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# Evolving Technologies in Orthodontics: The Example of the Direct 3D Printed Aligners: A Literature Review

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## Abstract

Orthodontics has witnessed significant advancements in recent decades. One such innovation is the advent of three dimensional (3D) printed aligners, which offer a promising alternative to traditional wire-and-bracket appliances and conventional ready-made or in-house aligners. The aim of this literature review was to critically appraise the available data and information in the literature about the direct printed aligner, its raw material and to compare it with the traditional thermoformed aligners. The research question of the study was what the proprieties are, the mechanical behaviors, the hazards of the resin used, and the aligners fabricated from the direct 3D-printed process compared to the traditional in-office or aligners made by companies. The answers were elaborated according to the PICO method: Problem: the different properties and related challenges of the use of the new materials in orthodontics, Intervention: the new resins used in and aligners produced by direct 3D-printing, Comparison: aligners produced by companies and made in-office with thermoforming, Outcome; Are the new materials used and the process of fabrication advantageous compared to the thermoformed aligners? The analysis of the studied literature showed that 3D direct printed aligners have some promising advantages in comparison with thermoformed aligners. However, studies of high-quality levels are still required to explore more in depth the potential and the limitations of this new way of manufacturing clear aligners.

**Keywords**: 3D printed aligners, in-office aligners, thermoformed aligners.



## 1. INTRODUCTION

Dentistry has undergone significant changes in the past twenty years due to technological advancements like 3D imaging and additive manufacturing (Leonardi, 2022). A key application is the integration of 3D printing into orthodontics, enabling the digital production of various dental appliances, including aligners, occlusal splints, and surgical guides (Bachour *et al.,* 2022). In-house appliance fabrication offers advantages such as reduced delivery time and lower costs, but also presents challenges like the need for specialized equipment and staff training.

The aligner manufacturing process has evolved with digital technology, particularly with the introduction of Tera Harz TC85 resin, moving from traditional thermoforming to direct printing. This review aims to critically assess the literature on 3D-printed aligners and their materials in comparison to traditional options.

## 2. RESEARCH METHODOLOGY

This literature review was performed in response to the following question: what are the properties, mechanical behavior and hazards of the resin used in and the aligners fabricated from the direct 3D-printed process compared to the traditional in-office or aligners made by companies.

**The PICO** model was followed to answer the review question.

**Problem**: The different properties and related challenges of the use of new materials in orthodontics.

**Intervention**: The new resins used in, and aligners produced by direct 3d printing.
**Comparison:** Aligners produced by companies and those fabricated in-office using thermoforming techniques.
**Outcome**: Are the new materials used and the process of fabrication advantageous compared to the thermoformed aligners?

The search methodology was performed using the following keywords: 3D-printed aligners, in-office aligners, hazards, thermoformed aligners in combinations with different operators (AND, OR), the language of search was English, and the period of time was fixed from 01 January 2019 to 31 April 2024. The search was done in four databases: Medline, Google Scholar, Embase and Cochrane

## 3. RESULTS

Researching the databases with specific keywords resulted in a total of 1410 citations that were initially retrieved (Medline: n=290, Google Scholar: n=1250, Embase: n=60, Cochrane database: n=0). Following the identification and elimination of duplicates, the title screening process entailed the exclusion of articles that did not evaluate the subject matter. The abstracts of 80 publications were then meticulously analyzed; 19 of them were found unrelated to the objective of the review and were eliminated (Figure 1).

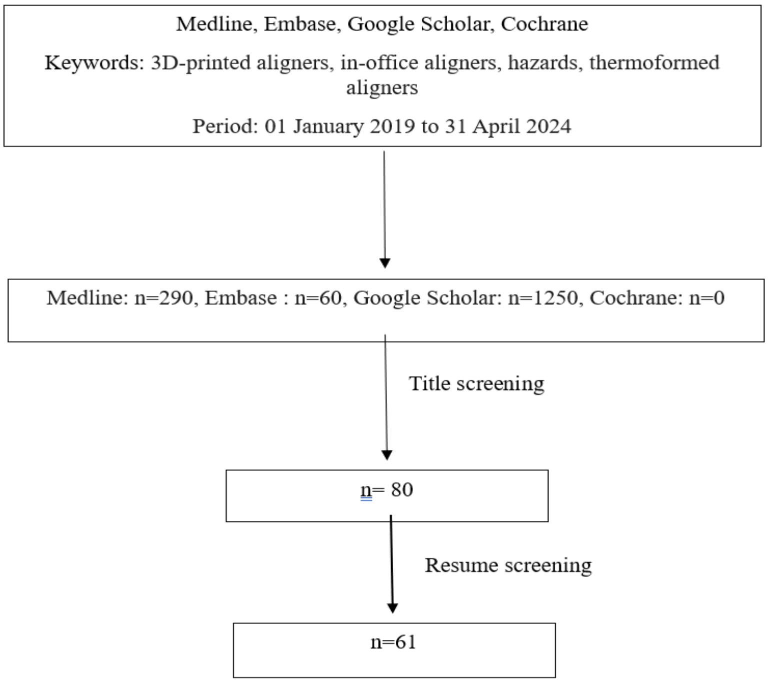



Figure 1: Flowchart of search methodology

## 4. DISCUSSION

### 4.1 The 3D printed aligners

#### 4.1.1 History of clear aligners

In 1945, Harold D. Kesling was the first to recommend rubber-based tooth positioners. He used wax models of patients' teeth to show that these devices could help finish orthodontic cases and gradually reposition misaligned teeth after braces. His work laid the foundation for modern computer-aided technology (CAT) in orthodontics, enabling significant tooth movements with thermoplastic materials. While Kesling saw potential for using a sequence of aligners for more extensive movements, he viewed it as impractical at the time (Kesling, 1945).

In 1964, Henry Nahoum improved upon Kesling's method by creating a vacuum-based device that fitted stone models of patients' teeth. He suggested making a plaster cast and adjusting the incisors with wax to reach the desired positioning. Thermoplastic materials could then be vacuum-formed over this model (Nahoum, 1964).

In 1971, Ponitz launched the "Invisible retainer" made of Biocryl, a mix of various plastics. This clear device was meant to finish and retain orthodontic treatments, allowing some limited tooth movements for retention (Ponitz, 1971).

In 1985, McNamara used Biocryl and a Biostar vacuum-forming device to create transparent retainers. This new device employed positive air pressure, unlike earlier methods that used vacuum pressure, although it was less durable than traditional options (McNamara *et al.*, 1985).

In 1993, Jack Sheridan refined the process by using polypropylene and a thermoplastic copolyester and introduced the "Essix appliance." This combined clear aligners with a slight reduction in tooth thickness, recommending positive air pressure for better shaping (Sheridan *et al.*, 1993).

Despite advancements, the goal of making small tooth adjustments with clear appliances remained. Creating these devices required taking impressions and adjusting teeth, which was labor-intensive. A breakthrough came with Invisalign in 1998, developed by Zia Chishti and Kelsey Wirth. This system used a series of removable polyurethane aligners designed digitally. It was the first orthodontic device made from transparent thermoplastic materials, employing modern CAD/CAM technology for a streamlined process to create 3D models and individual tooth movements (Melkos, 2005).

#### 4.1.2 Advantages, disadvantages and limitations of in-house aligners comparing with readymade aligners (Invisalign®)

There are three major benefits for clinicians who choose in-house production of aligners over aligner companies such as Invisalign®

**Price**: Creating aligners in-house can be more economical for clinicians than purchasing from external companies, as the cost includes 3D model printing and plastic sheeting. While the software can be pricey, more options may lower costs in the future, with various payment plans available. Additionally, 3D printer prices are becoming more reasonable, and many clinics already have thermoplastic aligner forming machines for producing orthodontic appliances

**Delivery time**: The second advantage of orthodontic aligners is their quick setup time. A moderate case can be digitally set up in about 30 minutes, or just 15 minutes without buccal segment movement. Many tasks can be delegated to trained staff, making the process efficient across various software. Initial steps include preparing models and marking tooth limits, which don't require specialized expertise. Clinicians then create a digital setup to plan treatment and align teeth before exporting the models, a task that can also be handled by dental staff. Future software versions may automate model preparation and exporting, and the production of three aligners takes about one hour, with aligners being ready the same day as impressions (Tozlu and Özdemir, 2021).

**Overall control**: In-house aligners have the advantage of allowing clinicians to quickly create personalized alignment and staging plans based on their expertise, eliminating delays caused by communication with company technicians. This control over the timeline enhances efficiency, as the clinician does not need to wait for a company to prepare the digital setup. However, producing aligners in-house requires a significant investment in time, resources, staff, and equipment like 3D printers and intraoral scanners. Alternatively, companies like Invisalign® offer treatment libraries that provide cost-effective, streamlined solutions for orthodontists.

#### 4.1.3 Design and manufacturing workflow

The initial stage involves converting the dental arches into a digital format, which is typically accomplished using an intraoral scanner. If necessary, the following step involves adjusting the occlusion. However, most of the time the occlusion is defined correctly during intraoral scanning. The next step involves the cleaning of the borders of the virtual dental models, either through an automated or manual process. Additionally, the model bases are constructed to provide the dental model with its definitive shape. The fourth step involves selecting the teeth that require segmentation by choosing them. Once done, the operator is prompted by the software to identify both mesial and distal contact points or surfaces of each tooth. This process splits each tooth from its adjacent neighbors. then the software utilizes calculations to estimate the approximate location of each tooth's root within the space. However, this estimation often lacks accuracy, soo the operator is invited to choose and rectify this tooth reference axes. The following phase involves the digital arrangement of the dental arches. Software programs of this kind generally offer comparable tools, allowing individual teeth to be adjusted using a tooth manipulator or by specifying the numerical value of the movement or the angle change. Then its time for Separating teeth movements into stages which is one of the utmost crucial aspects of clear aligner treatment design.

The workflow for creating printed aligners mirrors that of thermoforming aligners. During the export process, the orthodontist selects the direct export option for the aligners. This design process entails delineating the aligner's boundaries, determining its thickness, and establishing its offset. The files are then exported and forwarded to a 3D printer for production (Rajasekaran and Chaudhari, 2023).

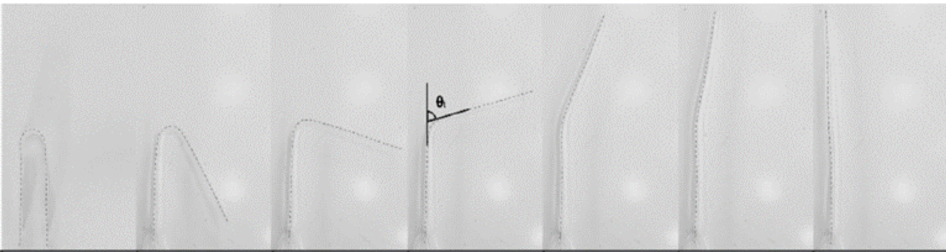
The available software for creating printed aligners includes Deltaface and Maestro. Deltaface software offers a unique feature that allows the aligner to be thickened in specific areas, providing increased rigidity where needed. For instance, if it is necessary to move a lower central incisor labially, the software can increase the aligner thickness on the lingual side according to the operator's designated millimetric determination. The revised aligner design technique recommends a consistent thickness of 0.5 mm for a week of use and 0.7 mm for ten days of use. The aligners are designed and exported as "Standard Tessellation Language" (STL) files from the program.

- **Special consideration for the Tera Harz TC-85 resin**

The resin used for 3D printing clear aligners must have specific physical, mechanical, optical, and biological properties. Graphy Inc (Seoul, Korea) developed the first photocurable resin named Tera Harz TC-85 DAC, which has brought a significant advancement to aligner technology in orthodontics over the past 3 years. This innovation enables practitioners to use 3D-printed aligners directly, eliminating the necessity for dental models.

This Tera Harz TC-85 DAC is a CE Class-II material approved by the Korean and United States FDA for direct 3D printing of clear aligners. This resin comes in two colors: clear and white. TC-85 DAC (clear) is completely transparent, while TC-85DAW (white) offers both durability and aesthetic appeal and has a shelf life of 12 months. The material's specific chemical structure could not be determined due to patent constraints. However, the findings from the attenuated total analysis of reflectance-Fourier-transform infrared spectroscopy suggested that the material is a polymer of aliphatic vinyl ester-urethane, potentially cross-linked with methacrylate functionalization with shape memory properties (Can *et al.,* 2022). This shape memory characteristic is attained by immersing the aligners in hot water. Following exposure to a bend at 80°C, the TC-85 specimen maintained its folded shape. However, when kept at 37°C over time, the specimens gradually reverted to their original shape. The initial recovery happened quickly, with more than half of the bending being resolved during the initial minute. Subsequently, the rate of form recovery diminished. Roughly 90% of the distortion was restored within 10 minutes, and the shape recovery ratio attained 96% after 60 minutes (Table 1). In comparison, under the same conditions, polyethylene terephthalate glycol (PETG) retained its deformed shape without any observed recovery (Lee *et al.,* 2022).

**Table 1: Shape recovery ratio of direct printed aligner (Lee *et al.,* 2022)**



| Elapsed time | 0 | 10 sec | 30 sec | 1 min | 5 min | 10 min | 60 min |
|---|---|---|---|---|---|---|---|
| Bending angle (°) | 177.00 ± 1.44 | 146.27 ± 3.92 | 107.23 ± 7.05 | 79.43 ± 6.45 | 31.53 ± 5.48 | 20.32 ± 5.49 | 6.90 ± 2.68 |
| Shape recovery ratio (%) | 0 | 17.36 ± 2.06 | 39.42 ± 3.90 | 39.42 ± 3.90 | 82.19 ± 3.09 | 88.52 ± 3.10 | 96.11 ± 1.50 |

Over time Graphy has modified the specific protocol for designing and printing aligners multiple times to optimize the printing results. The company also stated that Graphy's aligners are capable of being manufactured using any 3D printer.

- **Correct post-processing of aligners**

UV light is used for polymerization in 3D printers, but the process is incomplete due to the limited ability of the UV light to go through the entire object and the relatively low intensity of the UV light, as well as the presence of oxygen, which prevents full polymerization (Gauthier *et al.,* 2005).Therefore, a UV curing unit is required to totally cure the printed aligner, convert it into a biocompatible item, optimize its mechanical properties, and generate a transparent aligner. There are various UV curing units available in the market with different UV powers and curing methods for 3D objects; however, Graphy recommends using a specialized UV curing unit for printed aligners (Table 2).

Printed aligners are active devices that apply force to move teeth compared to other printed appliances. Consequently, to guarantee optimal mechanical characteristics, transparency, and biocompatibility of the aligner, the curing unit must possess high power and undergo aligner curing evaluation. The Cure M UV curing device (Graphy, Seoul, South Korea) was specifically engineered for printed aligners and possesses significant curing power. The presence of oxygen interferes with the complete polymerization of the aligners, compromising their transparency, particularly in the final days of usage. Additionally, the absence of oxygen during polymerization may improve the mechanical qualities of the aligners.

A newly introduced UV curing unit, Tera Harz Cure (Graphy, Seoul, South Korea), incorporates advanced technology featuring a nitrogen generator linked to a high-pressure (5-6 bars) air connection that compresses nitrogen into the unit's curing chamber, potentially improving the mechanical properties and transparency of printed aligners. Furthermore, resins, as indicated in the liquid's leaflets, are poisonous, irritant, and allergenic. In this pre-polymerization phase, they are unequivocally not biocompatible. Resins achieve biocompatibility during the printing phase, but predominantly during the UV curing phase.

After UV curing, the final steps involve removing supports and polishing the aligner to achieve high transparency. Finally, the company suggests putting the whole aligners in hot water for one minute (80°c; 85°c) with ultrasonic cleaning. After the first wash, rinse the aligners with running water and dry them.

The second wash is placing the aligners in boiling distilled water (100 °c) for 1 min to eliminate any potentially problematic substances for the patient and to create a more flexible aligner for easier insertion into the patient's mouth. However, subjecting the aligner to heat treatment may alter its mechanical properties, potentially affecting its performance in the mouth, a matter that requires investigation.

Furthermore, 3D printing is a multi-stage process where each step can impact subsequent steps. For printed aligners, adherence to the protocol at each stage is essential for a satisfactory printing result

Table 2: Graphy's conditions regarding the post curing unit (Graphy INC, 2024c)

| Provision | Unit | Condition | Remark |
|---|---|---|---|
| Light Source | | UV LED | |
| Wave Length | nm | 390 - 410 | |
| Operation Temp | °C | 5 ~ 35 | |
| Curing time | min | 30 / 30 | Post cure each side, the back and front of the printed aligner |
| UV energy | mJ/cm2 | 114000 ~ 120000 | UV energy when curing 5min. |
| LED Power | mW/cm2 | 380 ~ 420 | |

**4.1.4 Advantages and disadvantages of 3D-printed aligners compared with the conventional way**

**a. For the orthodontist**

- **Advantages**

✓ **Simplicity**

A primary advantage of printed aligners is the diminished number of manufacturing processes. Printed aligners are generated by exporting the virtual aligners from the software and subsequently importing them into the printer's software. The post-printing procedure comprises solely centrifugation, support removal, and UV curing. The capacity of an orthodontic clinic to have faster workflow facilitates the rapid delivery of aligners to the patient. A simpler and quicker workflow needs reduced manpower for aligner production (Panayi *et al.*, 2023).

✓ **Lesser time**

It is easier to produce aligners when printed dental models are taken off the production line. Manufacturing thermoformed aligners requires using non-recyclable plastic foils on the dental model. The procedure for pulling aligners from the models involves a time-consuming process of trimming surplus of aligner plastic, detaching the aligner from the model, establishing proper aligner borders, and polishing. On the contrary, printed aligners bypass all these procedures, minimizing time for the clinician and simplifying the process (Panayi *et al.*, 2023).

✓ **Fitting accuracy**

A study by Koenig *et al.*, found that printed aligners have greater fitting precision relative to two commonly used plastic foils in orthodontic practices. Fitting accuracy is a major issue with aligners. When aligners are not accurate, they are unable to properly grip the teeth, particularly smaller and less undercut teeth such as upper lateral incisors. This can lead to tracking loss and unsatisfactory orthodontic results. Nonetheless, this presents a non-ideal situation. They found that In Zendura FLXTM aligners, the mean absolute discrepancies varied from 0.076 ± 0.057 mm to 0.260 ± 0.089 mm, while in Essix ACETM aligners, they varied from 0.188 ± 0.271 mm to 0.457 ± 0.350 mm. For direct-printed aligners, the range was from 0.079 ± 0.054 mm to 0.224 ± 0.041 mm. The overall trueness, as indicated by the root mean square values, were 0.209 ± 0.094 mm for Essix ACETM, 0.188 ± 0.074 mm for Zendura FLXTM, and 0.140 ± 0.020 mm for the direct-printed aligners (Koenig *et al.*, 2022).

These results show that the trueness and precision were greater with printed aligners than with thermoformed aligners (Figure 1).

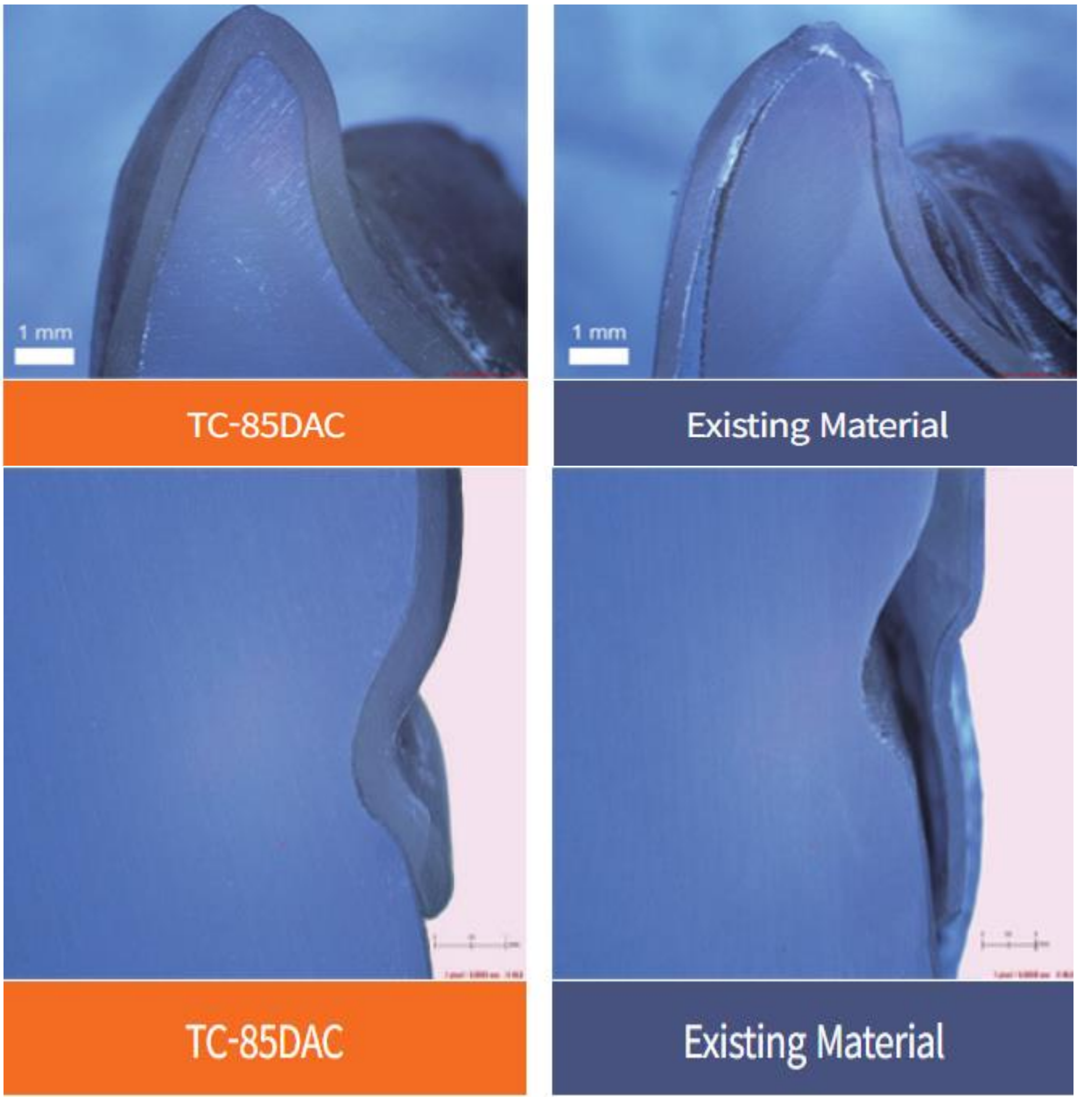



**Figure 1: Adaptation of direct printed aligners compared to that of conventional aligners Graphy's web site (http://www.itgraphy.com/ENG/bbs/content.php?co_id=sub0201_1)**

✓ **Consistent force delivery**

In research led by Se Yeon Lee and colleagues, it was found that at the transition temperature, materials of the deformed shape memory exhibit an elastic property, allowing them to return to their initial form. This shape recovery can produce forces capable of producing orthodontic tooth movement. The study revealed that TC-85 consistently applies a gentle force to the teeth when used in 3D printed clear aligners, thanks to its viscoelastic and flexibility properties. Moreover, it is anticipated that the force decay resulting from repeated insertion of the clear aligners will be minimized, leading to sustained orthodontic force. Additionally, its geometric stability at high temperatures and shape memory offers distinct advantages for clinical applications (Lee *et al.,* 2022).

New research conducted by Hertan *et al.,* shows that. the range of median stabilized forces shown by TFA (thermo-formed aligners) in response to 0.10–0.30 mm displacements was between 4.60 and 15.30 N. The median peak force ranged from 5.11 to 16.26 N. On the other hand, Direct printed aligners demonstrated stabilized forces in the median range of 0.73 to 1.69 N in response to 0.10—0.30 mm displacements. The median peak of force displacements ranged from 2.44 to 3.87 N (Figure 2).

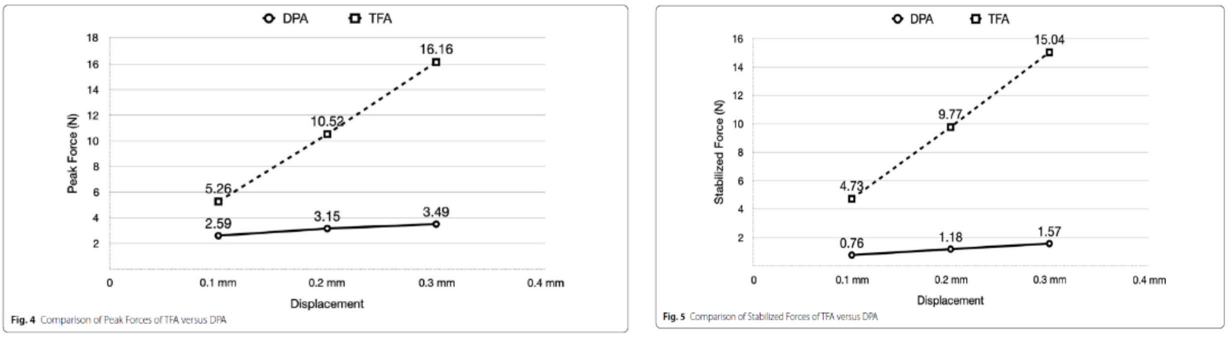



**Figure 2: Forces delivered by direct printed aligners compared to that of conventional aligners (Hertan *et al.*, 2002)**

So DPA exhibited considerably lower force levels than TFA which displayed a considerable and statistically significant rise in force (Hertan *et al.*, 2022).

According to Proffit, it's recommended that the ideal orthodontic movement forces should fall within the range of 10 to 120 grams (0.10 to 1.18 Newtons) (Proffit, 2012).

In comparison with Lee *et al.*, findings, this study concludes that directly printed directly aligners can apply forces that are biologically compatible to move teeth in orthodontic treatment. and able to provide a consistent force. in another sentence we can compare direct printed aligners with NiTi wires which can deliver gentle consistent forces across various displacements (Lee *et al.*, 2022).

✓ **Ageing**

In recent research conducted by Can *et al.*, an examination of 3D-printed aligners worn by patients for 1 week revealed that the mechanical properties (indentation modulus, hardness, and elastic index) of the aligners remained almost unchanged (Can *et al.*, 2022). The same research team also studied Invisalign aligners and found that their mechanical properties decreased by nearly 50% after 1 week of wear. It's worth noting that the printed aligners were produced utilizing the workflow standards of the initial printed aligners, making use of UV curing units in the presence of oxygen, a recognized agent that hinders complete resin polymerization (Gauthier *et al.*, 2005).

✓ **Customizerd design**

A key benefit of 3D-printed aligners is the ability to create aligners with consistent thickness. Having consistent thickness provides the benefit of applying homogeneous forces to the incorporated teeth. Koenig *et al.*, research revealed a 12% increase in thickness for 3D-printed aligners, whereas thermoformed aligners experienced a significant decrease in thickness (Koenig *et al.*, 2022). Another study demonstrated that the thermoforming process causes a reduction in the thermoformed aligner thickness in comparison to the initial plastic foil used (Bucci *et al.*, 2019). Lee *et al.*, studied the thermal deformation of aligner foil using a standardized block model. According to their findings, the thickness changed by 54% or more during the thermoforming process. Thermal deformation of the foils can lead to both expansion and shrinkage of the material, leading to a variation of thicknesses for different teeth (Lee *et al.*, 2022). This morphological variation may pose challenges in achieving improved clinical outcomes in tooth movement (Ryu *et al.*, 2018).

Thermoforming foils are manufactured at a specific thickness, making intentional alteration impossible. Printed aligners, on the other hand, offer greater flexibility by allowing for variable thickness in specific zones. The Deltaface CAD software features a command function that identifies tooth movement and delivers additional thickness to the designed areas. This allows the operator to choose the overall thickness of the aligner and set the specific extra thickness value as needed. When designing the aligner, the program automatically incorporates the additional thickness exclusively in areas where teeth are being repositioned. In the situation of movement of the lower incisors, the software includes material to the inner part of the lower anterior teeth. This additional thickness enhances the rigidity of the aligner at that location. However, there is no empirical evidence to support the idea that increased thickness could positively impact the effectiveness of aligner treatment. The software may also add thickness to the occlusal surfaces of posterior teeth if an open bite needs correction. Similarly, aligner thickness could be raised on the palatal part of the upper incisors in cases of deep bites.

- **Disadvantages**

✓ **Increased cost**

Specialized resin is necessary to produce aligners, and it comes at a higher cost than conventional resins. Additionally, a specialized UV and nitrogen curing unit is required for the aligner resin manufactured by Graphy, contributing to the overall production costs. When evaluating the adoption of this technology, it's important to conduct a return-on-investment analysis to determine whether printing aligners is financially feasible or if it's more practical for the clinician to utilize an existing aligner system (Panayi, 2023).

✓ **The lack of evidence**

A significant drawback is the limited and low quality of evidence available for this material. Many early studies on its effectiveness are conducted in vitro and are subject to biases due to limited data. More high-quality, prospective, randomized studies are necessary to confirm the reported advantages of this technology (Tartaglia *et al.,* 2021).

**b. For the patient**

The materials used in the human body can lead to cytotoxicity and iatrogenicity, which are negative effects on human cells. Cytotoxicity refers to a substance's toxicity level to cells, while estrogenicity involves endocrine-disrupting chemicals (EDCs) that mimic or disrupt hormones. Conducting cytotoxicity tests is essential to assess a material's toxicity.

Recently, substances like plastics and composite resins have been linked to Bisphenol A (BPA), a weak synthetic estrogen that may cause issues such as cardiovascular problems, type 2 diabetes, deformities, obesity, and certain cancers (Fenichel *et al.,* 2013). However, there has been limited research on the estrogenicity and cytotoxicity of 3D-printing resins and their products. A recent study investigated the BPA release and cytotoxicity of 3D-printed aligners. The aligners were soaked in sterile deionized water for two weeks, and the discharged factors were evaluated for cytotoxicity and estrogenicity. None of the factors released during the period of 14-day were determined to be estrogenic or cytotoxic (Pratsinis *et al.,* 2022).

Another recent study investigated the leaching from Graphy's aligner resin Tera Harz TC-85A indicates that there was no BPA release detected during the one-week period of immersion in water. However, UDMA (urethane) was identified, raising concerns about possible health risks, given that aligners are replaced every 1-2 weeks, which could result in recurring urethane release (Willi *et al.,* 2023)

On the other hand, it is important to note that the ageing process used by Pratsinis *et al.,* and Willi *et al.,* only consists of immersing the aligner in water, underestimating the impact on resin deterioration and release of substances influenced by intraoral factors such as temperature, PH, enzymatic and bacterial activity, as well as masticatory and occlusal forces.

The surface roughness of printed aligners plays an important part and it was found to be higher than that of Invisalign devices (Koletsi *et al.,* 2023). This increased roughness may result in the release of substances and small fractures, weakening the aligner's mechanical properties. Such roughness can stem from improper printing techniques or excessive brushing. The complex multi-step printing process can also contribute, as vertical printing creates "steps" from multiple material layers, while horizontal printing results in a smoother surface. Insufficient UV curing and intraoral aging can further elevate roughness and alter mechanical properties.

**c. For the environment**

The conversation about plastic waste in the ocean and climate change often starts with indifference and ends with the assumption that these issues will resolve on their own. The rise in PET-G production in the 1980s led to a surge in plastic bottle sales, with about 14% of all plastic produced being collected, and less than 20% of that being recyclable. Alarmingly, 91% ends up in landfills, oceans, or is incinerated. The World Economic Forum notes that a truckload of plastic is dumped in the ocean every minute.

Clear aligners are becoming increasingly popular in orthodontics due to their aesthetic appeal and comfort. However, this has raised concerns about plastic waste as patients use multiple plastic aligners, each disposed of after one to two weeks. These aligners often consist of PET, PETG, or TPU, contributing to environmental pollution and health issues. To tackle plastic waste, it's crucial to reduce consumption, improve recycling, and find alternatives. Yet, the orthodontic market shows no signs of decreasing clear aligner use. Many manufacturers do not provide recycling guidance or efforts to minimize waste. Although some plastic aligners can be recycled, this is insufficient given the vast quantity produced globally, and urgent action is needed to address environmental impacts.

Furthermore, Tartaglia *et al.,* have brought attention to the lack of documentation on the environmental impact of printable resins used in 3D models produced through the thermoplastic process. They are worried about energy usage, waste production, environmental contamination and pollution associated with this process (Tartaglia *et al.,* 2021). The authors propose that one potential solution to this issue is to incorporate the use of recycled materials in 3D printers to improve the sustainability of 3D printing technology (Tartaglia *et al.,* 2021), 3D-printed aligners offer a potential solution to the waste of millions of dental models which have no furthermore utility after thermoforming.

Elshazly *et al.,* are optimistic about the potential of shape memory polymers to create a single aligner that can replace three conventional aligners. This could lead to a reduction in the number of aligners used in orthodontic treatments, leading to lower fabrication costs and decreased plastic consumption (Elshazly *et al.,* 2021).

### 4.2 Future directions: what should be investigated more deeply

In dentistry, a thoughtful approach is crucial, especially when introducing new materials and technologies. Unlike medicine, which prioritizes thorough research, the rush to adopt new materials and machines in dentistry can lead to oversight. With the advent of 3D technology in orthodontics, it's essential to conduct extensive research to ensure the safety and efficacy of orthodontic appliances (Dawood *et al.*, 2015). Introducing printed aligners in orthodontics is relatively recent, and scientific studies in this area are scarce. Current research mainly focuses on material properties such as cytotoxicity, estrogenicity, leaching, surface roughness, mechanical properties and fitting accuracy.

A recent study by Zinelis *et al.*, demonstrated that different 3D-printers produce aligners with varying mechanical properties. This result is crucial, as it directly affects the quality of the aligners and, consequently, their ability to predictably and efficiently move teeth. Each printer utilizes different resin polymerization technologies, such as laser beams, light projectors, or LED, which significantly influence the mechanical properties of the aligners. Furthermore, parameters like power and exposure time/velocity, referred to as "irradiant exposure conditions," may also contribute to differences in printing outcomes. The study revealed that LED printers offered superior mechanical properties, particularly hardness, in the aligners, which holds considerable clinical significance. However, there is currently no evidence to suggest that these significant mechanical properties impact the clinical efficacy of orthodontic therapy (Zinelis *et al.*, 2022)

Another factor to consider is the possibility that the same printer may produce aligner files with different mechanical properties during repeated printing sessions. Evaluating intravariability in printing is essential for guaranteeing that the printer continuously generates aligners with identical mechanical properties on every single print.

Another important point that should be further investigated is the choice of 7 or 10-day protocols to change aligners. In addition, more in vivo research has to be done to study the impact on resin deterioration and release of substances influenced by intraoral factors such as temperature, pH, bacterial and enzymatic activity, as well as occlusal and masticatory forces to fully validate their biocompatibility properties (Tartaglia *et al.*, 2021).

Recently Graphy has produced another resin for directly printed aligners called TA-28, which has still not been investigated by independent researchers, yet according to Graphy TA-28 presents more flexural strength (up to the double) compared to TC-85.

In the future, investigating the possibilities of 4D printing, an evolution of 3D printing pioneered by Charles Hull in 1984 (Hull, 2012), which integrates time as the fourth dimension. Scientifically referred to as smart material printing, 4D printing seeks to alter the shape and/or behavior of a printed object in reaction to environmental stimuli such as mechanical, electrical, chemical, or thermal elements over time. A prospective smart material-based aligner might be engineered to respond to the wavelength of a light-curing unit, altering its force delivery amount or duration in response to specific areas illuminated by light. This capability could enable the aligner to apply differential forces to different areas, offering more precise treatment (Panayi *et al.*, 2023).

## 5. CONCLUSIONS

The emergence of 3D direct printed aligners has revolutionized clear aligner therapy in orthodontics. This work has delved into the details of 3D printed aligners, including material and mechanical characteristics providing a comprehensive understanding of the potential benefits and limitations of this innovative approach and materials compared to the traditional thermoformed aligners.

**Key findings**

- Technological Advancements: The advancements in 3D printing technology and resins have enabled the creation of highly accurate and complex aligner designs.
- Material Properties: The emergence of the resin Tera Harz TC85 as an appropriate material for 3D printed aligners is crucial for ensuring biocompatibility, mechanical strength, and transparency. While traditional thermoplastics have been widely used, exploring novel materials, such as resins, offers promising opportunities for enhanced performance.
- Clinical Applications: 3D printed aligners have demonstrated their effectiveness in treating a wide range of simple to mild orthodontic conditions, including mild to moderate crowding, rotations, and gaps.
- Advantages and Limitations: While 3D-printed aligners offer several advantages, including improved adaptation, force control, surface roughness, they also present certain limitations such us the need of temperature to activate the appliances. These limitations may include potential challenges in achieving complex tooth movements and the need for additional attachments.
- In the literature: No articles were found in the Cochrane database due to the recent introduction of the product to the orthodontic market and the absence of meta-analysis and systematic reviews speaking about this subject.

**Future Directions:**

- Material Research: Continued research into novel materials with enhanced properties, such as improved biocompatibility, mechanical strength, and transparency, is essential for optimizing 3D printed aligner performance.
- Clinical Studies: Further clinical studies and investigations are needed to evaluate the long-term safety and efficacy of 3D printed aligners in treating

various orthodontic conditions, particularly complex cases.

- Integration with Digital Dentistry: Exploring the integration of 3D printed aligners with digital dentistry technologies, such as intraoral scanners and artificial intelligence, can enhance treatment planning, monitoring, and patient engagement.
- Cost-Effectiveness: Addressing the cost-effectiveness of 3D printed aligners is crucial for ensuring their widespread adoption and accessibility. Strategies to reduce production costs and improve return on investment models for the orthodontists may be necessary.
- In conclusion, 3D direct printed aligners represent a significant advancement in orthodontic treatment, offering a new solution in clear aligner therapy. While challenges and limitations remain, ongoing research and development efforts have the potential to further refine this technology and make it accessible to a broader orthodontist's range and patient population. As the field of orthodontics continues to evolve, 3D printed aligners are prone to play a pivotal role in shaping the future of orthodontic care.

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