models.
- The 3D printed retainers showed the greatest deviation at the reference points located on the smooth surfaces of the teeth but showed close adaptation at the incisal edges and cusp tips.
- The 3D printed retainers seem to be comparable to the traditional vacuum formed retainers.
REFERENCES


