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Research article

A fully digital workflow for the design and manufacture of a class of metal orthodontic appliances

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A R T I C L E I N F O

Keywords:
Digital oral technology
Digital oral model
Computer-aided design
Three-dimensional printing
Orthodontic appliance

A B S T R A C T

Background: Traditional working procedures requires a lot of clinical processes and processing time.
Methods: The orthodontic metal appliances were made by applying oral scanners, digital images, computer-aided design and computer-aided manufacturing (CAD-CAM) printers.
Results: The computer digital technology simplified the manufacturing process for dental appliances and shorten the duration for clinical operation and technical processing.
Conclusions: The technique described in this paper can guarantee the accuracy of orthodontic appliances and bring revolution the field.
Clinical significance: The CAD-CAM technology provides a fully digital workflow for manufacturing metal orthodontic appliances, which saves a considerable amount of labor and material costs, and significantly reduces heavy metal pollution in the working environment of dental technicians.

1. Introduction

Malocclusion refers to disharmony of teeth, dental arch, jaw and craniofacial position caused by congenital factors or acquired environmental factors during the growth and development of children. Malocclusion is one of the common oral diseases, and can affect the appearance of teeth and the maxillofacial region, as well as the functions of chewing, swallowing and articulation, and it reduces the quality of life. The fluid-modulated data of malocclusion in children and adolescents in China in 2000 showed that the prevalence of deciduous teeth was 51.84 %, and the prevalence of dental replacement was 71.21 %. In addition, the prevalence of rate of

Abbreviations: 3D, three-dimensional; CAD-CAM, computer-aided design and computer-aided manufacturing; OELs, occupational exposure limits; SLM, selective laser melting; SLS, selective laser sintering.

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permanent dentition was 72.97 % [1]. With the development of the social economy and the increase of individuals' awareness of dental health, the demand for orthodontic treatment and appliances in children and adolescents has gradually increased.

The traditional manufacturing method of orthodontic appliances involves a complicated workflow, which relies heavily on manual labor and the consumption of large quantities of materials. Traditional orthodontic appliance workflows include taking a mold from the inside of a patient's mouth, making a plaster cast of the teeth, carving a wax mold on the plaster, and casting starting with hand waxing and polishing, which may introduce mistakes in each step [2,3]. Errors may occur due to the performance limitations of the die material. It is also easy to produce errors in the process of making the die and casting, which may be related to the dimensional stability of die materials, changes in temperatures, and the surface wettability of gypsum products. The presence of one or more of these variables can affect the accuracy of the orthodontic appliance. In addition, the manufacture of the appliance depends on operations by experienced dental technicians, which can cause occupational exposures to Co, Cr and Ni from the air in the workplace [4,5].

In recent years, the advancement of computer-aided design and computer-aided manufacturing (CAD/CAM) technologies has enabled digital workflow to be widely used in the manufacture of orthodontic appliances and dental dentures [6–11]. In dentistry, digital processes have been utilized in the manufacture of oral and maxillofacial surgical guides, precise orthodontics, periodontal surgeries, and dentures [12–19]. The digital processing procedures, which include intraoral scanning for data acquisition, object design, and three-dimensional (3D) printing, have been shown to improve the predictability of dental procedures [20,21]. In addition, they require fewer clinical appointments, optimize preclinical corrective instruments, introduce a higher level of standardization, and eliminate the shortcomings of traditional techniques [22,23]. The development of 3D printing technology, especially the widely-applicated low-cost 3D printers, has promoted its application in the dental field [10,24]. The CAD/CAM technology is expected to further accelerate and simplify the manufacturing process of casting tools while maintaining product quality. However, 3D printing has rarely been used in orthodontic metal appliances. The purpose of this paper is to describe the production of a kind of metal appliance via full digital process.

2. Materials and methods

An 8-year-old girl was brought in by her parents for orthodontia. Extra-oral examination revealed that the maxillofacial region beside the maxillary nose was concave, with the teeth not visible when smiling, and the profile was concave. Intraoral examination showed that the front teeth were in a 12/22 cross bite, with 11/21 shallow overjet and shallow overbite, while the rear teeth were shallowly covered, and the bilateral rear teeth were in a neutral position (Fig. 1A–E). In addition, the front teeth were slightly crowded. Panoramic examination revealed that the maxillary first molar and the first and second mastoid molar were healthy, and therefore, could be used as anchor teeth to support the traction device. Cephalometric analysis showed that the patient had Class III bone malocclusion and maxillary hypoplasia. A special written informed consent was acquired from the patient and her parents regarding publishing her photographs and dental records. Considering the age of the patient, our orthodontic treatment plan was to design a maxillary cast diffuser with traction hooks and a maxillary anterior traction mask. The main purpose of the treatment was to promote horizontal and sagittal development of the maxilla. Digital processing was adopted throughout the entire process of appliance manufacturing.

2.1. *Intraoral scanning*

An intraoral optical scanner (iTero, USA) was utilized to perform intraoral optical scanning of the upper and lower teeth, as well as soft tissues of the upper palate. In addition, the dental occlusal relationship was recorded, and standard tessellation language (STL) file was acquired [25]. The scanner was used to objectively generate maxillary, mandibular arch and palate data, and determine the occlusal relationship at the interapical position (Fig. 2A–E) [26]. After intraoral scanning, the patient's oral model data was directly sent to the dental laboratory. In the traditional manufacturing process, this step often requires nursing staff or dental assistants to first take alginate impressions from the patient's mouth, then pour gypsum models. After the models are completely dried for approximately 40 min, they are then delivered to the dental laboratory by a dedicated person. Compared to the traditional process, the current

Fig. 1. Pretreatment examination. (A) Lateral view; (B) Frontal view; (C) Lateral view; (D) Upper arch; (E) Lower arch.

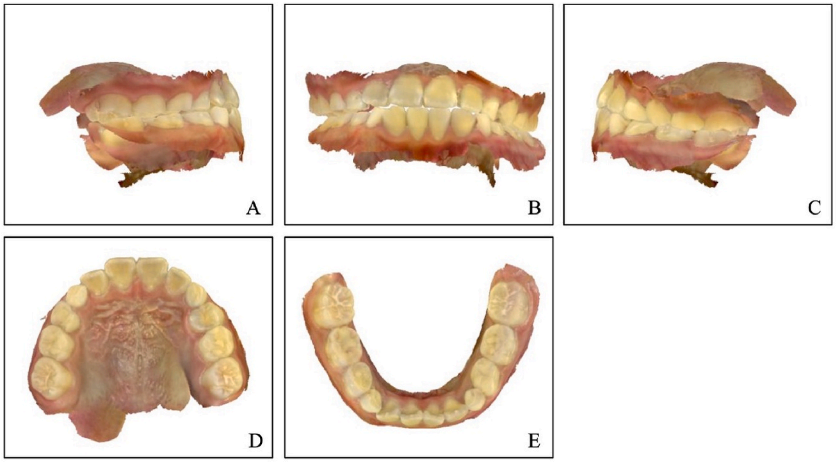

Fig. 2. Intraoral digital scanning imaging. (A) Lateral view; (B) Frontal view; (C) Lateral view; (D) Upper arch; (E) Lower arch.

method saves a significant amount of working time and manpower, conserves materials such as alginate and gypsum for impressions, and reduces patient discomfort during clinical procedures.

2.2. Digital model modification

Digital model modification. The data obtained from the intraoral scan were subsequently imported to the dental CAD software (3 shape, Denmark). The occlusal and sagittal planes were set, and the data boundaries were delineated. Subsequently, a base was added to the shell data of the maxillary and mandibular arch, which were superimposed to create a 3D virtual closed model. The traditional workflow first requires placing the gypsum model on an observation platform, drawing observation lines according to the position of the orthodontic appliance, manually filling and removing wax for undercuts. Then, a refractory model is duplicated, and further production of the wax pattern of orthodontic appliance on the refractory model is carried out. The process is complicated, time-consuming and labor-intensive. The steps to build a virtual model were as follows (Fig. 3):

- Establishing the occlusal plane. Three landmarks, namely the inter-tangential points of the upper central incisor teeth, and the proximal buccal tips of the left as well as right first upper molar teeth were utilized to construct the occlusal plane (Fig. 3A).
- Establishing the sagittal plane. The sagittal plane was defined as the incisal point passing through the upper central incisor teeth (Fig. 3B).
- Lining the maxillary dentition and soft tissue edges, and adding the base of maxillary arch and mandibular arch to complete the virtual model (Fig. 3C).

2.3. Manufacture of appliance

The abutment teeth involved in the appliance were first selected. Specifically, the left and right maxillary first molar, the first and second mastoid molar were selected as abutment teeth for this case (Fig. 4A). Subsequently, the positioning direction of the orthodontic appliance with the ring were determined according to the concave position of the base and its maxillary bilateral abutments (Fig. 4B). The concave was filled out. Then, the thickness of the band of the orthodontic appliance (cobalt-chromium alloy 0.7 mm is sufficient) and the space between the band and the abutment (generally set to 0.05 mm) was pre-set according to the characteristics of the printing material. The setting of thickness and reserved space for adhesion could be precisely controlled based on parameters of different materials. A full coronal ring prosthesis was subsequently formed by drawing a line from the gingival margin on the buccalatine side of the first molar to the cervical margin of the second molar and the first molar (Fig. 4C). Compared with the process for traditional manufacturing, the digital design software was able to automatically fill the concave based on the set orientation of the

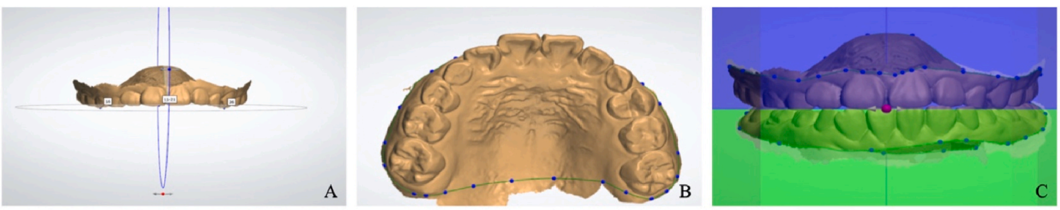

Fig. 3. Procedures to build a virtual model. (A) Setting up the occlusal plane; (B) Lining the edge of soft tissue; (C) Adding the bases.

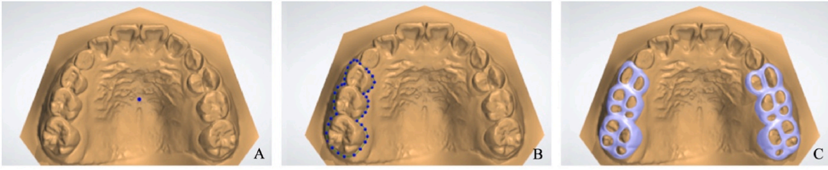

Fig. 4. Design and making of bands by applying 3 Shape Appliance designer software. (A) Determine the insertion path; (B) Choosing the butment; (C) Formation of a prosthesis.

positioning path. The anterior traction accessories were then placed on the left and right first mammary grinding teeth near the neck. The same reference plane was selected (Fig. 5A), and the traction hook was extended to the horizontal position near the root of the deciduous teeth (Fig. 5B). The design connector was placed between the palatal side of the left and right first molar and the first permanent molar to ensure a balanced and stable position of the bands on both sides during the 3D printing process (Fig. 5C). No cushioning of the hard palate was required. The occlusal surface of the maxillary first molar, the first and second mastoid molar were removed to expose the cusp part and avoid interfering with the occlusal interference as much as possible. Lastly, a honeycomb structure on the inner surface of the band was designed using the application of 3-Matic-Research 13.0, which increased the bonding and retaining area through structural changes (Fig. 6A–C). The honeycomb-like structure significantly increased the adhesive strength between the belt ring and the tooth surface, reducing the risk of appliance detachment during the orthodontic process. This is difficult to achieve with traditional manufacturing process, in which the wax pattern of the appliance is produced on the refractory model, which means the thickness of the wax pattern with the ring is uncontrollable, and there is no reserved space for adhesion. Compared to digital processing, the traditional process is complicated, and its accuracy highly depends on the skill level and experience of the technicians.

2.4. 3D printing

The data in STL format was subsequently imported to the typesetting software (3 shape, Denmark), and the spatial position and support rod were set. 3D printing was performed using the Sisma Metal Laser Printer (Sisma Mysint 100, Italy) (Fig. 7A) with selective laser melting (SLM) technology. The SLM construction platform was driven by a manufacturing piston, and was able to adjust the vertical axis. In addition to the piston, a powder feeding piston was present, which could be adjusted vertically. When working, the powder feeding piston rose, and the powder laying roller spread the powder onto the construction platform. Then, the laser beam partially or completely melted the powder. The build platform was filled again, and the process was repeated until the part was completed (Fig. 7B). The traditional technique involves creating sprues on the wax pattern of the orthodontic appliance, embedding it, and finally, completing the orthodontic appliance casting using the lost wax casting technique.

2.5. Annealing technique to release residual stress

Residual stress often occurs during 3D printing process, causing deformation of the printed parts and affecting accuracy during or after processing. It also leads to distortion of parts during use [27]. The residual stress was released through the annealing process, and the workpiece was placed in the sintering oven and slowly heated to a certain temperature (the annealing temperature of cobalt-chromium alloy is above 1000 °C). After holding for a period of time, relaxation occurred inside the metal, and were subsequently cooled slowly to prevent new residual stress (Fig. 8A–C). Therefore, the annealing process released stress and induced local plastic deformation of the metal through heating treatment to eliminate the released stress. Compared to 3D printing, lost wax casting can lead to problems such as shrinkage holes and incomplete casting.

2.6. Plasma polish and insertion of expander

After 3D printing, the connecting rod support device was cut off toremove, and the surface of the metal printer was sandblasted and polished by plasma. Then, the established maxillary retractor and buccal canal were combined with the printer by being welded to

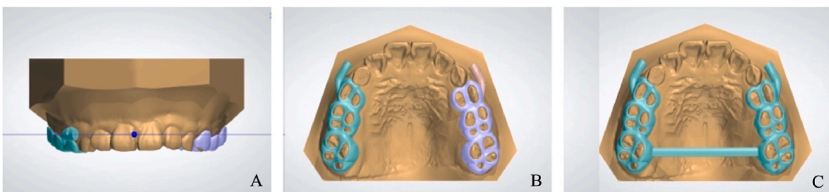

Fig. 5. Preparation of anterior traction accessories and connecors. (A) Selecting the same reference plane; (B) Design of the extension of traction hook; (C) Design of the posterior dental junction.

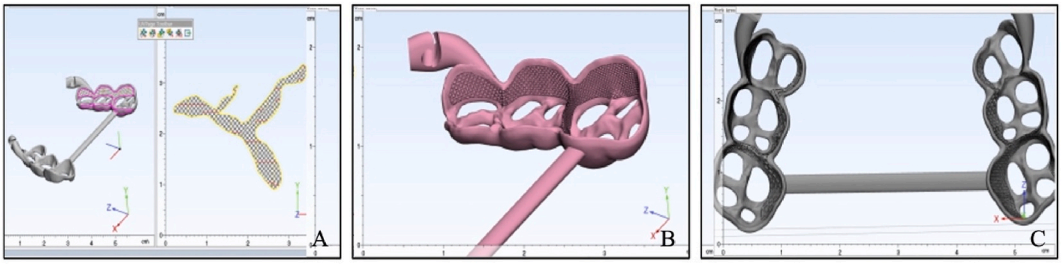

Fig. 6. Design of honeycomb structure in the inner surface of the ring. (A) 2D mesh form; (B) Conversion from the 2D form into a 3D form on the inner surface of the belt ring; (C) Generation of the belt ring with honeycomb-like structure on the basis of Boolean operation.

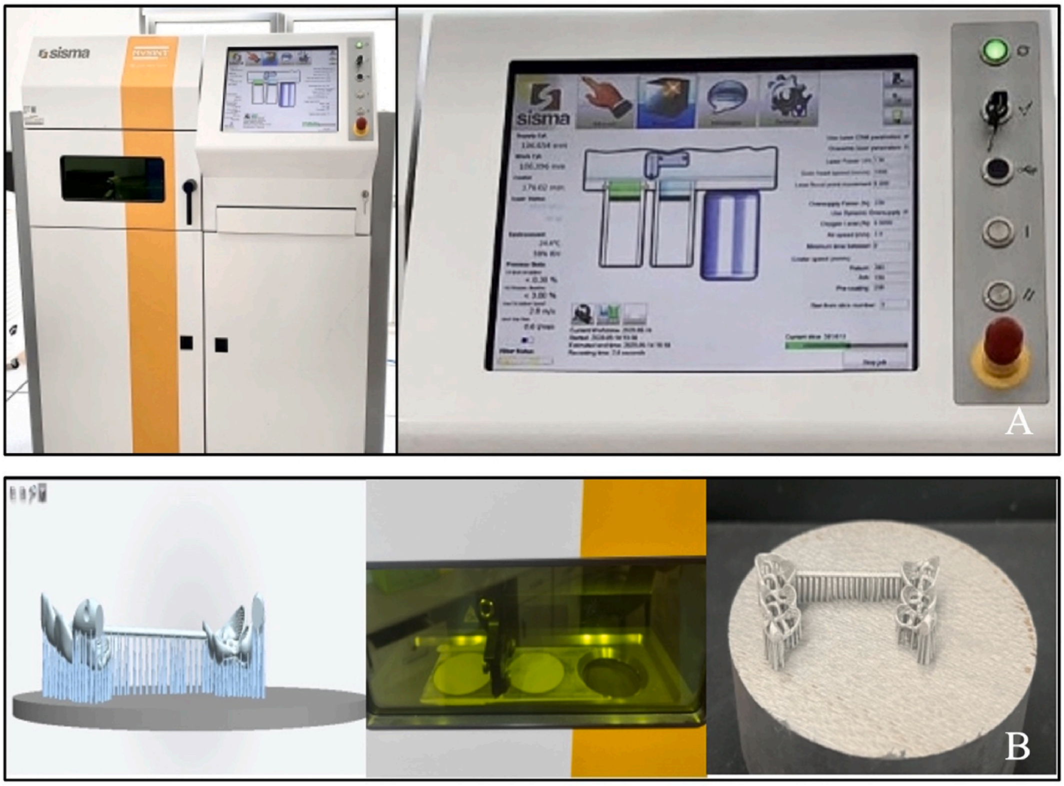

Fig. 7. 3D Printing. (A) Sisma Metal Laser Printer; (B) 3D-printed metal appliance.

form a complete appliance. Finally, the whole device was placed and fixed on the patient's maxillary arch (Fig. 8D–F). Traditional polishing process is prone to generating heavy metal particles such as Co, Cr, Ni, resulting in pollution in the working environment, while digital processing can automatically complete polishing inside the plasma polishing machine, reducing the exposure of dust.

3. Results

This paper described how a digital workflow with data merging has been applied to the design and manufacture of orthodontic appliances using a CAD-CAM system. From the oral scanning to the processing design and production of the appliance, digital techniques were utilized through the entire process, which was completed in only half a day. In contrast, it takes at least two days to process using traditional techniques.

4. Discussion

The application of digital oral scanning has the main advantage of reducing patients' discomforts such as vomiting [28]. The clinical procedure is fast and convenient, and patients' information can be transmitted directly to the dental technician via the Internet,

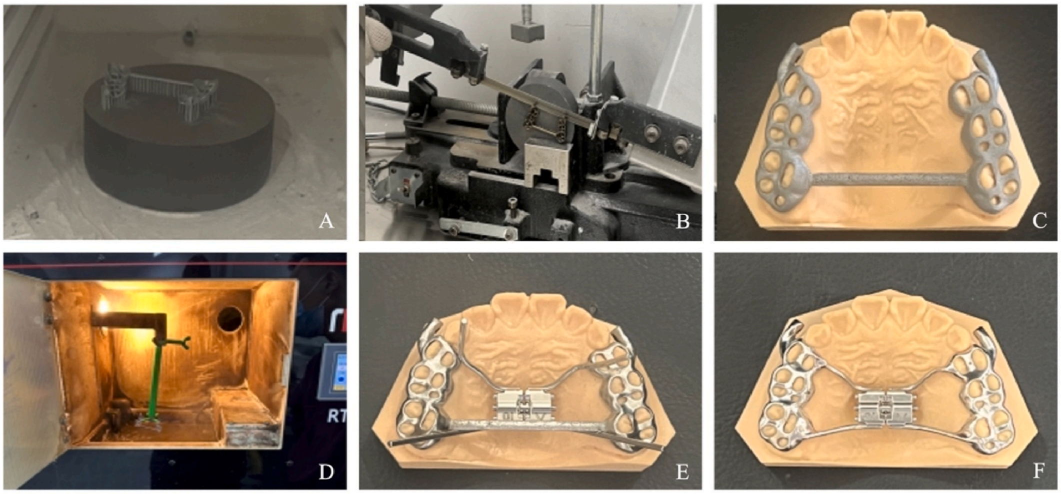

Fig. 8. Annealing and polish. (A) Stress release from sintering oven; (B) Cutting printed pieces; (C) 3D metal appliance matching model; (D) Plasma polishing; (E) Removal of the connecting rod; (F) Weld the finished bow expander.

saving time and facilitating communication with the technician. Compared with the traditional model, the digital model can avoid problems such as gypsum expansion, impression material deformation, casting shrinkage and other issues, thereby reducing errors and improving accuracy. In addition, it could save materials such as molds and impressions, reducing economic costs and making it more environmentally friendly. Furthermore, the digital model also greatly reduces the requirements for physical storage space of the model. Compared to traditional impression methods, oral digital optical scanning has a relatively lower accuracy for soft tissues. Therefore, if the fabrication design of orthodontic appliances involves soft tissue components, traditional impression methods may still be needed as supplementary.

The utilization of computer software to design the appliance is fast, accurate and efficient. The software could be used to design the inner surface of the belt ring into a honeycomb structure [29]. Compared with the traditional sandblasting process, the inner surface of the belt ring is more precised, and retains greater force, which can efficiently shorten the time for orthodontic treatment [8,9,22].

The 3D printing SLM technology was developed from selective laser sintering (SLS) [30,31]. SLS technology was developed based on a directly forming metal parts through rapid manufacturing. The main difference between the two processes is that the former is connected by partial melting, while the latter is by complete melting [32]. Unlike the SLS system, the SLM technology applied in this report could produce complex parts quickly and in small batches, regardless of the geometry of the part, which reduces the time required for cycles of product development and manufacture [33]. Compared with the traditional process, the parts formed by SLM have a small grain size, uniform structures and excellent mechanical properties, and they are not prone to defects such as segregation, porosity and deformation [34], which greatly reduces the stress on the parts and improves their service life. Compared to traditional lost wax casting process, SLM technology avoids problems such as shrinkage holes and incomplete casting. However, its limitations lie in its accuracy, which is related to the particle size, uniformity, and sphericity of the printing powder. Overall, the accuracy of this technology surpasses that of traditional lost wax casting process, and with the advancement of digitalization, it has been widely promoted and applied in various fields.

The working environment for technicians presents certain occupational health risks. Traditional processing procedures for appliance, especially metal appliances, are prone to producing heavy metal particles such as Co, Cr and Ni in the air. Countries such as Sweden have established occupational exposure limits (OELs) for Co, Cr and Ni in the air in the workplace to prevent lung cancer [35]. In addition, the traditional metal polishing process is also prone to producing dust, which may cause pneumoconiosis [36]. Skin contact with a high dose of cobalt may induce skin sensitization and allergic contact dermatitis [37]. Full digital design and processing techniques, especially closed 3D printing and plasma polishing, can prevent technicians from prolonged contact with metal particles and dust, and greatly improve the working environment.

Limitations of all-digital technologies include the accuracy of digital scanning, mesh quality conditions, errors in the design process, reliability of 3D printing, and deformation of castings during post-processing, post-polymerization, and fishing [38]. It has also been reported that illumination and color temperature may affect the authenticity and accuracy of oral scanners [7]. Previous studies have presented proof-of-concept clinical cases describing the digital workflow to manufacture a variety of appliances. Clinical studies other than these case reports are not available. The aesthetic properties of 3D-printed appliances are largely unexplored. The evidence on 3D-printed metallic appliances is also limited. The scientific evidence on 3D printable orthodontic materials and techniques should be strengthened by defining international standards for laboratory testing and by starting the necessary clinical trials [39]. The clinical efficacy of orthodontic appliances produced through fully digitalized manufacturing still needs further validation compared to those produced through traditional processing in clinical applications. In future research, a large number of clinical explorations and efficacy validations can be conducted for orthodontic appliances produced through an improved version of the fully digitalized processing workflow. Even with all the benefits arising from the digital workflow, few orthodontists have adopted this technique in their clinical practice, mostly due to a high cost and lack of technical preparation for proper execution [40], which is one of the limitations of the widespread application of fully digitalized processing.

Digital impressions are partially comparable to traditional impressions in terms of accuracy. The use of larger scanning heads can improve the accuracy of fabrication, while smaller scanning heads are more suitable for patients [41]. It is possible to obtain a digital impression of the entire maxilla using an intraoral scanner. However, the wider the dental arch, the lower the accuracy of the digital impression achieved in the mouth [24,26]. Nevertheless, these issues can also be present during conventional processes. In addition, the technology requires a certain degree of operating experience with CAD/CAM software and 3D printing technology.

CAD/CAM appliances, 3D imaging and digital treatment planning are regarded as future standards of care and are increasingly being incorporated into the orthodontic appliances. Understanding the technology adoption process can guide innovation to improve treatment and ease the transition into a digital workflow [42]. The 3D printer is now a technique that is easily accessible to orthodontists, increasing the production of different customizable appliances and promising a transition to a digital clinical workflow in the future [43].

With the development of the digital processing industry, clinical work patterns and processes are changing, and the requirements for technicians and doctors are constantly increasing. The U.S. Department of Labor has listed dental technicians as one of the most in-demand occupations (see website www.bls.gov). The full digital process can greatly improve the work efficiency of technicians, thereby alleviating the demand for technicians in the industry. For technicians, in addition to theoretical knowledge related to oral health, it is also essential to master modern science and technology, including new materials and digital technology. At present, denture processing has gradually transformed from a handicraft industry to one that encompasses digital technology, engineering and other scientific fields, requiring technicians to prioritize continuing education and stay updated on the latest technology. At the same time, doctors should regularly update their own knowledge and continually improve their techniques to stay abreast of the latest advancements in denture processing, thereby better serving their patients.

5. Conclusions

The full digital workflow of orthodontic appliance has a very promising future for development. In terms of accuracy and precision, it meets the orthodontic requirements for precision, personalization and comfort, and greatly improved the work efficiency, which is suitable for clinical application. With further development of technology, various types of orthodontic appliances are transitioning to fully digitalized processing workflows with a high feasibility. The fully digitalized processing workflows greatly liberate labor, increase productivity, reduce labor costs; at the same time, they avoid environmental pollution generated during the traditional manufacturing process, providing technicians with a safer and more comfortable working environment.

This paper described how a digital workflow with data merging applied to the design and manufacture of orthodontic appliances using the CAD-CAM system. It is estimated that fully digitalized processing workflows may be comprehensively developed and widely applied in manufacturing orthodontic appliances as a replacement of traditional process in the near future. However, further research is needed to confirm whether the accuracies of different types of orthodontic appliances are clinically acceptable.

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Data availability statement

Data will be made available on request.

Statement of ethics

Study approval statement: This study protocol was reviewed and approved by the Ethical Committee of Shanghai Stomatological Hospital, approval number [2021] 024.

Consent to participate statement: When conducting this study, written informed consent was obtained from the patient.

CRediT authorship contribution statement

Xin Yu: Writing – original draft, Visualization, Project administration, Investigation. **Jiaxin Li:** Project administration. **Liming Yu:** Project administration. **Yuhui Wang:** Project administration. **Zhicheng Gong:** Writing – review & editing, Supervision. **Jie Pan:** Writing – review & editing, Supervision, Resources, Methodology, Conceptualization.

Declaration of competing interest

The authors declare the following financial interests/personal relationships which may be considered as potential competing

interests:Xin Yu reports financial support was provided by Shanghai Municipal Health Commission. If there are other authors, they declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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