EGAS MONIZ SCHOOL of HEALTH & SCIENCE | INSTITUTO UNIVERSITÁRIO EGAS MONIZ

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MESTRADO INTEGRADO EM MEDICINA DENTÁRIA

EVOLVING TECHNOLOGIES IN ORTHODONTICS: THE EXAMPLE OF THE DIRECT 3D PRINTED ALIGNERS

Trabalho submetido por
Sahbi Dammak
para a obtenção do grau de Mestre em Medicina Dentária

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DEDICATORY

To two Women around me

My Mother Sahira MAALEJ

My Wife Imen CHAARI

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First and foremost, I would like to thank ***ALLAH*** the Almighty ***GOD*** for giving me the strength, knowledge and ability to undertake this study and to persevere and complete it satisfactorily More than 76 plane trips were taken, travelling to work, going back to studies during these past 10 months was not easy, without God´s blessings, this achievement would not have been possible. All praises go to ***ALLAH***

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RESUMO

A ortodontia tem experimentado avanços notáveis nas últimas décadas, impulsionada pela crescente adoção de tecnologias digitais. Dentre essas inovações, a fabricação de alinhadores ortodônticos por meio da impressão 3D direta tem se destacado como uma alternativa promissora aos métodos convencionais de produção.

Esta revisão da literatura tem como objetivo analisar criticamente a literatura científica disponível sobre a fabricação de alinhadores ortodônticos por meio da impressão 3D, com foco nas propriedades dos materiais empregados e na comparação com os alinhadores termoformados tradicionalmente utilizados em consultórios.

A pergunta de pesquisa centraliza-se nas propriedades mecânicas, biocompatibilidade e eficácia clínica dos alinhadores impressos em 3D, em comparação com os alinhadores fabricados por empresas especializadas. Adicionalmente, busca-se identificar os desafios e as oportunidades associados à adoção dessa nova tecnologia na prática clínica.

A revisão sistemática da literatura foi realizada nas bases de dados Medline, Google Scholar, Embase e biblioteca Cochrane, considerando artigos publicados entre janeiro de 2019 e abril de 2024. A seleção dos estudos incluiu critérios rigorosos de elegibilidade, visando garantir a qualidade e a relevância dos dados.

Os resultados da revisão indicam que a impressão 3D direta dos alinhadores oferece diversas vantagens para a fabricação de alinhadores ortodônticos, como maior precisão, personalização e rapidez na produção. No entanto, a literatura científica ainda é limitada em relação à avaliação a longo prazo da eficácia clínica e à comparação direta entre diferentes materiais e tecnologias de impressão.

Conclui-se que, embora a impressão 3D direta dos alinhadores represente um avanço significativo na ortodontia, são necessários estudos clínicos de alta qualidade para elucidar completamente o potencial e as limitações dessa tecnologia. Adicionalmente, a padronização dos protocolos de fabricação e a seleção adequada dos materiais são cruciais para garantir a segurança e a eficácia dos tratamentos ortodônticos realizados com alinhadores impressos em 3D.

Palavras-Chave: alinhadores impressos em 3D, alinhadores fabricados no consultório, alinhadores termoformados, perigos.

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 objective 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 search for the articles answering these questions was performed using the relevant related evidence-based published literature in English; the period was fixed from 01 January 2019 to 31 April 2024. The search was done in four databases: Medline, Google Scholar, Embase and Cochrane. The related keywords used separately or joined were 3D-printed, in-office, hazards, and 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, hazards. thermoformed aligners.

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CAD | Computer Assisted Design

CAM | Computer Aided Manufacturing

CAT | Computer Aided Technology

PU | Polyurethane

IPR | Interproximal Reduction

PETG | Polyethylene Terephthalate Glycol

CAT | Clear Aligner Treatment

DPA | Direct printed Aligner

TFA | Thermo Formed Aligner

DLP | Direct Light Printing

SLA | Stereolithography

MSLA | Masked Stereolithography

FDM | Fused Deposition Modeling

VPP | Vat Photopolymerization

I. INTRODUCTION

1 Contextualization

Dentistry has experienced substantial transformations in the past twenty years, mainly because of technological innovations and their application, notably Three-Dimensional (3D) imaging digital modelling, and additive manufacturing (Leonardi, 2022). One of the most notable applications of these technological developments is the integration of 3D-printing procedures into orthodontic workflows, which enables the digital production of various dental appliances, such as study models, aligners, occlusal splints, nightguards, retainers, trays for indirect bonding, surgical guides for dental implant, and also metal frameworks for expansion devices (Bachour et al., 2022). This technology also facilitates in-house appliance fabrication. This practice offers several advantages, allowing the management of each stage in the process, from treatment planning to final product delivery, to be managed within an orthodontic office. Such in-house production offers several advantages, including reduced product delivery time, elimination of shipping costs and miscommunications risks and decreased waste material by avoiding the need for model fabrication and thermoforming. However, it´s important to note that in-house fabrication also comes with its own set of challenges, such as the need for special equipment and personnel training. These aspects should be carefully considered when implementing this technology.

In-house designing and aligner fabrication have been utilized in the field. The aligner manufacturing process has been revolutionized with the recent advances in digital technology and material advancement. One of the innovations that has shifted the traditional plastic foil thermoforming process to direct aligner printing is the introduction of a new resin called Tera Harz TC85 (Graphy Korea). Nevertheless, special emphasis should be put on the proprieties, the mechanical behaviors, and the hazards of these new materials. Therefore, the present review aimed to critically appraise the available data and information in the literature concerning direct 3D-printed aligners and their raw materials, comparing them with traditional thermoformed aligners.

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).

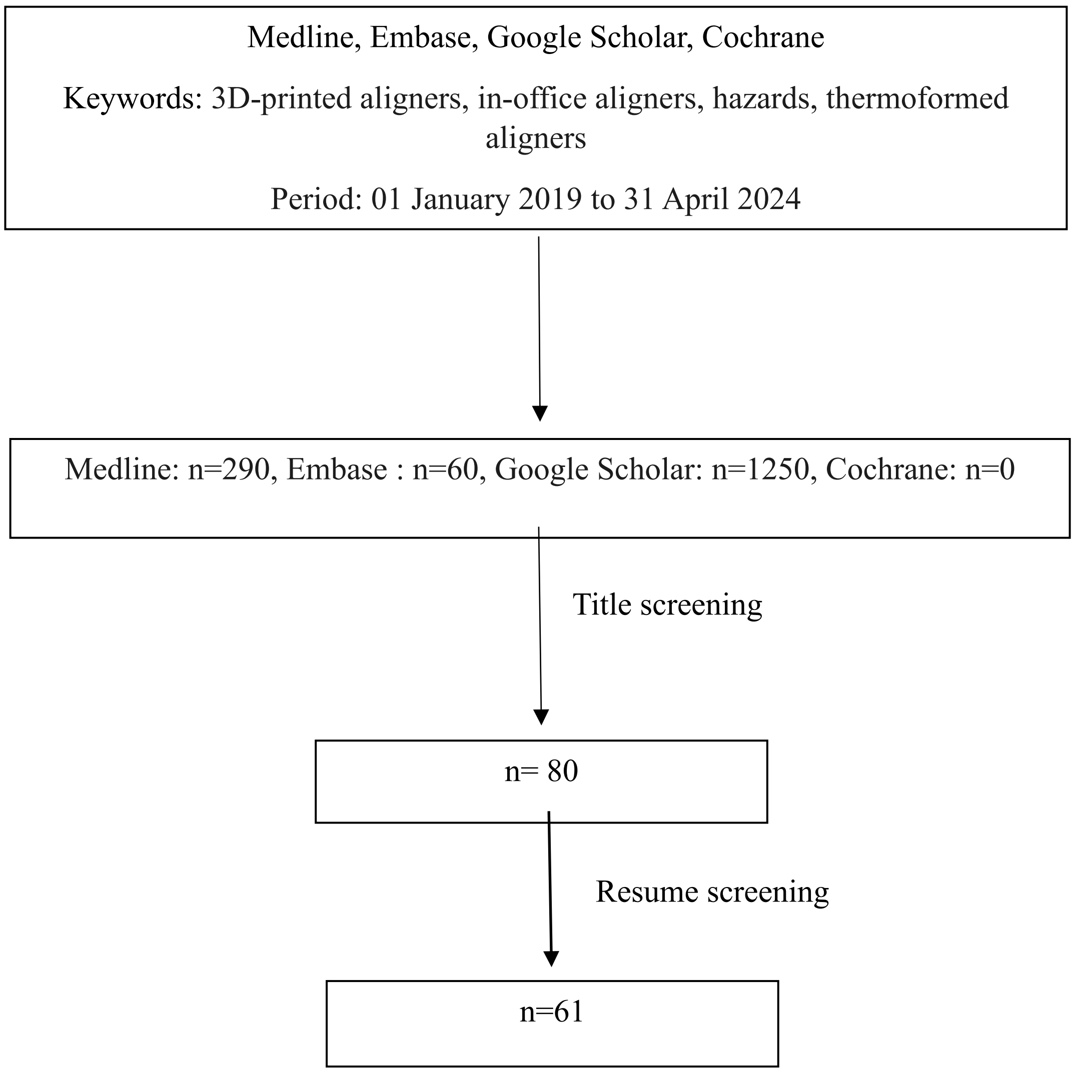


Figure 1: Flowchart of search methodology

II. DEVELOPMENT

1 The digital workflow of an orthodontic office

The term "digital" has an intriguing origin, stemming from the Latin word "digitus" meaning "finger." This word was initially used in its modern sense by the mathematician George Stibitz in 1942 (Ceruzzi, 2012). Initially, it referred to using fingers in counting, but with the advent of technology, it now signifies electronics and computing. In contrast, Analogue technology, the opposite of digital, does not involve converting the data into binary code.

Digitization is commonly known as transforming data, including text, images, sound, and objects, into a binary format that a computer can process. Conversely, transforming digital data into a physical form is defined as undigitization. An example of undigitization is when a digital dental model is retrieved from a computerized database and printed as a solid object.

Digital technology has become ubiquitous, with almost all human endeavors being digitized, resulting in storing an enormous amount of digital data in computers. The field of dentistry, along with other branches of medicine, has embraced and incorporated this technology into their clinical practices. Orthodontics is no exception, as incorporating digital technology in orthodontic treatment has enhanced predictability, efficiency, and effectiveness in all aspects of patient diagnosis, treatment, and record management (Christensen, 2017) . Furthermore, once performed manually, appliance design and fabrication, are increasingly being performed using digital tools (Dawood et al., 2015;Haahim Nainar, 1988). Although the complete digitization of orthodontic offices may need time, the trend towards digitalization is irreversible. Each new group of orthodontic residents is already confronted with evolving digital technologies and their potential benefits.

1.1 The analogue orthodontic practice

Analogue environments mainly characterize the current state of orthodontic clinics. Most diagnostic and treatment planning processes occur through analogue means. This traditional workflow necessitates the outsourcing or manual processing of dental casts, digital radiographs, examination documents, cephalometric analysis, intraoral and extraoral photographs, and treatment simulations. While the gathered information, whether analogue or digital, is crucial for patient diagnosis, treatment planning, and outcome assessment purposes, conversing a human being into separated 2D pieces of information leads to significant data loss (DiFranco et al., 2001). In "analogue" clinics, diagnostic records are gathered without using digital methods. Dental casts are obtained from impressions taken with alginate, clinical findings are documented on paper forms, and radiographs are chemically reproduced on film or photosensitive paper and are manually analyzed using acetate sheets. Using 2D photographs and film-based cameras to record 3D facial features further contributes to losing essential patient data. Analogue dental laboratories also execute numerous activities utilizing poured stone dental casts obtained from dental impressions. While traditional analogue workflow has been successful in the hands of experienced orthodontists, they present significant challenges when severe dental and skeletal disharmonies are present in the same patient. Moreover, presenting diagnosis, strategies of treatment, and anticipated results to patients or parents is more difficult when depending exclusively on analogue 2D information. Moving towards a more digitized workflow facilitates efficient communication, accurate diagnosis, and effective treatment planning (McNamara, 2000).

1.2 The semi-analogue or semi-digital orthodontic practice

The field of orthodontics has seen notable advancements with the integration of digital technology. Despite the strides made, clinics operate under a semi-digital model, primarily due to cost constraints. To fully harness the potential of multiple diagnostic data sources, it is imperative to push the boundaries of digital technology. With continuous research and development, the possibilities of digital technology to transform orthodontics are vast and promising (Redmond, 2001).

Digital technology has eliminated the cumbersome film processing and shifted towards paperless systems. Additionally, software programs like Microsoft Office PowerPoint helped to facilitate patient education and presentation (Redmond, 2001)

While digital sensors have been instrumental in reducing radiation exposure, manual registration of diagnostic radiographs remains time-consuming. However, the advent of Artificial Intelligence (AI)-powered software like Ceph X by ORCA Dental AI, has developed the process of automatic tracing and measurements modalities (Abraham, 2007) .This advancement has revolutionized the specialty, offering a time- efficient solution with similar accuracy to manual digitization (Abraham, 2007).

Despite significant progress, many clinics still operate under semi-digital models with limited use of digital technology due to cost constraints. However, to fully exploit the potential of integrating multiple diagnostic data sources, broadening the perspective on digital technology is imperative. The benefits of these advancements, such as improved efficiency and accuracy, outweigh the initial investment. With ongoing research and development, the future of digital technology in orthodontics is promising and full adaptation is worthwhile consideration.

1.3 The digital orthodontic practice

- **Surface and volume Scanning**

In recent years, significant developments have been witnessed in the technology behind intraoral scanners. It began with Dr. François Duret's invention of the first intraoral digitizer (Duret & Preston, 1991), which made it possible to obtain optical impressions. Since then, the need for a straightforward, reliable, and precise tool for digitizing teeth has fueled technological advancements. Studies reveal that intraoral scanners offer exceptional precision and accuracy, particularly for meeting orthodontic needs (Kim et al., 2018:Winkler & Gkantidis, 2020). They can scan various surfaces, including teeth, intraoral soft tissues, and occlusion registrations including centric relation.
This scanning can be incorporated with Cone Bean Computed Tomography (CBCT), which is beneficial for orthodontists to visualize the root position when planning tooth movements, ensuring that the roots remain within the alveolar bony envelope (Kapila, 2014).

- **Digital data analysis**

Advanced orthodontic software has revolutionized patient data management, enabling the swift and effortless analysis of various dental arch parameters such as arch length, Bolton ratio, occlusogram, and virtual dental setup. In addition to the superimposition of a series of CBCT images, treatment outcome assessment is simplified. Moreover, complete digital appliance presentations in /Two-Dimensional (2D) photographs and 3D videos enhance the accuracy and clarity of patient data. This centralized approach streamlines diagnosis, treatment planning, and patient education. Excitingly, some software, like Digital Smile Design or Hack Dental, can integrate digital photographs, despite being a 2D rendering of patients, and offer added benefits for treatment option simulation (Zimmermann & Mehl, 2015).

- **Computer Assisted Design:**

Computer-Aided Design (CAD) is a technology that utilizes computer software to design, analyze, and simulate dental components, such as crowns, bridges, veneers, and implants. It has significantly transformed the field of dentistry, enabling the precise and efficient creation of various dental restorations and appliances (Suganna et al., 2022).

Integrating CAD into dentistry has been a gradual process, with significant advancements occurring over the past few decades. Early applications of CAD in the dental field began in the early 1980s and were primarily confined to dental laboratories, where traditional milling machines were used to fabricate restorations based on digital designs. As technology evolved, chairside CAD/Computer-aided manufacturing (CAM) systems emerged; thanks to these advancements, clinicians and technicians can now easily create personalized orthodontic appliances. These appliances are rapidly gaining popularity in both clinical and laboratory settings (Suganna et al., 2022). With the help of CAD software like Delta Face (Coruo, Limoges, France) and Maestro (New Age, Pisa, Italy), it has become more straightforward for clinicians to create preplanned clear aligners and custom orthodontic appliances in their offices. Additionally, software packages offer orthodontic analysis and custom appliance design, including virtual orthodontic bracket bonding and indirect bonding transfer designs. Some CAD software, like Orthoanalyzer (3Shape, Denmark), even allows orthodontists to design specialized appliances like lingual arches and rapid palatal expanders (Graf et al., 2017: Graf, 2018).

- **3D printing**

3D printing, also known as additive manufacturing, entails the creation of a 3D object from a digital 3D model or a CAD model. This process is carried out under computer control, with the material being deposited, joined, or solidified, typically layer by layer. It encompasses a number of procedures in which materials such as polymers of plastic, liquids, or powder grains are fused to build the object. 3D printing has been prevalent for many years and has gained significant popularity in the medical and dental industries (Kodama, 1981). Nowadays, orthodontic clinics frequently employ 3D-printers to create dental models and in-house aligners, using a range of printers such as direct light printing (DLP), stereolitheoraphy (SLA), and masked stereolithography (MSLA). However, when printing aligners directly, the filament material must possess specific characteristics to endure the high temperature of the thermoforming machine. After printing, two additional machines are necessary for post-printing procedures. First, the printed object is submerged in a washing machine or ultrasonic cleaner with 91% isopropyl alcohol, aligning with the resin manufacturer's recommendations to eliminate residual uncured resin. Subsequently, a unique UV post-curing machine is utilized to complete the post-curing, with the time frame for this step dependent on the ultra-violet (UV) light source intensity, curing temperature, and manufacturer's guidance.

To conclude, a digital orthodontic office may have a range of devices and software to aid in their work, or they may have only a few. Some examples of these tools include:

- CBCT machine for volumetric imaging and a cephalometric x-ray machine.
- Intraoral scanner for registering the in-mouth surfaces.
- A 3D face scanner and CAD software for collected data analysis, treatment planning, simulation, and presentation to the patient.
- Additionally, they may possess CAD software for dental arch setup, aligner fabrication, aligner design, virtual bracket bonding, indirect

bonding transfer tray design, study model design, and custom metal appliance design like lingual arch and rapid palatal expander.
- Software for cephalometric digitization, analysis and interpretation. Furthermore, for performing Virtual Treatment Objectives (VTO) for orthognathic surgery cases.
- Software for model analysis.
- They could also have free CAD engineering software to create in-house appliances.
- A 3D printer (DLP, SLA, MSLA, or FDM).

Depending on the needs of a digital orthodontic office, they may have some or all the equipment and programs listed above. For offices that plan to create in-house aligners, it is advisable to have in addition the following tools:

- CAD software for aligner design.
- An isopropyl alcohol washing machine.
- A positive pressure thermoforming machine.

1.4 The future: artificial intelligence and virtual patient

The process of digitization is a revolutionary change in the field of orthodontics. It involves converting physical information into digital data that can be viewed on a computer screen. This data is subsequently imported to CAD software to create a "virtual patient" for orthodontic diagnosis, treatment planning, and simulation of tooth movement. Specialized CAD orthodontic software or alternative CAD freeware enables orthodontists to create and design customized appliances, such as clear aligners, which can be printed in-office (Suganna et al., 2022).

This workflow is only possible in an entirely digitized orthodontic office, becoming increasingly common as clinicians incorporate more digital technology into their practices. The ability to access the completed finalized digital data of the virtual patient enables the orthodontists to view this information in a spherical as opposed to the linear approach dictated by the analogue orthodontic office. This facilitates multi-planar and customized treatment planning for each patient, which is a significant advancement in orthodontic treatment.

The potential of artificial intelligence (AI) in orthodontics is on the horizon. Already, AI is assisting clinicians in diagnosis, treatment planning, and problem-solving, and it is only set to become more integrated into orthodontic practice. As data, storage becomes almost unlimited and cloud-based services are gradually implemented, the opportunities for dental specialists to access and evaluate patient data, especially for interdisciplinary treatment requirements, are expanding exponentially (Paquette, 2009).

It is crucial to note that while digital technology can enhance the skills of a good orthodontist, it cannot make an incompetent orthodontist good. Therefore, clinician expertise and skills are invaluable. Orthodontists must continue to hone their skills and keep up with the latest technological advancements. The capacity to create a virtual patient and to digitally design customized appliances and print them represents a notable evolution in orthodontics since the introduction of the preadjusted fixed appliance, and it remains in its early phases (Jheon et al., 2017).

2 In house clear aligners

2-1 History

In 1945, Harold D. Kesling was the first to advocate the use of rubber-based tooth positioners. He made them by using wax setups of patients' teeth and showed that these appliances could help in finishing and detailing treated cases and, in a sequential manner, repositioning residual misaligned teeth after debonding. This innovative work pioneered the basic principles of modern computer-aided technology (CAT) and the prospect of performing significant orthodontic tooth movements with thermoplastic materials. Kesling acknowledged the constraints of the technology at his disposal and anticipated that more extensive tooth movements may be achieved with a sequence of aligners. He proposed that treatment could advance by making little adjustments to the teeth in the setup. He acknowledged that this therapy modality currently appears impractical, although it remains a potential option, with the prospect of developing a technique for its practical implementation in the future (Kesling, 1945).

In 1964, Henry Nahoum enhanced Kesling's approach by creating a vacuum-based device that firmly adapted to a patient's stone models. The method suggested the creation of a plaster cast from which the incisors were cut out using a fissure bur or a goldsmith's saw. The segmented teeth were repositioned with wax on the stone model according to the intended result. A range of thermoplastic materials, such as acetates, vinyl, styrene, polyethylene, and butyrate sheets, may then be vacuum formed over the specified cast to produce a dental contour appliance capable of repositioning teeth(Nahoum, 1964).

In 1971, Ponitz made use of Biocryl, a composite of cellulose acetate butyrate, polyurethane, polyvinyl acetate-polyethylene polymer, polycarbonate-cycolac, and latex, to launch a "Invisible retainer". This vacuum-formed transparent plastic device was originally designed to finish, detail, and retain treated orthodontic cases with base plate wax on the pre-positioned cast. While it may achieve restricted orthodontic tooth motions, mostly through tipping movement, it can serve for afterward retention phase (Ponitz, 1971).

In 1985, McNamara employed Biocryl plastics and a Biostar vacuum forming device to produce invisible retainers for retention and final detailing. The distinction between the Biostar device and the prior vacuum former lies in its utilization of positive air pressure to conform the thermoplastic Biocryl to the cast s surface, as opposed to employing vacuum pressure. The author acknowledged that the durability over the time of this transparent removable retainer was inferior to that of traditional acrylic or bonded retainers (McNamara et al., 1985).

In 1993, Jack Sheridan enhanced the fabrication process of clear appliances by employing polypropylene and a 0.030" sheet of thermoplastic copolyester from Raintree Products, creating the term "Essix appliance" to refer to an aesthetic technique for aligning anterior teeth through the integration of clear appliances and interproximal tooth reduction. He also advocated for the application of a positive air pressure technique for the thermoforming fabrication method, similar to McNamara's suggestions, to reduce the sheet thickness by about fifty percent post-manufacturing (Sheridan et al., 1993).

Despite these advancements, the fundamental notion of achieving minor tooth motions with individualized transparent appliances remained unchanged. The fabrication of appliances involved creating imprints, pouring casts, sectioning individual teeth, and rearranging them into the correct alignment to achieve a final cast, necessitating repetition of this process at each clinical consultation, which was exceedingly labour-intensive and time-consuming. A resolution emerged as a transparent aligner system called Invisalign, including a sequence of removable polyurethane aligners digitally designed by Stanford graduates Zia Chishti and Kelsey Wirth, and introduced in 1998 by Align Technology in Santa Clara, CA. It was the earliest orthodontic device made from transparent, thermoplastic polymeric materials, relying on the use of contemporary CAD/CAM technology. The technique featured a multi-step procedure, beginning with the three-dimensional (3D) reconstitution of patients' dentition acquired using either an intra-oral scan or digital scanning of models. The subsequent phase entailed the segmentation of the individual crown utilizing a computer algorithm, in conjunction with establishing treatment plans visually displayed as a series of incremental tooth movements by a specified magnitude through the program. The next step involved the fabrication of physical models for each phase of tooth movement applying fast prototyping technology. The custom aligners were manufactured through a thermoforming technique and subsequently cut to their final specifications (Melkos, 2005).

2-2 Advantages, disadvantages and limitations comparing with ready made aligners (Invisalign)

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

2-2-1 Price

Creating aligners in-house can be a more economical choice for clinicians than purchasing them from external companies. The price of a single aligner takes into account the cost of a 3D model printing and plastic sheeting. Although the software used to fabricate aligners can be expensive, the growing number of options available in the market could result in lower costs in the near future. Clinicians can choose to buy licenses for a year or select monthly or case-based payment plans. Furthermore, the price of 3D printers is becoming more reasonable each year. While some high-end printers may be expensive, there are plenty of budget-friendly options to choose from. Finally, orthodontic clinics that already produce orthodontic appliances often have a thermoplastic aligner forming machine readily available.

2-2-2 Delivery time

The second advantage is the duration, which means the orthodontist is capable of delivering the aligners quickly. After scanning the patient's teeth digitally, a moderate case digital setup duration is around 30 minutes. If there is no buccal segments movement, it only takes about 15 minutes to set up.
One of the benefits of this procedure is that several of the most time-demanding tasks can be assigned to a staff member after a brief training session.

The market offers a variety of software options; Nevertheless, the ideas and operational sequence are nearly identical across all these software products. The initial step includes the model preparation, which requires loading and positioning of the models, cutting data in excess, filling holes and gaps, and marking the limits of the teeth. This procedure should always be carried out in the same way, and dental staff don't need any orthodontic expertise. The following step is creating a digital setup, where the clinician formulates the treatment plan, aligns the teeth along the arch form, establishes the sequence of the movement and respective speed, places attachments, and assesses the necessity for elastic wear or not.

The final step is exporting the setup models already created, which involves labeling and determining the height of the models, a task that can also be performed by dental staff. In future releases of the aligner software, the initial and last steps, namely model preparation and exporting, will be autonomously executed by the software as technology evolves. Soon, besides self-segmentation and exporting, auto-alignment will be an upcoming additional feature of the aligner software. Using a DLP printer, the production of three models concurrently requires around one hour. An additional 30 minutes are needed for post-processing, while vacuum forming of each aligner needs roughly 5 minutes.
To summarize a clinician may make ready to deliver aligners to patients on the same day impressions are taken.(Tozlu & Özdemir, 2021).

2-2-3 Overall control

When comparing aligners produced in-house by a clinic to those made by a company, the key benefit of in-house aligners is when the clinician has the ability to quickly create a personalized aligning and staging plan based on their expertise. This saves time and eliminates the need to communicate back and forth with a company technician who may not be a dental expert or may not be familiar with specific alignment rules. When a clinician makes their own digital setup, there's no need for the company to send the digital setup plan for further evaluation or modifications. On the other hand, when working with a company, the clinician has no control over the timeline for the preparation of the digital setup for a submitted case. Although the company notifies the clinician that the digital setup plan had been prepared for evaluation, it may not be a convenient moment for the clinician. Additionally, the digital setup treatment plan provided by the company may not be definitive. Therefore, using an in-house clear aligner system gives the clinician total control over the procedure's timeline.

Although there are benefits to orthodontists producing aligners in-house, it requires a significant investment of time and resources. This includes the need for staff to supervise aligner design and manufacturing, as well as the high cost of acquiring necessary equipment like 3D printers, intraoral scanners, and software for in-house fabrication. However, options like Invisalign offer treatment libraries that present a roadmap for examining comparable aligner cases, leading to cost-effective and streamlined solutions.

2-3 Design and manufacturing: a general overview

Over the past few years many orthodontic CAD software packages for designing and fabricating in-house aligners have been developed. These programs have a similar aligner design method, with variations in design options provided by them. For instance, some programs offer the ability to import CBCT scans and other tools to aid the orthodontist in designing the aligners. Software such as 3Shape Orthoanalyzer (3Shape, Danemark), DeltaFace, Onyx Ceph (Germany) , and Maestro Dental Studio require a one-time license purchase, while others like BlueSkyPlan (Italy) are free to install but in order to export study models an extra payment is needed. Regardless of the fee schedule, all software packages offer to the clinician various options to enhance the quality of treatment planning, including accurate values of every planned tooth movement, the option to stage each movement individually, and visualization of the suggested occlusal contacts.

At present, clear aligners are planned and fabricated by submitting all patient records to an external entity to design and manufacture the appliance. Invisalign is an example of a company that follows this workflow and also stores the data given to it for evaluation and future consideration to improve their treatment-planning algorithms and optimize the services and products it offers. Additionally, conventional orthodontic laboratories use CAD aligner software for designing and producing aligners, with the orthodontist playing a more significant role in designing the aligner, although most of the procedure is done by the laboratory technician. This option can be considered a midpoint between complete in-house aligner production and aligner made by companies like Invisalign (Figure 2).

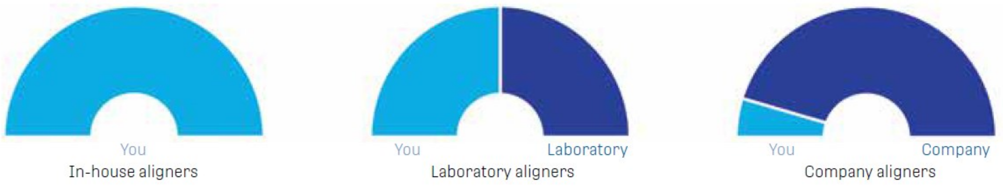


Figure 2: The contribution of the orthodontist in designing and manufacturing aligners in three different workflows (Adapted from Panayi et al., 2021)

2-4 The virtual versus the real life in aligner treatment

The shift to aligner treatment has resulted in a significant increase in screen time for dentists, who now must first address the virtual representation of the patient before moving on to the actual patient. However, the results achieved in the virtual model often do not match those in real life due to a absence of tracking, the behavior of the plastic material in reality, and the inadequate mechanical properties in vivo of the aligner. Additionally, the virtual setup process does not account for the impact of surrounding tissues, such as bone and soft tissue, on tooth movement, nor does it consider root dimensions, shape, and position relative to the bone. These limitations can be attributed to biological factors that avatars do not experience, such as slower bone remodeling or the proximity of a molar root to a sinus wall, which could affect the expected tooth movement. Furthermore, designing tooth movements on a virtual model does not pay attention to Newton's third law, which dentists must consider in their treatment planning.

Finally, a stainless-steel wire that measures 0.019 inches by 0.025 inches has a range of 12 degrees of movement in a 0.022-inch slot bracket. Similarly, a tooth has multiple degrees of movement inside an aligner due to its mechanical behavior. This means that an aligner may adapt to the teeth surface perfectly, but the patient's dentition may react differently than what was created on the virtual model. The aligner thermoforming foil is a crucial component of clear aligner treatment (CAT) (Inoue et al., 2020). This foil is responsible for exerting the forces and moments needed to move the teeth. Invisalign uses its innovative trademarked SmartTrack foil to perform minor tooth movements (0.1-0.2mm) with only one aligner. The Clear Aligner system (Scheu Dental) encounters larger setup steps and typically requires three foils per setup based on the Duran foil (0.5, 0.625, and 0.75mm). Other aligner thermoplastic material companies in the market include: Essix (Dentsply Raintree Essix), Zendura (Bay Materials), and Biolon (Dreve Dentamid) (Jindal et al., 2019).Studies have been conducted comparing the various thermoplastic materials(Condo' et al., 2018), particularly their mechanical properties (Ihssen et al., 2019; Jindal et al., 2019). Other factors that can affect or be affected by the aligner treatment, such as duration of exposure to intra-oral fluids (Bucci et al., 2019), root resorption (Elhaddaoui et al., 2017: Aman et al., 2018),aligner material cytotoxicity (Eliades et al., 2009; Martina et al., 2019) color stability (Liu et al., 2016), and attachments (Elkholy et al., 2019; Weckmann et al., 2020)have also been reported.

3 In-house aligners: design and manufacturing workflow

There are three categories of aligner treatment: full aligner treatment, hybrid aligner treatment (which combines fixed appliances with aligners), and aligner treatment of relapsed cases. The process of designing clear aligners using orthodontic CAD software programs is similar across the board. Additionally, some programs give the opportunity to design aligners for direct 3D digital printing.
The general steps are:

3-1 Importing the intraoral data/scan

The initial stage involves converting the dental arches into a digital format, which is typically accomplished using an intraoral scanner. In instances when polyvinyl siloxane impressions were obtained, a desktop scanner might be employed. Impressions may be instantly scanned or alternatively, plaster casts might be created and subsequently scanned. All relevant patient information is recorded in the patient chart, and the intraoral scan of the dental arches is then imported. A variety of tools exist for capping, removing, and smoothing to edit and enhance dental arch scans.

3-2 Occlusion adjustment

If necessary, the following step involves adjusting the occlusion. However, it's worth noting that intraoral scanning usually defines the occlusion correctly. To verify that the digital model is positioned in the appropriate reference plane, three points are chosen on each arch to mark out and orient the occlusion plane, similar to the method employed in Orthoanalyser.

3-3 Border cleaning and base generation

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.

3-4 Tooth segmentation and numbering

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 and also defines the default angle (rotation around Z) of the teeth. The final stage is segmentation, during which the software performs a calculation and displays each tooth that is set to be moved in different colors. It is of utmost importance to ensure that every tooth is checked thoroughly. If there is an incorrect segmentation, the operator has the option to manually correct the issue.

3-5 Tooth axes definition

In this stage, the user defines the central point of teeth. This middle point serves as a reference point for measuring all types of movement during the setup stage. The software attempts to determine the estimated root position of each tooth in space through calculations, but this is often not precise. Two investigations by Athanasiou and Halazonetis have revealed that available software cannot accurately estimate the anterior tooth root inclination of digital models (Dastoori et al., 2018; Magkavali-Trikka et al., 2019). Therefore, manual correction of the tooth axes is necessary. The CBCT data of the patient can be imported to visualize the exact root positions, but unfortunately, radiation may hinder CBCT scanning for numerous patients, except if it is necessary for other medical purposes.

3-6 The final virtual setup

The next step is to set up the dental arches virtually. Tooth manipulators or numerical definitions of movement or angulation change are common tools in similar software programs. In cases where teeth are moved into an area of mild dental crowding, interproximal reduction (IPR) is necessary. The software calculates and displays the space needed on the tooth's mesial and/or distal side when this is attempted. The amount of IPR required must be assigned in the correct location inside the software.

Separating teeth movements into stages is one of the utmost crucial aspects of clear aligner treatment design. It is not accurate to perform this task in a separate stage. The software couldn't determine which tooth must be moved first for an effective and smooth treatment flow. For example, to create a room by distalizing maxillary molars, the implementation of various stages of movement is required. The initial phase must involve the molars. Subsequently, a second phase wherein the crowded teeth are repositioned into the space generated by the molar distalization is incorporated. This can be achieved via the Orthoanalyser software by utilizing the "Add sequence" option.

Detailed planning and control of each tooth movement, as well as whole teeth movements, are essential for optimal software working. Staging can be displayed on a computer screen or printed as a PDF document. During the configuration procedure, the necessary attachments for these movements must be positioned. The software features a database of diverse attachments (elliptical, hemispherical, etc.) that may be readily changed according to the patient's requirements. Attachments can be bonded to the teeth or incorporated within the teeth (called negative attachment). Attachments designed externally can also be imported for utilization within the software.

Moreover, the selective application of attachments as anchorage points for aligners is essential for stabilizing the aligners during tooth movement. Furthermore, the capacity to make use of all teeth as a support to counteract the displacement of one or two teeth is a notable advantage of aligner therapy. Sequential labeling must be added to each virtual model to be printed in the last stage. It is beneficial to mark the number on the buccal surface of the immobile final molar, ensuring that each aligner is distinctly numbered. Upon the completion of this sequence of setup processes, the clinician can picture out the quantity of aligners necessary for the treatment. The maximum degree of tooth movements (linear or angular) achievable by an aligner remains uniform all over the same case. However, there comes an option to modify the default numbers utilizing a given table by the software. Additionally, at this stage, the software automatically creates a Bolton analysis (Bolton, 1962).

3-7 Exporting of files

The clinician must select whether the aligners will be directly printed on a 3D printer or if dental casts will be made first, from which the aligners will be formed.

3-7-1 Dental models printing and aligner thermoforming

Should this option be selected, the printed working models may be constructed as hollow and base-less to conserve material. Nevertheless, caution must be given to avoid model damage while detaching it from the printer's platform due to its diminished structural integrity. Furthermore, excessively thin models may undergo distortion during the thermoforming process of aligners due to the heat required to soften the plastic material. Camardella et al conducted a study comparing the printing accuracy of models derived from intraoral scans, utilizing several model base designs and different 3D printers. The research indicated that models produced with the polyjet printing process exhibited precision, irrespective of the base design of the model. Conversely, objects with a horseshoe-shaped base produced by the SLA 3D printer exhibited transverse constriction. Models using horseshoe-shaped bases, and a posterior connection bar produced via a SLA 3D printer demonstrated accuracy when contrasted with models exhibiting a conventional base (Camardella et al., 2017).

Dental model printing

Virtual dental models can be transformed into real objects by printing or undigitizing them. A study conducted by Rebong et al. demonstrated that FDM casts were more accurate than plaster casts in terms of dimensional changes. Meanwhile, SLA and polyjet models showed expansion in intra- and inter-arch measurements and shrinkage at the vertical dimension (Rebong et al., 2018). Nonetheless, these findings were only relevant to the particular resin, FDM filament, and printers employed in the research. Dental model resin and a UV light source for polymerization, such as a laser beam, light projector, or LCD light source, are employed in printing, which is usually performed using SLA, DLP, or MSLA printers. After printing, the dental cast is cleaned with 91% isopropyl alcohol and undergo post-printing curing. Although FDM printers are not as commonly used for working model printing, they are less expensive than resin printing systems and do not require any further post-printing procedures. Proper room ventilation is necessary because isopropyl alcohol is an irritant chemical substance. One drawback of using FDM printers is that a special filament is required to resist the high temperature of the thermoforming procedure, which could result in inaccurate aligner fabrication due to deformation of the dental cast.

Aligner thermoforming

After the 3D printing of the working model, the next step is to perform aligner thermoforming. This procedure utilizes thermoforming machines that operate with vacuum or positive pressure, in conjunction with diverse thermoforming plastic films. Vacuum thermoforming equipment may exert pressure up to one bar, corresponding to standard atmospheric pressure at sea level. Nonetheless, there is no restriction on the magnitude of pressure that can be applied by positive thermoforming pressure machines. Utilizing a thermoforming machine capable of exerting the requisite pressure is essential for the precise fabrication of aligners. A distinct template aligner is generated by the software to aid in the bonding of attachments to the teeth. This template aligner is typically fabricated from a thinner foil, such as Duran 0.5 mm, to facilitate removal.

Tracking

During the aligner treatment process, an orthodontist may take a new intraoral scan at any stage to compare it to the initial one. This comparison is made possible using the superimposition feature. Additionally, the orthodontist may also superimpose the new intraoral scan with the corresponding virtual dental cast. By doing so, the clinician can verify if the teeth are moving as intended with the specific aligner at the current stage of treatment. If refinement stage is necessary, the orthodontist can use the setup option to add a new "stage" of treatment, the latter will enable additional tooth movements (Robertson et al., 2020).

3-7-2 For direct printing of aligner

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 & Chaudhari, 2023).

3-7-2-1 Special consideration for the Tera Harz TC-85 resin

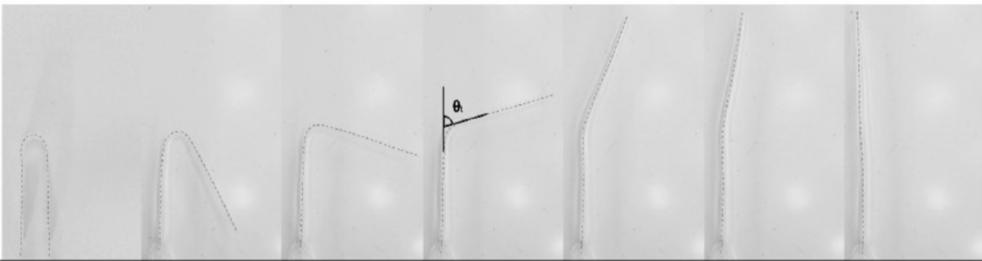
The resin used for 3D printing clear aligners must have specific physical, mechanical, optical, and biological properties.

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 (Table 2).

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).

Table1: 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

Table 2: Other general properties of Tera Harz TC-85 (Graphy INC, 2024b)

Properties	**Unit**	**TC-85 DAC**	**Remark**
Color	-	clear	
Density	g/cm3 @ 25°C	1.061 ± 0.02	
Viscosity	cps @ 25°C	500 ± 100	Book Field
Solid content	% @ 80°C x 1h	≥ 98	
Shore Hardness (D)	-	≥ 85	
Flexural Strength	Mpa	≥ 65	ISO 20795-2
Flexural Modulus	Mpa	≥ 1500	ISO 20795-2

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.

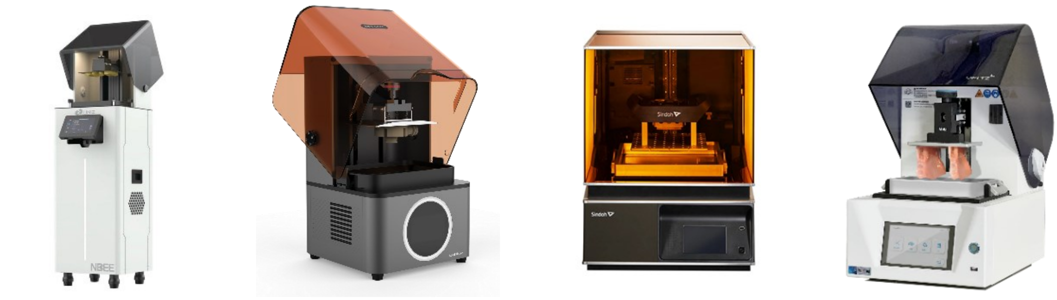
3-7-2-2 Presentation of the equipment necessary for processing Tera Harz TC-85 resin

3-7-2-2-1 Usable 3D Printers

The company website indicates that many 3D printers are compatible with their products, but for printing the aligners, they are recommending only one, which is the UNIZ NBEE.(Graphy INC, 2024a) (Figure 3, Figure 4, Figure 5).

SprintRay Pro95 SprintRay Pro55 Asiga MAX UV

Figure 3: DLP printers for Tera Harz TC-85(Graphy INC, 2024a)



UNIZ NBEE shining3D AccuFab- Sindoh A1 SD Veltz VL1

Figure 4: LCD printers for Tera Harz TC-85 (Graphy INC, 2024a)

Sindoh A1+

Figure 5: SLA printer for Tera Harz TC-85 (Graphy INC, 2024a)

3-7-2-2-2 Ultrasonic Cleaner

Figure 6: Tera Harz Care (Ultrasonic cleaner and warmer for aligners) (Graphy INC, 2024c)

3-7-2-2-3 Centrifuge

Figure 7: Tera Harz Spinner (Graphy INC, 2024d)

3-7-2-2-4 Curing Machine

Figure 8: Tera Harz Cure, a curing unit with a nitrogen generator that allows oxygen-free polymerization (Graphy INC, 2024c)

3-7-2-3 Special features of printing aligners with Tera Harz TC-85 resin

The approach used for designing and producing directly printed aligners differs from that of thermoformed aligners. The software utilized for designing printed aligners is essentially similar to that employed for thermoformed aligners. The technique for achieving the setup and digital allocation of attachments is identical for both types. Following the setup, the orthodontist or the dental technician must digitally construct the initial malocclusion model to generate the aligner that the program will use to make all consecutive aligners.

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.

3-7-2-4 Printing of aligners: Digital Light Processing technique

Digital Light Processing (DLP) is a 3D printing technology known for its method recognized for its capacity to quickly generate highly intricate geometries with microscale precision (Hoon et al., 2022). This Vat Photopolymerization (VPP) additive manufacturing method uses a liquid vat of photopolymer resin and an ultraviolet (UV) light source to solidify the resin through polymerization. In accordance with stereolithography principles, the VPP printer emits UV light onto the resin surface in the specified mask configuration, permitting only the connected printed component to progress in the z-direction. The UV light is subsequently concentrated on the subsequent layer, and printing proceeds layer by layer. Attaining optimal part quality necessitates the consideration of multiple parameters, such as DLP UV exposure intensity, exposure duration, printing orientation, and post-curing, while understanding the relationships among these factors is essential (Lee et al., 2022).

3D printers employing VAT technology, like Stereolithography (SLA), are necessary for the production of aligners. At present, there exist three classifications of VAT printers: SLA, Direct Light Projection (DLP), and masked SLA or LCD. The most commonly printers employed are DLP, each possessing distinct printing software and supporting positioning techniques. Supports are essential for effective and precise printing, are carefully placed in required locations, usually performed automatically. Aligners may be oriented horizontally or vertically on the virtual printer platform. The printing direction (horizontal or vertical) does not significantly impact the mechanical qualities of three-dimensional (3D)-printed aligners (Camenisch et al., 2024). However, horizontal positioning increases printing speed due to fewer layers but requires more

supports and prints fewer aligners at once. Vertical orientation leads to reduced printing speed and fewer supports, allowing for the simultaneous printing of more aligners, however with an elevated chance of errors due to the increasing number of printed layers. The printing definition of the z-axis is 100 µm, guaranteeing sufficient printing precision. It is essential to stir the homogenous resin for a few minutes before use, and the resin temperature should be around 30 °C to avoid the possibility of failure.
After printing Graphy recommends using a centrifuge to remove any residual resins (that was not cured) for 6 minutes as an alternative to the use of isopropyl alcohol.
Then wipe it clean with a cotton swab to make sure of the elimination of all the residual of the resin.

3-7-2-5 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 3).

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 3: 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	℃	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 The 3D printed aligners

4-1 Advantages and disadvantages compared with the conventional way

4-1-1 For the orthodontist

4-1-1-1 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 9).

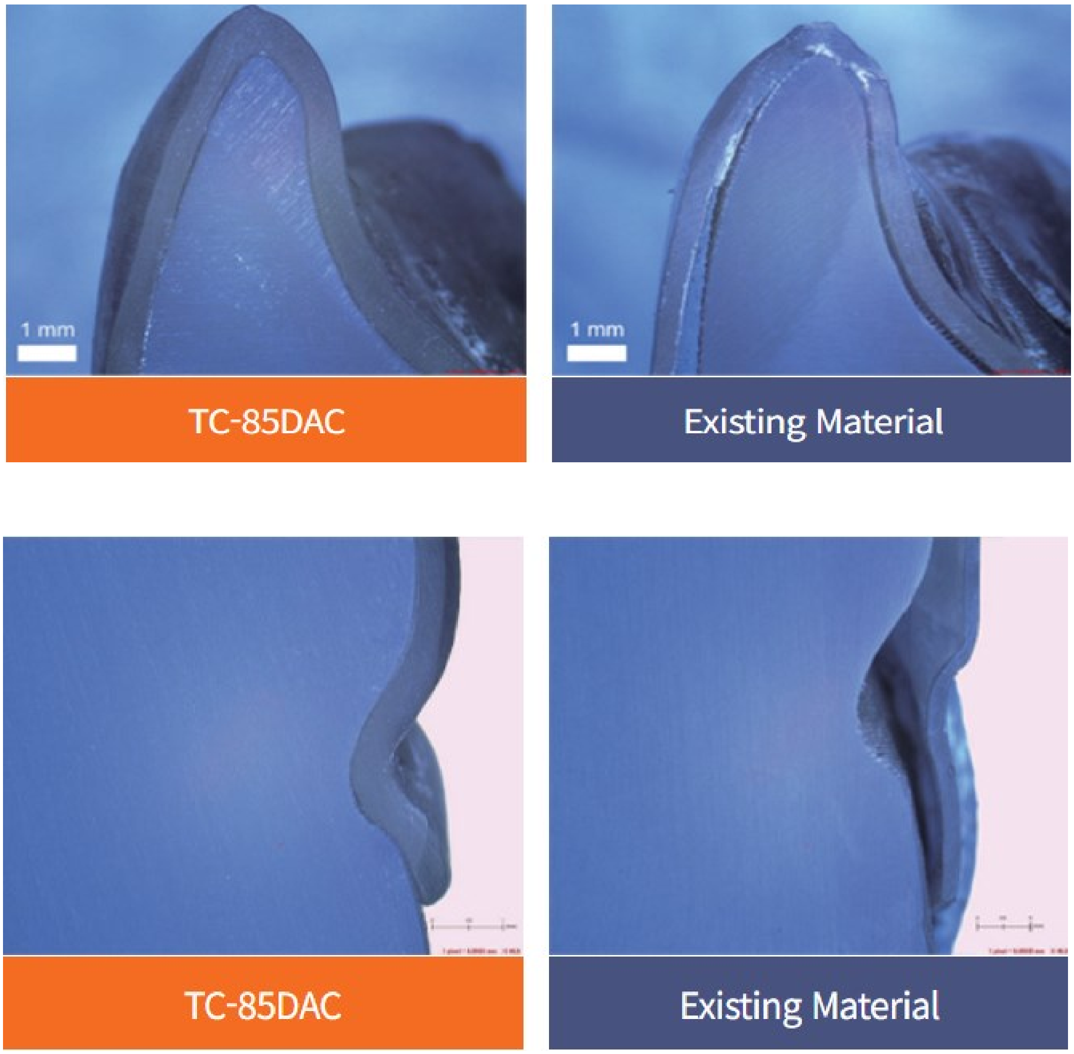


Figure 9: Adaptation of direct printed aligners compared to that of conventional aligners. Graphy's web site (http://www.itgraphy.com/ENG/bbs/content.php?co_id=sub0201_1)

- **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 10).

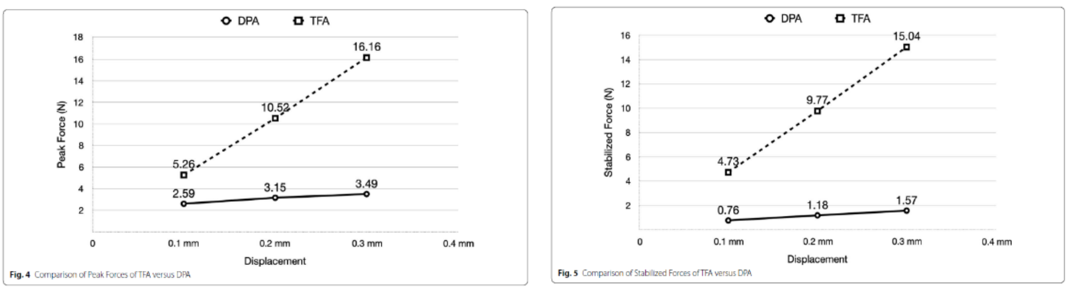


Figure 10: Forces delivered by direct printed aligners compared to that of conventional aligners.(Hertan et al., 2022)

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).

- **Customized 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.

4-1-1-2 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).

4-1-2 For the patient

The impact of materials utilized in the human body on human cells results in cytotoxicity and iatrogenicity, which are considered to be unfavorable effects. Cytotoxicity refers to the degree of toxicity a substance has on human cells, while estrogenicity involves the actions of endocrine-disrupting chemicals (EDCs) that imitate, obstruct, or disrupt hormones inside the body's endocrine system. The conduction of cytotoxicity tests is crucial for determining the toxicity of a material in human cells.

Over the past few decades: plastics, Composite resins, and plastic foils for thermoformed aligners have been linked to the release of Bisphenol A (BPA), which mimics estrogen (a weak synthetic estrogen), leading to issues for males as well as other problems such as cardiovascular problems, type 2 diabetes, deformities, obesity, and certain cancers (Fenichel et al., 2013). However, Limited research has been undertaken to investigate the estrogenicity and cytotoxicity of 3D-printing resins and their resultant 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 roughness of the surface was evaluated for the printed aligner compared with Invisalign devices. The results indicated that the surface roughness was higher for the printed aligner than for Invisalign (Koletsi et al., 2023). This high roughness could trigger the release of various substances. And may cause small fractures in the aligner, weakening its mechanical properties. Roughness may be intrinsic to 3D-printed aligners as a result of improper printing techniques or extreme brushing. The sensitive multi-step printing process may lead to roughness caused by different conditions during design, printing, or curing. For instance, printing aligners in a vertical orientation involves the deposition of numerous material layers, resulting in "steps" on the aligner, whereas horizontal positioning yields fewer layers and a more uniform surface. This disparity may lead to additional roughness throughout the entire aligner surface. Insufficient UV curing may lead to a textured aligner surface. Intraoral ageing, affected by the adverse oral environment, influences multiple aspects of aligners and may also lead to elevated roughness and alterations in their mechanical properties. Transparency is a key feature that enhances the invisibility of clear aligners. Heightened roughness could cause the aligner to appear foggy due to decreased light penetration, possibly reflecting light back and making the aligner more visible in the mouth. The study showed that increased roughness could potentially affect the clinical effectiveness and safety of aligners.TC-85 displays geometric stability at elevated temperatures without undergoing thermal shrinkage, as proven by Kim. This characteristic can be extremely advantageous in a clinical setting. The use of TC-85 in producing transparent aligners aids in managing hygiene and disinfection. Typically, microorganisms begin to inhabit the surface of clear aligners six hours after they are inserted, resulting in the development of biofilm that obstructs complete coverage of the teeth and impedes successful tooth movement. As a result, healthcare providers advise patients against cleaning or disinfecting their aligners at high temperatures due to the potential for distortion in thermoplastic materials like PETG. An examination of the thermal behavior of materials has demonstrated that temperatures exceeding 60°C can deactivate Streptococcus mutans and similar lactic acid bacteria, which play a significant role in causing dental caries. Additional research is necessary to confirm that cleaning aligners at high temperatures does not compromise their functionality and has a disinfecting effect in clinical practice. The shape memory characteristic of TC-85 enables aligners to exert orthodontic forces on the teeth consistently at physiological temperature, without suffering from force deterioration due to aligner deformation. This feature benefits patients wearing aligners, as they can soak them in warm water before use to enhance flexibility, alleviate discomfort, and ensure a better fit. Even if the aligner becomes distorted when worn on the teeth, it will revert to its original printed shape and rigidity at 37°C, allowing it to maintain a constant orthodontic force on the teeth (Lee et al., 2022).

4-1-3 For the community

The discussion over plastic trash in the ocean and climate change typically begins with a stifled yawn and concludes with an assurance that the issues will somehow resolve themselves. The escalation in PET-G production resulted in a significant rise in plastic bottle sales during the 1980s, and subsequently, there has been a swift proliferation in plastic utilization owing to its affordability, ease of manufacture, and straightforward transportability. Approximately 14% of all plastic ever produced is generally collected, and less than 20% of that is recyclable, with merely 9% of the recycled plastic ultimately being processed for reuse. Ninety-one per cent is either landfilled, dumped in oceans, or burnt. The World Economic Forum has estimated that an entire truckload of plastic garbage is discarded into the ocean every minute (KLine, 2021).

The use of clear aligners for orthodontic treatment is becoming more popular due to their appealing appearance and comfort compared to traditional fixed appliances, alongside the intensive campaigns by commercial manufacturers. Patients generally utilize several plastic aligners, each worn for one to two weeks before disposal, raising environmental worries about the buildup of plastic waste (Bichu et al., 2023). Most transparent plastic aligners are composed of PET, PETG, or TPU, along with other petroleum-derived polymers, which emit various nano plastics. These plastics impact not only the oceans, marine life, and climate change, but also human health.

Potential strategies to decrease plastic usage consist of measures to diminish plastic consumption, hence reducing production and enhancing recycling opportunities. Nonetheless. The present orthodontic market indicates no decline in the utilization of clear aligners, and for aligner manufacturers, identifying substitutes for plastic in clear aligner production is implausible (KLine, 2021) and most of these companies typically do not offer instructions to the dentist or the patient on how to recycle used aligners, nor do they make an effort to minimize the resulting plastic waste. Yet recycling a small number of plastic aligners at specific places is not a sufficient solution because of the large amount of aligner waste produced worldwide, Additionally, we are facing a very short time frame to mitigate serious environmental impacts, which requires reducing plastic usage and seeking alternative options.

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)

III. 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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