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The new additive era of orthodontics: 3D-printed aligners and shape memory polymers—the latest trend—and their environmental implications

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Abstract

The era of printed aligners has just began in the orthodontic field. Orthodontists have become more interested in 3D-printed in-office aligners. Treatment due to this technology can become faster and more efficient. Advantages highlighted by newly introduced materials for manufacturing processes of 3D aligners present the possibility of overcoming limitations faced by thermoformed aligners, making them a potential replacement of thermoformed aligner. Advances in aligner material, especially shape memory polymers, have the potential to bring about radical transformations in the clinical applications of clear aligner therapy. Safety and cytotoxicity of printable resins along with its mechanical properties must be scientifically studied extensively before it is cleared for clinical use. In addition, with the increased use of aligners, awareness of the environmental burden of plastic waste should be emphasized. Attention should be directed into the development of recyclable materials for aligners along with establishing clear recycling guidelines and patient education programs on proper recycling methods. With the introduction of Graphy's clear biocompatible photocurable resin, which is equipped with a shape–memory function and is printed in an environmental friendly way by reducing carbon emissions. Direct 3D printing represents the future of clear aligner therapy, and more studies to test these new technologies and materials are required.

Keywords:

3D printing, aligners, polymers, shape memory, thermoformed

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Introduction

The need for aligners in orthodontics stemmed from the increasing demand for esthetic and invisible orthodontic treatment. Trial and error has been going on for almost 80 years, starting from the production of the tooth positioner by Dr. Kesling in 1945.[1]

The tooth positioner was invented to correct minor irregularities that remained after the orthodontic bracket was removed. The positioner was made of rubber material on a dental setup and was worn full time to produce effective tooth movement. Subsequently, Nahoum[2] introduced a vacuum-formed dental contour appliance. The appliance comprised two blocks (upper and lower dental arches) and was used mainly for anterior teeth. Later, in 1993, the Essix appliance was introduced by JJ Sheridan.[3] The appliance was used as an orthodontic retainer. He combined the Essix retainer with an interproximal reduction to correct minor orthodontic problems. Interproximal reduction is now widely acclaimed as a technique that is commonly used in aligner treatment and was first introduced by ML Ballard in 1944.[4]

It was not until 1997 when Zia Chishti and Kelsey came up with an aligner system

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called Invisalign from Align Technology, Santa Clara, Calif, USA, where they combined the use of plastic foils (Essix) with the concept of tooth positioner.[5] Their method produced the first orthodontic appliance fabricated using transparent and thermoplastic polymeric materials with the aid of modern CAD/CAM technology. With this invention, the original method of manual fabrication of clear aligners was eliminated, and mass production workflow was created. Currently, the early manual methods are no longer used for aligner fabrication, and the current digital fabrication method uses CAD/CAM technology.[6] Nowadays, more companies, such as Sure Smile Aligners (Charlotte, North Carolina, USA), Clear Image Aligners™ (Orange, California, USA), Orthocaps® (Hamm, Germany), Clear Aligner® (Iserlohn, Germany), Nuvola® (Rome, Italy) etc., are present in the market, making aligners a mainstream treatment modality that is here to stay.[6]

All companies involved in aligner production now use three main technologies: computer-aided design (CAD) software and 3D printers and scanners. Aligners were initially manufactured on multiple plaster models where the teeth had to be segmented and rearranged in the dental model with the aid of wax to hold them to their bases. The concept of plaster teeth segmentation using orthodontic CAD software and 3D printers to produce multiple dental models converted the analog aligner production to a digital one. This eliminated the need to pour multiple plaster models, cut and reposition teeth using wax, and then vacuum-form aligners. The aligner production process has now become easier, with teeth segmentation and repositioning happening within the software, enabling ample production of virtual dental models ready to be printed.[7]

The essence of aligner treatment is the type of material used. For thermoformed aligners, their plastic foil properties are altered during manufacturing and transformation to aligners by multiple factors, including intraoral conditions such as saliva-induced alterations and temperature changes in the mouth.[8]

Several 3D printers, thermoforming machines, and plastic foils with different specifications and capabilities are present in the market. With extensive digital technological advancements, 3D printers have evolved parallelly, allowing the printing of various resin materials.[9]

With 3D printers becoming more advanced, cheaper, and more compact, the concept of in-office aligner production gained popularity.

The ability to print aligners directly without the need for a dental model printing step could be the next big step in the aligner treatment revolution. This major achievement was made by Graphy (Seoul, Korea), a Korean-based company that introduced in 2019 a resin material called TC-85DAC as the first aligner resin for direct aligner printing.

The era of printed aligners has just begun in the orthodontic field, so evidence-based studies are limited. Studies on material mechanical properties, surface roughness, cytotoxicity, estrogenicity, leaching, and fitting accuracy are required. Furthermore, comparison of printed aligners with thermoformed ones has to be studied extensively.

3D-printed aligners could be the next paradigm shift in orthodontic treatment. This article aims to review the manufacturing processes of 3D aligners; explore materials with different properties introduced in the market; discuss their advantages, disadvantages, and limitations; and present evidence-based studies on clinical effectiveness. This article also intends to highlight the potential cytotoxicity risk of printable resins and the hazards associated with the uncontrolled use of nonrecyclable materials as well as provide future recommendations and solutions.

3D-Printed Aligner Materials and Manufacturing Processes

Multiple materials are used for the 3D printing of appliances in dentistry. Materials currently used for 3D printing in orthodontics include acrylonitrile–butadiene–styrene plastic, stereolithography materials (epoxy resins), polylactic acid, polyamide (nylon), glass-filled polyamide, silver, steel, titanium, photopolymers, wax, and polycarbonate.[10]

Various 3D printing methods, such as fused filament fabrication, selective laser sintering or melting, stereolithography apparatus, multijet photocured polymer process, HP multijet fusion technology or continuous liquid interface production technology, and powder binder printing, may be used for the direct printing of aligners. However, 3D printing via photopolymerization from clear resins seems to be a promising option as the specific characteristics and requirements of the material properties are more appropriate.[11,12] Although diverse materials are present in the market, not one 3D printable material currently available commercially meets the standards of biocompatibility, translucency, and appropriate mechanical properties.[9,13] The only exception is Tera Harz TC-85 (Graphy, Seoul, South Korea), which according to the company website has been approved by multiple international agencies, including the Korea Food and Drug Administration, European Commission, and U.S. Food and Drug Administration.[14]

The 3D printing of an orthodontic aligner essentially starts with the same initial steps as those for thermoformed aligners. First, an intraoral scan of the patient is obtained and imported into the orthodontic CAD software, where the initial malocclusion is viewed, attachment type and placement are planned, and aligner thickness is adjusted. Once the aligner is fully planned, the design is exported in the "Standard Tessellation Language" format. The subsequent step of printing the aligner depends on the 3D printer used as each printer uses a different technology, software, and methods of support positioning. Supports are very important for precise and accurate printing. The speed of printing differs between horizontally and vertically positioned 3D-printed aligners. Vertically positioned aligners have fewer supports and are printed more slowly, whereas horizontally positioned aligners have the of more support along with higher printing speed owing to fewer layers that must be printed [Figure 1]. To ensure adequate printing accuracy, the z-axis resolution used for printing is 100 µmH. The printing resin used should be homogenous; hence, stirring for a few minutes is essential. The controlled resin temperature should be approximately 30°C to avoid the possibility of failure. Once printing is completed, the 3rd step involves removing the aligner from the platform of the printer and placing it in a centrifugation machine with its internal parts facing the outside to remove excess uncured resin. The centrifugation time is approximately 5–6 min at a speed of 500–600 rpm. In the 4th step, the supports are removed and the aligner is cured in a dedicated UV curing unit. The unit is called Tera Harz (Graphy, Korea, Seoul). The curing is done according to manufacturer recommendations for printed aligners with high-intensity LEDs and nitrogen generators to ensure curing without the presence of oxygen. The key factor is that the presence of oxygen inhibits complete polymerization, which affects the mechanical properties of the aligner.[15] Upon complete polymerization, the aligner becomes fully biocompatible, and its color changes from yellow to transparent. After curing, the 5th step involves polishing the aligner in needed areas, for instance, where the supports used to be. Finally, the aligner is immersed in hot water for a few seconds, removing any possible residue of substances that could create problems for the patient.[7]

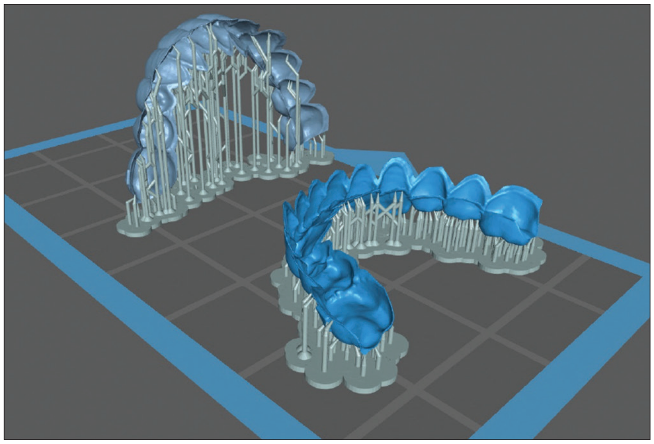


Figure 1: Virtual positioning of the aligner in vertical and horizontal orientations.7

Printed aligners are the new big step in aligner evolution. Every company in the market is eager to produce and sell the next thing without adequate research on its effectiveness or safety. The real responsibility falls on orthodontists to properly evaluate and produce scientific evidence for this new treatment modality.

Advantages of 3D-Printed Aligners

A few studies have been conducted, which have highlighted some of the advantages of 3D-printed aligners. A summary of these advantages includes the following:

1. **Skipping the dental model printing step:** Directly printing the aligner decreases the overall manufacturing process, which leads to faster workflow and quicker aligner delivery to the patient [Figure 2].
2. **The ability to have a small digital lab in the orthodontic office:** Removing the dental model printing step, thermoforming step, and aligner removal from the model and trimming step eliminates the need for a large working space to store multiple models and machines. The need for a handpiece to remove the aligner from the dental model is also eliminated, making the aligner production a faster, smoother process. As the printed aligners do not go through those time-consuming steps, this saves time for the orthodontist and creates an easier and cleaner procedure.
3. **Dustless, plasterless, and cleaner lab environment:** The thermoformed aligner should be cleaned and polished at its extremities, creating a smooth border. All these processes generate a large amount of dust and small particles, which creates a dirty, polluted work environment that is hazardous to the working personnel. All these processes are eliminated in case of 3D-printed aligners, resulting in a cleaner, healthier, and dust-free office, which is advantageous to both lab technicians and users of the office space.
4. **The ability to produce multiple aligners at the same time:** As the aligners are directly designed to be printed in the software, multiple aligners can be printed simultaneously without affecting their accuracy or quality, making en-mass aligner production possible.
5. **Relieving the environment from pollution:** Millions of nonrecyclable dental models are produced with

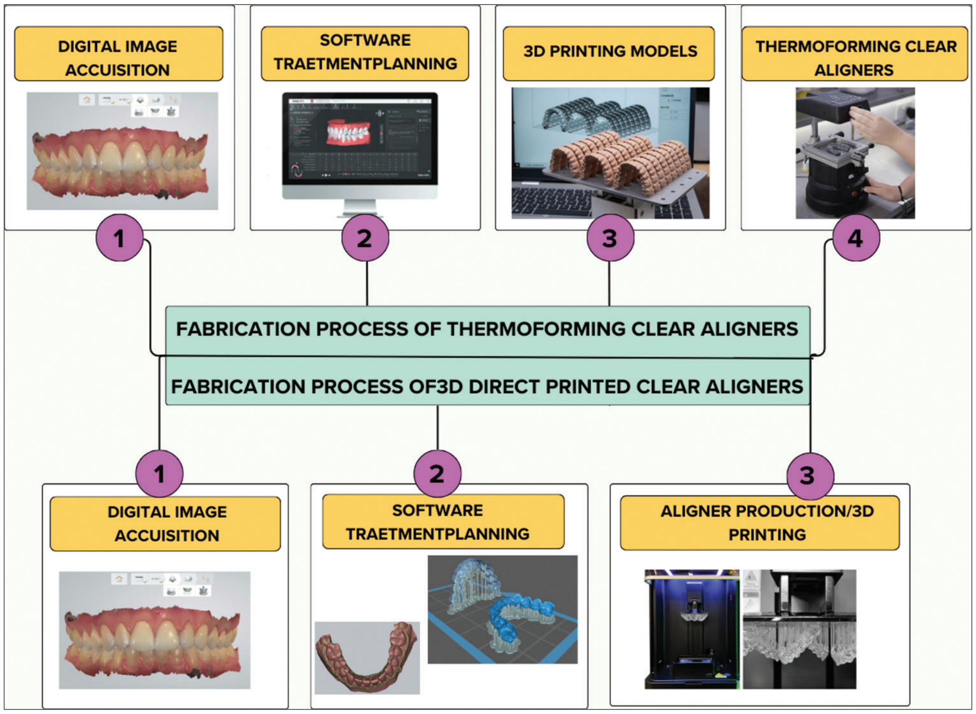


Figure 2: Workflow of clear aligner fabrication

every thermoformed aligner, thereby polluting the environment. Eliminating dental models and directly printing the aligners help reduce waste and protect the environment. In the future, the development of a recyclable material to print the aligner would be an enormous contribution to saving the planet.

6. **Fabrication of aligners with higher precision:** Small teeth, such as upper lateral incisors and round premolars, and the lack of an undercut that permits grip are the most common reasons for problems associated with the fitting accuracy of aligners. The inability to grip the teeth would lead to unsatisfactory tooth movement. The nature of 3D-printed aligners allows higher precision, which leads to better fitting and higher effectiveness.
7. **Higher control over tooth movement:** The thickness of thermoformed aligner is reduced after the thermoforming procedure. An advantage of printed aligners is the ability to print aligners with uniform thickness, which ensures the delivery of uniform forces to all teeth. Another advantage is the ability to have customized thickness as extra thickness can be added in specific areas, enabling better control and correction of malocclusion.
8. **Enhanced esthetics:** With the previously mentioned customizable thickness, better aligner fitting, and higher precision of tooth movement, the need for multiple tooth attachment and auxiliary elements is reduced, and the overall esthetics of aligner treatment is improved.

Physical and Mechanical Properties of 3D-Printed Aligners

With every introduction of a new material or appliance, it is essential to emphasize the importance of *in vitro* and *in vivo* research before the material is released for clinical use on patients. Just as any other orthodontic appliance, directly printed aligners should be tested extensively before this technology replaces the conventional thermoformed aligners. In recent years, a few studies investigating the properties of printed aligners have been conducted. The first study, which was performed by Eliades *et al.*, examined printed aligners after 1 week of intraoral use. Their result indicated that the mechanical properties (hardness, indentation modulus, and elastic index) of the printed aligner were almost intact. Another study by the same research group examined Invisalign aligners, showing a decrease in mechanical properties by almost 50% after 1 week of wearing. However, it is important to mention that the aligners were printed using an old protocol that uses UV curing units in the presence of oxygen, which is a substance that is well known to prevent complete polymerization.[16,17] Another study was by Koenig *et al.*, who evaluated the fitting accuracy of two thermoformed aligners and one 3D-printed aligner. The results showed better accuracy for the 3D-printed aligners; these were found to have decreased yield strength and elastic moduli compared with conventional polyethylene terephthalate glycol (PETG). The initial force for stress relaxation under high temperature (80°C) was 18N, but for 1% elongation, the residual static force decreased to approximately 1N. A finding was that for repeated loads, stress relaxation decreased and residual static force increased.[14,18] In the clinical setting, an optimal orthodontic force of 0.098–1.18 N is recommended depending on the required teeth movement.[19] Excessive force may lead to adverse effects on the teeth and surrounding tissues, including root resorption. Ren *et al*.[20] stated that if a light, constant force is applied to the teeth, a physiological movement can be induced. To measure the forces delivered by printed aligners, Hertan *et al*.[21] measured vertically delivered forces by printed aligners and the force profile of thermoformed aligners. Forces from vertical displacements ranged from 0.10 mm to 0.30 mm. Intraorally, forces delivered in the vertical dimension by printed aligners were more consistent and of lower magnitude than those of thermoformed aligners. The median stabilized forces exerted by thermoformed aligners in response to 0.10–0.30 mm displacements ranged from 4.60 N to 15.30 N. Meanwhile, the median stabilized forces exerted by 3D-printed aligners ranged from 0.73 N to 1.69 N. This result suggests that direct-printed aligners may demonstrate an improved ability to deliver forces within the accepted range of optimum forces for tooth movement.[20] The thickness of directly printed aligners is customizable; a uniform thickness is a major advantage of printed aligners, allowing equal force delivery to all teeth. Koenig *et al*.[18] observed that printed aligners have a thickness of 12%, whereas thermoformed aligners have a significantly lower thickness. Another major factor that affects the thickness of thermoformed aligners is the thermoforming procedure. A study by Bucci *et al*.[22] indicated that thermoformed aligners have significantly less thickness after the thermoforming procedure compared with the original thickness of the plastic foil. Advances in CAD software enable the design of complex geometric shapes and objects that can be printed. Currently, multiple orthodontic CAD aligner software, i.e., Deltaface (Coruo, Limoges, France), provides the option of variable thickness in areas where the operator desires to add material thickness. For instance, in the case of incisor labial movement, the software automatically increases the aligner thickness on the palatal side of the incisor. On the contrary, in the case of lateral incisor derotation, the aligner adds extra thickness to the distal lingual and mesial labial parts of the tooth. However, both *in vitro* and *in vivo* studies on the effectiveness of the increased aligner thickness should be conducted. Zinelis *et al*.[23] studied the effect of using different 3D printers to print the same 3D aligner file and proved that the mechanical properties of directly printed aligners printed with different 3D printers were not the same. This is important in proving that printing is not a consistent and stable procedure but depends on the printer being used. Another property that was investigated is surface roughness. A study comparing printed aligners with Invisalign appliances demonstrated the higher surface roughness of the former.[24] This could be attributed to any of the steps during the manufacturing process, designing, printing, or incomplete UV curing. For instance, positioning the aligner on the printer platform either vertically (more layers) or horizontally (fewer layers) creates a difference in surface roughness. Intraoral conditions also affect various aligner properties and cause "intraoral aging," which is a process induced by the harsh oral environment. This process could also increase the surface roughness of printed aligners and lead to discoloration or pigmentation, accumulation of plaque, and increased material leaching.[25,26]

Cytotoxicity and Estrogenicity of 3D-Printed Aligners

As an intraoral appliance material, thermoplastic polymers are expected to be safe and not leach out any potential toxins that may cause adverse local or systemic reactions. Furthermore, the material should not be carcinogenic in nature and not produce any developmental defects.[27] There is an ongoing debate about the possibility of potentially toxic effects associated with the use of invisible aligners. Furthermore, the rapid influx of multiple commercial aligner systems calls for the continued need to test the cytotoxicity of orthodontic clear aligners produced by various manufacturers.[28] Several studies have been performed to investigate the potential cytotoxicity of thermoplastic materials used to fabricate various commercial clear aligner brands. The materials tested in the study exhibited varying levels of toxicity[29] [Table 1].[30] Another undesirable effect on the human body is estrogenicity, which is the action of endocrine-disrupting chemicals that mimic, block, or interfere with hormones in the body's endocrine system. A study by Eliades *et al*.[31] evaluated the potential release of bisphenol-A from the thermoplastic material used to fabricate Invisalign aligners and reported the absence of any estrogenic or toxic effects of the aligner material on human gingival fibroblasts.

With the recent introduction of 3D-printed resins in the orthodontic field, there is an urgent need for high-quality research on the adverse effects of 3D-printed materials on human cells. These materials are highly toxic before 3D printing, but the toxicity decreases gradually postpolymerization. Postcuring and processing are essential for eliminating the toxicity as recommended for the manufacture of 3D-printed materials.[32] Limited studies have been conducted to determine the cytotoxicity and estrogenicity of 3D-printed resins and their products [Table 2].[30] A study by Harris *et al*. investigated the cytotoxicity and estrogenicity of directly printed aligners by evaluating their biological and behavioral effects.

Table 1: A summary of cell viability (cytotoxicity) at each time point (7 or 14 days) or solution concentrations (5%, 10%, and 20% vol/vol) of different thermoformed clear aligner materials

Brand	Category	Composition	Cell viability (%)	Days or final solution concentration (% v/v)	Cytotoxicity
Duran (Scheu-Dental GmbH, Iserlohn, Germany)	Thermoformed	Polyethylen terephthalate glycol (PETG)	84.6±4.02	14 days	Slight
Biolon (Dreve Dentamid GmbH, Unna, Germany)	Thermoformed	Polyethylene terephthalate glycol (PETG)	64.6±3.31	14 days	Slight
Zendura (Bay Materials LLC, Fremont, CA, USA)	Thermoformed	Polyurethane resin (PU)	74.4±2.34	14 days	Slight
SmartTrack™ (Align Tech, San Jose, CA, USA)	Thermoformed	Multilayer aromatic thermoplastic polyurethane/copolyester	78.8±6.35	14 days	Slight
SmartTrack™ (Align Tech, San Jose, CA, USA)	Thermoformed	Multilayer aromatic thermoplastic polyurethane/copolyester	94.07±3.00	7 days	No
SmartTrack™ (Align Tech, San Jose, CA, USA)	Thermoformed	Polyurethane	82.6±13.6	5% 7	Slight
			60.3±8.8	10% 2	Slight
			54.5±23.1	20% h	Moderate
Eon (Eon Holding, Amman, JO)	Thermoformed	Polyurethane resin (PU)	85.1±18.3	5%	Slight
			54.8±16.8	10%	Moderate
			60.4±20.7	20%	Slight
Suresmile (Dentsply-Sirona, Charlotte, NC, USA)	Thermoformed	Polyurethane resin (PU)	85.4±16.4	5%	Slight
			70.7±15.8	10%	Slight
			56.8±11.3	20%	Moderate
Clarity (3 M, St Paul, MN, USA)	Thermoformed	Polyurethane resin (PU)	89.3±15.0	5%	Slight
			72.9±21.1	10%	Slight
			71.8±15.4	20%	Slight

Cytotoxicity: No, cell viability >90%; Slight, cell viability 60%–90%; Moderate, cell viability 30%–59%; Severe, cell viability <30%

Table 2: A summary of cell viability (cytotoxicity) at each time point (7 or 14 days) or solution concentrations (5%, 10%, and 20% vol/vol) of different 3D clear aligner materials

Brand	Category	Composition	Cell viability (%)	Days or final solution concentration (% v/v)	Cytotoxicity
E-Guard (EnvisionTEC, Rockhill, SC, USA)	3D printed	Photopolymer	75.06±8.98	7 days	Slight
Dental LT (Formlabsinc)	3D printed	Photopolymer	77.74±3.22	7 days	Slight
TC85A (Graphy, Seoul, South Korea)	3D printed	Photopolymerizable polyurethane	97.6±14.6	5% 4	No
			98.3±15.9	10% 8	No
			92.0±13.0	20% h	No

Cytotoxicity: No, cell viability >90%; Slight, cell viability 60%–90%; Moderate, cell viability 30%–59%; Severe, cell viability <30%

Aligners were immersed in sterile deionized water for 14 days. Cytotoxicity and estrogenicity of the released factors on human gingival fibroblasts and estrogen-sensitive MCF-7 and estrogen-insensitive MDA-MB-231 breast cancer cell lines were assessed using the MTT (3-[4,5-dimethylthiazol-2-yl]-2,5-diphenyltetrazolium bromide) assay. 17β-Estradiol and bisphenol-A were used as positive controls. The results indicated that if at all any factors were released during the 14-day aging of 3D-printed aligners in water, these were not cytotoxic for human gingival fibroblasts and did not affect their intracellular reactive oxygen species levels. Moreover, these putative eluates did not exert any estrogenic effects based on an E-screen assay.[33]

Aligner treatment requires a constant change of trays, thus exposing the same individual to additive sources of the material regularly. In cases where the aligner is not tested for material leaching or when the aligner is releasing chemical substances, the effect on the patient could be dangerous. A systematic review of the biological effects of 3D resins used in clear aligners and retainers also revealed that direct aligners might be more cytotoxic and genotoxic than thermoplastic aligners, particularly those that have not been subjected to a final surface treatment.[34] Most published articles are based on *in vitro* studies. Although these are valid and important, *in vivo* and clinical studies must be performed to evaluate the 3D-printed aligners clinically, determining the presence and levels of cytotoxic monomers released and their effects on patients. With limited data available on their biological effects, orthodontists must be careful and selective when using these aligners in simple cases with short treatment times, especially given the possible implications for the young patient's fertility.

Environmental concerns of 3D-printed aligners

Clear aligners are in increased demand by orthodontic patients owing to their superior esthetics and comfort as well as aggressive commercial marketing. However, an important point that needs to be emphasized is the increase in plastic waste that gets dumped into the ocean, affecting the health of marine life and eventually causing climate change. The plastic burden on the environment related to clear aligners has become a major concern, with the Economic World Forum estimating that an entire truckload of plastic trash is dumped into the ocean every single minute.[35] Every patient is typically provided multiple plastic aligners, each of which generally ends up as trash within a week, with no hope of recycling. Clear plastic aligners are mostly composed of polyethylene terephthalate, PETG, or TPU thermoplastic polyurethane, apart from other petroleum-based polymers that release various nanoplastics.[36] These plastics impact not only the environment but also our overall health. Deleterious health effects due to the presence of plastics in our food are serious. Studies estimate that there are 93,000–236,000 tons of microplastics in the world's oceans, with traces of microplastics in most of the seafood that we consume. In addition, the food or drink served in plastic containers may contain traces of nanoplastics that directly enter our gut. These nanoplastics can penetrate cell membranes, causing cell destruction or mutation.[36] Another possible risk is cross-infection dissemination as the aligners are used intraorally and disposed in common trash.[37] Solving this problem needs the cooperation of all parties involved in clear aligner therapy, mainly the aligner manufacturer, clinician, and patient. Aligner companies need to invest in the research and development of alternative materials for clear aligner fabrication, increase treatment accuracy, reduce the number of aligners needed for each treatment, and provide guidelines to the clinician or patient about ways to recycle used aligners. Certain initiatives have been taken to make patients aware of proper aligner disposal and recycling methods. "Impress," a Europe-based orthodontic clinic, launched an aligner recycling initiative, promoting sustainability and encouraging all patients to recycle their aligners.[38] Another initiative by Spotlight Oral Care in the United States has launched the Spotlight Oral Care Aligner Free Recycling Program. This program encourages patients to deposit their clear aligner packaging material, clear aligners, and aligner cases from all clear aligner brands, which in turn would be sent over to TerraCycle, a global organization, to be recycled.[39] The recently introduced shape memory polymers (SMPs) can reduce the number of aligners used per orthodontic treatment.

A typodont study by Elshazly *et al*.[40] demonstrated that SMPs could enable the fabrication of a single shape-changing aligner that could replace up to three successive conventional aligners. Another promising resin is Graphy's 3D printing resin. The manufacturer claimed it to be equipped with a shape memory function, and according to Graphy, the aligners can be produced using any 3D printer. They also stated that the printing process reduces carbon emissions and produces less refuse as no cutting is needed and is beneficial for the environment.[14,15] An ideal evolution of aligner therapy could be the use of recycled materials in 3D printers to enhance the sustainability of 3D printing technology. Advancements in bioactive materials for the practical application of bioactive surface coating on biodegradable thermoplastic materials or direct 3D-printed materials in treating malocclusions should be encouraged, and more research is warranted.

Emerging Trend: SMPs

The efficiency of aligner therapy can be substantially improved with constant developments in aligner material properties. Materials that can respond appropriately to various types of external stimuli, such as electrical, thermal, or magnetic impulses, and generate a predictable and repeatable response are known as smart materials or stimuli-responsive materials.[41] Shape memory materials are a category of smart materials that can display an alteration in their macroscopic shape upon the application of an appropriate stimulus. Upon receiving a stimulus, the material retains this temporary shape stably and reverts to its original shape on the reapplication of another stimulus.[42,43] SMPs, alternatively known as actively moving polymers, constitute a subcategory of shape memory materials.[43,44] The mechanism of SMPs relies on two crucial traits: the presence of a stable polymer network that determines the original shape of the material and the presence of a reversible polymer network that allows the material to be transformed to an altered or temporary shape.[45,46] The properties of SMPs include low density, considerable elastic deformation, and high chemical stability, and these materials can be programmed to display adjustable physical properties. SMPs are relatively transparent, making them well-suited as clear aligner materials. Shape memory polyurethane resins comprise both polar and nonpolar molecules that can be distinguished into microdomains of hard and soft segments. This combination allows the material to achieve both high strength (from the hard segments) and high toughness (from the soft segments), which can enhance the durability of the orthodontic aligner.[47,48] In addition, the polyurethane resin is considered resistant to stain depositions, which enables the aligner to remain clear in the intraoral environment for a longer duration [Figure 3]. A study by Elshazly *et al*.[40] concluded that aligners made of SMPs could be the material of choice for orthodontic clear aligner therapy in the future.

Graphy

In September 2021, the South Korean manufacturer Graphy presented the first direct 3D-printed aligner produced from the printing resin manufactured by the company. This resin is based on a patented technology called Tera Harz TC-35 [Figure 4], which is a clear biocompatible photocurable resin. The company claims it to be equipped with a shape–memory function that, according to Graphy, is the only one available in the market currently. Another feature is the ability of the aligner to rotate teeth by up to 35° owing to its precise fit [Figure 5],[49] which other aligners may struggle to achieve.[15] In addition, Graphy claims that the aligners can be thoroughly disinfected. Most companies do not recommend manual brushing of aligners as they may get scratched and bacteria may enter, which makes additional cleaning agents necessary. However, Graphy does include brushing in its recommendations. The material remains stable in hot water of up to 100°C for 1–2 min, which helps in disinfection. The protocol of designing and printing has been changed several times by the company to perfect the printing outcome. One of the most important steps in 3D aligner printing is UV curing. 3D printing is the process of manufacturing a 3D object via polymerization, giving the object its shape and properties. 3D printing is also responsible for the objects' internal UV curing. However, 3D printing is not sufficient to print a 3D object successfully. Many UV curing units with different properties are available in the market. At first, Graphy released a UV curing unit called Cure M, which was solely dedicated to the curing of aligners. Multiple alterations were made to the curing protocol. In the initial trials, the presence of oxygen inhibited complete polymerization.[15] In an effort to idealize the printing outcome, a new UV curing unit called Tera Harz was released [Figure 6], which is based on a complex technology where a nitrogen generator linked to a high-pressure air connection compresses the gas into the curing chamber of the unit. A curing time of 14 min in the presence of nitrogen disperses oxygen and creates an oxygen-free environment inside the curing chamber. Graphy claims that this new protocol improves the mechanical properties and transparency of the aligner. However, these hypotheses should be scientifically proven via research.

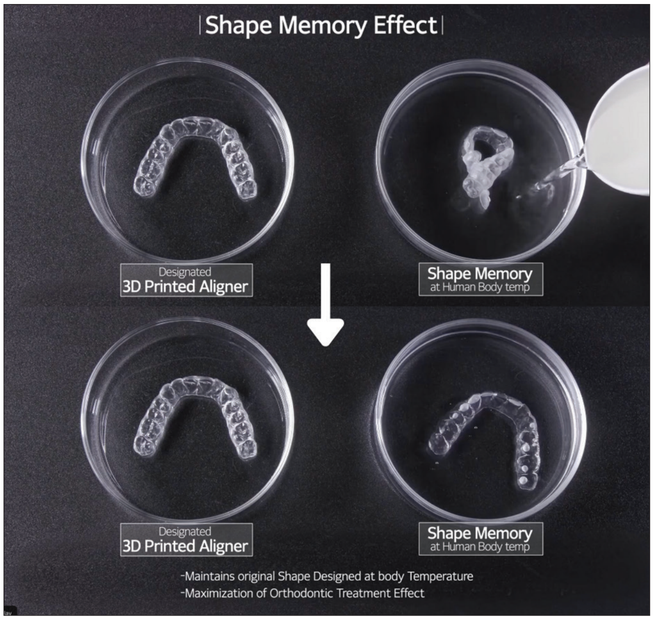
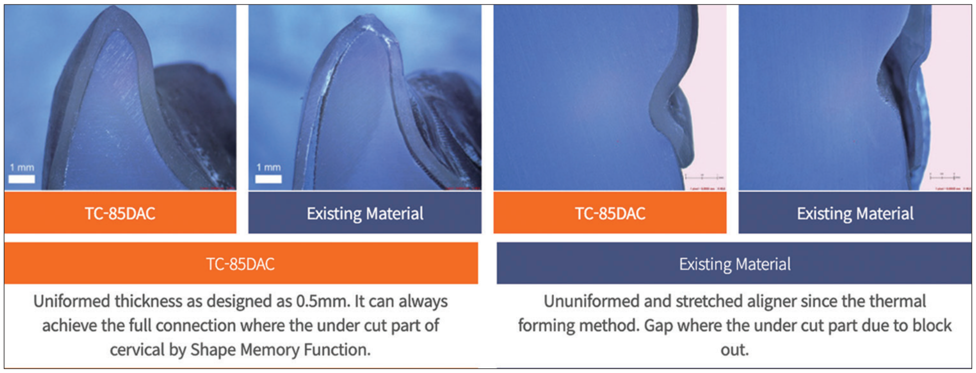


Figure 3: Ability of shape memory aligners to regain their shape under intraoral conditions

Figure 4: Tera Harz TC-35



Uniformed thickness as designed as 0.5mm. It can always achieve the full connection where the under cut part of cervical by Shape Memory Function.

Ununiformed and stretched aligner since the thermal forming method. Gap where the under cut part due to block out.

Figure 5: Thickness comparison between Graphy's aligner and thermoforming aligner[49]

Figure 6: Tera Harz UV curing with a nitrogen generator that allows oxygen-free polymerization

Conclusion

With the rapid emergence of new direct 3D-printed aligner materials and the increasing cost of commercial clear aligners, orthodontists have become more interested in 3D-printed in-office aligners. Clear aligner therapy, owing to this technology, can become more efficient, faster, easier, and pose fewer problems to the patient.

This comprehensive review has attempted to cover the entire gamut of manufacturing processes of 3D aligners, materials currently used for the fabrication of such aligners, and elucidate the mechanical, chemical, thermal, and biological characteristics that are crucial in determining their clinical performance in the oral environment. This paper has also endeavored to highlight the advantages, disadvantages, and limitations of the biomechanics of 3D-printed resins and aligners, specifically linked to the properties of the aligner material itself.

Advances in aligner materials, especially SMPs, have the potential to radically transform the clinical applications of clear aligner therapy, reducing the biomechanical constraints in comparison with conventional fixed orthodontic appliances. 3D-printed aligners, with the advantages mentioned, are sufficient to encourage companies to produce new aligner resins and improve them to attain the required efficacy, making them a better alternative for the existing thermoformed aligners.

The safety and cytotoxicity of printable resins warrant special attention, and the clinical performance of 3D-printed aligners must be scientifically studied and evaluated to compare the obtained data with those of thermoformed aligners. Orthodontics has definitely entered a new additive era. Increased awareness of environmental issues and implications among aligner manufacturers, prescribing orthodontists, and users is essential so that our climate change goals are aligned with ensuring sustainability. Biodegradable thermoplastics and 3D direct-printed materials could also be a promising solution.

Data availability statement

No new data were generated or analyzed in this study.

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Conflicts of interest

There are no conflicts of interest.

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