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(Review Article)

3D nasoalveolar moulding: A complete digital workflow model

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Abstract

Nasoalveolar moulding (NAM) is a paradigm shift from the presurgical orthopaedics used extensively over the past 20 years in infants with cleft lip and palate. It has been proposed that the gap between the clefted segments be filled up before surgical repair via presurgical nasoalveolar moulding. To attain the best practical and aesthetic results, it is a straightforward yet effective treatment that must be started at the appropriate age and time.

In order to enhance treatment outcomes, convenience of use, compliance, and cost-effectiveness, recent developments in NAM therapy have focused on implementing changes to the nasal stent or intraoral moulding plate. Specifically, 3D technology has been used to improve the efficiency of NAM device design and develop standardised, objective methods of determining progressive morphological changes during therapy. The article discusses various methods that use 3D printing technology to produce tangible components from a virtual therapeutic strategy. It also looks at how developments in computational methods and printing materials could open up novel opportunities for computer-assisted NAM therapy.

Keywords: Nasoalveolar moulding; Presurgical orthopaedics; Cleft lip and palate; 3D printing; Cleft orthodontics

1. Introduction

In some form, orofacial clefts affect approximately 250,000 newborns annually. It is believed that one in every 600–800 babies worldwide have a cleft palate. These children are born in developing or impoverished countries that comprise the majority. Since most of these cases are located in rural areas, where access to health care is either severely lacking or non-existent compared to urban, this already appalling condition is made worse.[1] Patients with cleft lip and palate (CLP) experience complex behavioural and medical challenges as they grow from infancy through childhood and adolescence. These concerns include dysphagia, chronic otitis media, speech impairment, dental abnormalities, and growth nutritional deficiencies.[2] Patients need encompassing, multidisciplinary care that is customised to each patient's requirements and easily accessible. The fields of plastic surgeons, otolaryngologists, paediatricians, geneticists, oral and maxillofacial surgeons, paediatric dentists, orthodontists, audiologists, speech pathologists, nurses, and social workers can all be included on this integrated team of specialists.[3]

Presurgical infant orthopaedics (PSIOs) are used in conjunction with surgical intervention by specialist paediatric plastic surgeons to strengthen lip repair, assist with arch alignment, and optimise on the inherent growing potential of tissues.[4] The Latham appliance and nasoalveolar moulding (NAM) are the two main presurgical infant orthopaedics treatments used in CLP care at this time.[5] The NAM is a passive, removable acrylic appliance based on methacrylate that guides closure of the cleft space by elevating the affected nostril or nostrils and elongating the nasal columella. In

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contrast, the Latham technique uses an active appliance surgically fixed to the alveolar ridges to promptly align the alveolar segments.[6]

The purpose of this review is to provide an in-depth evaluation to the advantages and disadvantages of using digital technologies in presurgical orthopaedics for infants with CLP.

2. Material and methods

The entire digital workflow involves taking 3D image data of an infant's maxilla using an intraoral scanner, importing the data into the appropriate computer-aided design (CAD) software environment, and virtually modifying the digital model to create a harmonic alveolar arch. This process produces a series of digital models representing each stage of movement. Next, the digital model of the NAM appliance is designed using the virtual modified model, and biocompatible materials are used to 3D print the actual NAM appliances. (Flowchart Figure 1)

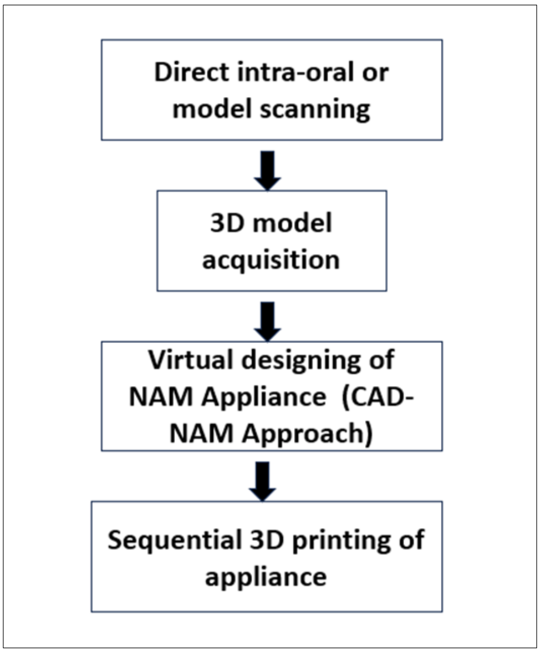

Figure 1 Flowchart of digital workflow in 3D printing of Appliance

2.1. Armamentarium

Various tools will be required at each stage of the entire digital workflow to fabricate NAM appliance customised to each patient:

- Intraoral scanner for 3D image acquisition
- Computer programmes for virtual model design
- 3D printer for manufacturing a NAM appliance

2.2. 3D model acquisition

The first step in the digital workflows for NAM therapy is to acquire a model of the patient's anatomy related to the cleft in order to facilitate virtual treatment planning and appliance construction. Optical surface scanning technologies are used in the majority of NAM treatment digital workflows to produce a digital model from a stone cast using a traditional impression. **(Figure 2)** Silicone based material are recommended to make impression of cleft region however, generating an impression in infants with clefts involves risks of aspiration and retention of impression material in the cleft, in addition to the challenges of patient compliance and movement.[7] To overcome this scenario, sedation may be warranted by the clinician in some cases. In any situation, the impression procedure should be carefully planned against the risks related to the intended acquisition method, and should be taken in a facility equipped to manage airway emergencies.[8]

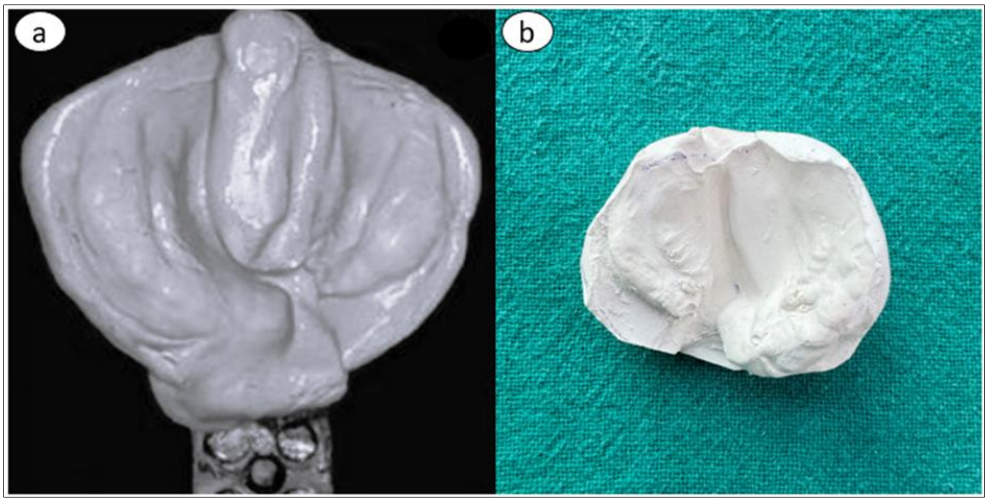

Figure 2 a) Silicone based impression material with tray; b) Dental stone cast

In context of the limitations of conventional impression methods, some studies propose the direct generation of digital models of the cleft anatomy using intraoral scanners. However, the size of the scanner in relation to the size of the baby's oral cavity, the time needed for scanning, and risks related to anaesthesia are obstacles to the widespread use of intraoral scanners in infants with clefts.[9-10] **(Figure 3)** The research points to the possibility of digitally recording an infant's cleft anatomy with intraoral scanning technologies, but it also highlights several issues that need to be resolved before the method can be widely applied clinically for NAM treatment. To determine the potential clinical utility of the approach beyond isolated cases, it is necessary to study the dimensional accuracy of digital models created from intraoral scans of newborns with clefts.[11]

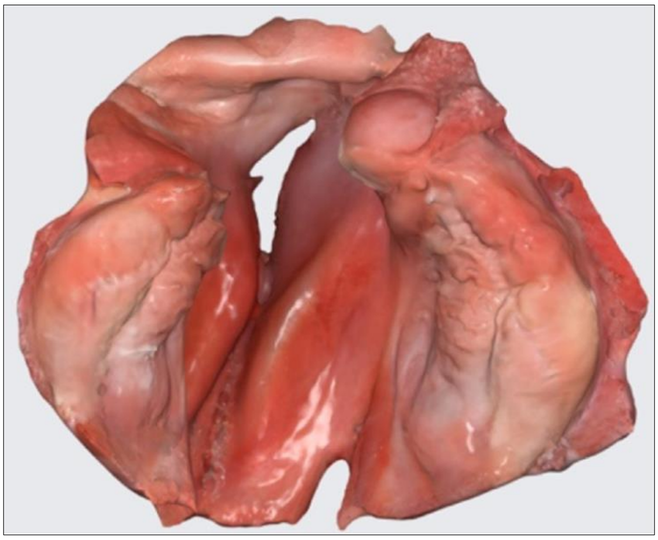

Figure 3 Direct Digitally scanned oral cavity of CLP infant[21]

2.3. Computer aided designing of NAM Appliance (CAD-NAM approach)

The process of designing the appropriate set of models and digitally manipulating the position of the alveolar segments through several sequential processes with the aid of computer software tools is known as "CAD-NAM", and clinical applications of this method have been made for treating patients with both unilateral and bilateral CLP.[12-13] The imported models are subdivided into the two posterior lateral alveolar segments and the premaxilla. The segments were virtually altered in a sequence of steps to progressively reduce the cleft gap and realign the segments to get the ideal arch shape. To avoid damaging the baby's normal development, the models should be broadened by around 1 mm per month to allow an infant's growth. Furthermore, the amount of segment moulding alterations that can be done weekly should not exceed 1 mm and the stages ought to be organised according to how severe the original abnormality was.[14]

2.4. Sequential 3D printing

The final digital design is exported as an STL file for 3D printing, depending on the printer being used, it allows for the fabrication of objects with a minimum layer thickness of 28 microns. The method basically involves taking a 3D computer file and cutting it into a number of cross-sectional slices. The 3D object is then rapidly produced by printing each slice on top of the other and has a thickness of approx. 1.5 mm. If the components could all fit inside the machine's build environment and the retention arm could be produced without assembly, it was feasible to construct multiple NAM appliances at once. The entire appliance series takes about 2 hours to complete. (Figure 4)

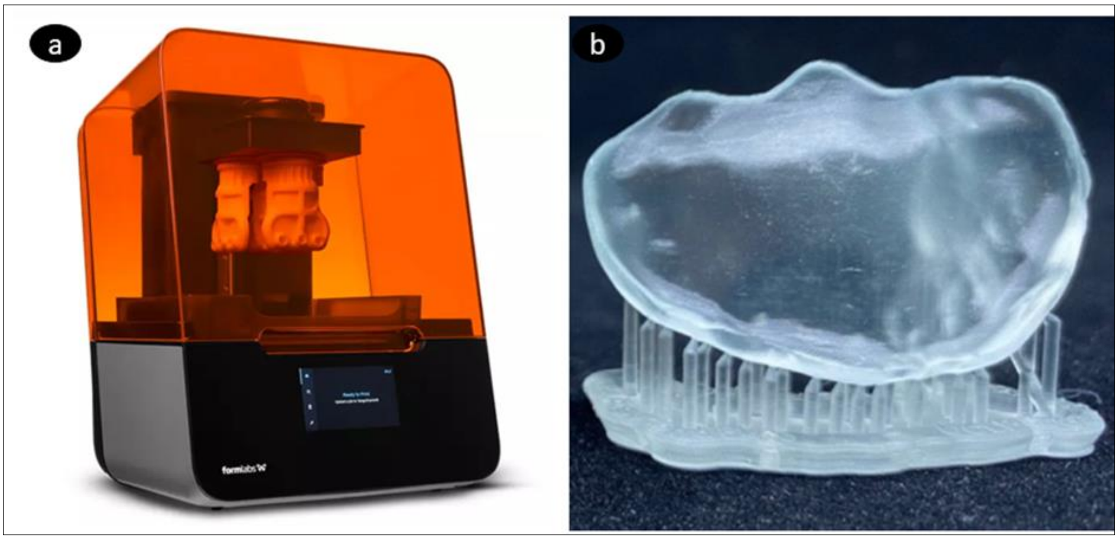

Figure 4 a) 3D Printer; b) Printed NAM Appliance[21]

3. Discussion and review of literature

An intraoral scanner can capture three-dimensional virtual images of the oral cavity, from these images, a 3D archive can be created, 3D diagnostic data can be obtained, laboratories and orthodontists can communicate, and virtual setups and treatment plans are possible. 3D imaging techniques have been widely used in the craniofacial field and are more accurate than manual methods.

A study conducted on five patients who had complete unilateral CLP using software for reverse engineering, digital models created from stone cast scans were adjusted to realign the alveolar segments in eight to ten phases. The programme was primarily used by the authors to modify the digital models' mesh in order to place the alveolar segments in the appropriate positions for each phase. Each of the 3D-printed models was then used to construct a typical NAM appliance, producing a set of appliances that were delivered to the parents all at once along with instructions for taping and exchanging appliances. Prefabricated NAM therapy was claimed to produce the same results as traditional methods: nasal morphology, nasal columella lengthening, and cleft gaps narrowing.[13] Similarly, another study involved the nasoalveolar moulding (NAM) technique being used on seven infants who had bilateral cleft lip and palate prior to cleft lip surgery. A 3-dimensional laser scanner scanned the upper denture casts. Using a fast-prototyping technique, the solid model was printed using the exported digital geometric data. On the basis of these solid models, the NAM appliances were constructed. Both the NAM process and the treatment target could be estimated with the use of computer-aided design. Using a quick prototyping system, the appliances might be made.[15]

A pilot study conducted by Grill et al to compare two methods of semi-automated CAD-NAM and rapid NAM approach. Both methods produced a harmonic alignment of the alveolar crest and greatly narrowed the clefts.[16] Gong et al. used computer-aided nasoalveolar moulding to treat 19 bilateral CLP infants and 21 untreated babies as controls. The study's findings included reduction of the cleft gap, correction of the alveolar midline deviation, retraction of the projection and outward rotation of the premaxilla segment, and normalisation of the alveolus's contour.[17] To enhance the anatomic location of the cleft in patients with CLP and prepare them for primary lip repair, this study utilised two distinct techniques to create NAM appliances. The patient had an MRI of the face for digital NAM appliance manufacturing in addition to an intraoral scanning for conventional NAM appliance fabrication. Next, we compared the two appliances by taking measurements using landmarks. The external arch width of the 3D-NAM and the conventional NAM differed in a statistically significant way. Statistics-wise, all other NAM measurements were equivalent. The interchangeable fit of both appliances on both models was also clinically successful. With this approach, it may be possible to fabricate NAM equipment without the necessity for an intraoral impression or the unfavourable consequences that accompany it.[18] To assess and compare the accuracy and retention of moulding plates when used as NAM appliance for newborns with CLP, a laboratory-based study was conducted. On 3D printed working models, three distinct materials were used: polymethyl methacrylate (PMMA), a hard clear aligner made of PET-G polymer, and a dual-layered hard and soft clear aligner made of a combination of PET-G and EVA. The virtual gap between the data obtained from the moulding plate and the working model following optical scanning at each of the assigned places for each plate was used to measure accuracy. PET-G moulding plates demonstrated superior fit and greater retention in comparison to PET-G/EVA and PMMA moulding plates. It may be inferred that the precision and efficacy of the NAM appliance on CLP patients are greatly influenced by both the technique and the material employed.[19] To improve the maxillary arch dimensions of children with unilateral CLP before surgical lip repair, a new 3D-printed nasoalveolar moulding appliance was introduced, and its efficacy was measured. Random assignments were made to place the eligible newborns in the new appliance groups or the no-treatment (control) group. The new appliance group used virtual models created by 3D scanning of the maxillary models for segmentation and approximation of the alveolar segments. Three models—one for each of the three activation steps—were created from approximate movement. Each of these models underwent virtual appliance building, which was followed by the appliance's 3D printing. Based on the study's findings, it can be stated that the newly developed 3D-printed appliance provides an easy-to-use method for enhancing arch dimensions in newborns with CLP before surgical lip repair.[20]

4. Conclusion

The manufacturing of NAM appliance is made possible by computer-aided workflows that make use of digital imaging technology, virtual treatment planning, and 3D printing. These methods are more efficient than earlier approaches. Orthodontists may now easily access 3D printing technology, which increases the creation of various customisable appliances and may eventually lead to a shift to a digital clinical process. The numerous computer-aided workflows for NAM manufacturing have different specifics, but they all aim to improve the care of patients who have cleft lip and palate. Advancements in technology have the potential to enhance the production of 3D-printed NAM equipment. Nevertheless, more research on the safety and therapeutic effectiveness of these developing workflows is required before a general patient deployment is appropriate. There may be a chance to replace the conventional NAM appliance with this method because of its many advantages.

Future aspects

Over the past ten years, the NAM therapy workflow has significantly changed to incorporate 3D printing, digital imaging, and virtual planning to enable the creation of NAM appliances. It is imperative that intraoral scanners be enhanced with smaller scanner probes that facilitate comfortable fit and mobility within the baby's oral cavity. Additionally, advanced picture compilation algorithms that facilitate rapid and accurate modelling of cleft spaces and edentulous spans are crucial. Similar to this, advancements in computer algorithms might make it possible to combine data from intraoral scans with information from other medical imaging modalities, such as computed tomography, magnetic resonance imaging, or ultrasound, to help with the virtual planning of NAM therapy by taking into account other tissues, like skeletal structures. In the same way that treating cleft lip and palate necessitates a highly interdisciplinary team, advancements in computer-assisted NAM therapy will also demand collaboration across different areas in order to provide patients with state-of-the-art care.

Compliance with ethical standards

Disclosure of conflict of interest

No conflict of interest to be disclosed.

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