J Oral Res
research in oral sciences

REVIEW

PRE-SURGICAL NASOALVEOLAR MOLDING FOR COMPLETE UNILATERAL CLEFT LIP AND PALATE. SCOPING REVIEW

Modelado nasoalveolar prequirúrgico en pacientes con fisura labio alveolo palatina unilateral completa. Revisión de alcance

Macarena Garrido,[1] Michelle Cataldo,[2,3] Cynthia Dabed,[2,4] Darling Rivera.[4,5]

Received: April 08, 2025 | **Accepted:** May 16, 2026 | **Published online:** June 17, 2026

ABSTRACT

Introduction: Cleft lip and palate is a frequent congenital malformation with a significant impact on facial function and aesthetics. Pre-surgical nasoalveolar molding (PNAM) emerged as an early orthopedic technique to correct them. **Objectives:** To describe the state of the art of nasoalveolar molding in a pre-surgical treatment of unilateral complete cleft lip and palate and its benefits.

Material and Methods: A systematic review was conducted in *PubMed* and *Scopus*, using the PICO strategy and PRISMA guidelines, focusing on studies published between 2020 and 2024 that evaluated PNAM in unilateral complete clefts, in English and Spanish, excluding single cases, incomplete, bilateral clefts, and syndromic patients. The mesh and boolean terms used were *"cleft lip," "cleft palate," "molding"* AND *"nasoalveolar."*

Results: Of a total of 695 studies, 8 articles were selected that met the inclusion criteria. Benefits of PNAM in correcting cleft lip and palate were observed, including: (1) improvements in nasal symmetry, (2) reduction of the alveolar cleft, and (3) alignment of the alveolar segments, based on the principle of neonatal plasticity. This treatment facilitates primary surgery and dental alignment, although with significant variability due to the lack of standardized protocols. Additionally, PNAM reduces the psychological and financial burden on families, improving the quality of life of the patients.

Conclusions: PNAM is a useful technique in the early orthopedic management of cleft lip and palate, offering aesthetic and functional benefits in the immediate, short, and long term. However, further clinical studies are needed to support its long-term effectiveness and to promote the standardization of protocols.

Keywords: *Cleft lip; Cleft palate; Nasoalveolar molding; Orthopedic procedures; Therapeutics; Systematic review*

1. Facultad de Odontología de la Universidad de Valparaíso, Valparaíso, Chile.
2. Especialidad de Ortodoncia y Ortopedia Dentomaxilofacial, Universidad de Chile, Santiago, Chile.
3. Servicio de Salud Metropolitano Occidente, Santiago, Chile.
4. Fundación Gantz, Santiago, Chile. Socio Smiletrain.
5. Hospital Dr. Exequiel González Cortés, Miguel, Santiago, Chile.

Corresponding Author:
Macarena Garrido. Facultad de Odontología de la Universidad de Valparaíso, Subida Leopoldo Carvallo 211, Playa Ancha, Valparaíso, Chile. **Phone:** (+56-9) 73241353. **E-mail:** maca.garrido14@gmail.com

Garrido M, Cataldo M, Dabed C & Rivera D. Pre-surgical nasoalveolar molding for complete unilateral cleft lip and palate. Scoping review. J Oral Res. 2026; 15(1) 46-61. https://doi.org/10.17126/joralres.2026.005

ISSN Print 0719-2460 - ISSN en línea 0719-2479

RESUMEN

Introducción: La fisura labiopalatina es una malformación congénita frecuente con un impacto significativo en la función y estética facial. El moldeado nasoalveolar pre quirúrgico (PNAM) emerge como una técnica ortopédica temprana para corregirla. **Objetivo:** Describir el estado del arte de los moldeadores nasoalveolares en el tratamiento prequirúrgico de las fisuras labiopalatinas unilaterales completas y sus beneficios.

Materiales y métodos: Se realizó una revisión sistemática en *PubMed* y *Scopus*, utilizando la estrategia PICO y las directrices PRISMA, enfocándose en estudios publicados entre 2020 y 2024, que evaluaron el PNAM en fisuras unilaterales completas, en idioma inglés-español, excluyendo casos únicos, fisuras incompletas, bilaterales y pacientes sindrómicos. Los términos mesh y booleanos utilizados fueron *"cleft lip"*, *"cleft palate"*, *"molding"* AND *"nasoalveolar"*.

Resultados: De un total de 695 estudios, se seleccionaron 8 artículos que cumplían con los criterios de inclusión. Se observaron beneficios del PNAM para corregir las fisuras labiopalatinas, entre los cuales destacan: (1) mejora en la simetría nasal, (2) reducción de la fisura alveolar y (3) alineación de los segmentos alveolares, basándose en el principio de plasticidad neonatal. Este tratamiento facilita la cirugía primaria y la alineación dental, aunque con una gran variabilidad debido a la falta de protocolos estandarizados. Además, el PNAM reduce la carga psicológica y financiera para las familias, mejorando la calidad de vida de los pacientes.

Conclusión: El PNAM es una técnica útil en el manejo ortopédico temprano de la fisura labiopalatina, ofreciendo beneficios estéticos y funcionales a nivel inmediato, corto y largo plazo. No obstante, se requieren más estudios clínicos que respalden su eficacia en el tiempo y fomenten la estandarización de protocolos.

Palabras clave: *Labio leporino; Fisura del paladar; Modelado nasoalveolar; Procedimientos ortopédico; Terapéutica; Revisión sistemática.*

INTRODUCTION

Orofacial clefts, including cleft lip (CL), cleft lip and palate (CLP), and cleft lip, alveolus, and palate (CLAP), are the most frequent congenital malformations in the facial region. They represent the second most common birth defect globally, with an estimated development between the sixth and the eight weeks of intrauterine life often accompanied by various dental anomalies. They also represent the second most frequent congenital defect (13% of all birth defects).[1,2] Their etiology is multifactorial, involving genetic and environmental factors that contribute to their development and manifestation.[3] Regarding the prevalence of oral clefts, according to the WHO, it varies between 3.4 and 22.9 per 10,000 births. Globally, the incidence of cleft lip and/or palate is estimated at 1 in 500 to 1,000 births. In Chile, according to the Latin American Collaborative Study of Congenital Malformations (ECLAMC), the rate is 0.7 per 1,000 live births for cleft palate and 1.4 per 1,000 for cleft lip.[4]

These alterations impact hearing, aesthtics, speech, and social integration, requiring a multidisciplinary approach from birth to adulthood.[1] McNeil pioneered in pre-surgical infant orthopedics; and since then, other techniques have been created and evolved.

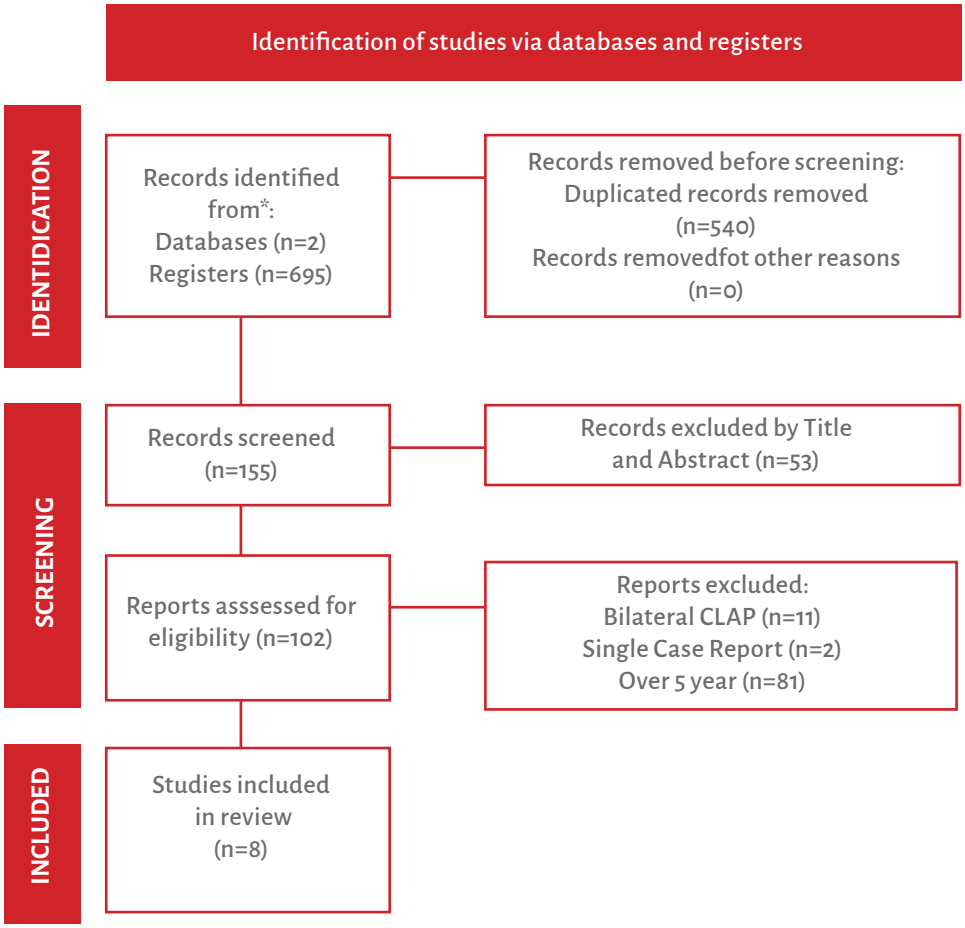
Later, Grayson *et al.*,[5] described the first pre-surgical nasoalveolar molding device (PNAM) — an intraoral acrylic molding plate with nasal stents designed to redirect misaligned tissues and nasal cartilage, offering an innovative approach compared to the traditional method for patients with unilateral or bilateral clefts.[6]

Historically, nasoalveolar molding has been used as a pre-surgical orthopedic intervention in the treatment of patients with cleft lip and palate (CLAP). This treatment is prior to primary cheilorhinoplasty, typically performed between 3 and 6 months of age, as established in the Clinical Guide “AUGE FISURA LABIOPA-LATINA”.[4]

This technique aims to reduce the size of the alveolar cleft, achieve nasal symmetry, and center the columella in patients with unilateral flap.[7]

To this date, there is little evidence regarding the different types of PNAM and the techniques currently performed, even the Ministerial Clinical Guide for Cleft Lip and Palate[4] states that "since there is no evidence for or against performing Pre-surgical Orthopedics (PSO), it is suggested to indicate it according to the surgeon's experience". So, the main objective of this study aims to describe the state of the art regarding nasoalveolar molding devices indicated in patients with complete unilateral lip and palate cleft and their benefits, according to the literature.

Figure 1
PRISMA flowchart showing selection procedure of articles



MATERIALS AND METHODS

Search strategy

The literature search was conducted in January 2025 following de Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines. In the first stage, the elements to be studied were identified for which the following PICO (Participant Intervention Comparison Outcome) table was created (Table 1) and the research question was raised: What is the state of the art on pre-surgical orthopedic treatment in patients with complete Unilateral Cleft Lip and Palate (UCLP)?

The *PubMed and Scopus* databases were reviewed by researchers MG and MC. The keywords used for the search were: *"cleft lip," "cleft palate," "molding,"* and *"nasoalveolar,"* as described in Table 2. MeSH terms were combined using only the Boolean operator "AND" to obtain specific information regarding nasal molding devices in patients with cleft lip and palate. All selected articles were retrieved, analyzed, and read by all authors.

Selection strategy

The articles in the electronic search were initially selected according to the eligibility criteria (Table 3) and duplicate studies extracted from the *PubMed* and *Scopus* databases were eliminated.

RESULTS

A total of 695 articles were identified for evaluation. Duplicates were then removed, leaving 540 articles for title and abstract review. Those that aligned with the main objective were selected, resulting in 102 articles that were read in full text. Finally, 94 were excluded for not meeting the eligibility criteria, leaving a total of 8 articles selected for this review (Figure 1). Of the studies included, only one long-term study was included as it provided results of interest to the present study for the pre-surgical phase. Only results up to the time of surgery were considered. The most relevant findings from each study are summarized in Table 4 below.

Table 1

Participant Intervention Comparison Outcome (PICO) table describing the elements to be studied

P — Participant	I — Intervention	C — Comparison	O — Outcome
Pre-surgical complete unilateral Cleft Lip and Palate patients.	Any PNAM-based treatment.	Control groups with or without nasoalveolar molding devices treatment.	Alveolar cleft reduction, nasal symmetry improvement, columellar deviation, and dentoalveolar changes.

Table 2

Search terms and results according to the two databases used in this study

***PubMed* search**	
"cleft lip" AND *"cleft palate"* AND *"molding"* AND *"nasoalveolar"*	333
"cleft lip" AND *"cleft palate"* AND *"molding"* AND *"nasoalveolar"*	362
Final Results	695

Table 3

Eligibility criteria for screened articles

Inclusion criteria	Exclusion criteria
- Texts in Spanish or English. - Observational, cohorts, clinical trials, control-case studies. - Children under five years at treatment start with complete unilateral cleft lip and palate. - Published between January 2020 to December 2024.	Single case report studies. - Children over 5 years at treatment start with incomplete and/or bilateral cleft lip and palate. - Syndromic patients.

Table 4

Most relevant characteristics and findings from each study selected for review

Author	Type of study	Objective	Type of dispositive	Evaluation	Results
Dinh et al.[8]	Prospective longitudinal study.	Pre-surgical evaluation in infants with unilateral cleft.	15 mm self-curing acrylic plate. The NAM device required the placement of a nasal stent from the first day of therapy.	All casts were scanned and measured using three-dimensional technology before and after treatment.	There was a statistically significant increase in nostril height on the cleft side, a decrease in nostril width and columella angle, and a decrease in cleft width and midline deviation after treatment with the pre-surgical nasoalveolar molding device.
Thakur et al.[9]	Retrospective study.	To analyze nasal changes before and after PNAM in patients with complete UCLP.	A light-cured acrylic resin plate was used as a soft lining to mold the alveolus, and a nasal stent was placed to avoid irritation of the nasal and palatal mucosa. Adhesive tape was applied to the lips to apply constant pressure to the maxilla for approximation of the lip defect.	Nasal fossa and nasal cusp height, columella length, nasal fossa width, nasal base width, and nasal base and nasal fossa width were measured.	A highly significant increase in nasal fossa height, nasal dome height, and columella length was observed after treatment. Horizontal measurements: A highly significant reduction in nasal fossa width and nasal base width was observed after treatment.
Lautner et al.[10]	Retrospective study	To evaluate the effects of nasoalveolar molding on unilateral clefts, using 3D scans of dental models before and after treatment.	An intraoral acrylic plate was installed from the second day of life for 24 hours. Acrylic stents were placed in the second week of life, and nasal wires in the third week.	All cast models (beforend after treatment) awere 3D scan ned, and cleft volumes and anterior space widths were assessed using computer-assisted evaluation.	NAM resulted in a significant reduction (p<0.05) in alveolar space volume and anterior cleft width from birth until lip closure, while half of the control group showed slight increases in cleft volume.

The Table 4 continues on the next page →

Table 4

Most relevant characteristics and findings from each study selected for review

Author	Type of study	Objective	Type of dispositive	Evaluation	Results
Zheng et al[11]	Retrospective study	To establish a stable three-dimensional (3D) coordinate system to investigate the effects of alveolar molding of the maxillary scleral occlusion (MSO) in patients with non-syndromic unilateral cleft lip and palate (UCLP), based on the Frankfort horizontal (FH) plane.	The maxillary intraoral molding plate was made of acrylic resin.	Silicone models were obtained and scanned using a 3D laser scanner before and after MSO treatment. A 3D coordinate system based on the FH reference plane was constructed to measure distance, angle, and length variables.	This study revealed high reproducibility and reliability for most reference points. At the end of MSO treatment, the cleft gap was reduced, with the alveolar segments becoming normally aligned and the anterior points of both alveolar segments rotated toward the cleft side. The use of the FH plane to establish a rigorous and stable 3D system is significant. PNAM therapy is effective in reducing the severity of maxillary deformity not only on the non-cleft side, but also on the cleft side.
Thakur et al[12]	Comparative Clinical Trial	To evaluate the efficacy and efficiency of the modified and conventional Grayson PNAM in patients in relation to morphological and anatomical changes in the maxillary alveolus, nasal symmetry, number of visits, and treatment duration.	Maxillary intraoral plate with self-curing acrylic resin. A retentive button was fabricated and positioned at a 40° –45° downward angle from the horizontal. The labial rim of the intraoral plate supports a wire with an adjustment loop, and at its end, a nasal stent was wrapped with self-curing acrylic. Modified Grayson PNAM: the nasal stent was fabricated with 0.032" TMA wire. Conventional Grayson: the PNAM device supports a nasal stent made of 0.036" stainless steel wire.	A digital analysis was performed on standardized photographs and 3D-scanned maxillary study models.	In both groups, when evaluating nasal measurements, a statistically significant decrease was observed in nasal width and an increase in the angle of columella deviation, as well as a decrease in the length of the nasal fossa and an increase in the length of the columella in Group I. In the evaluation of the maxillary study model, a statistically significant decrease ($p<0.05$) was observed in the width of the alveolar cleft in both groups and a lateral deviation of the Group I, while Group II showed an increase in the width of the palatal cleft.

The Table 4 continues on the next page →

Table 4

Most relevant characteristics and findings from each study selected for review

Author	Type of study	Objective	Type of dispositive	Evaluation	Results
Ocak et al[13]	Retrospective study	Evaluating the effects of NAM therapy on maxillary arch dimensions and malocclusion characteristics in patients with unilateral cleft lip and palate (UCPL).	NAM with surgical tape and nasal stents in patients. Nasoalveolar molding appliance with horizontal tape and nasal stent.	The cast models were digitized and the following measurements were taken: Intercanine width (A–A´): linear distance between the primary canine cusps. Intermolar width (B–B´): linear distance between the mesiobuccal cusps of the second primary molars. Arch length (CX+DX): sum of the linear distances from the incisal point to the distal surfaces of the second primary molars. Arch depth (X–Y): from the incisal point to the line between the distal surfaces of the second primary molars.	Intercanine and intermolar widths showed statistically significant differences according to the type of cleft. There was no statistically significant effect of NAM therapy on maxillary arch parameters or malocclusion characteristics (p>0.05). The prevalence of anterior crossbite was 12.1% in the NAM group and 23.8% in the non-NAM group.
Parhofer et al[14]	Retrospective cohort	To evaluate the effects of the PAM (Passive Alveolar Model) and NAM (Nasal Alveolar Model) on alveolar arch perimeters in infants with complete unilateral, non-syndromic cleft lip and palate using 3D scanned maxillary models obtained during the first week of life and after completion of orthopedic treatment and before lip closure	Group 1: PAM (Passive Alveolar Model), modified Hotz device. Group 2: NAM with nasal stent.	Models were scanned during the first week of life and prior to lip closure (12 weeks of age). Six anatomical landmarks were determined, and four transverse and three sagittal distances were measured.	Treatments based on NAM significantly reduced the anterior cleft width and medial rotation of the segments. Treatments based on PAM showed better results associated with transverse and sagittal growth.

The Table 4 continues on the next page →

Table 4

Most relevant characteristics and findings from each study selected for review

Author	Type of study	Objective	Type of dispositive	Evaluation	Results
Yurdaka et al[15]	Retrospective study	To evaluate the outcomes of early nasal molding with this approach, with an average follow-up of 2 years in patients with severe unilateral cleft lip and palate.	Greyson PNAM with a modified nasal stent, made of soft acrylic. In the initial session, an L-shaped tape was placed in the alar groove of the non-cleft nose and lip, and then stretched until the columella was as vertical as possible. The tape was then secured to the cleft lip. The device was inserted and then secured in the mouth with elastic bands and tape. Finally, the modified nostril retainer was placed in the nose and secured to the cheek with tape.	Appropriate clinical and photographic records were obtained at the four defined time points. The assesments were stages: T1: Within the first two weeks of life and before the placement of the NAM (nose-anchored mandibular advancement device); T2: After the pre-surgical PNAM (nose-anchored mandibular advancement device); T3: Approximately 1.81 months after primary lip closure surgery, T4: Approximately 2.2 years after the baseline of T3.	The columellar angle increased post-treatment (NAM), approaching an adequate posterior angle after surgery (T2-3) and remaining stable at T4. Post-treatment (PNAM) increased the inclination of the nasal fossa axis at the cleft, the nasal fossa on the non-cleft side (NAI-NC), the nasal floor width (NFWR), and the columella length ratio (CLR), all of which remained stable at T4. The treatment did not result in an improvement in the alar base height index (ABHR), as the mean ABHR remained similar at all-time points (T1, T2, T3, T4).

En of Table 4.

Table 5

Nasoalveolar molding protocols used in each study selected for review

Author	Approximate age of treatment start	Impression material	Type of appliance/ device	Adjustment time	Time of treatment
Dinh et al[15]	3 months	Rapid-setting alginate.	NAM and nasal stent. A hard, transparent acrylic resin plate was applied, and the soft denture lining material was added to it. The 15 mm thick plate was covered with a 22-gauge stainless steel wire soft tissue lining. NAM and nasal stents were in place from the first day of therapy	Patients were observed, and the appliances were adjusted adjusted every 14-day visit. A thin layer of vaseline was applied over the nasal stent at the time of each insertion. insertion.	4 weeks

The Table 5 continues on the next page →

Table 5

Nasoalveolar molding protocols used in each study selected for review

Author	Approximate age of treatment start	Impression material	Type of appliance/ device	Adjustment time	Time of treatment
Thakur et al[9]	PNAM was between 10 and 15 days.	Custom acrylic tray and impression material were used.	PNAM: Light-cured acrylic orthodontic resin. A soft denture liner was used to mold the socket, and the nasal stent was also lined to prevent irritation of the nasal and palatal mucosa. A lip bandage was applied to maintain constant pressure on the maxilla.	10-15 days	6 months
Lautner et al[10]	Intraoral acrylic plate to be used from the second day of life and for 24 hours.	Not mentioned	Wire and acrylic stents bonded to an intraoral prosthesis	Intervals of 1 to 2 weeks	NAM group: 119 days. Control group: 129 days.
Zheng et al[11]	Not mentioned	The orthodontist took impressions of the maxillary models using siliconesrubber.	The hard, transparent acrylic resin (Denture Base Materials Type II; Shanghai New Century Dental Materials Co., China) was added sequentially, and the nasal stent was gradually modified to impart convexity and elevation to the alar cartilage.	Interval of 1 week.	Not mentioned
Thakur et al[12]	Average age: 15 to 20 days.	Intraoral maxillary impression with high-density impression material.	Intraoral maxillary plate with self-curing acrylic resin. A retentive button was fabricated and positioned at a 40°–45° downward angle from the horizontal to achieve adequate activation and prevent the appliance from detaching from the palate. 1. Modified Grayson PNAM technique: the nasal stent was fabricated with 0.032" TMA wire. 2. Conventional Grayson techtechnique: the PNAM device supports a nasal stent made of 0.036" stainless steel wire.	With the modified Grayson PNAM, the patient was reviewed every 15 to 20 days, compared to 7 to 10 days with the conventional Grayson PNAM technique.	6 months.
Ocak et al[13]	Within 10 days after birth.	Not mentioned	NAM with surgical tape and nasal stents in patients.	7-10 days	3-4 months

The Table 5 continues on the next page →

Table 5

Nasoalveolar molding protocols used in each study selected for review

Author	Approximate age of treatment start	Impression material	Type of appliance/ device	Adjustment time	Time of treatment
Parhofer et al[14]	After the first week of life.	Not mentioned.	Passive alveolar molding (PAM) and nasoalveolar molding (NAM).	Not mentioned.	Not mentioned.
Yurdak et al[15]	Following the T1 period and preceding T2	Not mentioned.	Nasal molding was performed using a modified nostril retainer fabricated from soft acrylic.	Each week	The nasal retainer was worn every week for 3-6 months.

En of Table 5.

Table 6

Benefits and limitations of the use of the PNAM

Benefits of the PNAM	Limitations of the PNAM
Significant reduction of the alveolar cleft space.	Skin irritation from adhesive tapes.
Improves alignment of the cleft alveolar segments.	Ulcers or irritation of the oral mucosa.
Improves nasal symmetry by repositioning the lower alar cartilage.	Fungal infections due to poor hygiene
Verticalizes the columella and septum.	Lack of family commitment to treatment adherence.
Facilitates nasal and labial surgical interventions and reduces the need for secondary surgeries or subsequent corrective procedures.	Need for periodic adjustments.

DISCUSSION

McNeil was the pioneer of the concept of an intraoral device designed to align cleft alveolar segments. However, it was Grayson who refined this idea by developing the presurgical nasoalveolar molding device (PNAM), an innovative device whose objective is not only to reshape the alveolar ridges but also to reshape the nasal cartilages, approaching a more functional and aesthetically normal anatomy. He also proposed that practitioners periodically modify the nasoalveolar molding plate at weekly intervals to progressively guide the segments toward their correct alignment.[11]

However, nasoalveolar molding is a clinical technique that does not follow a standardized protocol, as shown in Table 5; consequently, the effects of nasoalveolar molding are conditioned by the specific protocols imple-mented in each case.[10]

During the first months of life, newborns exhibit plasticity and flexibility in their cartilage due to the high levels of estrogen and hyaluronic acid provided by the mother in the final stage of gestation. This principle is the basis for nasoalveolar molding. According to available statistical data, the nasal correction achieved through this method cannot be attained solely through surgery.[9,10]

Impact of PNAM Treatment

One of the main purposes of PNAM for patients with cleft lip and palate is to improve nasal symmetry, thereby enhancing the patient's aesthetics and social integration.[8,9] In the last decades, numerous studies have been conducted on the molding effects of PNAM. However, the results of these studies are variable.[10]

According to the evidence, a significant improvement in nasal symmetry has been found after PNAM therapy, with a significant increase in nostril height, nasal dome height, and columella length on the cleft side.[9] This increase is attributed to the positive pressure actively exerted by the nasal stent against the nasal alae on the cleft side to help reshape the nose from its original flat form to a convex one, while also affecting the morphology of the non-cleft side.[8,9]

Regarding the nasal stent, it is usually used once the cleft width has been reduced to 5 mm, in order to achieve soft tissue laxity and prevent an increase in nostril circumference. However, in the study by Titiz *et al.*,[15] the possibility of introducing the nasal stent immediately was evaluated, achieving similar favorable results to those mentioned above, without the risk of causing a large nostril.

A significant decrease in the width of the nasal fossa and nasal dome was observed on the cleft side compared to the non-cleft side.[9,12] When comparing the conventional technique with its modified version, which is distinguished by the use of a 0.036 stainless steel wire in the former and a 0.032 titanium-molybdenum alloy in the latter, the results obtained were similar, showing an improvement in nasal morphology in both vertical and horizontal directions.[8,12]

In addition, it has been documented that improved transmission of the force generated by the adhesive tape can promote greater verticalization of the columella compared to the classic method. Titiz *et al.*,[15] compared their technique with Grayson's, where the tape is placed in an "L" shape, from the alar groove of the nose and the side of the non-cleft lip to the cheek on the cleft side, correcting the columella's axis within the limits allowed by the soft tissues. In Grayson's technique, the applied force is absorbed primarily by the soft tissues of the non-cleft nasal fossa. However, in the modified technique presented by Titiz *et al.*,[15] the modified nasal retainer in the non-cleft nasal fossa transmits the force generated by the tape and pushes the columella toward the midline, achieving a verticalization of 49.84°, greater than that obtained with the classic method.

These results are consistent with the findings of Lautner *et al.*,[10] who stated that the effectiveness of the NAM increases when the plate is properly supported on the palatal tissues and the labial segments are secured with tape through the cleft.

Another key objective of the NAM is the harmonization of the dental arch and the alveolar cleft region. A significant reduction in cleft space has been observed, leading to decreased lip tension.[8,10] These results were corroborated by Lautner *et al.*,[10] and Dinh *et al.*,[8] when comparing models using 3D measurements, as well as by Thakur *et al.*,[8] when comparing the conventional Grayson technique with the modified one, demonstrating that proper alignment of the alveolar segments using non-surgical techniques provides a solid foundation for suc-cessful surgical lip closure.[8,10,12]

Early orthopedic treatment in patients with cleft lip and palate (CLAP) results in changes on both the cleft and non-cleft sides of the maxilla. It has been observed that on the non-cleft side, the anteroposterior maxillary alveolar length decreases after intervention, compared to the total arch length.[8] This phenomenon is also supported

by the findings of Parhofer *et al.*,[14] who compared the effects of the Passive Alveolar Modeler (PAM), a group that received the modified Hotz appliance, and the Nasoalveolar Modeler (NAM), as described by Grayson, on alveolar arch growth. Their findings indicated that patients treated with NAM experienced a significant reduction in anterior and medial maxillary width, while in the PAM group, these measurements remained stable. This change appears to be due to a greater mesial rotational effect of the major and minor alveolar segments, caused by the extraoral force of the adhesive tape, rather than anteroposterior maxillary growth. As a consequence, a midline shift of approximately two-thirds is observed, along with a reduction in the width of the anterior fissure.[8,14]

Zheng *et al.*,[11] even observed a significant reduction in the inclination of the smaller segment when evaluating the coordinates in 3D programs, results that suggest that bone remodeling and rotation of the alveolar segments not only occur on the non-fissured side, but also on the fissured side, evidencing the impact of the treatment on both structures.[11]

However, Ocak *et al.*,[13] in their study indicates that there are no significant differences in maxillary arch measurements under NAM treatment in patients with cleft lip and palate (CLAP), regardless of its type (complete or incomplete). They also note that authors who document a reduction in cleft width, improved nasal symmetry, and decreased cleft severity in patients with unilateral CLAP may have found that these clefts form in the early stages of dental development, up to the first 6 months of life, with little follow-up over time.[13]

Furthermore, these authors point out that NAM therapy did not have a significant effect on the malocclusion characteristics observed, primarily because these patients had not yet reached peak mandibular growth, which could contribute to changes in conjunction with restricted maxillary growth and compression of the remaining scar.

Finally, Parhofer *et al.*,[14] observed that in patients treated with PAM, the most significant changes occurred in sagittal measurements, accompanied by lateral rotation of the smaller alveolar segment. In contrast, with patients treated with NAM, the predominant effect was transverse compression of the maxilla. This suggests that the use of PAM could be more beneficial in cases of Class III malocclusion, severe maxillary compression, or mesial collapse of the smaller alveolar segment, as it allows for passive stimulation of growth in both directions.[14] Furthermore, several studies have indicated that the correct positioning of the alveolar segments promotes the eruption of permanent teeth in optimal locations, which positively impacts long-term occlusal stability.[8,9]

The scientific evidence analyzed supports the nasoalveolar molding technique as an effective, useful, passive, non-surgical, painless, and easily adaptable method that allows for redirecting the growth of soft and hard tissues, reducing cleft size, improving symmetry, facilitating surgery in the short term, and reducing the risk of scarring due to excessive retraction after surgery.[8-10,13]

The scientific literature indicates significant advantages in the use of the nasoalveolar molding device (NAMD), including the possibility of facilitating future surgical intervention for nasal correction. Further-more, it is associated with simpler surgery and a reduced need for subsequent interventions such as bone grafts in later stages.[8,9]

Thakur *et al.*,[9] compared the conventional nasoalveolar molding technique with a modified PNAM technique, concluding that the latter is a favorable option due to several advantages: (1) it requires less office

time; (2) it facilitates adjustments, and it reduces the need for subsequent nasal and dentoalveolar corrective procedures.[3]

According to Titiz *et al.*,[15] the use of NAMs that are not directly attached to an intraoral plate offers multiple advantages. These include allowing the patient to be fed with bottles specifically designed for infants with sucking difficulties and enabling continued use even if lesions or fungal infections occur that require a temporary interruption of treatment. However, in cases of severe clefts, it is recom-mended that the structure be complete, that is, that it includes its nasal stent, to achieve better control of the forces when aligning the segments.[15]

Parents play a vital role in the treatment, as they must be active participants for the success of nasoalveolar molding,[10] especially when family members observe evident changes in the child within a short period, increasing their motivation. Additionally, the spaces created in the conformers allow for better airflow, reducing family anxiety by facilitating adequate breathing for the infant.[15] Dinh *et al.*,[8] Thakur *et al.*,[9] and Lautner *et al.*,[10] reaffirm the benefits in reducing the long-term psychological burden on the patient and their family. Further-more, they point out that it improves expectations regarding the treatment outcome and reduces the financial burden,[8,9,10] especially considering that in more severe cases, this treatment can be more complex and long-lasting, even into adulthood.[14]

Manufacturing Protocols and Digitization Processes

Part of the treatment includes adjustment sessions where the acrylic plate is polished; however, this guideline is unclear, as it does not define specific areas for adding or removing resin, making the procedure highly dependent on the operator's experience. Therefore, it is not uncommon to observe unsatisfactory results after PNAM treatment, such as non-adherent alveolar processes or overlapping alveolar arches.[11]

In this context, technological advances have led to improvements in the fabrication of the PNAM. Zheng *et al.*,[11] created a 3D coordinate system that allows for the objective description of changes in cleft palate segments, based on points defined by the author at the level of the tuberosity and the FH plane. Unlike common measurements, these coordinates represent not only the amount of molding but also the direction of this change. Because of this, dentists can modify the appliance according to the direction of change, activating and relieving pressure. In other words, they can guide dentists to improve the PNAM treatment procedure more precisely and efficiently.

This has resulted in measurements and evaluations having a high interrater reliability coefficient, demonstrating better results in terms of reliability and sensitivity, as well as contributing to reduced laboratory time and eliminating the need for physical storage.[11,13]

This innovative process has allowed for more precise alveolar modeling in each appliance, making the PNAM more efficient, optimizing processes, and reducing follow-up visits.[11]

Side effects of NAM

The reviewed literature mentions mucosal ulceration and skin irritation as side effects of PNAM, especially on the cheeks. Therefore, the use of protective skin tape is recommended; the position should be changed at least once a week after it has completely dried. Applying dermal cream to reduce skin irritation and moisturize the exposed cheek is also recommended.[8]

In the treatment of patients with large cleft lip and palate, the choice of material

for nasal stents is crucial. Titiz *et al.*,[15] warn that orthodontic acrylic stents, even with a smoothed external surface, carry a high risk of nasal mucosal injury. This is because soft tissue tension in large clefts reduces the space available for stent insertion. To minimize complications in these cases, the exclusive use of soft acrylic is recommended. Soft acrylic stents with wings facilitate fixation to the face with adhesive tape, eliminating the need for support at the nasal base, unlike silicone stents, where soft tissue resistance requires anchoring to the floor of the nasal cavity. Furthermore, activation of retainers and tape adhesion are simpler with acrylic stents compared to silicone stents.[15]
Table 6 below summarizes the main benefits and side effects reported in the literature on the use of the nasoalveolar modeler.

Limitations of the studies

While this study provides valuable evidence on the potential effectiveness of the PNAM, its retrospective observational nature and the small number of studies limit the generalizability of the results. Larger and more heterogeneous randomized controlled clinical trials are needed to robustly validate the current findings, using standardized and/or clearly established protocols with long-term follow-up to assess the reliability of the results and the long-term benefits of the PNAM in patients with cleft lip and palate. Furthermore, the available evidence on the emerging techniques described in the reviewed literature is still preliminary. The scarcity of high-quality longitudinal and comparative studies prevents a rigorous evaluation of their efficacy and safety compared to established protocols.[10,12,13]

CONCLUSIONS

Nasoalveolar molding represents a valuable technique in the early treatment of patients with cleft lip and palate for pre-surgical cleft management. Scientific evidence supports its ability to significantly improve nasal anatomy and alveolar alignment, resulting in short-term aesthetic and functional benefits.
While the Nasoalveolar Molding (NAM) technique shows promising results, it is crucial to recognize the variability in clinical protocols and the need for greater standardization. The operator's experience and the active collaboration of the parents are determining factors in the success of the treatment. Larger, and more heterogeneous, randomized controlled clinical trials are needed to validate the current findings and assess the long-term stability of the results.
Future research should focus on comparing different techniques and protocols, as well as evaluating the long-term effects of PNAM on facial growth and devel-opment.
In summary, PNAM presents itself as a valuable tool in the comprehensive management of patients with cleft lip and palate, with the potential to significantly improve their quality of life. However, further research is needed to optimize the technique and ensure predictable and lasting results, not only within the dental field but also in an interdisciplinary context.

REFERENCES

1. Shaik N, Eggula A, Pudi S, Yemineni BC, Jagati S, Cheduravally TR. Presurgical Orthopedic Nasoalveolar Molding in Cleft Lip and Cleft Palate: Case Report. Int J Clin Pediatr Dent. 2023;16(4):659-662. https://doi.org/10.5005/jp-journals-10005-2487. PMID: 37731793; PMCID: PMC10507294.
2. Baeza-Pagador A, Tejero-Martínez A, Salom-Alonso L, Camañes-Gonzalvo S, García-Sanz V, Paredes-Gallardo V. Diagnostic Methods for the Prenatal Detection of Cleft Lip and Palate: A Systematic Review. J Clin Med. 2024;13(7):2090. https://doi.org/10.3390/jcm13072090. PMID: 38610855; PMCID: PMC11012824.
3. Luyten J, De Roo NMC, Christiaens J, Van Overberghe L, Temmerman L, De Pauw GAM. Rapid maxillary expansion vs slow maxillary expansion in patients with cleft lip and/or palate: a systematic review and meta-analysis. Angle Orthod. 2023;93(1):95-103. https://doi.org/10.2319/030122-188.1.
4. Ministerio de Salud. Guía Clínica AUGE fisura labiopalatina. 3ra ed. Chile: Ministerio de Salud; 2015. 5-71.
5. Grayson BH, Shetye PR. Presurgical nasoalveolar moulding treatment in cleft lip and palate patients. Indian J Plast Surg. 2009;42 Suppl(Suppl):S56-61. https://doi.org/10.4103/0970-0358.57188. PMID: 19884682;
6. Ahsanuddin S, Ahmed M, Slowikowski L, Heitzler J. Recent Advances in Nasoalveolar Molding Therapy Using 3D Technology. Craniomaxillofac Trauma Reconstr. 2022;15(4):387-396. https://doi.org/10.1177/19433875211044622. Epub 2021 Sep 3. PMID: 36387323; PMCID: PMC9647384.
7. Al-Qatami F, Avinoam SP, Cutting CB, Grayson BH, Shetye PR. Efficacy of postsurgical nostril retainer in patients with unilateral cleft lip and palate treated with presurgical nasoalveolar molding and primary cheiloplasty-rhinoplasty. Plast Reconstr Surg. 2022;150(3):623-629. https://doi.org/10.1097/PRS.0000000000009426.
8. Dinh TTN, Van Nguyen D, Dien VHA, Dong TK. Effectiveness of Presurgical Nasoalveolar Molding Appliance in Infants With Complete Unilateral Cleft Lip and Palate. Cleft Palate Craniofac J. 2022;59(8):995-1000. https://doi.org/10.1177/10556656211026493. Epub 2021 Jun 24. PMID: 34164995.
9. Thakur S, Singh A, Diwana VK, Rani A, Thakur NS. Dynamic changes in nasal symmetry after presurgical nasoalveolar molding in infants with complete unilateral cleft lip and palate. Afr J Paediatr Surg. 2020;17(1-2):1-4. https://doi.org/10.4103/ajps.AJPS_5_18. PMID: 33106444; PMCID: PMC7818664.
10. Lautner N, Raith S, Ooms M, Peters F, Hölzle F, Modabber A. Three-dimensional evaluation of the effect of nasoalveolar molding on the volume of the alveolar gap in unilateral clefts. J Craniomaxillofac Surg. 2020;48(2):141-147. https://doi.org/10.1016/j.jcms.2019.12.012.
11. Zheng J, He H, Kuang W, Yuan W. Novel Three-Dimensional Coordinate System to Analyze Alveolar Molding Effects of Pre-Surgical Nasoalveolar Molding on Infants With Non-Syndromic Unilateral Cleft Lip and Palate. J Craniofac Surg. 2020;31(3):653-657. https://doi.org/10.1097/SCS.0000000000006148. PMID:3198 5599.
12. Thakur S, Jishad C, Singhal P, Chauhan D. Comparative clinical evaluation of modified and conventional Grayson's presurgical nasoalveolar molding technique in infants with complete unilateral cleft lip and palate. Dent Res J (Isfahan). 2021;18:68. PMID: 34584646; PMCID: PMC8428282.
13. Ocak I, Akarsu-Guven B, Karakaya J, Ozgur F, Aksu M. Effects of nasoalveolar molding on maxillary arch dimensions and malocclusion characteristics in primary dentition patients with cleft lip and palate. Int J Paediatr Dent. 2024;34(1):94-101. https://doi.org/10.1111/ipd.13102. Epub 2023 Jul 3. PMID: 37351851.
14. Parhofer R, Rau A, Strobel K, Gölz L, Stark R, Ritschl LM, Wolff KD, Kesting MR, Grill FD, Seidel CL. The impact of passive alveolar molding vs. nasoalveolar molding on cleft width and other parameters of maxillary growth in unilateral cleft lip palate. Clin Oral Investig. 2023;27(9):5001-5009. https://doi.org/10.1007/s00784-023-05119-7. Epub 2023 Jun 23. PMID: 37353667; PMCID: PMC10492684..
15. Titiz Yurdakal S, Oral E, Gelgör İE. Outcomes of Presurgical Nasoalveolar Molding using Modified Nostril Retainers in Patients with Unilateral Cleft Lip and Palate at an Average Follow-up of 2 Years. Turk J Orthod. 2023;36(4):254-260. https://doi.org/10.4274/TurkJOrthod.2023.2022.98.

CONFLICT OF INTERESTS

The authors declare no conflict of interest.

ETHICS APPROVAL

It is not necessary.

FUNDING

Does not have a source of financing.

AUTHORS' CONTRIBUTIONS

Macarena Garrido: Conceptualization and design, formal analysis, writing of the original draft, and writing, review, and editing.

Michelle Cataldo: Conceptualization and design, formal analysis, and writing, review, and editing.

Cynthia Dabed: Methodology and validation, formal analysis, writing, review, and editing, supervision, and project administration.

Darling Rivera: Methodology and validation, formal analysis, writing, review, and editing, supervision, and project administration.

ACKNOWLEDGEMENTS

None.

ORCID

Macarena Garrido
0009-0006-3113-2534
Michelle Cataldo
0009-0007-3453-638X
Cynthia Dabed
0009-0002-0100-5455
Darling Rivera
0000-0002-0994-9373

PUBLISHER'S NOTE

All statements expressed in this article are those of the authors alone and do not necessarily represent those of the publisher, editors, and reviewers.

PEER REVIEW

This manuscript was evaluated by the editors of the journal and reviewed by at least two peers in a double-blind process.

PLAGIARISM SOFTWARE

This manuscript was analyzed Compilatio plagiarism detector software. Analysis report of document ID. 82078a1b5aae734e0828ec71155efdd94799dabb

ISSN Print 0719-2460 - ISSN Online 0719-2479
https://joralres.com/index.php/JOralRes