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A dual-layered 3D-printed appliance for pre-surgical orthopedics in infants with cleft lip and palate

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ABSTRACT

Objective: This clinical protocol paper introduces a dual-layered Presurgical Infant Orthopedics (PSIO) technique, designed to improve treatment outcomes for infants with Cleft Lip and Palate (CLP). The protocol utilizes a combination of an outer hard splint layer and an inner soft splint layer, fabricated using virtual construction and 3D printing. This approach aims to overcome the limitations of traditional PSIO methods by offering digitally customized, biocompatible appliances.

Materials and Method: The PSIO technique was applied to two cases: a 14-day-old male with bilateral CLP and a 26-day-old female with unilateral CLP on the left side. Fabrication involved intraoral scanning to create a digital model, followed by planning of molding vectors and 3D printing of the dual-layered appliances. Each layer was sequentially printed using distinct materials suited to their functional requirements. The treatment duration extended over five months for both cases.

Results: In the bilateral CLP case, the PSIO appliance facilitated increased lateral sulci distance, reduced intertuberosity width, medialization of the premaxilla, and approximation of the alveolar segments. This resulted in notable improvements in nasal symmetry and a reduction in the cleft gap prior to surgery. The unilateral CLP case demonstrated significant cleft gap reduction, enhanced nasal symmetry, and increased intercanine width.

Conclusions: The proposed dual-layered PSIO technique represents a significant advancement in the presurgical management of infants with CLP by incorporating digitally designed and directly 3D-printed appliances. This approach offers streamlined molding, minimizes caregiver burden, and reduces the risk of mucosal irritation while delivering precise and predictable treatment outcomes. Although promising, this protocol is based on case reports, and clinical trials are needed to further validate its effectiveness.

Introduction

The integration of cutting-edge technologies, including intraoral scanning, computer-aided design (CAD), computer-aided manufacturing (CAM), and 3D printing, has the potential to transform the conventional process of creating customized Presurgical Infant Orthopedic (PSIO) appliances. PSIO has been refined for over a century, taking a significant turn with Grayson's Presurgical Nasoalvelar Molding (PNAM) appliance which primarily focuses on enhancing the alignment of the alveolar process, nose, and lips by passive molding.[1]

Despite advancements in the field, PNAM is linked to a significant burden of care. This includes conventional impressions used in PSIO for managing cleft lip and palate (CLP) present considerable challenges. They frequently result in inaccuracies and various complications, including foreign body aspiration, respiratory obstruction, cyanosis, difficulties in removing the impression, and allergic reactions to the impression materials. These concerns underscore the necessity for more dependable and patient-friendly alternatives.[2,3]

Digitization provides a modern approach to capturing precise oral and facial structures, through intraoral scanning and the realm of 3D printing in cleft care offers a customized, precise, and efficient appliance, ultimately improving patient outcomes and experiences.[4] While digital scanning and 3D printing offer innovative solutions, they are often associated with high costs and certain disadvantages, such as the need for specialized equipment and training. The advent of digitization in PSIO for cleft care has been well documented in literature studies by Yu Q. et al.[5] in 2013 and Gong X[6] in 2017 wherein they utilized CAD for nasoalveolar molding in 15 unilateral cleft lip and palate (UCLP) infants and 19 bilateral cleft lip and palate (BCLP) infants respectively. In 2019, OrthoAligner NAM by Batra P et al.[1] was introduced in a case series where 4 UCLP infants were treated with 15 aligner sets that were designed digitally, in conjunction with a nasal elevator (Dynacleft). Subsequently in 2022, Batra P et al.[7] compared AlignerNAM and Grayson's technique, demonstrating a successful decrease in the cleft size and improved nasal anatomy, with AlignerNAM decreasing patient visits by 75%, leading to a significant reduction in travel and consumable costs

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by one-third. Abd El Ghafour M[8] in 2020 introduced D-NAM where they virtually constructed and 3D printed appliances in 14 infants with UCLP.

In recent years, numerous cleft centers worldwide have adopted intraoral scanning and CAD/CAM technology for PSIO. In this article, we propose a digital workflow of a PSIO appliance consisting of two layers, an outer hard splint resin, and an inner soft splint resin, bonded with liquid resin. The appliance is designed by direct 3D printing of its layers which incorporates the movements of the alveolar segments and premaxilla at every stage to reduce the cleft defect prior to chelioplasty.

Case 1

A 14-day-old male with non-syndromic, complete BCLP with a protruded and deviated premaxilla to the left side was referred to our cleft centre. On clinical examination, the cleft alveolar gap on the right side was 11 mm, and on the left side was 2 mm with a poor nasal tip projection and a deficient and malposed columella. A total nostril width of 25.7 mm with the nasal dome height of 5.5 mm on the left side and 4 mm on the right side was recorded (Fig. 1A).

Case 2

A 26-day-old female with non-syndromic complete UCLP on the left side was referred to our cleft center. On clinical examination, the cleft alveolar gap was 9 mm and the ala and columella of the nose were collapsed on the left side with a columellar deviation angle of 28.3° Additionally, the nostril on the cleft side was flattened with a deviated nasal septum to the noncleft side by 5 mm, total nostril width of 24.3 mm and a nasal dome height of 3 mm (Fig. 1B).

Protocol for appliance fabrication

Intraoral scanning

The digital workflow involved chairside intraoral scanning performed with a Trios 3-Shape scanner(3Shape, Copenhagen, Denmark). The infant was stabilized onto the caretaker's lap in supine position with their head facing toward the operator's lap and the scanner was navigated carefully to record the crucial anatomical structures within 2 min.

Virtual setup

A 3-D virtual model of the maxillary arch was constructed for the manufacturing of the novel PSIO appliance by using the OnyxCeph™ 3D pro, Inc.(Milan,Italy) software. With the virtual base parallel to the occlusal plane, the vectors for alveolar molding were planned by defining the cleft segments into three individual fragments: the right and left alveolar arches and the premaxilla with special attention for the 3-D control of the premaxilla for BCLP cases. Focusing on the primary goals of medializing the premaxilla, aligning, and approximating the alveolar cleft segments, lateral and outward growth was allowed, thereby decreasing the alveolar gap.[9] The cleft segments were split into two: the right and left alveolar arches, for UCLP cases. The objective was to approximate the alveolar cleft segments by rotating the major segment so that the frenum is positioned in the center of the arch and outward and lateral movement of the minor segment, thereby reducing the alveolar gap. The amount of movement necessary to achieve the intended outcome was programmed at 1 mm per step to gradually mold the alveolar segments (Fig. 2A and 2B).

Appliance fabrication

The appliance consisted of two layers: an outer layer made of hard splint resin and an inner layer made of soft splint, graphy TA-28 for hard shell and TE-151 for soft layer. The outer layer typically has a thickness ranging from 1.2 to 1.5 mm, while the inner layer is thinner, typically between 0.8 to 1 mm (Fig. 2C, 2D, and 2E). After establishing the required stages, the STL file format was exported and subsequently printed by the Uniz NBEE Dental 3D DLP/LCD stereolithographic printer (Fig. 2F).

The two layers were manually united by applying a fine coat of liquid soft splint resin between them. This liquid resin was cured using a Cure UV post-cure unit according to the manufacturer's instructions, with nitrogen infusion for a duration of 20 min to ensure the layers bonded securely (Fig. 2G, 2H and 2I). For both cases, six consecutive PSIO appliances were created to execute the molding procedure of the alveolar segments.

The extension arm was digitally designed (as shown in Fig. 2J) and digitally integrated with the outer shell using hard splint resin for 3D printing to rotate the more significant maxillary segment toward the midline using elastic traction and lip taping extraorally. The digital workflow, from intraoral scanning to appliance delivery, has been illustrated (Fig. 3). Whether in clinical practice, laboratory tasks, management protocols, or even scholarly publishing, structured digital workflows play a crucial role. This approach ensures systematic process management, especially in techniques that demand well-defined steps for effective outcomes.[10]

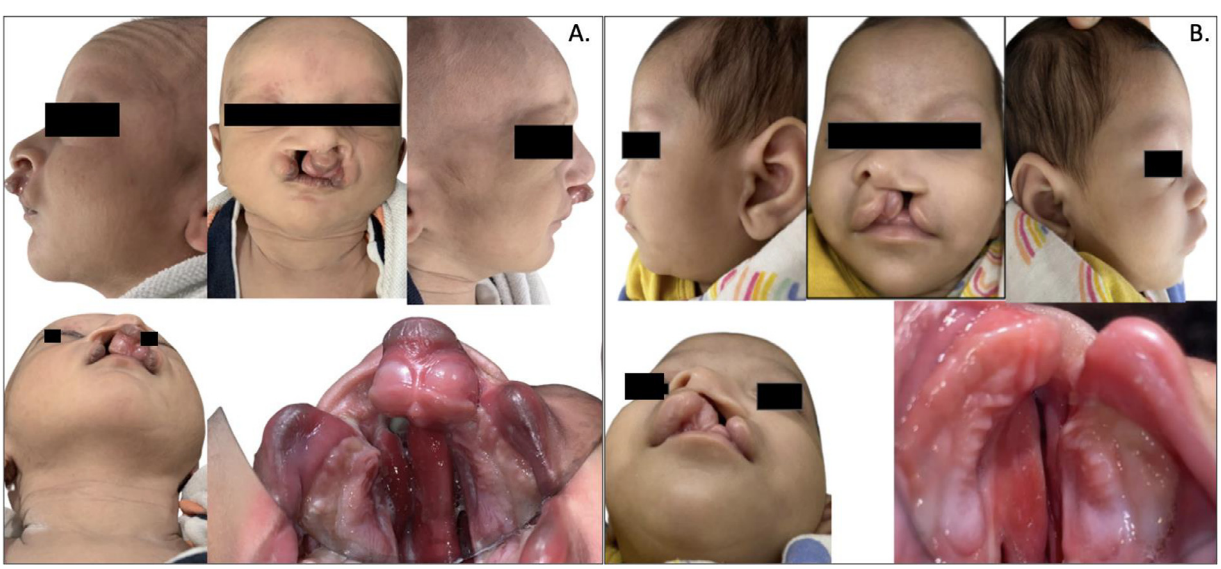

Fig. 1. A Pre-treatment extraoral and intraoral photographs of an infant with complete BCLP, B- Pre-treatment extraoral and intraoral photographs of an infant with complete UCLP.

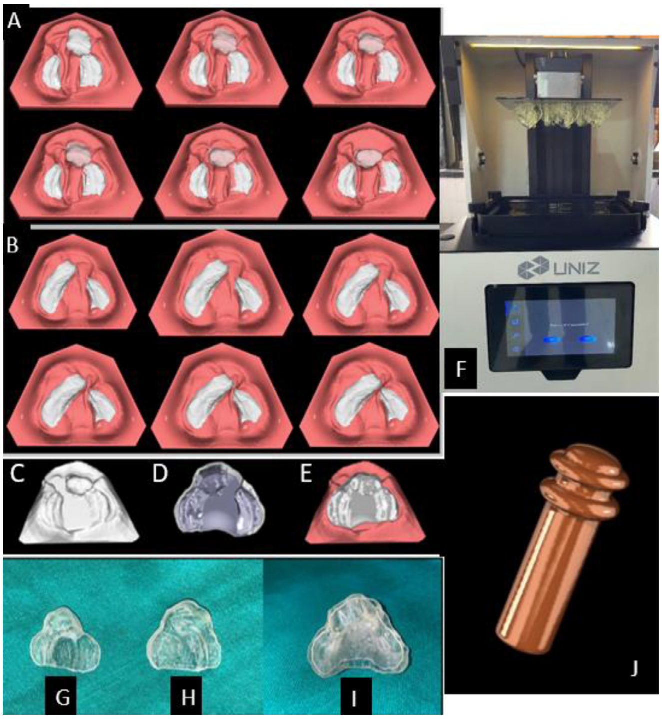

Fig. 2. (A) Virtual plan for cleft closure for infants with Bilateral Cleft lip and Palate, (B) Virtual plan for cleft closure for infants with Unilateral Cleft lip and Palate, (C) Cleft area blocked out digitally, (D) PSIO appliance designed in 2 parts. Purple part is printed in soft splint material and silver part is printed in hard splint material, (E) Silver part printed from hard splint material seen from top, (F) The Uniz NBEE Dental 3D Printer (G) Soft layer, (H) Hard layer, (I) Two-layered appliance before curing, (J) Virtual retention arm extension for rotating alveolar segments.

Nasal molding

As the treatment commenced with an intraoral appliance, which was utilized for the initial 3 to 6 weeks. Once the cleft defect width reduced to 5 mm, a Dynacleft nasal elevator was incorporated approximately three months after the treatment began.[11,12]

Treatment progress

The appliance was delivered, and the caregiver was provided with instructions regarding wear time and maintaining the appliance after feeding (Fig. 4). The customised appliance maintains its position independently, however the posterior retention can be reinforced with denture adhesive (Polident Denture Adhesive) to keep it securely in place. Anteriorly the appliance stability is provided by a retention arm, which is an extension of the intraoral appliance, supporting elastic traction and enabling the rotation of maxillary segments through the use of elastics and external lip taping. The therapy spanned 18 weeks, during which the appliance was replaced every 3 weeks to gradually achieve the specified objectives of alveolar and nasal molding.

The 3-weekly treatment progress for the cases has been illustrated in Fig. 5.

Treatment results

PSIO with the novel appliance was carried out for a duration of 5 months. Linear and angular measurements[13] were analyzed on the study models using the GOM Inspect software (v 2.0.1, 2018).

In Case 1, premaxilla medialization was performed, leading to the alignment of the alveolar segments and a notable enhancement in columella length, which resulted in satisfactory nasal symmetry before surgery, as depicted in Fig. 6A. A complete closure of the cleft defect was achieved. The distance between lateral sulci increased from 26.8 mm to 30.4 mm, while the intertuberosity width decreased from 22.3 mm to 21.02 mm, which the anterior length of the palate (T0: 7.5 mm; T1: 7.6 mm) and the total palatal length (T0: 28.6 mm; T1: 28.5 mm) did not change significantly post-presurgical molding. These findings suggest that there is an expansion at the intercanine width in the maxillary segment during this timeframe, aligning with the typical growth pattern of the maxilla in healthy infants within their initial year.[14] Our result implies that the novel method employed here doesn't hamper maxillary growth. The assessment of the nasal symmetry revealed a significant reduction in the nasal width (T0: 25.7 mm; T1:20.1 mm) and a significant symmetrical increase in the nasal height on the right and left sides.

In Case 2, the cleft gap was notably reduced from 9.1 mm to 0 mm ($p < 0.001$) through alveolar segment approximation, accompanied by significant nasal elevation, achieving satisfactory nasal symmetry preoperatively (Fig. 6B). The intercanine width significantly increased from 29.1 mm to 34.5 mm post-alveolar molding suggesting a significant

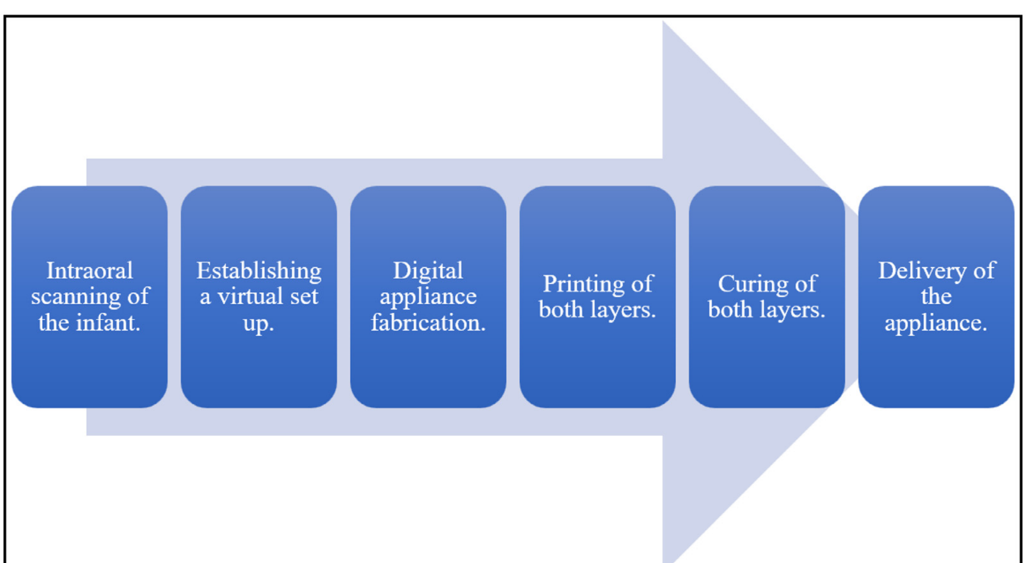

Fig. 3. Digital Workflow for this technique.

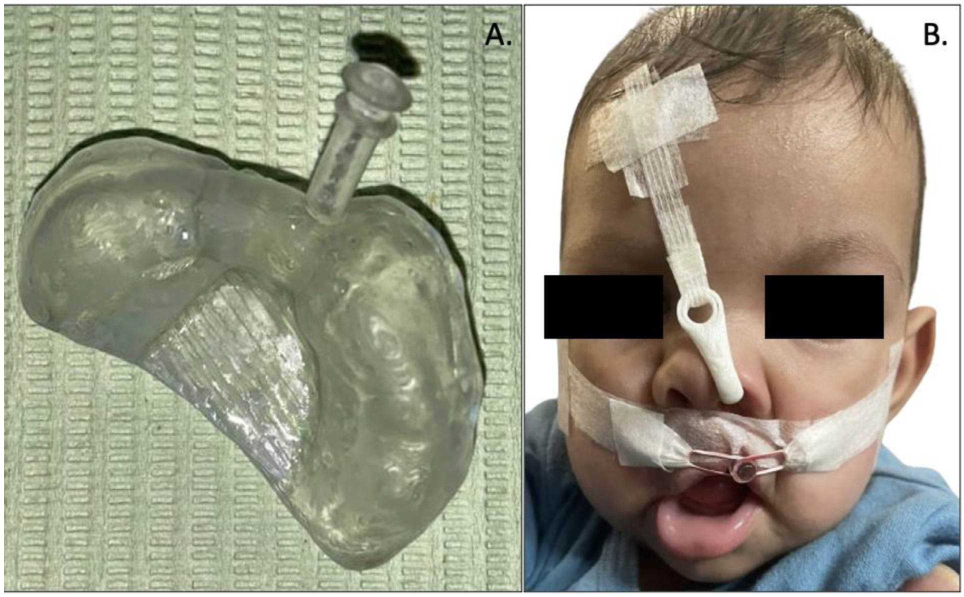

Fig. 4. Appliance delivery: 3D printed appliance(A.) and Appliance in situ.

transverse growth. The smaller [MS-(PL-PS)] cleft segment from the intertuberosity line expressed a notable growth from 19.6 mm(T0) to 23.8 mm at T1 which is comparable with sagittal distance of the larger [ML-(PL-PS)] cleft segment (24.1 mm at T1). The achievement of this successful outcome relies on the careful execution of essential procedures, such as digitally blocking undercuts on the virtual model and maintaining regular clinical appointments. The 3D models of two successive casts (before and after treatment) were aligned along the X-axis (sagittal plane), Y-axis (posterior limit to posterior superior line), and Z-axis and were superimposed using the midpoint of the intertuberosity line to evaluate the alteration in arch configuration following treatment (Fig. 6C and 6D).

Following the conclusion of presurgical alveolar molding, the patients were directed for lip repair surgery. The postoperative results for both cases demonstrate the effective application of PSIO, which played a role in achieving a favourable surgical result (Fig. 7).

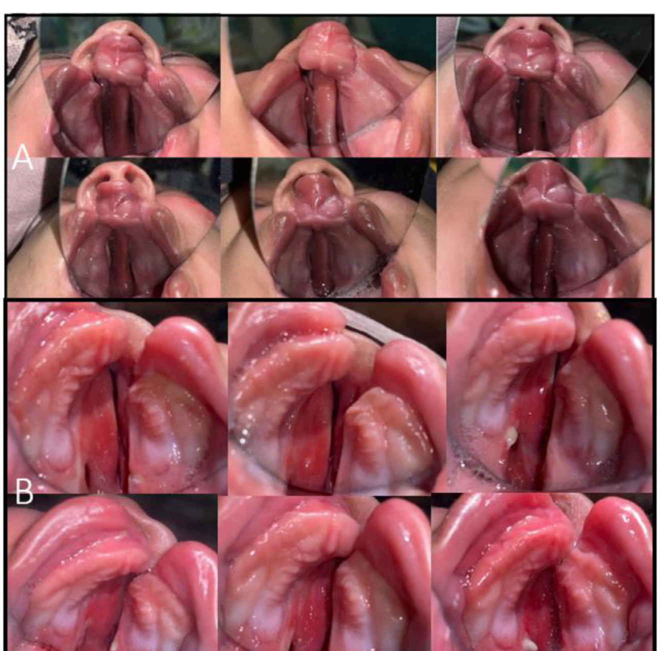

Fig. 5. Treatment progress photographs taken every 3 weeks showing changes in the alveolar segments. A) BCLP infant, B) UCLP infant.

Discussion

The strategic integration of digital technology into cleft treatment has proven to be a promising alternative to traditional NAM methods with the potential to produce favourable outcomes while enhancing the comfort and convenience of patients.

One of the most common materials used in the fabrication of the traditional PSIO appliance is Polymethyl methacrylate (PMMA) which is associated with a low degree of polymerization, and a greater residual monomer causing allergic reactions.[15,16] Besides, multiple visits for appliance adjustment, arbitrary addition, and trimming of the inner surface of the PSIO plate, in the conventional method contribute to the inherent limitations compared to digital fabrication methods in terms of accuracy, efficiency, and consistency.

Nextdent Ortho Flex, Senertek Clear-A, Graphy TE-151 are a few examples of soft splint resin while KeySplint hard, Nextdent OrthoClear, Senertek Splint, Graphy TC-85 DAC are the hard splint resin material that may be used to effectively 3-D print the dual-layered PSIO appliance. The above mentioned resin materials have class I biocompatibility clearance with ease of maintenance, excellent dimensional stability, and resistance to material fatigue.[17,18]

The current method streamlines the alveolar molding process by removing the need for manually adding a soft liner and selective acrylic trimming procedures that are imperative in Grayson's technique. Vector planning, involving all movements of the alveolar segments and premaxilla, is conducted virtually, thereby enhancing the predictability and precision of both appliance activation and outcomes.

The previous CAD/NAM studies[1,3,5,6] focused only on vector planning for the movements of the cleft segments. In this study, all movements were simulated on the virtual model and the complete construction of the appliance was also virtually completed, eliminating the printing of multiple maxillary models.[8]

Although the potential adoption of a digital workflow in cleft centres is closely related to its available resources in our perspective, underscores one of the first documented cases globally treated with the novel direct 3D printed dual-layered PSIO appliance. This technique combines a soft shell for the comfort of infants with a hard shell designed to deliver precise force vectors in a digital NAM appliance. Although the

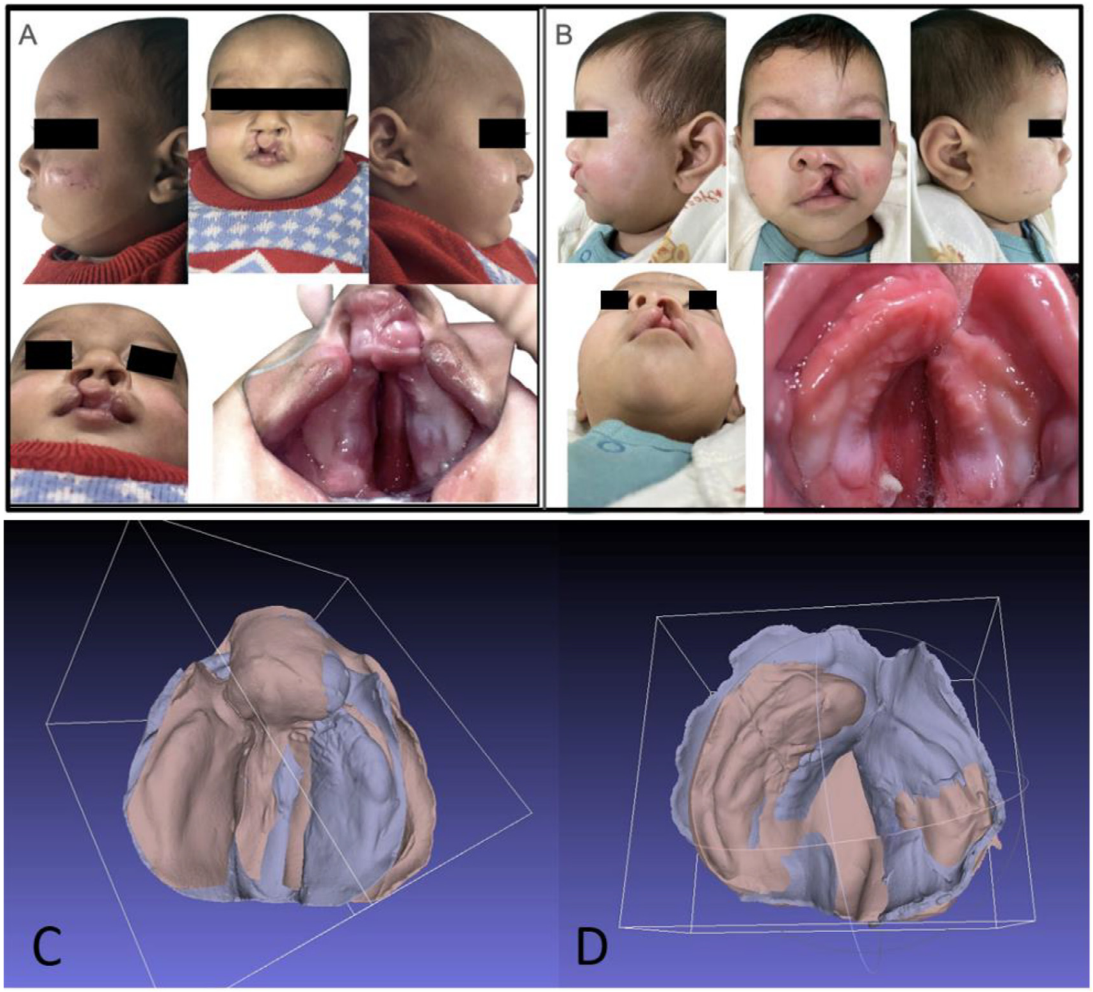

Fig. 6. Extraoral and intraoral photographs after presurgical infant orthopedics. A) BCLP infant, B) UCLP infant, Superimposition of study model scans at pre-PSIO and post-PSIO in the MeshLab software(Version 2021.10) of (C) BCLP infant and (D) UCLP infant.

higher costs and technical workflow associated with digital scanning and 3D printing can be challenging, these factors are ultimately outweighed by the substantial decrease in complications and inaccuracies commonly linked to traditional NAM appliances. A more definitive evaluation of the appliance's effectiveness can be achieved by comparing this innovative technique with other established methods like Grayson's technique, the AlignerNAM system, and similar approaches.

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Fig. 7. Post-lip surgery extraoral photographs of the infant: (A.)BCLP and (B.)UCLP.

approaches.The current method streamlines the alveolar molding process by removing the need for manually adding a soft liner and selective trimming, procedures that are subjective in Grayson's technique. Vector planning, involving all movements of the alveolar segments and premaxilla, is conducted virtually, enhancing the predictability and precision of both appliance activation and outcomes.The current method streamlines the alveolar molding process by removing the need for manually adding a soft liner and selective trimming, procedures that are subjective in Grayson's technique. Vector planning, involving all movements of the alveolar segments and premaxilla, is conducted virtually, enhancing the predictability and precision of both appliance activation and outcomes. The current method streamlines the alveolar molding process by removing the need for manually adding a soft liner and selective trimming, procedures that are subjective in Grayson's technique. Vector planning, involving all movements of the alveolar segments and premaxilla, is conducted virtually, enhancing the predictability and precision of both appliance activation and outcomes.The soft splint resin material offers a blend of strength and flexibility, prioritizing patient comfort. The hard splint resins boast easy cleanliness maintenance and excellent dimensional stability outside the oral cavity. Moreover, their distinct modulus change with temperature bolsters resistance against material fatigue, ensuring remarkable durability despite frequent intraoral usage.The soft splint resin material offers a blend of strength and flexibility, prioritizing patient comfort. The hard splint resins boast easy cleanliness maintenance and excellent dimensional stability outside the oral cavity. Moreover, their distinct modulus change with temperature bolsters resistance against material fatigue, ensuring remarkable durability despite frequent intraoral usage.The soft splint resin material offers a blend of strength and flexibility, prioritizing patient comfort. The hard splint resins boast easy cleanliness maintenance and excellent dimensional stability outside the oral cavity. Moreover, their distinct modulus change with temperature bolsters resistance against material fatigue, ensuring remarkable durability despite frequent intraoral usage.The soft splint resin material offers a blend of strength and flexibility, prioritizing patient comfort. The hard splint resins boast easy cleanliness maintenance and excellent dimensional stability outside the oral cavity. Moreover, their distinct modulus change with temperature bolsters resistance against material fatigue, ensuring remarkable durability despite frequent intraoral usage.The soft splint resin material offers a blend of strength and flexibility, prioritizing patient comfort. The hard splint resins boast easy cleanliness maintenance and excellent dimensional stability outside the oral cavity. Moreover, their distinct modulus change with temperature bolsters resistance against material fatigue, ensuring remarkable durability despite frequent intraoral usage.Top of Form Bottom of Form

Ethics approval and consent to participate

A written consent from the patient's caregivers 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 the following financial interests/personal relationships which may be considered as potential competing interests:The authors have no conflict of interest. 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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References

1. Batra P, Gribel BF, Abhinav BA, Arora A, OrthoAligner Raghavan S. NAM": a case series of presurgical infant orthopedics (PSIO) using clear aligners. *Cleft Palate Craniofac J*. 2020;57(5):646–655.
2. Grayson BH, Maull D. Nasoalveolar molding for infants born with clefts of the lip, alveolus, and palate. *Clin Plast Surg*. 2004;31(2):149–158.
3. Al Khateeb KA, Fotouh MA, Abdelsayed F, Fahim F. Short-Term efficacy of presurgical vacuum formed nasoalveolar molding aligners on nose, lip, and maxillary arch morphology in infants with unilateral cleft lip and palate: a prospective clinical trial. *Cleft Palate Craniofac J*. 2021;58(7):815–823.
4. Thakkar D, Benattia A, Bichu YM, et al. Seamless Workflows for In-House Aligner Fabrication. *Semin Orthod*. 2023;29(1):17–24.
5. Yu Q, Gong X, Wang GM, Yu ZY, Qian YF, Shen G. A novel technique for presurgical nasoalveolar molding using computer-aided reverse engineering and rapid prototyping. *J Craniofac Surg*. 2011;22(1):142–146.
6. Gong X, Yu Q. Correction of maxillary deformity in infants with bilateral cleft lip and palate using computer-assisted design. *Oral Surg Oral Med Oral Pathol Oral Radiol*. 2012;114(5):S74–S78.
7. Batra P, Gribel BF, Abhinav BA, Raghavan S, Arora A. A comparative evaluation of presurgical infant orthopedics of modified Grayson's technique with clear aligners incorporating a nasal elevator in patients with unilateral cleft lip and palate. *Am J Orthod Dentofacial Orthop*. 2022;162(5):714–727.
8. Abd El-Ghafour M, Aboulhassan MA, Fayed MMS, et al. Effectiveness of a novel 3D-printed nasoalveolar molding appliance (D-NAM) on improving the maxillary arch dimensions in unilateral cleft lip and palate infants: a randomized controlled trial. *Cleft Palate Craniofac J*. 2020;57(12):1370–1381.
9. Bhagat R, Vandekar M, Vaid NR, Park JH, Kook YA. A staged expansion screw protocol to retract the premaxilla in BCLP infants with delayed nasoalveolar molding. *J Clin Pediatr Dent*. 2021;45(2):123–128.
10. Vaid NR, Adel SM. Contemporary orthodontic workflows: a panacea for efficiency? *Semin Orthod*. 2023;29(1):1–3.
11. Monasterio L, Ford A, Gutiérrez C, Tastets ME, García J. Comparative study of nasoalveolar molding methods: nasal elevator plus DynaCleft® versus NAM-Grayson in patients with complete unilateral cleft lip and palate. *Cleft Palate Craniofac J*. 2013;50(5):548–554.
12. Abhinav BA, Batra P, Chander Sood S, Sharma K, Srivastava A, Raghavan S. Comparative study of presurgical infant orthopedics by modified grayson method and dynacleft with nasal elevators in patients with unilateral cleft lip and palate-a clinical prospective study. *Cleft Palate Craniofac J*. 2021;58(2):189–201.
13. Batra P, Ashith MV, Mittal S, Hussain A, Mustafa K, Sood S. Effects of nasoalveolar molding therapy on alveolar morphology in unilateral cleft lip and palate using two different approaches. *J Cleft Lip Palate Craniofacial Anom*. 2015;2(2):107.
14. Bruggink R, Baan F, Kramer GJ, et al. Three dimensional maxillary growth modeling in newborns. *Clin Oral Investig*. 2019;23:3705–3712.
15. Elzahar HB, El-Okaily MS, Khedr MH, Kaddah MA, El-Shahawy AA. Novel cold cure acrylic denture base with recycled zirconia nano-fillers that were functionalized by HEMA Agent Incorporation: using the Sprinkle Approach. *Int J Nanomedicine*. 2022;17:4639.
16. Rashid H, Sheikh Z, Vohra F. Allergic effects of the residual monomer used in denture base acrylic resins. *Eur J Dent*. 2015;9(04):614–619.
17. Monaco C, Kronenberger R, Talevi G, et al. Advancing surgical arrhythmia ablation: novel insights on 3D printing applications and two biocompatible materials. *Biomedicines*. 2024;12(4):869.
18. Oday R, Abid M, Dziedzic A. The accuracy and retention of presurgical infant orthopaedics constructed from different polymer materials: a comparative study. *J Taibah Univ Med Sci*. 2024;19(2):379–389.