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Digital management of low cost presurgical plates for young patients with palatal cleft

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Abstract:
Introduction: The early management of cleft lip and palate is not consensual. However, the use of a passive prosthetic obturator appliance is often recommended for feeding in new-borns and infants with palatal cleft. Making an impression in these young patients is stressful due the presence of cleft undercuts, and this recording needs to be repeated every 2-3 months due to maxillary growth.

Aims: The aim of this article is to show how digital workflows may help rendering impressions less stressful and the fabrication of passive presurgical plates less expensive.

Methods: Using an intraoral scanner, a software and a 3D-printer, this case series illustrates the design and the fabrication of 3D-models in the first case, of custom trays in the second case and of passive presurgical plates in the third case.

Results: Intraoral scanners simplify the impression, while chairside 3D-printing provides at low cost either customised devices, plates or prostheses.

Conclusion: The development of computer-aided design/computer-aided manufacturing (CAD-CAM) systems may help medical teams overcome their apprehension for making these therapeutic appliances.

Key words: *Additive manufacturing (AM), cleft lip and palate (CLP), computer-aided design/computer-aided manufacturing (CAD/CAM), intraoral scanning (IOS); children*
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INTRODUCTION

Since the 1950s, passive presurgical prosthetic plates have been fitted in new-borns with palatal cleft, and renewed continuously until veloplasty (in two-step surgeries) or palatoplasty (in single step surgeries).[1,2] According to their prescribers, these appliances exhibit several advantages, such as the standardisation of tongue positioning, physiological swallowing, facilitated nutrition, maxillary growth guidance and parents' involvement in the treatment.[3,4] These plates require an impression of the maxilla to be fabricated, and the technical management of a palatal cleft impression is often left to the prosthodontist's expertise. However, making an impression in children, and especially in new-borns, is stressful for non-experienced dentists who do not necessarily have the right tools. Furthermore, these repeated plates involve financial costs for the patients.

One of the current protocols is to make a physical impression on the conscious child in the presence of parents. Some children require precautions, such as being close to an oxygen source, a pulse oximeter and a surgical aspiration. High viscosity vinyl polysiloxane (VPS) or alginate is used as impression material, and is supported either by the dentist's fingers or by a custom tray. Indeed, child stock trays are usually too large for new-borns, but small custom trays can be obtained from casts of previous patients with a similar cleft. The major risks of the impression step are obstruction of airways, cyanosis and impression material in undercuts. This stressful and uneasy step has to be repeated every 2.5 months approximately to follow the maxillary growth. Finally, the finished plates are associated with financial costs, due to laboratory work, in addition to all previous medical costs.

The development of digital technologies opens up some opportunities in the field of prosthetic appliances.[5] Intraoral scanners (IOS) allow accurate and more comfortable impressions, dental software guides the computer-aided design (CAD) of plates/splints, and milling or additive manufacturing permit the rapid and cheap computer-aided manufacturing (CAM) of the prosthesis.[6–8] The construction of a passive palatal plate can completely benefit from these advances.[9] However, each case is complex with a requirement to personalise the workflow to the specificity of the clinical situation. This case series aims to show some applications of digital technologies used in our prosthodontics department for making palatal plates in young patients with palatal cleft.

Clinical reports

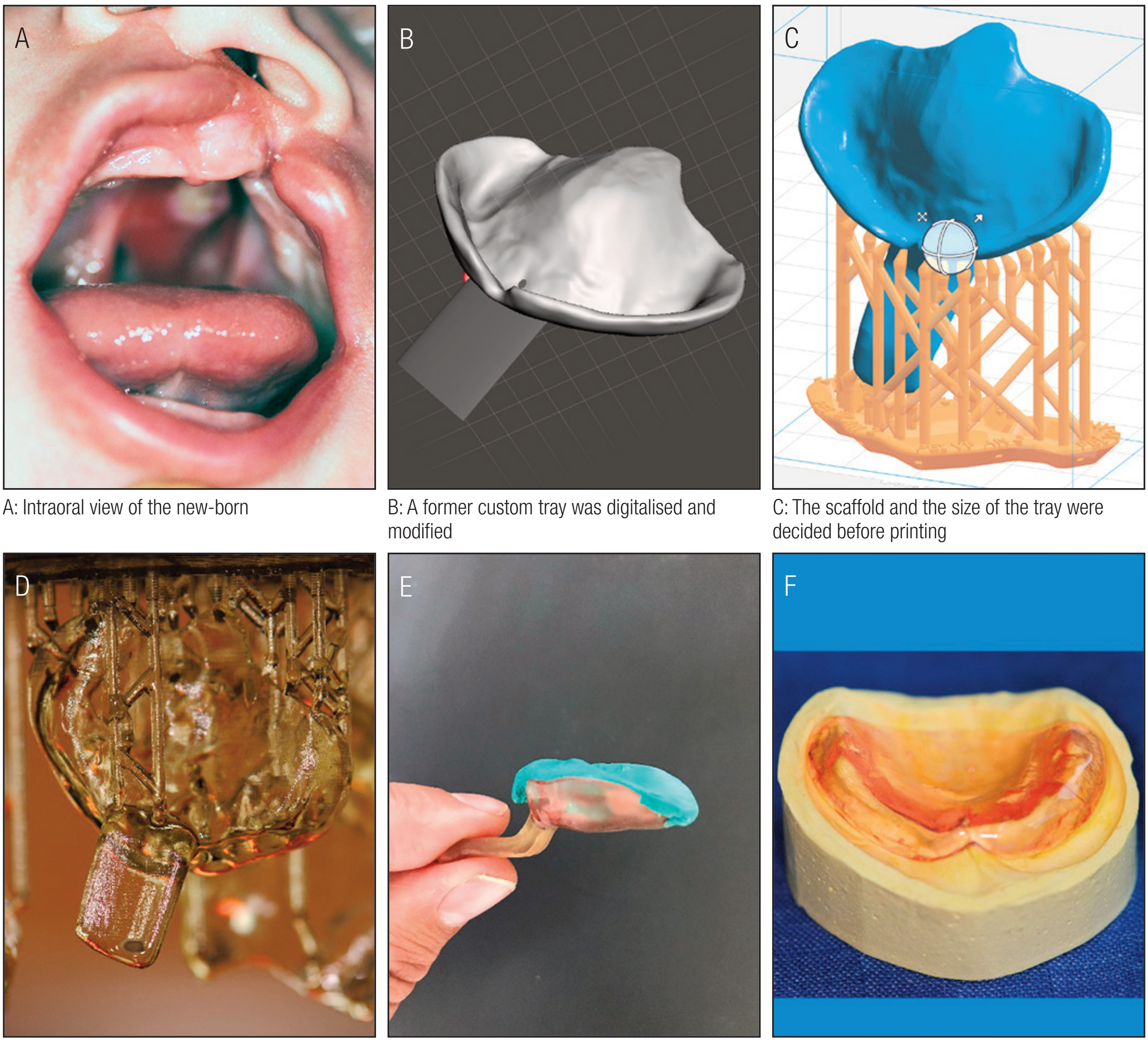
The patients' parents gave their written informed consent.

Case 1: digitalisation and 3D printing of a custom tray

A new-born boy with a unilateral cleft was referred to our department to improve feeding with a drinking palatal plate (*Figure 1a*). This cleft was located on the left side, 1cm in size, ranging from lip to soft palate, with an eroded nasal mucosa due to repeated lingual contact. The child had been breastfed since birth, in association with complementary bottles (Haberman Medela). The veloplasty, cheiloplasty and tympanostomy tube were scheduled at 6 months old. Child stock trays were known to be too large to fit in the mouth.

During the first consultation, the maxillary arch and the cleft were approximately measured (cleft form and distances between maxillary tuberosities). A similar arch form from another patient was found in the custom tray archives. An IOS (Trios 3, 3Shape A/S) was used to digitalise the tray. The STL file was imported in Meshmixer (v3.5, Autodesk) to briefly post-processing artefacts and holes (*Figure 1b*). The file was then opened with the printer software Preform (v3.5, Formlabs) to build the printing-necessary scaffolds and to decide the

Figure 1 a-f: Digitalisation and 3D printing of a custom tray



A: Intraoral view of the new-born

B: A former custom tray was digitalised and modified

C: The scaffold and the size of the tray were decided before printing

D: Printing of the tray

E: Tray after VPS impression

F: A plate was traditionally fabricated on the cast.

dimension scale of the tray (*Figure 1c*). Support touchpoints were not on the intaglio surface. The file was then sent to the stereolithographic printer (250 mW laser, Form2, Formlabs) to be fabricated layer after layer in biocompatible resin (Dental SG, Formlabs, CE Class I, EN-ISO10993-1:2009/AC:2010) (*Figure 1d*). The layer thickness was set at 100 microns. The tray was washed in three baths of isopropyl alcohol (IPA) for 5 minutes each. Compressed air was used to blow IPA away from tray surface. Post-curing was then performed under 405 nm ultraviolet light for 30 min at 60°C. Scaffolds were then removed. The tray was polished and sterilised using an autoclave. For the impression, the tray was classically coated with adhesive and VPS (*Figures 1e,f*).

Case 2: Digital scanning of the arch and 3D printing of the cast

A young girl, aged 4, had undergone a primary cleft lip repair in another country 6 months before and the primary soft/hard palate closure had been performed 6 months before, using palatal flaps. The alveolar cleft was planned to be treated with a bone graft. In the meantime, she was referred for making a palatal plate to improve oral functions, disturbed by a wide sequellar fistula.

The maxillary arch was digitalised with an IOS (Trios 3, 3Shape A/S) recording the dental arch from one tuberosity to the other, followed by more palatal recordings of the same 'U' pathway, until recording of the palate was complete (*Figure 2a,b*). The teeth adjacent to the cleft required an additional recording. The areas close to the cleft were difficult to record due to the depth of the defect and buccal tissue mobility. This surface file was sent to Meshmixer for creating a clean virtual cast, that included blocking out undercuts and zones that should be released for growth.

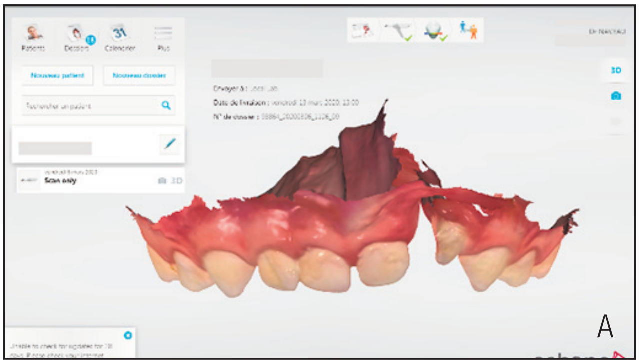
The cast was then printed by the Form2 (*Figure 2c*). The dental technician manually filled the cleft with autopolymerising resin to design the palate form. Due to the presence of teeth and the absence of usable undercuts for clasps, a thermoplastic resin was used to make a splint during dental care (an acrylic plate was scheduled later on) (*Figure 2d*).

Case 3: Digital scanning of the arch and 3D printing of the plate

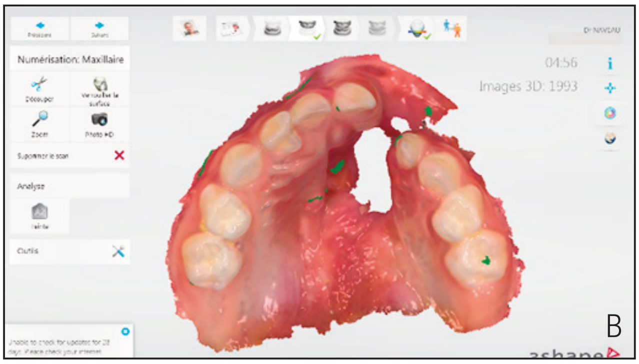
Another new-born boy, 3 weeks old, with a unilateral cleft was referred to our department for fabricating a drinking palatal plate. The maxillary arch was digitalised with an IOS (Trios 3, 3Shape A/S), without a lip retractor, in 5 minutes (with pauses). This surface file was sent to Exocad software (v2.2, Align Technologies) for creating a clean virtual cast (*Figure 3a*).

An artificial palate needed to be simulated on this cast for supporting the plate. To this end, the previously mentioned (*Figure 1*) custom tray was opened in Meshmixer. The buccal borders were trimmed, and a 1cm extrusion was performed

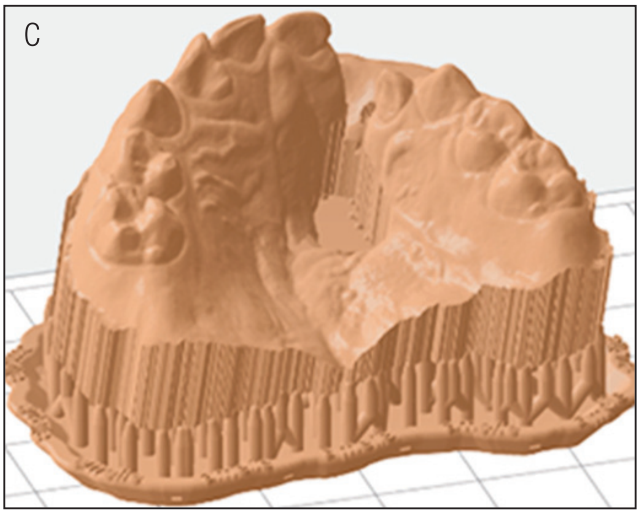
Figure 2 a-d: Digital scanning of the arch and 3D printing of the cast



A: Frontal view of the maxillary arch



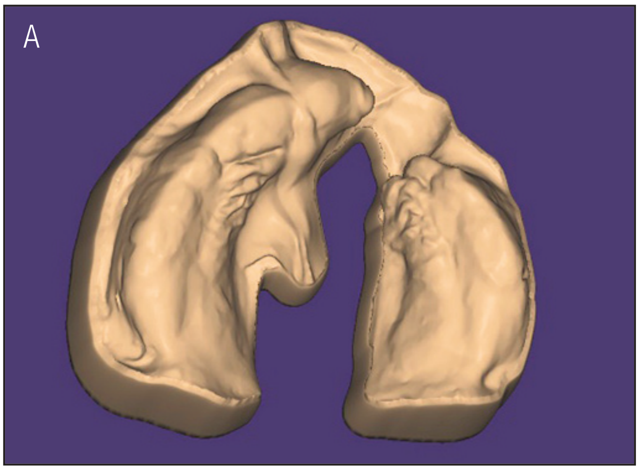
B: Palatal view



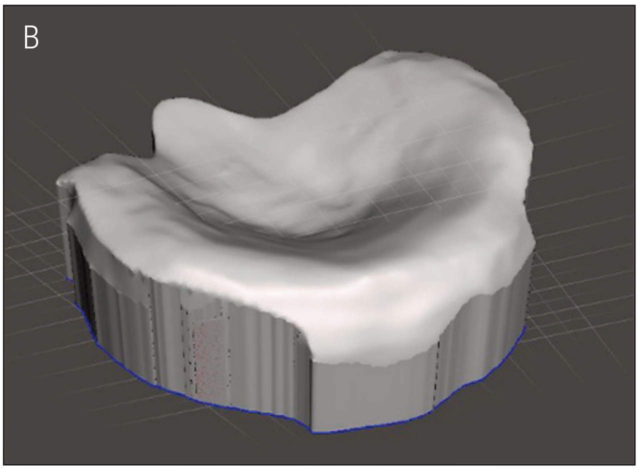
C: Cast printing project in Preform

D: A thermoplastic splint was first made on the printed cast during the dental cares (an acrylic plate was scheduled later)

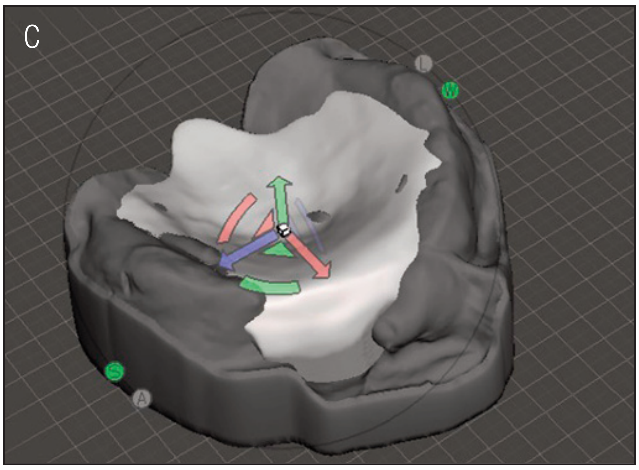
Figure 3 a-f: Digital scanning of the arch and 3D printing of the plate



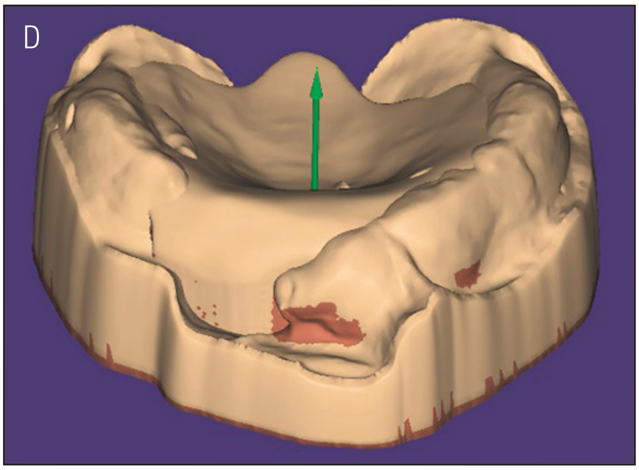
A: The maxillary arch was digitalised with Trios 3 and turned into a virtual cast (Exocad)



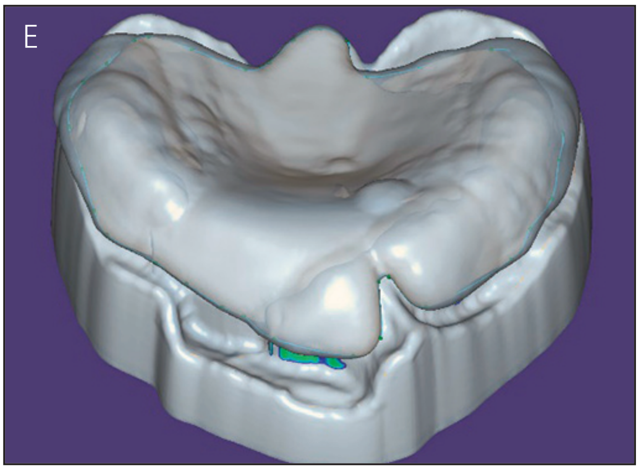
B: The *Figure 1* custom tray was opened in Meshmixer and also turned into a solid



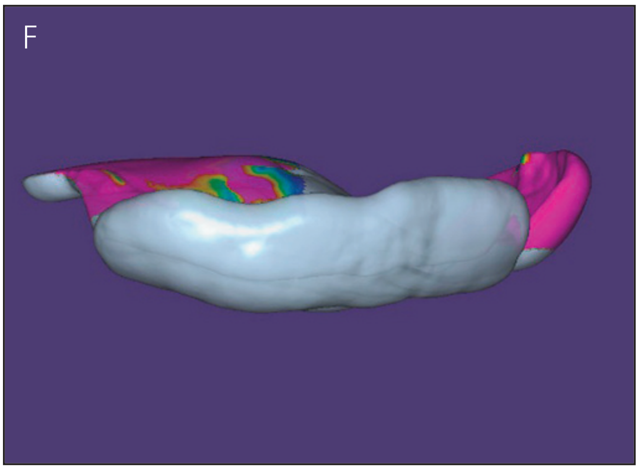
C: Both casts were then combined



D: Undercuts were blocked out (Exocad)



E: Plate was designed with a 2.5mm thickness



F: Lateral view of the final STL file ready for manufacturing (areas in colour have a thickness slightly under the original 2.5mm).

perpendicularly to the occlusal plane to create a solid cast (*Figure 3b*). Both dental arches and artificial palate casts were then combined to create a unique cast (*Figure 3c*). The 'bite splint' module of Exocad was used to block out undercuts of the cleft defect (*Figure 3d*). The borders of the plate were drawn point by point, and the plate was designed with a 2.5mm thickness (*Figures 3e,f*). The resulting STL file was sent to the 3D printer for fabrication with Dental LT resin (Formlabs).

Discussion

The purpose of the impression is to ensure sufficient registration of the palatal shelf, alveolar ridges, vestibules, the edges of the cleft, and the median bud for the case of full bilateral lip and palatal clefts. Digital scanning is a very comfortable way for recording dental arches.[10] However, some limitations come from the tip size, which is sometimes too large for a new-born mouth, causing regurgitation and requiring multiple recordings when the new-born starts crying. Besides the previously mentioned advantages, digital scanning allows follow-up of the maxillary growth, or to fabricate post-surgery protective plates (as children tend to keep the habit of touching the cleft with their finger).

It is possible to digitally create or modify trays that are adapted to new-born dimensions and to clefts' specificities. The digitalisation of the trays allows the creation of a collection which can be shared through a digital cloud. Nowadays, available resins for 3D printing have the required certifications to stay in the patient's mouth either one day (Biocompatibility Class I CE) or longer (Class IIa). Similarly, plates that used to be produced from plaster models by cold-curing PMMA or with the vacuum-forming technique after blocking undercuts with wax, can now be printed or milled accurately with resin or polylactic acid.[6] The resulting casts can also be used for educational purposes with patients or students.[11]

Some specialised centres perform nasoalveolar moulding by using a drinking plate extended with a nasal stent.[12] Intraoral moulding consists in closing the cleft between the two alveolar segments in unilateral clefts, through weekly adjustments (grinding of pressurised areas) and several impression-takings. However, some interesting digital workflows, similar to orthodontic clear aligners, have been proposed to simplify the procedure.[13–15] A CAD/CAM Tübingen Palatal Plate was also developed for patients suffering from Robin Sequence (RS), with a base plate and a velar extension ending above the epiglottis to shift the base of the tongue forward and open the airway.[16]

In summary, the digital workflow improved our patient care. The most significant advance is the use of optical impressions instead of traditional impressions, which improved the patients' and dentists' comfort. The cost of fabrication was also improved, as 3D-printers and 3D-printing resins are not that expensive. However, in our department, the remaining limitation is the amount of time dedicated to modelling for non-experienced users. Moreover, having the plates 3D-printed by an exterior lab is often costly, which does not solve the financial issue of this repeated treatment.

Conclusion

Treatment with a passive plate is controversial, as the beneficial effects are difficult to distinguish from the combined action of surgery, treatment, and the degree of dysfunction in breathing, sucking and swallowing. However, some indications such as the post-surgery protection or assistance in feeding may benefit from these plates. The digital impression and CAD/CAM technologies presented here increase the comfort and accessibility by providing an easy-to-use software solution and the possibility to outsource the production procedure.

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References

1. McNeil C. Orthodontic procedures in the treatment of congenital cleft palate. *Dent Rec* 1950; **70**: 126-132.

2. Burston W. The early orthodontic treatment of alveolar clefts. *Proc R Soc Med* 1965; **58**: 767-771.

3. Hotz M, Gnoinski W. Comprehensive care of cleft lip and palate children at Zürich university: a preliminary report. *Am J Orthod* 1976; **70**: 481-504.

4. Hotz MM, Gnoinski WM. Effects of early maxillary orthopaedics in coordination with delayed surgery for cleft lip and palate. *J Maxillofac Surg* 1979; **7**: 201-210.

5. Naveau A, Bou C, Sharma A. Evolution of topics in maxillofacial prosthetics publications. *Int J Prosthod* 2018; **31**: 565-568.

6. Meglioli M, Naveau A, Macaluso GM, Catros S. 3D printed bone models in oral and cranio-maxillofacial surgery: a systematic review. *3D Print Med* 2020; Accepted.

7. Krey K-F, Ratzmann A, Metelmann PH, Hartmannd M, Rugee S, Korda B. Fully digital workflow for presurgical orthodontic plate in cleft lip and palate patients. *Int J Comput Dent* 2018; **21**: 251-259.

8. Patel J, Winters J, Walters M. Intraoral digital impression technique for a neonate with bilateral cleft lip and palate. *Cleft Palate Craniofac J* 2019; **56**: 1120-1123.

9. Shanbhag G, Pandey S, Mehta N, Kini Y, Kini A. Virtual noninvasive way of constructing a nasoalveolar molding plate for cleft babies, using intraoral scanners, CAD, and prosthetic milling. *Cleft Palate Craniofac J* 2020; **57**: 263-266.

10. Chalmers EV, McIntyre GT, Wang W, Gillgrass T, Martin CB, Mossey PA. Intraoral 3D scanning or dental impressions for the assessment of dental arch relationships in cleft care: which is superior? *Cleft Palate Craniofac J* 2016; **53**: 568-577.

11. Calonge WM, AlAli AB, Griffin M, Butler PE. Three-dimensional printing of models of cleft lip and palate. *Plast Reconstr Surg Glob Open* 2016; **4**: e689.

12. Grayson BH, Santiago PE, Brecht LE, et Cutting CB. Presurgical nasoalveolar molding in infants with cleft lip and palate. *Cleft Palate Craniofac J* 1999; **36**: 486-498.

13. Grill F, Ritschl L, Bauer F, Rau A, Gau D, Roth M *et al.* A semi-automated virtual workflow solution for the design and production of intraoral molding plates using additive manufacturing: the first clinical results of a pilot-study. *Sci Rep* 2018; **8**: 11845.

14. Dalessandri D, Tonni I, Laffranchi L, Migliorati M, Isola G, Bonetti S, *et al.* Evaluation of a digital protocol for pre-surgical orthopedic treatment of cleft lip and palate in newborn patients: a pilot study. *Dent J (Basel)* 2019; **7**: 111.

15. Bous RM, Kochenour N, Valiathan M. A novel method for fabricating nasoalveolar molding appliances for infants with cleft lip and palate using 3-dimensional workflow and clear aligners. *Am J Orthod Dentofacial Orthop* 2020; **158**: 452-458.

16. Xepapadeas AB, Weise C, Frank K, Spintzyk S, Poets CF, Wiechers C, *et al.* Technical note on introducing a digital workflow for newborns with craniofacial anomalies based on intraoral scans - part II: 3D printed Tübingen palatal plate prototype for newborns with Robin sequence. *BMC Oral Health* 2020; **20**: 171.