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3D printed removable functional appliances for early orthodontic treatment – Possibilities and limitations

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A R T I C L E I N F O

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A B S T R A C T

The early treatment of certain malocclusions, such as class II division 1, is recommended to decrease the likelihood of upper incisor trauma. However, the lack of skilled technicians and economic constraints prevent the availability of well-known removable functional appliances. The orthodontic profession is undergoing changes, and automation may offer a solution to these challenges. This article discusses the potential for automating the production of two commonly used removable orthodontic appliances. While CAD-CAM systems have streamlined dental manufacturing, 3D printing is a popular option for certain manufacturing processes. However, the adoption of 3D printing for orthodontic devices faces hurdles, such as redesigning devices for this new manufacturing process, material considerations, and necessary certifications. To showcase the potential design and manufacturing process of 3D printed devices that fall under the category of appliances similar in type and style to FR II and Sander II, the article centers on these two widely recognized appliances. As it is currently not possible to replicate all analog features in 3D, it may be appropriate to use a more general name for the FR II and Sander II appliances. In summary, the article examines the potential and limitations of automation in orthodontic appliance manufacturing.

Introduction

The early treatment of certain malocclusions, such as class II division 1, is recommended to decrease the likelihood of upper incisor trauma.[1] However, the lack of skilled technicians and economic constraints prevent the availability of well-known removable functional appliances. It is becoming increasingly challenging to find employees, especially dental technicians who specialize in orthodontics. Additionally, many patients and offices are facing economic challenges, which means we need to search for suitable solutions. To tackle these problems, we must adapt, and one possible solution is automation. This could enable us to manufacture products, such as removable appliances for early orthodontic treatment, in a more cost-effective manner, with fewer or no technicians required. Essentially, there are three options available for utilizing removable functional appliances in early treatment of Class II division 1:

1) fully customized and made according to established rules by a trained technician,
2) prefabricated myofunctional appliances (PMAs)
3) digitally designed and fabricated using computer-aided design and manufacturing (CAD/CAM) technology, followed by 3D printing.

About FR II and Sander II

The Fränkel II appliance is a functional orthodontic appliance.[2] Typically used in the early stages of treatment, the Fränkel II appliance can be highly effective for growing patients.[3,4] Skilled technical expertise is necessary to produce the appliance, given its complex design, to ensure optimal treatment outcomes.[5] However, due to the challenges associated with manual manufacturing and the intricate nature of the design, the use of the FR II appliance has become less common in recent years. The

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Sander II orthodontic appliance, like the Fränkel, is a functional removable appliance. However, its design and manufacturing process is relatively simple, especially when compared to that of the Fränkel, due in part to the use of prefabricated parts. Nevertheless, a skilled technician is still required for its proper construction. Despite this, the Sander II orthodontic removable appliance has been proven to be an effective treatment option for correcting class II malocclusions.[6] We can conclude that the effects of functional orthodontic appliances in correcting Class II malocclusion have been thoroughly evaluated.[7] However, considering the challenges mentioned above, what is the method to produce them?

About PMAs

Prefabricated myofunctional appliances (PMAs) have been heavily promoted and are currently a topic of much debate. They are pre-made devices that are available in various sizes and shapes to accommodate different patients. PMAs have become popular due to their low cost, immediate availability, and the desire of parents to prevent potential dental problems such as incisor trauma. It can be concluded that PMAs are a product of our current societal and orthodontic climate. However, the effectiveness of PMAs in treating Class II division 1 malocclusion in the short-term has been shown to be lower than activators. Nevertheless, the cost-effectiveness of PMAs remains a significant advantage. It is important to note that these findings should be interpreted with caution, as further high-quality, long-term research is necessary to fully understand the benefits and limitations of PMAs.[8]

About 3D

A hybrid approach, combining handcrafted manufacturing with the idea of pre-made appliances, could be used to address the current challenges in orthodontics. This approach could involve digital design and 3D printing to create customized orthodontic devices. Today, CAD-CAM systems have transformed dental manufacturing by streamlining the process and final manufacturing stages can be completed using 3D printing or milling machines. However, the adoption of 3D printing is hindered by obstacles such as the need to review current devices and consider material certifications and mechanical properties. Recently, there has been a surge in articles exploring the possibility of 3D printing − mostly a twin block design but also the functional regulator (FR).[9−11] Another article describes the fabrication of a milled Twin-block with an expansion screw using intraoral scanning and digital bite registration without an analog impression or construction bite. Later, computer-aided design and manufacturing technology was used to design and build the appliance, with the mandibular advancement being simulated digitally using a virtual articulator.[12] In this article, we will examine the potential for automated production of two commonly used and well-evaluated removable orthodontic appliances: The Fränkel II (functional regulator − FR II) and the Sander II appliance. Our preference is to use terminology that the design and ultimate production are rooted in the initial appliance concept but can be accurately classified as appliances that are comparable in type or style to FR II and Sander II. We will explore the current possibilities and limitations of automation and provide an outlook on what improvements are necessary.

What did we do?

There are several software programs commonly used to design 3D printed orthodontic appliances, each with its own unique features and capabilities. These software programs allow orthodontic professionals (clinicians and technician) to design and customize orthodontic appliances for individual patients, using digital scans of the patients. The resulting digital models can be used to create 3D printed orthodontic appliances with a high degree of precision and accuracy.[13,14] Here are some software examples that fit this description: Exocad, Meshmixer, Blender, Blue Sky Plan, OnyxCeph, Ortho Analyzer and many more.

Iin this article Rhino 3D is utilized, also known as Rhinoceros, version 6.0, developed by Robert McNeel & Associates in Seattle, WA. Rhino 3D is a widely used 3D modeling software that finds application in diverse fields such as architecture, industrial design, and product design. It features a plethora of tools for creating and manipulating complex 3D geometry, including free-form surface modeling, mesh editing, and 3D rendering. The software supports a range of file formats, facilitating easy sharing of models with other software programs. Rhino 3D is known for its unique Spline Base or B-spline feature, which is used for drawing curves. These curves form the foundation for creating surfaces and volumes. Rhino's open structure enables it to function as a development platform, allowing both expert and non-expert programmers to customize and automate the software, thereby expanding its functionality. Moreover, Rhino's licensing is affordable and owned. Additionally, Rhino offers a comprehensive training program, with multiple training centers available for various fields of study. Developers can also design and create a wide variety of plugins, leveraging Rhino's Open System to develop different plugins for different areas of use. Geometries created with Rhino can be exported to laser cutting machines, milling machines, or 3D printers. In this article, the authors demonstrate the process of designing orthodontic devices, specifically the Frankel II and Sander II, using Rhino 3D modeling. The redesign of such devices requires an understanding of the function of each component, including metallic and acrylic elements, and an evaluation of their synergies to identify areas for improvement.

To expedite the design process for an FR II or Sander II, a library of various parts is stored. The user can assemble the final device from these parts. Fig. 1 showcases the final version of a functional regulator type II (Fränkel/FR II), where different colors represent pre-designed parts that can be selected to construct the final appliance. By following established analog manufacturing guidelines, these parts can be scaled and adjusted to achieve optimal clinical results. Moreover, individual components of the FR II and Sander II can be personalized to cater to patient-specific factors such as the distance to the teeth, gingiva, or frenula. The use of a

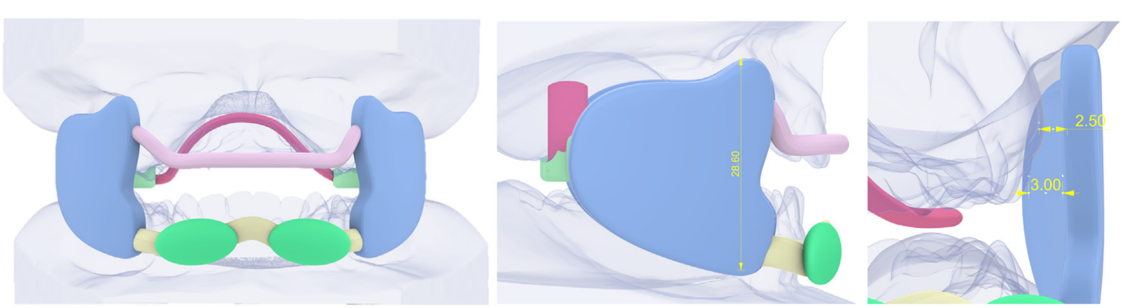

Fig. 1. a) The digital design depicts the final version of a functional regulator type II (Fränkel/FR II), with different colors indicating the pre-designed parts that can be chosen to create the final appliance. b) These parts can be scaled and adapted using established analog manufacturing rules to achieve the best clinical outcome. c) Additionally, individual components of the FR II can be customized based on individual patient factors such as the distance to the teeth, gingiva, or frenula.

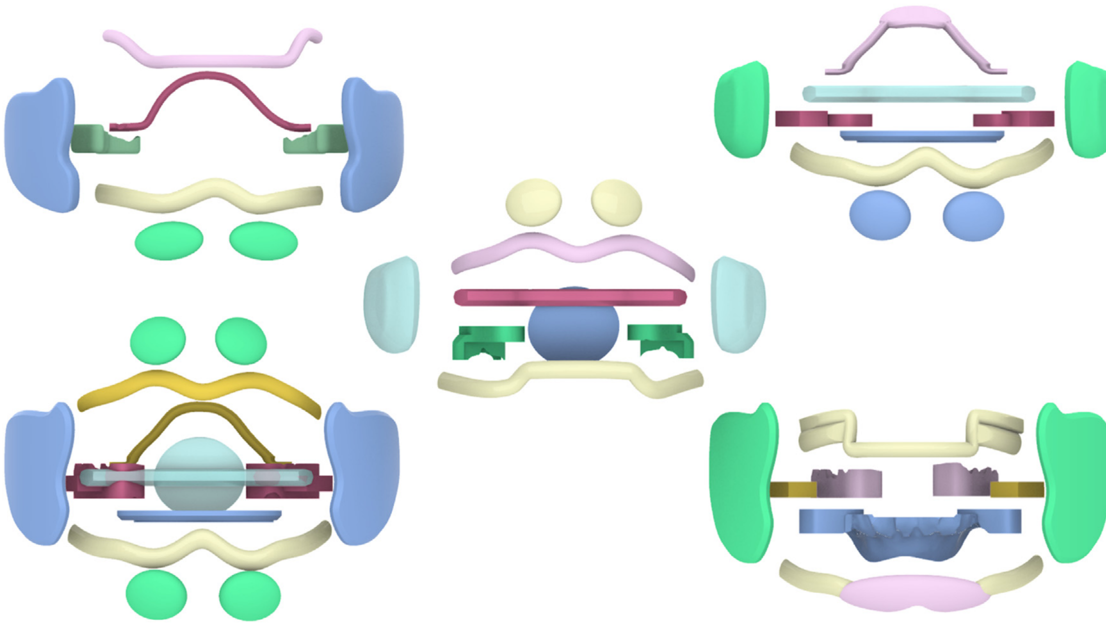

Fig. 2. By utilizing a library of components, we can create numerous combinations of Fränkel type appliances. The availability of a configurator enables doctors to design appliances using preformed modules, which is an effective tool for communication with technicians, and patients.

component library allows for the creation of several permutations of Fränkel- or Sander type appliances. A configurator is also available, which facilitates communication between doctors, technicians, and patients during the appliance design process using pre-designed modules (Figs. 1 and 2). The orthodontist or dental technician assumes the role of a CAD designer.

Scan and bite registration

The use of digital scanners for impression making and cast fabrication in dentistry is rapidly gaining popularity.[15] In a CAD environment, the technician has two options to generate a model: scanning physical models or using intraoral scans. It is crucial to incorporate a construction bite during the scanning process. Digital bite registration is a prevalent method employed to capture the patient's bite relationship, which is necessary when designing functional orthodontic appliances such as FR II or Sander II. It is imperative to consider the bite in all directions while designing these appliances, and preset configurations can be utilized to guide tooth eruption effectively. The process is illustrated visually in Fig. 3.

Printing and cleaning

After the appliance is assembled, it is saved in an STL file format, which is suitable for 3D printing. Although the scientific evidence on 3D-printable orthodontic materials is limited, it is expected that 3D printing technology will be extensively used in clinical practice soon. To consolidate the evidence, international standards for laboratory testing and thorough clinical investigations are necessary. Aligners are the most studied application of 3D printing in orthodontics, but there is a lack of consistency in mechanical property tests, and biocompatibility tests do not fully account for intraoral conditions. Further research, including clinical trials, and defining international standards are required.[16]

There are several biocompatible 3D printing resins commonly utilized in orthodontics, such as Dental LT Clear Resin from Formlabs, KeySplint Soft from Keystone Industries, NextDent Ortho Rigid from Vertex Dental, EnvisionTEC E-Ortholign from EnvisionTEC, Tera HARZ TC 85 from Graphy, among others. Over the years, we have extensively tested KeySoft resin from Detax and have chosen to focus on this product due to its excellent elastic properties that make it durable enough to withstand chewing loads and accidental fractures. KeySoft resin is

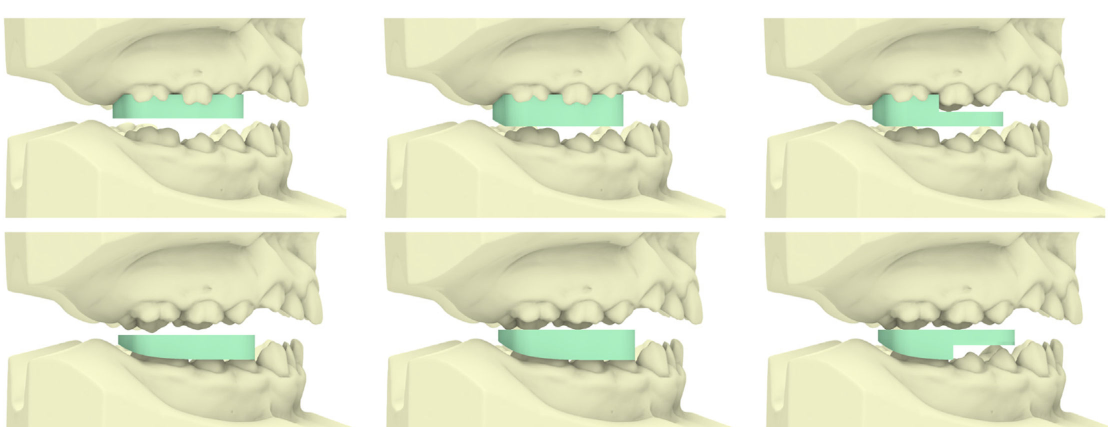

Fig 3. When designing a FR II, one of the crucial factors to consider is the bite in all room directions. Additionally, preset configurations can be established to guide the eruption of specific teeth or prevent further eruption of others.

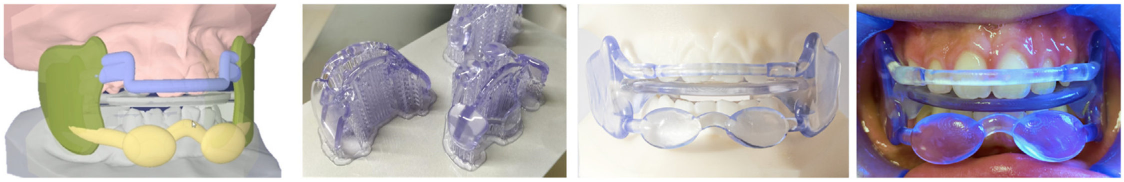

Fig. 4. Illustrates all stages of a CAD/CAM FR II appliance. These stages include:
a) the final digital/virtual design, b) the printed parts still exhibiting the support structure, c) the polishing and adaptation on a 3D printed model (optional), and d) The final fitting of the appliance in the patient's mouth reveals a slight difference between the design, the printed appliance, and the intraoral fit. Correcting this difference proves to be challenging due to the absence of a wire, which makes straightforward adaptation impossible.

specifically designed for dental splint therapies and can be stored for several months. It's clear-transparent formulation allows for visual control, and it is easy to work with during post-production, and can be used with many printers already parameterized for the product. It has high initial hardness and final strength, a low-viscosity approach for low material consumption and quick cleaning, and high mechanical bending and breaking strength, making it strong without being brittle. Moreover, KeySoft resin is BPA-free, neutral in odor and taste, and is classified as a medical device Cl. IIa. A DLP printer was utilized for physical production, and after printing, the supports are removed, and the device is finished and polished.[17,18] The device is then checked on models before being delivered to the clinician

Fig. 4 displays the various stages involved in creating a CAD/CAM FR II appliance. These stages include the final digital/virtual design, the printed parts with support structure, the optional polishing and adaptation on a 3D printed model, and the final fitting of the appliance in the patient's mouth. However, there is a slight difference observed between the design, the printed appliance, and the intraoral fit, which is challenging to correct due to the absence of a wire. In Fig. 5, an early intervention for a class II/1 deep bite patient is depicted, utilizing a 3D printed and digitally designed FR II appliance. This appliance showed positive clinical effects and remained intact for six months. Nonetheless, there is room for improvement in the clinical fit of some parts, and reactivation can only be achieved by redesigning and reprinting the appliance, which can be considered a drawback.

Discussion

The system offers several benefits, such as enabling clinicians to capture impressions using traditional methods or intraoral scanning and sending them to the recipient company via email, saving time, material, and courier costs. In case the impressions are not reliable, the process can be repeated at no additional cost, eliminating the need for a physical model. To streamline the manufacturing process of orthodontic devices, virtual preparation can be utilized to create a protocol for a specific device that can be divided into virtual pre-formats, which can be adapted and stored in a library. This reduces the virtual modeling time for a technician, while the physical realization can be entrusted to 3D printers. However, a clinical/technical comparison during the design stage is necessary to avoid a prepackaged system that does not consider the specific needs of the case. The device can be viewed before printing, which reduces errors in communication. There is also a reduction in waste products and greater flexibility in product customization. While some may argue that reduced manual activity in the era of digital technology can affect the quality of the final product, it is important to note that digital technology enhances our design ability and offers interesting solutions. It is still the mind that guides the arm, whether using a micromotor or a mouse. This innovative work in designing and modifying these two removable functional appliances provides a valuable reference point for colleagues and clinicians. There is still much to be explored and accomplished in the field of orthodontic device manufacturing. But what needs to be done better?

Is Hybrid the future?

The future of manufacturing removable functional appliances will likely be a combination of digital and analog processes, rather than strictly one or the other. However, it is crucial to have a fundamental understanding of the appliances and carefully evaluate which parts are better suited for digital manufacturing versus manual production. When it comes to the original designs of the FR II and Sander II appliances, their digital versions should be considered more generic as they differ in

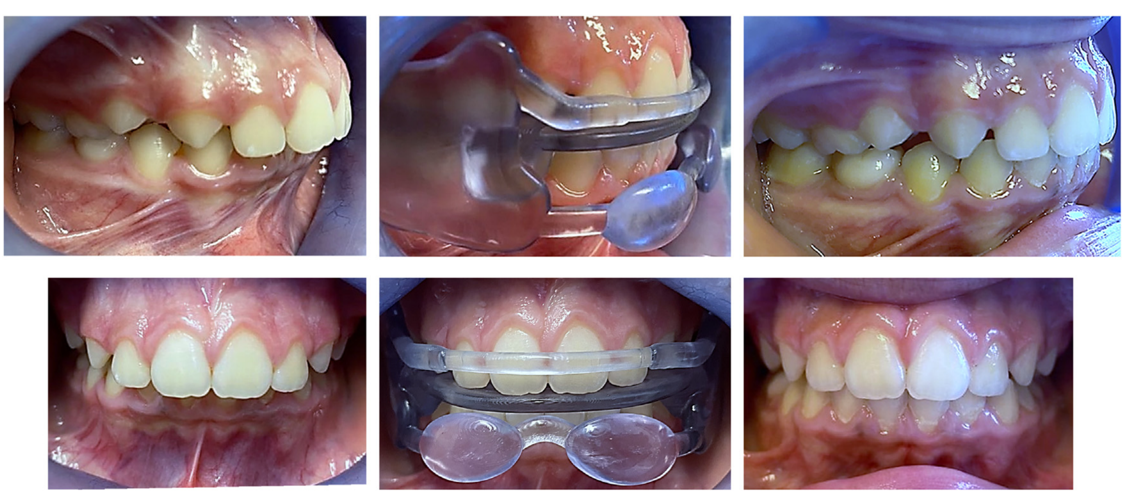

Fig. 5. An early intervention is displayed for a class II/1 deep bite patient, utilizing a 3D printed and digitally designed FR II appliance. The appliance yielded positive clinical effects and remained intact throughout its 6-month usage. However, the clinical fit of some parts could be improved, and reactivation can only be achieved through redesigning and reprinting the appliance, which can be considered a disadvantage

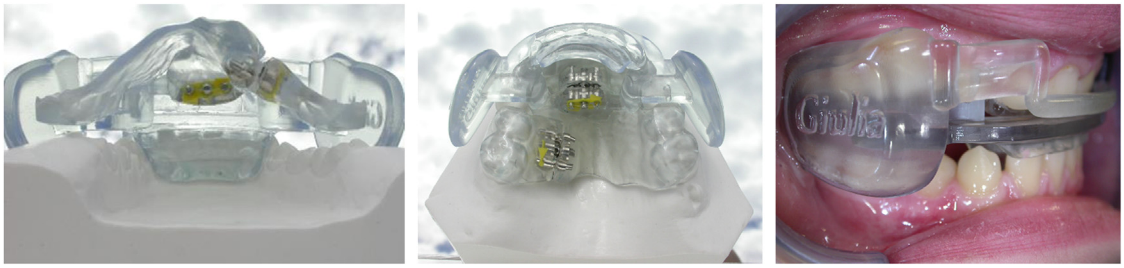

Fig. 6. Displays the possibilities of personalizing a 3D fabricated functional appliance by incorporating premade screws. Furthermore, the patient's name can be engraved with ease.

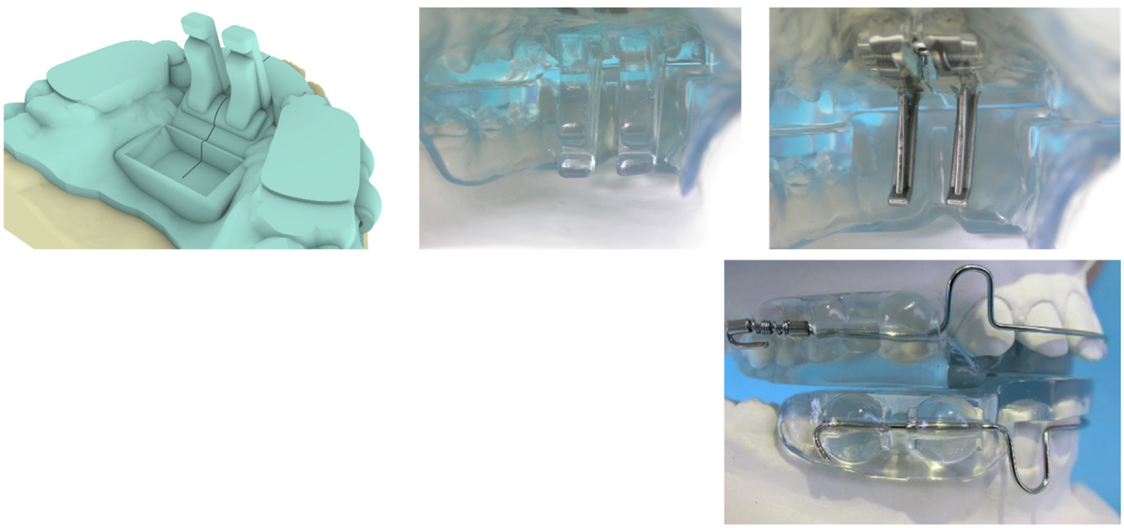

Fig. 7. It is demonstrated how the Sander II appliance can be employed to display additional possibilities for tailoring 3D-printed functional appliances. One can opt for utilizing the original Sander screw from FORESTADENT or incorporate a conventional expansion screw with 3D-printed probes. Combining the digital version of the 3D-printed Sander with analog wires can be advantageous, as it permits a hybrid style that merges 3D printing with manual handcrafting

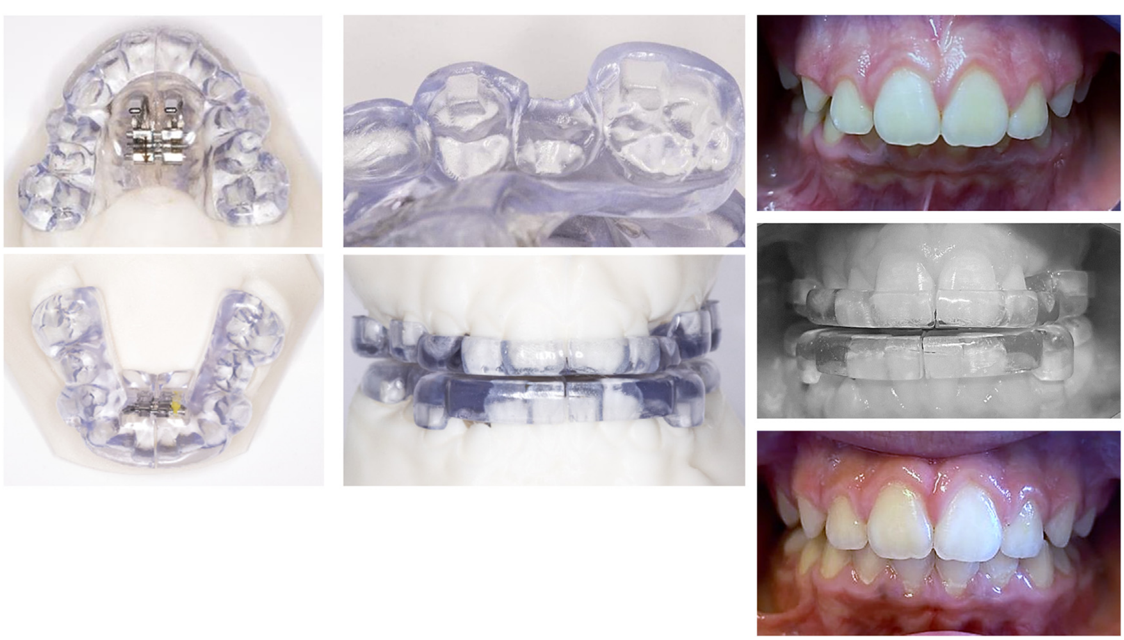

Fig. 8. When using 3D-printed removable appliances, anchorage on the teeth can pose a challenge. One solution is to adopt a hybrid style that incorporates hand banded wires as anchorage clamps. Another approach depicted in this picture is the use of bonded attachments. However, caution must be exercised during their application to avoid impeding tooth eruption. To achieve this, it is necessary to carefully stage the process and incorporate an aligner-style setup.

some respects and have limitations. Therefore, they should be referred to as FR II and Sander II type designs. Fig. 6 demonstrates how premade screws can be incorporated into a 3D-printed functional appliance to allow for personalization. The patient's name can also be easily engraved. Fig. 7 showcases additional possibilities for tailoring 3D-printed functional appliances using the Sander II appliance. One can choose to use the original Sander screw or a conventional expansion screw with 3D-printed probes. Combining the digital version of the 3D-printed Sander with analog wires can create a hybrid style that merges 3D printing with manual handcrafting. Fig. 8 illustrates the challenge of achieving anchorage on teeth when using 3D-printed removable appliances. One solution is to use a hybrid style that incorporates hand-banded wires as anchorage clamps. Another approach is to use bonded attachments, but caution must be exercised during application to avoid impeding tooth eruption. A carefully staged process and an aligner-style setup can help achieve this.

Conclusion

Although functional appliances produced via 3D printing work, they still require improvements.

1. Due to software limitations, IT management requires plug-ins. Developing dental technician devices necessitates software engineering skills, and modeling should be more intuitive and user-friendly. Virtual configurators can facilitate a fully digital workflow, making 3D devices comparable to aligners.
2. Continued resin development is necessary to enhance their biocompatibility and functionality. An ideal resin has not yet been discovered or certified.
3. Further investigation is required for material mixing and wire implementation, particularly for reactivation wires, which are currently lacking.
4. To respect and protect the original designs of the FR II and Sander II appliances and the extensive publications related to them, their digital versions should be regarded as more generic, as they differ in some respects and have limitations. As a result, they should be referred to as designs of the FR II and Sander II type.

It is crucial not to neglect orthodontic skills as AI becomes more prevalent in design, potentially reducing the incentive for ongoing cultural learning.

Patient consent

Patient consent was obtained.

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Author contributions

All authors attest that they meet the current ICMJE criteria for Authorship.

Declaration of Competing Interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

References

1. Thiruvenkatachari B, Harrison J, Worthington H, et al. Early orthodontic treatment for Class II malocclusion reduces the chance of incisal trauma: results of a Cochrane systematic review. *Am J Orthod Dentofacial Orthop*. 2015;148(1):47–59.
2. Fränkel Rolf. Die Funktionsregler und das Prinzip der Enthemmung. *Fortschritte der Kieferorthopädie*. 1963;24(3-4):440–456.
3. de Almeida Marcio Rodrigues, Henriques José Fernando Castanha, Ursi Weber. Comparative study of the Fränkel (FR-2) and bionator appliances in the treatment of Class II malocclusion. *Am J Orthod Dentofacial Orthop*. 2002;121(5):458–466.
4. Freeman David C, McNamara Jr David C, Baccetti T, et al. Long-term treatment effects of the FR-2 appliance of Fränkel. *Am J Orthod Dentofacial Orthop*. 2009;135(5): 570.e1-570.e6.
5. McNamara Jr, James A, Huge Scott A. The Fränkel appliance (FR-2): model preparation and appliance construction. *Am J Orthod*. 1981;80(5):478–495.
6. Martina R, Cioffi I, Galeotti A, et al. Efficacy of the Sander bite-jumping appliance in growing patients with mandibular retrusion: a randomized controlled trial. *Orthod Craniofac Res*. 2013;16(2):116–126.
7. D'Antò V, Bucci R, Franchi L, et al. Class II functional orthopaedic treatment: a systematic review of systematic reviews. *J Oral Rehabil*. 2015;42(8):624–642.
8. Mohammed Hisham, Čirgić Emina, Rizk Mumen Z, et al. Effectiveness of prefabricated myofunctional appliances in the treatment of Class II division 1 malocclusion: a systematic review. *Eur J Orthod*. 2020;42(2):125–134.
9. Roser Christoph, Hodecker Lutz D, Koebel Chris, et al. Mechanical properties of CAD/CAM-fabricated in comparison to conventionally fabricated functional regulator 3 appliances. *Sci Rep*. 2021;11(1):14719.
10. Graf Simon, Tarraf Nour Eldin, Vasudavan Sivabalan. Direct printed removable appliances: a new approach for the Twin-block appliance. *Am J Orthod Dentofacial Orthop*. 2022;162(1):103–107.
11. Cousley Richard RJ. The digital Twin Block appliance: concept, design and fabrication. *J Orthod*. 2022: 14653125221138586.
12. Sofrata Abier H, Cattaneo Paolo M, Cornelis Marie A. Computer-aided design and manufacture of a milled Twin-block: workflow and use in a clinical patient. Have we entered the digital era? *AJO-DO Clinic Companion*. 2022;2(5):431–438.
13. Favero Christian S, English Jeryl D, Cozad Benjamin E, et al. Effect of print layer height and printer type on the accuracy of 3-dimensional printed orthodontic models. *Am J Orthod Dentofacial Orthop*. 2017;152(4):557–565.
14. Venezia Pietro, Ronsivalle Vincenzo, Rustico Lorenzo, et al. Accuracy of orthodontic models prototyped for clear aligners therapy: a 3D imaging analysis comparing different market segments 3D printing protocols. *J Dent*. 2022;124: 104212.
15. Sehrawat Sonam, Kumar Ajay, Grover Seema, et al. Study of 3D scanning technologies and scanners in orthodontics. *Mater Today*. 2022.
16. Goracci Cecilia, Juloski Jovana, D'Amico Claudio, et al. Clinically relevant properties of 3D printable materials for intraoral use in orthodontics: a critical review of the literature. *Materials*. 2023;16(6):2166.
17. Cousley Richard RJ. Introducing 3D printing in your orthodontic practice. *J Orthod*. 2020;47(3):265–272.
18. Groth Christian, Kravitz Neal D, Jones Perry E, et al. Three-dimensional printing technology. *J Clin Orthod*. 2014;48(8):475–485.