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Mechanical and geometric properties of thermoformed and 3D printed clear dental aligners

Prashant Jindal,[a] Mamta Juneja,[a] Francesco Luke Siena,[b] Divya Bajaj,[a] and Philip Breedon[b]
Chandigarh, India, and Nottingham, United Kingdom

Introduction: The aim of this research was to compare compressive mechanical properties and geometric inaccuracies between conventionally manufactured thermoformed Duran clear dental aligners and 3D printed Dental Long Term (LT) resin-based clear aligners using 3D modeling and printing techniques. **Methods:** Impressions of the patient's dentition were scanned and using 3D modeling software, dental models were designed and 3D printed. These printed models then underwent vacuum thermoforming to thermoform a clear Duran thermoplastic sheet of 0.75-mm thickness into clear dental aligners of the same thickness of 0.75 mm. For the same dental model, aligners were also designed and 3D printed to 0.75-mm thickness creating biocompatible clear dental aligners using Dental LT resin utilizing a Formlabs 3D printing machine for direct usage by the patients. Five observers calculated teeth height for both types of aligners for evaluation of geometric deviations. Both types of aligners were subjected to compression loading of 1000 N to evaluate their load vs displacement behavior. **Results:** 3D printed cured clear dental aligners were found to be geometrically more accurate with an average relative difference in tooth height of 2.55% in comparison with thermoformed aligners (4.41%). Low standard deviations (0.03-0.09 mm) were observed for tooth height measurements taken by all the observers for both types of aligners. 3D printed aligners could resist a maximum load of nearly 662 N for a low displacement of 2.93 mm; whereas, thermoformed aligners could resist a load on only 105 N for 2.93-mm displacement. Thermoformed aligners deformed plastically and irreversibly for large displacements; whereas, 3D printed aligners deformed elastically with reversibility for lower displacements. **Conclusions:** 3D printed and suitably cured Dental LT resin-based clear dental aligners are suggested to be more suitable for patient use as they are geometrically more accurate; this presents an opportunity to make processing time savings while ensuring an aligner is mechanically stronger and elastic in comparison with the conventionally produced thermoplastic-based thermoformed clear dental aligners. (Am J Orthod Dentofacial Orthop 2019;156:694-701)

The demand for superior and esthetic orthodontic treatment has risen dramatically because of an increased awareness toward oral hygiene. Improvements in orthodontic treatments and appliances have led to enhancements within the dentofacial sector. Seventy-five percent of adult patients are dissatisfied with their dental appearance.[1] Improvements in patient esthetic appearance are therefore becoming more frequent and attracting patients to treat even minor functional disorders in an attempt to raise their confidence as a result of an esthetically superior dentofacial appearance. Because of the availability of this treatment, there has been an increase in demand for superior functional and esthetic orthodontic appliances. With the advent of Rapid Prototyping (RP) technologies, revolutionary advancements have taken place in the manufacturing of products in several fields such as medical, dentistry, automobiles, machines, artistry, etc. From the dentistry applications viewpoint, RP is one of the most efficient tools for 3D printing of complex anatomical structures[2] to manufacture models that can replace plaster models which are vulnerable to environmental conditions, storage, breakage, and human errors. RP also allows the reproduction of a physical 3D model by adding material layer-by-layer, this is referred to as additive manufacturing.[3] Common RP techniques include stereolithography, selective laser sintering, and Fused Deposition Modeling (FDM).[4]

[a]University Institute of Engineering and Technology, Panjab University, Chandigarh, India.
[b]Medical Engineering Design Research Group, Nottingham Trent University, Nottingham, United Kingdom.
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Address correspondence to: Philip Breedon, Director of Medical Engineering Design Research Group, Nottingham Trent University, Nottingham, NG1 4FQ, United Kingdom; e-mail, philip.breedon@ntu.ac.uk.
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Hazeveld et al[5] introduced RP as an approach to fabricate replica dental plaster models. Initially, plaster models were scanned using a dual-sensor scanner to form 3D surface models in a Standard Tessellation Language (STL) format. These STL files then underwent various RP methods such as a jetted photopolymer, digital light processing, and 3D printing to generate 3D models. These models were then compared for dimensional accuracies using a set of digital calipers. Mean differences in measurements of clinical crowns were found to be 0.04 mm for digital light processed models, −0.02 mm for jetted photopolymer models and 0.25 mm for 3D printed models. Because the dimensional errors were minimal, it was concluded that 3D printed models could be a suitable replacement for conventional plaster models.

El-Katatny et al[6] reported superior geometric accuracies obtained using FDM printing for the fabrication of anatomical replicas using models of different human sizes and gender. The results indicated an overall absolute average deviation of 0.24% and an average standard deviation of 0.16% for the skull models, thereby emphasizing the impact of 3D printing in medical applications. Lee et al[7] evaluated the accuracy of teeth printed using FDM and PolyJet printing techniques. Molar teeth were extracted, scanned, and printed. Geometric comparisons of the height of printed and original molar teeth (17.226 mm) indicated superior accuracy of PolyJet printing (17.219 mm) in comparison with FDM (17.083 mm).

Clear dental aligners are widely used in orthodontics as an esthetic solution for alignment of misaligned teeth by developing various stages of aligner models.[8] The conventional process of fabricating an aligner is based on obtaining a dental impression on plaster models from the patient and then thermoforming a biocompatible thermoplastic transparent sheet using a vacuum thermoforming machine.[9] Geometric inaccuracies are common and are often caused during the impression collection and thermoforming processes; this could be minimized through the utilization of digital technologies, 3D modeling, and RP techniques.

Plaster models can be scanned and modeled to develop various alignment stages. These stages can then be 3D printed with superior accuracies and accordingly, a thermoformed aligner sheet can be used to fabricate aligners with minimal geometric errors. To further reduce these errors, if a clear biocompatible aligner could be 3D printed for direct patient usage, then all the intermediate steps compromising the inaccuracies could be eliminated. In addition, direct aligner printing presents an opportunity to save on time, workforce, and expertise.

Manufactured aligners could have inherent limitations such as dimensional instability, low strength, and reduced wear resistance. These issues could be associated with material characteristics and with the manufacturing processes. The manufacturing process could also introduce unexpected limitations in the resulting aligners, which would be a critical element to control in order to establish resulting forces on teeth. Several studies demonstrated that the aligner thickness could significantly influence resulting forces.[10] Tensile tests were conducted on polymer materials before and after thermoforming to understand the effect of the manufacturing process. The effects of aging under human saliva were also evaluated. With aging, both tensile yield stress (49.49 MPa) and elastic modulus (1368 MPa) decreased in comparison with the thermoformed specimen (53.52 MPa and 1693 MPa). For specimens tested before thermoforming, both yield stress (49.29 MPa) and elastic modulus (1531 MPa) were weaker than thermoformed specimens.

Ahn et al[11] described the inherent limitations (dimensional instability, low strength, poor wear resistance) of thermoplastic polymer materials used in orthodontics and suggested using multi-hybrid materials with a 3 layer combination of polyethylene terephthalate glycol, thermoplastic polyurethane, and reinforced resin core to overcome these limitations. Tensile testing was performed on rectangular specimens for these hybrid layers materials and the maximum tensile load-bearing capacity enhanced by nearly 80%. The testing findings presented by Ahn et al,[11] demonstrated that improvements in dental aligners could be achieved if optimal material and manufacturing methods are used.

Johal et al[12] reported the significance of geometric inaccuracies related to proper fitment of dental aligners on models. Four thermoformed clear aligners were used with specific biomarkers and statistical analysis used to analyze the results. Subsequent scanning and analyzing of the casts and thermoformed retainers were performed in a dedicated area using a coordinate measuring machine in order to calculate their respective fit at the incisor and first molar regions. Statistically significant differences were observed in the fit behavior of all 4 thermoform materials.

Cone-beam computed tomography, and 3D printing proved to be efficient methods for designing and fabricating thermoplastic retainers in comparison with the conventional thermoformed alternatives in terms of geometric measurements.[13] However, for thermoformed and 3D printed retainers, strong statistical agreement in measurements was also observed.

Commercially available aligners perform differently depending on their thickness and construction material.

In an ideal situation, an aligner should apply a light force that is constant over time. For an aligner to exert safe but efficacious forces, the ideal material should be fairly stiff with high yield strength capable of ensuring that the force applied is within the elastic range. The stress relaxation curve should, therefore, be reasonably flat, demonstrating its ability to exert constant and continuous forces over time. Duran and F22 Aligner materials exhibited faster stress decays during the 24-hour stress relaxation period compared with Erkoloc-Pro and Durasoft.[14]

Aligners fabricated from thicker materials (>0.75 mm) always produced significantly higher forces than those fabricated from thinner material (<0.5 mm). A strong correlation was shown between mechanical properties of the thermoplastic materials and force produced by the aligners. Duran and Erkodur aligner materials were suggested to be more effective for teeth movements in comparison with Hardcast as their hardness, and elastic modulus was nearly twice to that of Hardcast.[15]

Based on the results reported on mechanical properties of different aligner materials, it has been shown that 3D printing technologies provide superior geometric configurations in manufacturing, especially related to dentistry applications. However, no work has been published on the compressive properties of dental aligners, especially when considering that mastication and biting processes in a human jaw are frequent and demanding. In addition, compressive forces generated by excessive clenching are also presented in other conditions. To date, there are limited findings relating to the comparison of mechanical and geometric properties between 3D printed and thermoformed clear aligners.

In this article, we aimed to use a biocompatible Dental Long Term (LT) resin material for printing clear dental aligners using a stereolithography Form 2 printer and compare its compressive and geometric properties with a conventional Duran based thermoformed aligner for proposing its suitability to a patient suffering from the problem of teeth misalignment.

MATERIAL AND METHODS

The fabrication of dental aligners using 3D printing of biocompatible materials is an exploratory research area that involves numerous factors to be considered including minimizing human error, discarding outliers (gums) from aligners, maintaining balanced environmental factors, and hygienic maintenance. The production of aligners involves various crucial phases from the scanning of the dentition to the usability testing of aligners to ensure it can perfectly fit over the teeth to achieve the required teeth alignments across every stage. The detailed description of all the significant steps used for designing and fabrication of dental aligners are given below.

Scans of the mandibular region of the patient's dentition were taken using negative impressions; following this, a model using alginate was created. The negative impression was taken with complete care, taking into consideration the required size of the tray to fit the dentition and properly mixing the catalyst with putty so that no swirls exist in the original putty color. Deep biting was carried out to ensure even pressure from both the front and the back sides of the mouth. Adequate time was given for the putty to settle and stabilize to ensure an accurate impression could be acquired. The cast or mold of the teeth was statically scanned using a 3Shape E1 Blue LED Multi-line laboratory scanner with an accuracy of 10-12 μm[16] to generate an STL file for carrying out the further phases of computer-aided design and computer-aided manufacturing.

The scanned STL file of the patient's teeth was loaded into the computer-aided design and computer-aided manufacturing software (Maestro Studio, Pontedera, Italy) which was used to study and analyze the phases for treatment. A series of steps were performed on the original dentition as required by the predicted successive stages while planning the treatment process. The steps that were performed included the loading of the STL file, marking of the missing teeth, measuring the width of each tooth and identifying the ideal arch length to check the interproximal reduction. The boundary of the teeth over the dentition was marked by point plotting; this is a necessary process as there should be no sharp edges or overlapping of the aligner with the gums.

For the fabrication of the thermoformed aligners, this initially requires the 3D printing of the dental models. The scanned STL files were loaded into the 3D printer interfacing software to print the physical dental models (Fig 1, *A*).

To manufacture the clear thermoformed dental aligner, the 3D printed models were used under vacuum thermoforming process with a pressure of 4 bar at 70°C to thermoform clear thermoplastic Duran[17] sheet 0.75-mm thickness into a clear dental aligner of the same thickness as 0.75 mm (Fig 1, *B*). A total of 5 aligners were thermoformed.

During the software modeling of the teeth, an aligner is generated based on the negative impression of the dental model. The thickness of an aligner that can provide the required alignment was defined as 0.75 mm, and the final STL file format compatible for 3D printing was generated accordingly for 3D printing. Dental LT clear resin material is a Class IIa long-term biocompatible resin with high resistance to fracture and wear is ideal for hard splints, retainers, and other direct-printed long-term

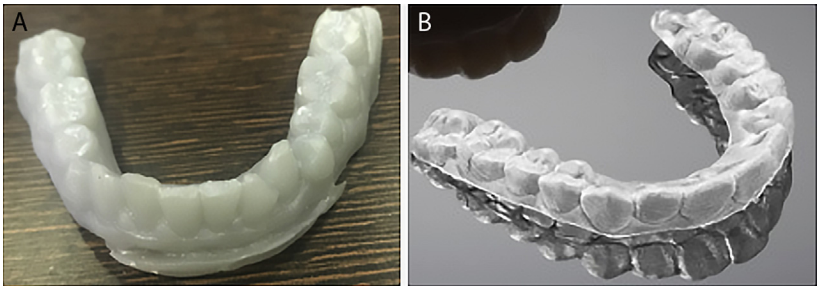

Fig 1. A, 3D printed dental models; **B,** vacuum thermoformed thermoplastic Duran clear dental aligner.

orthodontic appliances.[18] It conforms to the essential requirements and provisions of the Council Directive 93/42/EEC and Medical Device Directive 2007/47/EC.[19,20] This material was used to directly print 0.75-mm thick clear dental aligners obtained from a modeled image of the misaligned mandible stage of a patient using the Formlabs Form 2 3D printer (Somerville, Mass).

The aligners were orientated to ensure that minimal support material was applied within the internal structure to allow quick postprocessing finishing. Each aligner was rotated to 25° within the x-axis to ensure standardization throughout all the 3D printed dental aligners. Rotation cannot exceed 30° as this will compromise precision and lead to poorly fitting parts.[21] The anterior portion of the dental aligner must always be directed upward, and away from the build platform, failure to do so can result in a suction cup error being present (Fig 2, *A*) and inaccurate parts being printed.

The PreForm software (Version 2.17.1, Formlabs) can automatically generate the support structure required; however, manual manipulation is still often required to ensure optimization of the 3D printing process. Before set up, the correct orientation and layout position (models spaced >5 mm) was established and within the defined specification to ensure successful 3D printing. The support structure is fundamental, and if parts fail to be sufficiently supported, the part will either fail to print or produce a model with many inaccurate features or bodies.

Unsupported 3D models with minima errors are displayed using red markers as demonstrated in (Fig 2, *B*); manual support structure corrections were made accordingly to overcome these errors, thus allowing the aligners to be adequately supported. Upon successful printing of the dental aligners (Fig 3, *A*), the parts are washed using isopropyl alcohol (96% or higher) and then initially dried using compressed air to ensure no excess resin or isopropyl alcohol remains on the model which can result in splotches of unwanted material curing on the models. The washed and dried models are then cured, which then is followed by postprocessing tasks, which include the removal of the support structure (Fig 3, *B*) using the standard cutting tools.

For post cure treatment, the optimal settings for 3D printed parts are dependent on the material used, the size of the model, and the model's geometry. Optimal postcuring is also dependent on the type of equipment used to cure the parts. For this study, the Form Cure was used; this postcuring solution uses a 405-nm light source (13 multidirectional light-emitting diodes) in combination with a heated cure chamber capable of temperatures reaching 80°C.[22,23]

The Form Cure is an automated postcuring chamber that uses UV-light treatment to ensure materials obtain full polymer conversion. The specification for the Dental LT clear material used for this study states that printed parts require curing using a Blue UV-A 315-400 nm or UV-Blue 400-550 nm source for 10 minutes to ensure biocompatibility.[21] Postcuring the parts for a duration >10 minutes allows the material to reach its optimal mechanical properties.[23] However, finding a correct combination between temperatures and time duration during postcuring is required based on the desired applications and acceptable mechanical properties for each task.

Variable curing conditions were set up to quantify the effects of temperature and time on the mechanical properties of these aligners. Five specimens were printed for 2 curing conditions stated as 80°C for 20 minutes and 80°C for 15 minutes.

Compression testing was conducted utilizing an Instron 3367 universal testing machine (Instron Corp, Wilmington, De) for applying a maximum of 1000 N compressive force on all the aligner specimens, these were compressed between 2 flat plates, with the lower plate stationary and upper plate moving at a rate of 50 N/min under a 1000 N load cell. The behavior of aligner deformation with load application was obtained using the compatible data acquisition software.

RESULTS

It is challenging to assess the effect of improved learning acquired by individuals when completing a

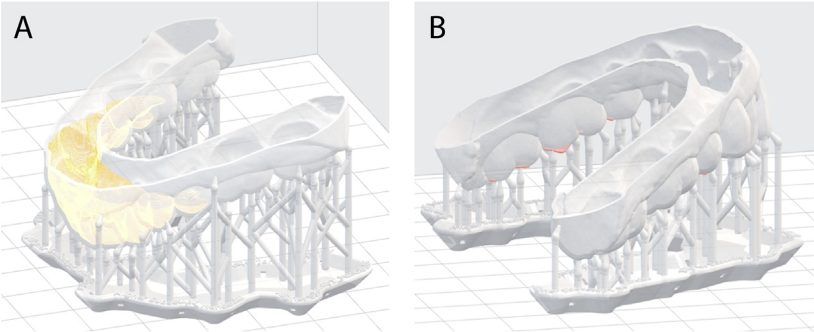

Fig 2. A, Suction cup error; **B,** support minima error.

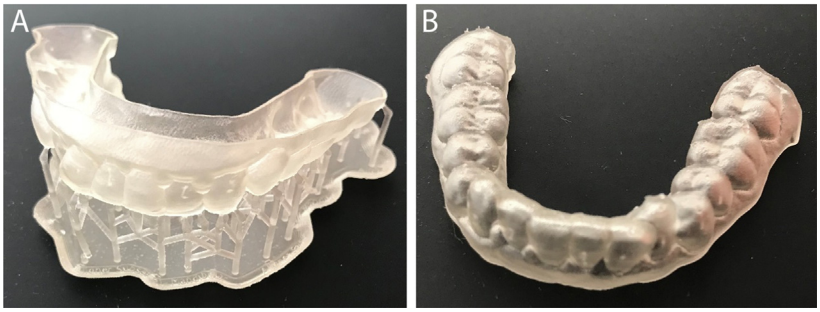

Fig 3. A, Printed and cured dental aligner with supports; **B,** supports removed from dental aligner.

task multiple times as minor adjustments are made. Thus, for the dimensional accuracy testing, the height of each tooth in the mandibular dentition was measured by 5 different observers once at each of the required locations, which accounts for any potential learning bias that could have affected the measurements collected. The distance between the points of intersection of the midline of the tooth on the buccal surface with gumline and at the incisal edge was taken as the height of the crown for the selected tooth. Nomenclature for tooth numbering has been shown for clarity (Fig 4).

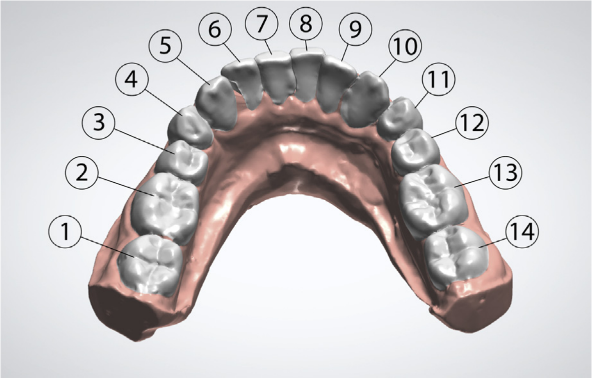

Fig 4. Convention used to represent postprocessing tooth in Table.

Table indicates the mean average measurements by the 5 observers for each tooth, standard deviation among the measured data for each tooth, the absolute difference (Equation 1) and relative difference (Equation 2) for each model concerning STL file image data. Average relative differences from the STL file for 3D printed aligners was found to be 2.55%; whereas, the thermoformed aligner was 4.41%, which indicated that the 3D printed aligners could provide better fitment results because of their superior geometric measurements. These findings are evident even from the average absolute difference between 3D printed aligner (0.21 mm) and thermoformed aligner (0.37 mm). The standard deviation for the measurements obtained by the 5 observers for each tooth was found to be low (0.03-0.09 mm) for both types of aligners indicating expected values,

Table. Geometric comparison among STL, 3D printed, and thermoformed aligners

	STL file	*3D printed aligner*				*Thermoformed aligner*			
Tooth no.	*Height of tooth (mm)*	*Mean height of tooth (mm)*	*Standard deviation (mm)*	*Absolute difference (mm)*	*Relative difference (%)*	*Mean height of tooth (mm)*	*Standard deviation (mm)*	*Absolute difference (mm)*	*Relative difference (%)*
1	6.14	6.10	0.06	0.04	0.65	6.13	0.08	0.01	0.16
2	7.50	7.69	0.03	0.19	2.53	6.69	0.07	0.81	10.80
3	7.80	7.82	0.05	0.02	0.26	7.59	0.09	0.21	2.69
4	8.91	9.20	0.08	0.29	3.25	9.14	0.07	0.23	2.58
5	9.53	9.59	0.08	0.06	0.63	8.65	0.05	0.88	9.23
6	8.00	8.15	0.07	0.15	1.88	8.66	0.08	0.66	8.25
7	8.20	8.27	0.06	0.07	0.90	8.72	0.08	0.52	6.39
8	8.55	8.07	0.08	0.48	5.61	8.72	0.08	0.17	1.99
9	8.31	9.17	0.07	0.86	10.35	8.12	0.07	0.19	2.29
10	9.08	9.32	0.05	0.24	2.64	9.08	0.06	0.00	0.00
11	9.70	9.78	0.09	0.08	0.82	9.07	0.07	0.63	6.49
12	7.67	7.94	0.06	0.27	3.52	7.43	0.07	0.24	3.13
13	6.10	6.16	0.09	0.06	0.98	6.07	0.08	0.03	0.49
14	7.46	7.58	0.07	0.12	1.61	6.93	0.06	0.53	7.10

which were close to the mean values of tooth heights.

$$\text{Absolute Difference(mm)} = |(\text{STL value} - \text{Model value})| \quad (1)$$

$$\text{Relative Difference(\%)} = \frac{|(\text{STL value} - \text{Model value})| \times 100}{(\text{STL value})} \quad (2)$$

Compression testing conducted and presented in figure 5 shows the load resistance behavior with displacement among uncured 3D printed clear aligners, cured 3D printed aligners, and thermoformed clear aligners. Uncured aligners exhibited plastic flow with high deformation as the load increased attaining a maximum load of 380 N and displacement nearly 6.1 mm. Aligners cured at 80°C for 20 minutes could resist a maximum load of nearly 662 N before suddenly fracturing into brittle pieces. Aligners subjected to 80°C for 15 minutes indicated maximum resistance load of 531 N with a brittle fracture in the end. Cured aligners deformed elastically and final deformation was nearly 2.93 mm. Thermoformed aligners' deformation with increased load was similar to uncured 3D printed aligners. The deformation was plastic with larger and irreversible deformation up to nearly 8.6 mm with a maximum load of 584 N. Plastic flow without any resistance to the external load indicates poor resistance to deformation.

DISCUSSION

Advancements in the product-based industries are becoming more prominent, and many of the enhancements in the technologies are possible with the evolution of 3D printing. Orthodontics is one of the major domains in which 3D printing has evolved the treatment methods. Up until now, the use of 3D printing in orthodontics has mostly been limited to the fabrication of physical models of upper and lower dentition, which are clinically accurate for treating patients.[10] This methodology could be used for fabrication of clear orthodontic retainers by 3D printing the dental models and thermoforming of aligners.[24] In this article, the mechanical and geometric comparison between the cured 3D printed aligner, uncured 3D printed aligner, and thermoformed aligner has been discussed.

Cured aligners that were 3D printed exhibited superior dimensional accuracy and compressive mechanical strength in comparison with uncured 3D printed aligners and thermoformed aligners. Dental LT resin used to fabricate clear dental aligners is an approved biocompatible material whose monomer is based on the acrylic ester.[25] The limited chain mobility of the cross-linked polymer network and higher flux during curing generates a large number of radicals.[18] The mobility of unreacted double bonds becomes a limiting condition in the overall conversion of double bonds during postcuring. The kinetic chain generated because of propagating radical leads to extra cross-linking of the resin during

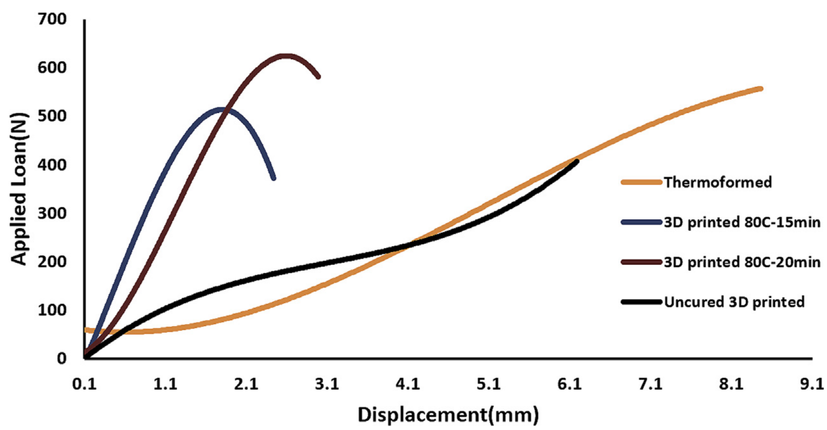

Fig 5. The behavior exhibited by different aligner sets.

printing. The behavior ultimately enhances the mechanical properties of the printed parts.[26]

Postcuring enhanced the compressive strength of the 3D printed aligner material in comparison with the uncured aligner. The maximum resistant load was nearly 75% higher than uncured and maximum deformation was nearly 70% less, thus indicating that cured printed aligners are more rigid and brittle. The average magnitude of the biting force of a human is nearly 500 N.[27] Hence, the cured printed aligners can reliably sustain the mastication and biting force. Thermoformed aligners are fabricated out of thermoplastic Duran, and their plastic deformation with load application showed excessive irreversible deformation. Deformation beyond 10%-15% strain causes irreversibility because of its yielding. With displacements found to be between 1.5-2.5 mm for the Duran thermoformed aligners, the maximum load resistance was found to be nearly 200 N, which holds more importance than maximum load resistance of 584 N.

Because human biting and mastication is a continuous process, and the aligner is not supposed to be a one-time use product, its reversibility factor is critical. For safe and effective usage, an ideal aligner material should be stiff with a high yield strength and have a flat relaxation curve.[14] Thermoformed aligners exhibited a fairly flat curve, but because displacement and deformation were much higher than recovery. We suggest that it remains unsuitable during mastication and biting processes. Conversely, cured printed aligners were found to be stiff with higher-yielding and lower displacement with reversible deformation. Thus, cured printed aligners could be recommended to be used as a clear dental aligner under all conditions.

CONCLUSIONS

With the advent of 3D printing techniques, accurate orthodontic products and time-saving dentistry processes have become a regular practice among scientists, medical professionals, and industrialists. Clear dental aligners provide a long-term treatment process for aligning misaligned teeth of patients for their perfect esthetic smile. However, because the conventional process of thermoforming is time-consuming, an RP solution for directly printing a mechanically strong and biocompatible aligner could always be preferred. Dental LT resin is an approved Class IIa biocompatible material, and its mechanical strength is ensured with the postcuring conditions.

The experimental studies conducted have provided significant insight into the procedure of designing and printing of clear aligners that can be used by the patients. Clear findings are reported related to the effects of varying the curing temperatures and time durations that can provide sufficient mechanical strength to these clear dental aligners. Thermoformed aligner manufacturing is time-consuming and requires a high level of expertise. In addition, patients need to repeatedly remove and wear them during different periods and activities of eating, biting, and mastication. The primary reasons for thermoformed aligners demonstrating weaker compression strength and more extensive irreversible deformation are because of the fact these are thermoplastic-based materials.

In comparison, a high yielding, higher load resisting, and lower deforming clear dental aligners obtained from 3D printing could provide a superior alternative solution to this established practice. In this article, we have been able to successfully suggest the suitability of 3D printed and cured clear biocompatible dental aligners instead of thermoformed aligners because of their superior geometric accuracy, load resistance, yielding, stiffness, and lower deformation. Curing conditions can be further engineered to design customized strength clear dental aligners for suitability of patients based on their variable biting forces, which could further assist in reducing manufacturing costs.

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