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Review Article

Dentistry Section

An Update on 3D-printed Orthodontic Aligners

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ABSTRACT

Clear Aligner Treatment (CAT) is an orthodontic technique used to align teeth with removable and scarcely visible appliances. Conventionally, these are produced through the process of thermoforming. The inherent disadvantages of thermoforming include increased surface roughness leading to plaque accumulation, compromised biomechanics due to a reduction in force delivered and flexure of the aligner, and altered mechanical properties, such as increased opacity, water sorption, and hardness. Direct Three-dimensional (3D)-printed aligners, or Direct Printed Aligners (DPA), introduce a new frontier to aligner technology and are a recent addition to the ever-improving field of orthodontics. Through 3D printing, the various disadvantages of thermoformed aligners like surface roughness, extent and definition of aligner borders, undercuts, and differential thickness of the aligner can be controlled to enhance the accuracy of aligner fit with lesser reliance on attachments. 3D printing of aligners is more environmentally friendly since there is no subtractive process for thermoforming or post-processing of the TA. Various methods of 3D printing, such as selective laser melting, selective laser sintering, Stereolithography (SLA), and Digital Light Processing (DLP), can be applied to the printing of clear aligners. Challenges in printing primarily involve maintaining transparency and designing support during the printing process. The present review aimed to include a detailed description of all aspects of direct 3D-printed aligners.

Keywords: Clear aligner appliances, Orthodontic appliances, Printing, Removable, Three-dimensional

INTRODUCTION

The Clear Aligner Treatment (CAT) is an orthodontic technique that aims to align teeth through the use of removable and barely noticeable appliances [1]. Although conceptualised by Harold D. Kesling in 1945, the pivotal moment in the history of aligners occurred in 1998 with the introduction of Computer-aided Design (CAD)/ Computer-aided Manufacturing (CAM) technology by Zia Chishti and Kelsey Wirth [2]. Consumer awareness, and consequently the demand for aligner treatment, has surged in the last decade, particularly among adult patients, those with aesthetic concerns, and individuals with periodontal compromise [3]. The increased comfort of removable appliances during activities such as eating, brushing, and flossing provides patients with a more pleasant experience, potentially contributing to a higher preference for aligners over fixed appliances [4].

Drawbacks of Thermoformed Aligners (TA)

Thermoforming of the aligner sheet reduces both the delivered force and the flexure of the appliance [5]. Additionally, aligners permit the deposition of plaque on their surfaces, which is comparable to fixed appliances, partly due to surface roughness formed during the thermoforming process [6]. Ryu JH et al., reported increased opacity, water sorption, and hardness after thermoforming the tested material [7]. The irregularities in thickness also affect the fitting accuracy of the aligner [8]. This process might help bypass thermoforming errors and potentially exceed its quality [9]. Aligner setups typically include 0.25 mm of movement in each set. Studies indicate a discrepancy of 0.3 mm in some regions between the clear aligner and the model after thermoforming [10,11]. This discrepancy could imply that the planned tooth movement may not accurately translate to the treatment outcome.

Direct 3D-printed Aligners

Direct 3D printing of the aligner refers to an aligner that has been printed without the intermediate thermoforming process, thus negating the requirement of a physical model for aligner fabrication. Direct 3D printing offers the potential for improved precision, shorter supply chains and lead time, and lower costs [12,13]. Direct printing potentially might enable control of differential thickness and increase the versatility of aligner biomechanics and application [14]. Direct 3D printing of aligners has an edge over conventional methods since it allows digital design of the appliance borders, smooth edges, and digitally defined undercuts leading to a better fit. Since errors associated with making a cast and thermoforming process would be negated, direct printing would result in higher precision of fabricated aligners. The thickness of the aligner at varying regions of the aligner can also be customised, reducing the need for attachments [15]. DPA produces substantially fewer carbon emissions and less waste since there is no subtractive process of 3D printing a model for the thermoforming process nor post-processing of the TA [16].

3D Printing Technologies

Additive printing or 3D printing was first invented by Wilfried Vancraen in 1990 [17]. It has revolutionised many industries, from prosthodontics, restorative dentistry, and implantology to instrument manufacturing [18]. Among the various types of additive manufacturing or 3D printing, Vat photopolymerisation is most suited to 3D aligner printing.

During the process of photopolymerisation, a light-curable resin, i.e., a photopolymer, is stored in a Vat and treated with visible or Ultraviolet (UV) light from different types of sources depending on the type of Vat polymerisation, which initiates polymerisation to form a solid resin. Operating on this principle, multiple layers of resin are sequentially fabricated from a sliced Standard Tessellation Language (STL) file [19].

Vat photopolymerisation is of three types: SLA, DLP, and continuous DLP/continuous liquid interface production. The Liquid Crystal Display technique (LCD) is a subtype of DLP. The challenge of 3D printing an aligner lies within its design—an intricate shell structure—with the added demand for transparency. For instance, producing small patent features in clear materials using 3D printing might be difficult and may necessitate the use of biocompatible photoquenchers [20]. However, as seen in studies by Zinelis S and Panayi N and Venezia P et al., accuracy and the mechanical properties of a DPA rely not only on the type of printer but also on differences between different companies [21,22]. The salient features of the different types of 3D printing technologies for aligners are mentioned in [Table/Fig-1] [23-28].

3D printer	Minimum layer thickness	Initiator source	Mechanism of action	Other features
Stereolithography (SLA)	20 microns	Laser	Ultraviolet laser light scans the vat at a single point and polymerises the resin.	SLA produced models with the highest accuracy in comparison to DLP and an LCD printer [23]. Dental application includes onlays and dental implant placement guides are routinely produced by SLA [24].
Digital Light Processing (DLP)	30 microns	Projector	A projector directs light on selective areas of the resin layer using minuscule mirrors (digital micromirror devices) to project an image over the vat and resin is polymerised in layers.	DLP printing is faster and enables the construction of objects with a better resolution. DLP can produce objects with high clarity, thermal resistance, flexibility, springiness, water resistance, and durability [25,26]. DLP can only handle one material per print because the item is made from a single photopolymer solution in a vat [27,28]. Since in a DLP-type 3D printer, curing of the liquid photosensitive resin is by use of a high-definition projector as a light source, the resin may be polymerised thicker than the predetermined desired thickness. However, 3D printers based on DLP 3D printing technology can produce more accurate results than 3D printers based on LCD 3D printing technology in terms of printing dental models [26].
Continuous digital light processing/ Continuous liquid interface production	50 microns	LEDs and Oxygen	Polymerisation is inhibited at the interface of an oxygen permeable window at the bottom of the vat, through which UV LED light passes and polymerises the resin.	
Liquid Crystal Display technique (LCD)	25 microns	Liquid crystal display panel	Light from an LED panel irradiates to liquid resin through transparent areas, while the opaque areas of the LCD panel obstruct the light. The irradiated resin solidifies in a layer.	LCD printers {Selective Laser Sintering (SLS), L12, and KAR) tend to provide higher HM, EIT and nIT compared to DLP ones (MIC and PRO)} [21].

[Table/Fig-1]: Salient features of different types of Vat photopolymerisation technologies [23-28].

Resins used for Manufacture of Direct Print Aligners

A direct print aligner material must be compatible with 3D printing, aesthetic, durable, stable, biocompatible, cost-effective, and possess appropriate mechanical properties [14]. The resins currently used to print DPA have been described below in [Table/Fig-2] [27-36].

Designing Software

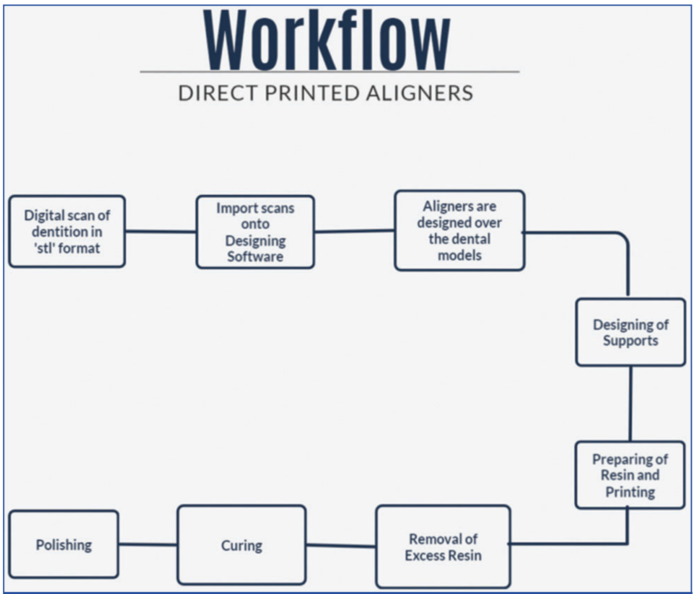
For designing aligners for direct printing, software options have been on the rise in recent years. Available software includes OnyxCeph™ (Image Instruments, Chemnitz, Germany), Maestro 3D (Ortho Studio v.5.2, AGE Solutions S.r.l., Pontedera, Italy), Deltaface (Coruo, Limoges, France), Lux Align by LuxCreo (USA), Blue Sky Plan by Blue Sky Bio (USA), and uLab Systems, Inc. (California, USA). Deltaface software permits location-specific differential thickening of the aligner to either facilitate or restrict tooth movement [37,38]. Workflow for Fabrication of Direct Print Aligners [Table/Fig-3].

Resins	Characteristics
E-Ortholign	It was introduced in February 2018 by EnvisionTEC Inc.
	It was proposed to be used as a "first aligner" i.e., an aesthetic retainer to be used until clear aligners were delivered for fine-tuning and minor corrections post-debonding of orthodontic case [27,28].
	Reported to be biocompatible, stable, flexible, and strong material for the direct 3D printing of clear aligners, however, no literature evidence was found to support these claims [27,28].
Dental Long Term Clear V1	Dental LT Clear V1 resin is an approved Class IIa biocompatible material i.e., long-term biocompatible resin with high fracture resistance according to EN-ISO 10993-1:2009/AC: 2010 (ISO Standard, 2009). Dental LT® is used for making retainers, functional appliances, and gnathological splints [29].
	The yield stress of Dental LT® Clear V1 resin DPA varies between 35.7 and 48.8 MPa with time, with older samples having the highest values. Deformation ranged between 3.9 and 4.3 mm, with older samples having lower values [30].
Accura 60®	It was introduced by 3D Systems, Rockhill, South Carolina.
	Clear resin with a postcure density of 1.17 g/cm^3 [31]. There is not much literature regarding mechanical properties of aligners 3D-printed with Accura [32].
Tera Harz TC-85	In September 2021, Graphy Inc, South Korea introduced Graphy, a DPA with shape memory, made from a photocurable resin.
	Another claim made by the company is that a rotation correction of 35 degrees is possible with the Graphy aligner [33].
	TC-85 is a urethane polymer which is aliphatic and contains vinyl esters [34].
	Although DLP-type 3D printers with a set thickness of 100 μm are generally used to print aligners with TC 85 material, it is compatible with other types of printers as well.
	The product has CE certification and is approved by the US Food and Drug Administration, Korea Food and Drug Administration (KFDA), and the European Commission (EC) [35].
	Manufacturers claim that TC-85 aligners are stable in water at upto 100°C for 1 to 2 minutes which may aid disinfection however, there is no literature to support this claim as yet. The aligners can therefore be dipped in warm water before wearing them to make them flex and allow a more comfortable and accurate fit. The aligner will regain its original printed shape and stiffness at 37°C, regardless of deformed along the dentition [35].
Dental Clear Aligner (DCA) Material	It was introduced by LuxCreo (USA) in April 2023. The resin is cleared for use for direct print aligners.
	It acquired FDA Class II 510 (k) clearance, which allows it to be marketed as a safe and effective device.
	It is described to be a tough, flexible, and accurate clear aligner material with high transparency without manual polishing, enabled by LuxCreo's Digital Polishing™ technology [36].
	Flexural strength: 38.45 MPa, Flexural Modulus: 1219 MPa, Ultimate Tensile Strength: 34.93 Mpa, Tensile Modulus: 990 MPa [36].

[Table/Fig-2]: Resins used in DPA [27-36].

Designing the Aligner

The aligner is designed virtually using drawing tools on the pre-treatment model. The software automates the subsequent sets of aligners depending on the desired tooth movements. While the aligner thickness generally ranges from 0.25 mm to 1.2 mm, the thickness of the aligner can be customised locally to favour or restrain tooth movement [37,39]. The trim line and border of the aligner may be customised to a high trim line or a low trim line depending on the amount of force required during the stage of treatment [39]. Another important factor to note is the management of undercuts in the aligner design. Black triangles or generalised spacing need to be blocked out, or aligner material in these spaces may act as a wedge and unintentionally open up spaces. Blocking out undercuts may also lead to loss of retention, and care needs to be exercised during this process [37]. Once designed, the



[Table/Fig-3]: Flowchart describing the workflow for production of Direct Printed Aligners (DPA).

aligners are exported to the printing system in Standard Tessellation Language (STL) format. Each printer has its software for printing with different tools and ways of support positioning. Supports should be designed and positioned where needed for accurate 3D printing.

Designing of Supports

The supports can be designed so that the aligner sets are printed vertically or horizontally. Horizontal positioning allows for faster printing; however, fewer sets can be printed in a cycle because the aligners would occupy more space and require more support. When positioned vertically, the aligner would require fewer supports and allow for more sets to be printed in each cycle, but printing would take more time and have a higher risk of errors due to an increase in the number of layers. The z-axis resolution for printing used is 100 μm, which ensures adequate printing accuracy [40].

Preparing the Resin and Printing

To reduce the risk of failure, the resin must be homogeneous and stirred while maintaining its temperature around 30°C [40].

Removal of Excess Resin

All resins before printing and UV curing are toxic and allergenic. Once printing is finished, the aligner is removed from the printer's platform and placed in a centrifugation machine with its internal parts facing outward to remove the excess uncured resin. Centrifugation should take approximately 5-6 minutes at 500-600 rpm. Manual resin removal can be done after centrifugation. Failure to eliminate resin from the aligner might lead to excessive curing of the resin and an ill-fit of the aligner due to the increased internal thickness of the aligner [40].

Curing

The supports can be retained after curing to prevent distortion of the shape of the aligner. The next step is to remove the supports and cure the aligner. In the Graphy system, direct print aligners are cured in a UV curing unit called Tera Harz (Graphy, Korea, Seoul). This curing unit is designated for printed aligners with high-intensity LEDs and is equipped with a nitrogen generator to ensure curing in the absence of oxygen, as oxygen inhibits complete polymerisation which could affect the mechanical properties of the aligner. Complete polymerisation enhances the transparency of the aligner while also producing a fully biocompatible aligner [40]. Although the same wavelength (405 nm) was used by all printers, other important parameters that determine the extent and depth of cure remain unknown [41].

Polishing

Following curing, the aligner is polished using rotating handpiece brushes, and a thin layer of resin may be applied to achieve a smoother surface, followed by 2-3 minutes of additional curing. Polishing is primarily done at the junctions of the supports and the aligner. Finally, the aligner is submerged in hot water for a few seconds to remove the remaining resin or other particles [40,42].

Properties of Direct Printed Aligners (DPA)

Aligners in clinical use are subjected to forces that are both short-term and long-term in nature. The properties of different DPAs as reported in the literature are described in [Table/Fig-4] [29,34,35,43-45].

Cytotoxicity

The 3D-printed materials are initially very toxic, and after polymerisation, the toxicity gradually reduces. Therefore, post-curing and processing,

Author	Groups studied	Results
1. Dimensional accuracy		
Jindal P et al., (2019) [29]	Group 1- Dental LT DPA Group 2-TA	DPA was geometrically more accurate with an average relative discrepancy in tooth height of 2.55% as compared to TA (4.41%).
Edelmann A et al., (2020) [43]	DPA of different thicknesses printed using Dental LT resin and Grey V4	The Dental LT aligners had larger deviations in thickness than Grey V4. The average thickness deviation from the input file for dental LT aligners of 0.500-mm, 0.750-mm, and 1.000-mm groups was 0.254±0.061 mm, 0.267±0.052 mm, and 0.274±0.034 mm, respectively. Average thickness deviations between the Grey V4 were 0.076±0.016 mm, 0.070±0.036 mm, and 0.080±0.017 mm respectively.
Koenig N et al., (2022) [44]	TC-85 DPA TA	DPA demonstrated greater accuracy and trueness than TA. The overall trueness represented by root mean square values ranged from 0.209±0.094 mm (Essix ACE^{TM}), 0.188±0.074 mm (Zendura FLX^{TM}) for the TA groups and 0.140±0.020 mm for the DPA.
Lee SY et al., (2021) [35]	TC-85 DPA TA	The average thickness of DPA was 12% higher than the set thickness of 0.5 mm.
2. Mechanical properties		
Jindal P et al., (2019) [29]	Dental LT DPA TA	DPA could resist a higher load (662 N) with low displacement (2.93 mm).
Hertan E et al., (2022) [45]	TC-85 DPA TA	In the vertical dimension DPA delivers more consistent and lower forces than TA. The median stabilised forces demonstrated by DPA in response to 0.10-0.30 mm displacements were in the range of 0.73 to 1.69 N; the median peak force demonstrated ranged from 2.44 to 3.87 N.
Lee SY et al., (2022) [35]	TC-85 DPA TA	Lee SY et al., also found that DPA displayed significantly more stress relaxation than TA. In comparison to TC-85, PETG had significantly greater yield strength and elastic modulus, but TC-85 had a much wider elastic range (4.65%) suggesting that each set of TC-85 aligners could achieve a larger range of tooth movement without lasting distortion [34]. The elastic moduli of PETG and TC-85 were 1479.54 MPa and 1186.40 MPa, respectively. Stiffness of PETG was significantly higher ($p<0.01$).

3. Thermomechanical properties		
Lee SY et al., (2022) [35]	TC-85 DPA TA	At 37°C the DPA demonstrated shape memory and recovered 90 percent of deformation within 10 minutes and 96 percent after 60 minutes.
Can E and Panayi N (2022) [34]	TC-85 DPA TAs (Invisalign and conventional TA)	The characteristics tested included elastic index (IT), indentation modulus (EIT), indentation relaxation (RIT) and Martens hardness (HM). The DPA tested in this study was more susceptible to intraoral wear than TA because the HM of the unused aligners was found to be close to or lower than that of the TA. The EIT of the unused DPA control group was found comparable to Invisalign® but higher than that reported for conventional TA. As a result, when compared to traditional TAs, DPA and Invisalign® appliances may offer larger counter forces under the same strain. In comparison to Invisalign® (40.0-40.8%) and traditional TAs (34.0-35.9%), the DPA's IT (29.4%), a measure of the material's brittleness, was found to be significantly lower, indicating a more ductile behavior. Yet, compared to Invisalign®, the relaxation index was found to be significantly higher, indicating a higher decay of orthodontic pressures.

[Table/Fig-4]: Dimensional accuracy, compressive and tensile strength and thermomechanical properties of 3D-printed aligners [29,34,35,43-45].
PETG: Polyethylene terephthalate glycol

as advised by the manufacturers of the resins, are essential for reducing the levels of toxicity [46]. DPA materials exhibited higher levels of cytotoxicity within the first 24 hours, which then slowly and progressively decreased. These results suggest that further investigation is required to evaluate the therapeutic efficacy of DPA and determine their qualities in an intra-oral environment [46]. Dental LT® resin and Accura 60 SLA have not yet received clearance for use in DPA. However, based on the E-screen assay, neither Dental LT nor Accura 60 demonstrated any oestrogenic effects. The study found Dental LT clear resin to be less cytotoxic than Accura 60 SLA [47]. According to Rogers HB et al., exposure to Dental LT® caused a severe phenotype that led to rapid gamete degeneration before meiosis resumed and may have a negative effect on reproductive health. The polycarbonate-based material Accura 60® demonstrated the highest level of cytotoxicity on day 1, and variations in intragroup cell viability for Accura 60® were statistically significant. This is due to the increased BPA leaching associated with polycarbonate. Animal studies and in vivo studies are required to confirm the effect of DLT on reproductive health [48].

CONCLUSION(S)

Direct Printed Aligners (DPAs) are the future in the field of orthodontics. With the right setup and a digital workflow in place, a DPA can quickly replace its conventional counterpart. The mechanical properties of DPAs are, to a large extent, dependent on the 3D printer used, and thus, differences in their clinical efficacy are anticipated. Forces delivered by DPAs in the vertical dimension are more consistent and of lower magnitude. However, in order to safely apply the use of 3D aligners to everyday clinical practice, to widen the scope of its application, and to draw decisive conclusions on the effectiveness of direct-printed aligners, further studies, possibly Randomised Control Trails (RCTs), should be conducted.

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