Presurgical Nasoalveolar Molding—Efficacy and Biomechanics in Management of Cleft Lip and Palate: A Review of the Literature

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Abstract

Presurgical infant orthopaedics (PSIO) appliances are used in the management of cleft lip and palate. Frequently, among all PSIO appliances utilized is presurgical nasoalveolar molding (NAM) appliance. In this review, we looked for the application of the NAM appliance, its efficacy, and biomechanics. A comprehensive search strategy was performed in two databases (Google Scholar and PubMed) for articles using NAM in the treatment plan of patients with cleft lip and palate. Six articles were included in this study with one randomized control trial, two retrospective, and three case reports studies. The studies reveal the NAM is efficient as a presurgical modality treatment for complete cleft lip and palate with multiple benefits, including reducing surgical scars and alveolar gap, used as feeding plate, improve nasal contour, and decreased the number of rectifying surgical procedure.

Keywords

- nasoalveolar molding
- biomechanics
- presurgical orthopedics
- cleft lip
- cleft palate

Introduction

Cleft lip and palate (CLP) is a split in the palate and upper lip and considered as the most common congenital craniofacial anomaly in different ethnicities and populations around the world particularly in developing countries.[1,2]

There are many challenges and difficulties encountered during the management of CLP patients. One being closure of large cleft in presence of anterior maxillary hypoplasia.[3] Indeed, scar formation of soft tissue may be of a great concern after cleft lip surgery.[4] Additionally, many patients with CLP are affected by psychosocial functioning like satisfaction with facial appearance and behavioral problems.[5,6]

In management of CLP surgical intervention must be factored for all patients.[7] However, surgical repair alone sometimes may have a severe impact on maxillary growth.[8] Presurgical management of CLP allows for better surgical repair with minimal tissue distortion.[4,8–11] In general, presurgical infant orthopaedics (PSIO) aims to improve the success of surgical repair, feeding, and the deviation of nasal cartilage into a more symmetrical form. In addition, it has the ability for lengthening the deficient columella. Moreover, severe impact on positive psychosocial outcomes.[12–14]

There are different types of PSIO techniques with different mechanics to achieve different objectives. The

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conventional techniques focused mainly on elastic retraction of the protruding premaxilla and stabilizing after surgical repair. This technique does not directly affect the nasal deformity which is one of the main characteristics of CLP.[15–18] In 1993, Grayson et al developed a technique that can improve the nasal deformity as well as the molding of the alveolar process.[19] Repositioning and molding of the nasal cartilage could happen because of the plasticity of cartilage in newborn infants discovered by Matsuo et al.[20–22] Proteoglycan is an intercellular material responsible for elasticity. Matsuo et al believe that estrogen causes an increase in hyaluronic acid. The abundant amount of hyaluronic acid causes disconnection of intercellular material resulting in a lack of elasticity. The long-term effect of nasoalveolar molding (NAM) has shown significant benefits in the treatment of unilateral (UCLP) and bilateral CLP (BCLP).[21,23,24] Our aim in this literature review is to assess the effectiveness and the biomechanics of NAM that has been used in patients with CLP.

Methods

The materials and methods are based on comprehensive search strategies that have been validated and standardized.

Search Strategy

Within the period 2016 to 2021, an electronic search of two different databases (Google Scholar and PubMed)[25] was performed using the following Medical Subject Headings terms: ((((((((((((((nasoalveolar molding) OR (Nasoalveolar molding)) OR (nasal molding)) OR (NAM)) OR (presurgical NAM)) AND (biomechanics)) OR (Mechanics)) AND (presurgical orthopedics)) OR (PSO)) OR (preoperative orthopedics)) AND (cleft lip)) OR (cleft palate)) OR (cleft maxilla)) OR (cleft alveolus)) OR (cleft)) OR (CLP)) According to a bibliographic search, out of 101 studies selected only 6 studies fulfilled the criteria (►**Fig. 1**).

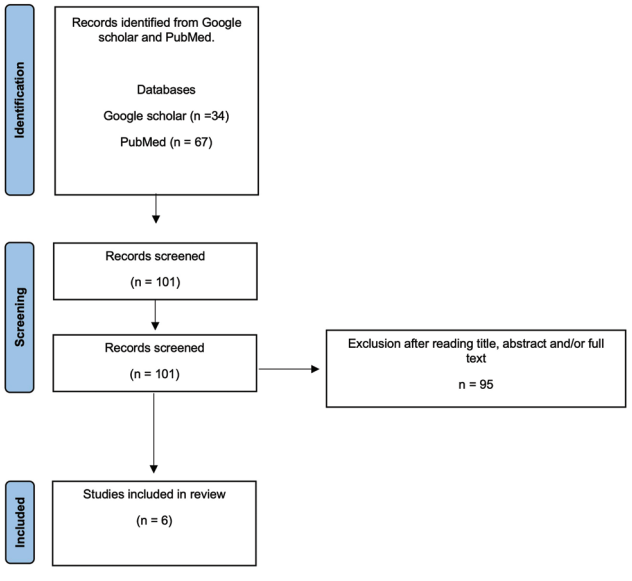

Fig. 1 Flowchart of studies that were considered for inclusion.

Inclusion Criteria

Search criteria included all human randomized control trials, retrospective cohort studies, case series, case reports, and follow-up studies related to NAM appliance from 2016 to 2021 and have free access on the following databases Google Scholar and PubMed.

Exclusion Criteria

Based on the research criteria all studies where the management of the CLP not including NAM, inaccessible article, or review article were excluded.

Results

This review included clinical original studies within the last 5 years from Egypt, Italy, the United States, and three studies from India. According to the methodological quality, the studies have various designs—one study was a randomized control trial, two studies were retrospective cohort studies, and the remaining three studies were case reports. A total of 205 patients were enrolled in the studies. Two hundred and one patients were with UCLP and the remaining four patients had BCLP. Objectives of the studies varied with different outcomes after using NAM or assessment of patients treated by NAM. Six studies were included and classified by categories (►**Table 1**).

Saad et al[12] measured the three-dimensional (3D) progressive changes of maxillary geometry in 20 patients with UCLP and Chour et al [26] measured the efficacy of NAM in five patients—four of them with BCLP and one patient with UCLP. Rubin et al[14] measured midface growth in 56 school-aged children with nonsyndromic UCLP. Staderini et al[13] assessed the 3D morphological changes following NAM by the application of computer-guided technologies in one patient. Correction of UCLP by using NAM in 2 days old patients reported by Doifode et al.[27] Moreover, Subramanian et al[28] assessed the efficacy of a developed NAM in 45 female babies with complete UCLP. The prospective randomized control trial study compared two groups each consisting of 20 patients, one group was treated by NAM and the other by non-NAM. Saad et al depended in their study on the measurement of poured stone casts, which they scanned by using laser machine and underwent computer-aided design and then analyzed with 3D software three times before the NAM, 3 weeks after using NAM, and 6 weeks later. They found that the alveolar gap in the NAM-treated group had been reduced especially in the third week after using NAM specifically in the anterior region and they concluded that using NAM treatment for CLP is effective in minimizing the cleft severity with less deterioration to vertical and transverse growth of the arch.[12] The two retrospective studies' (Rubin et al and Chour et al) main aims were to evaluate midface growth in patients with UCLP treated with NAM (Rubin et al) and to assess the efficacy and effectiveness of NAM in treating UCLP and BCLP patients Chour et al—61 patients. Fifty-six school-aged children with complete UCLP were analyzed with an average age of 8.6 years old. The midface growth analyzed with cephalmetric tracing on 3 soft tissues relationships

Table 1 Characteristics of studies selected for the review

Author, Year, Country	Design	Population	Type of cleft lip and palate	Outcome variable/s	Main conclusion
Saad et al, 2020, Egypt	Randomized controlled trial	20 patients	UCLP	The amount and rate of cleft gap changes, midline position, transverse, sagittal, and vertical growth	The NAM treatment is effective in minimizing cleft severity and realigning maxillary segments without the deterioration of the transverse and vertical arch growth
Staderini et al, 2019, Italy	Case report	One patient	UCLP	Evaluation of dimensional changes in the nasolabial area in cleft lip and palate patients undergoing PNAM	Improvement in the symmetry of the nasolabial area obtained with the presurgical orthopaedic treatment
Rubin et al, 2019, USA	Retrospective cohort study	56 patients	UCLP	NAM protocol on midface growth in school-aged children with nonsyndromic UCLP	The NAM treatment protocol does not appear to impact skeletal or soft tissue facial growth in school-aged children with nonsyndromic UCLP
Subramanian et al, 2016, India	Case report	One patient	UCLP	Developed a modified NAM device to suit the needs of the patients coming from distant places for the treatment. This device helps in reducing the number of frequent visits the patient needs to take to the craniofacial center	The advantage of the TMA wire is that it is more resilient, and hence, activation can be done once in 2 weeks
Doifode et al, 2018, India	Case report	One patient	UCLP	Correct cleft lip and palate by using NAM	The use of NAM has removed surgical scars related to conventional columella reconstruction and has decreased the number and price of revised surgical procedures
Chour et al, 2020, India	Retrospective Clinical study	5 patients	BCLP and UCLP	To assess the efficacy of the NAM procedure in treating cleft lip and palate patients before surgical closure of the lip	NAM helped in reducing the size of the clefts in cleft lip and palate patients and a better nasal contour was seen to be achieved with this procedure before the surgical closure of the lip

Abbreviations: BCLP, bilateral cleft lip and palate; NAM, nasoalveolar molding; PNAM, presurgical nasoalveolar molding; TMA, titanium molybdenum alloy; UCLP, unilateral cleft lip and palate.

(A'N'B, Sn-CT-LS, G'-Sn-Pg) and 4 hard tissues relationships (SNA, SNB, ANB, ANS-Me/N-Me %). Tracing were then scanned into Dolphin imaging software and serial measurements were made. After that, other non-presurgical infants' orthopaedic cephalometric measurement was compared (with age of 9), which they obtained from published data (Eurocelft center). They did not utilize PSIO. Their result was that NAM treatment does not affect skeletal or soft tissue facial growth. Chour et al included in their study patients with BCLP and UCLP. Their simple size consisted of five patients—four patients with BCLP and one patient with UCLP—and the average age of patients was 26 days. They used NAM for an average period of 80 days. The measurements for the patient with UCLP were 14 mm pre-NAM and six post-NAM reduction was 8 mm. Patients with BCLP had an average reduction of 2.75 mm on the right side and 4.4 mm on the left side. The conclusion showed there was a severe impact of using NAM for patients with either UCLP or BCLP.

The remaining three studies in this literature review were case reports for 16, 2, and 45 days old children with complete UCLP. Staderini et al assessed the morphological changes in the patients after NAM. Doifode et al assessed the effect of NAM in the treatment of CLP. Whereas Subramanian et al introduced a modified NAM device to decrease the number of appointments. Staderini et al performed their treatment by using NAM as an active plate to reduce the transverse discrepancies until the alveolus cleft was reduced by approximately 5 mm, and then used a passive plate till the appointment for lip surgery. Four plates were used in 8 months' duration of treatment with 2 months' duration for each plate. After that, the reduction of the asymmetry index was assessed by the 3D photographs which they obtained using the 3dMD. The asymmetry index showed a noticeable change after using NAM. Doifode et al used NAM for their patients and found a great improvement and healing with a scar formation. Subramanian et al used a modified NAM device. For a 45-day female patient, NAM was used with a different component in the nasal stent. Their device uses a nasal stent wire with 0.32 titanium molybdenum alloy (TMA), which aimed to reduce the number of visits to the clinic during NAM treatment. The advantage of TMA is that the activation does not take longer time and that will not annoy the child. In addition, activation is needed only one time per 2 weeks instead of one per week.

Discussion

In this review, the authors looked for biomechanics and efficiency regarding presurgical NAM. The major concerns for using NAM are to reduce the severity and minimize the distance of CLP either inpatient with UCLP or BCLP, correct and improve the nasal deformity, and repair the lip without scar formation.[29–31] In the studies included in this review, different techniques with different measurement methods and different designs were used to assess the NAM.

Efficacy of NAM

Regarding the efficacy, the majority of the studies supported NAM.[12,13,26–28] Saad et al found that there was a change in the midline, transverse, sagittal, and vertical growth in reducing the alveolar gap.[12] Staderini et al by the application of 3D technologies that provided quantifiable morphological changes showed significant improvement in the symmetry of nasolabial area. Moreover, Subramanian et al proved NAM not only provided molding function but also acted as a feeding plate. In addition, Doifode et al concluded that NAM reduced the surgical scars and decreased the number of rectifying surgical procedure. Additionally, Oliveira et al found that NAM helps to centralize the premaxilla and reduce the cleft palate, resulting in a significant improvement of the dental arch and providing excellent surgical outcomes.[32] Furthermore, Chour et al found that NAM was helpful in reducing the size of the CLP with better nasal contour. One of the contradictions of NAM is in midface growth for the patient with CLP treated by NAM interpreted as the treatment protocol appeared to have no impact on skeletal and soft tissue facial growth by Rubin et al.[14] However, this is a radiographic study, and it measures the cleft patients at the young age in which most of the changes already happened. Generally, the major numbers of the studies supported the efficacy of NAM.

Biomechanics

The components of NAM are an acrylic molding dental plate with a retention button that is placed anteriorly, an intranasal stent, and micropore tapes base and retention tapes (►**Fig. 2**).[33] According to the anatomical features of ULCP, the maxillary bone is separated into two different segments. On the side of the cleft, there will be the lesser segment and the greater segment on the opposite side. One of the main aims of using NAM is to minimize the space between these two segments, where the acrylic molding plate plays a major role. Another component of NAM appliance is micropore tape which will provide the forces to the checks in a horizontal direction. The retention tapes will be attached to the retention button by the orthodontic elastic. By adding and removing hard and soft acrylic in a specific part of the acrylic molding dental plate approximating happens. In a general role, removing hard acrylic will lead to lesser resistance, and adding soft acrylic will provide more force. The lesser segment is usually medially displaced specifically the anterior portion opposite to that greater segment is straightened (►**Fig. 3**).[33] As needed to approximate the two segments, remove hard acrylic on the buccal side for the lesser segment and the palatal side for the greater segment. Moreover, adding soft acrylic will provide an additional force on the palatal side for the lesser segment and the buccal side for the greater segment. In addition, one intranasal stent is used for nasal molding that will aim to correct the nasal projection and will help in treating the symmetry of alar cartilage. In UCLP, there is one nasal stent, and in BCLP, there are two nasal stents. The nasal stent is fabricated from a custom bent

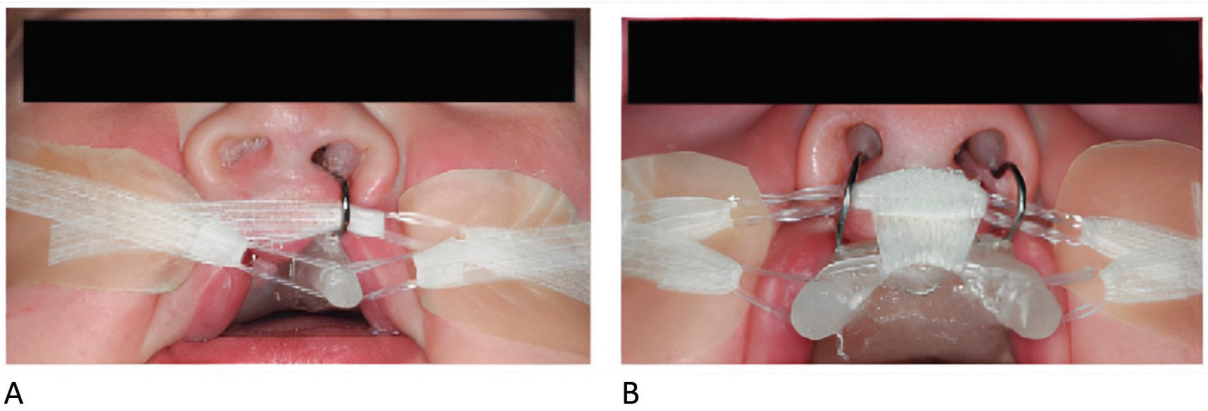

Fig. 2 (**A**) Unilateral cleft lip and palate (UCLP) with nasoalveolar molding (NAM) appliance. (**B**) Bilateral cleft lip and palate (BCLP) with NAM appliance. (Reproduced with permission of Steven and Goudy).[33]

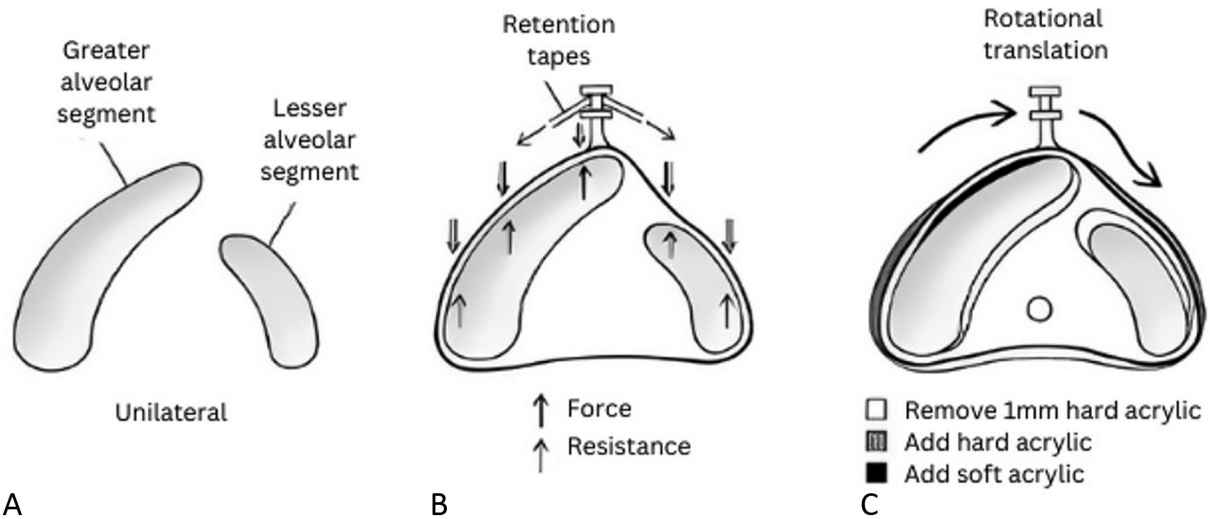

Fig. 3 (**A-C**) Biomechanics of unilateral cleft lip and palate (UCLP). (Reproduced with permission of Steven and Goudy).[33]

0.036-inch stainless steel wire, soft denture liner, and hard acrylic. The wire takes the form of the letter "S" and the portion that will be intranasal resembles the letter "R." The bent wire is then integrated into the appliance with hard acrylic around the retention button. Hard acrylic is also added to the R-shaped intranasal portion of the appliance, giving it a bilobed and kidney bean form. Intranasal portion of the nasal stent is added with soft denture liner. The stent is positioned in the nostril such that the inferior lobe supports the nostril apex, and the superior lobe projects the nasal dome and tip.

However, in patients with BLCP, the maxilla will be separated into a premaxilla and two lateral alveolar segments (►**Fig. 4**).[33] The lateral two-segment is often medially displaced, and the premaxilla is protrusively positioned. So, as discussed, microtapes will provide the force that will be generated posteriorly. As a result, resistance will be from the buccal side of the two lateral alveolar segments. To minimize that removing hard acrylic on the buccal side for the lateral alveolar segments will minimize the resistance. Furthermore, to give free space for alveolar molding, hard acrylic is removed on the palatal side in the premaxilla region. Indeed, adding soft acrylic in palatal aspects for both lateral alveolar segments will generate more force to move to the free side where the hard acrylic is removed. As well as adding soft acrylic on the labial side for the premaxilla (►**Fig. 4**).[33] In BLCP, two nasal stents are used where they are attached together by soft denture liner, and they are used to elongate the columella. The nasal stent scope of activation is determined visually to not cause excessive force that may lead to injury of the nasal mucosa.

Conclusion

Presurgical NAM has been used since long time as a part of the treatment of CLP prior to surgical procedures. It aimed to improve the nasal projection, the alar cartilage, and reduce the distance between the maxillary bone segments. However, with the minimal complications of NAM like irritation of the mucosa, it still proves to be effective.

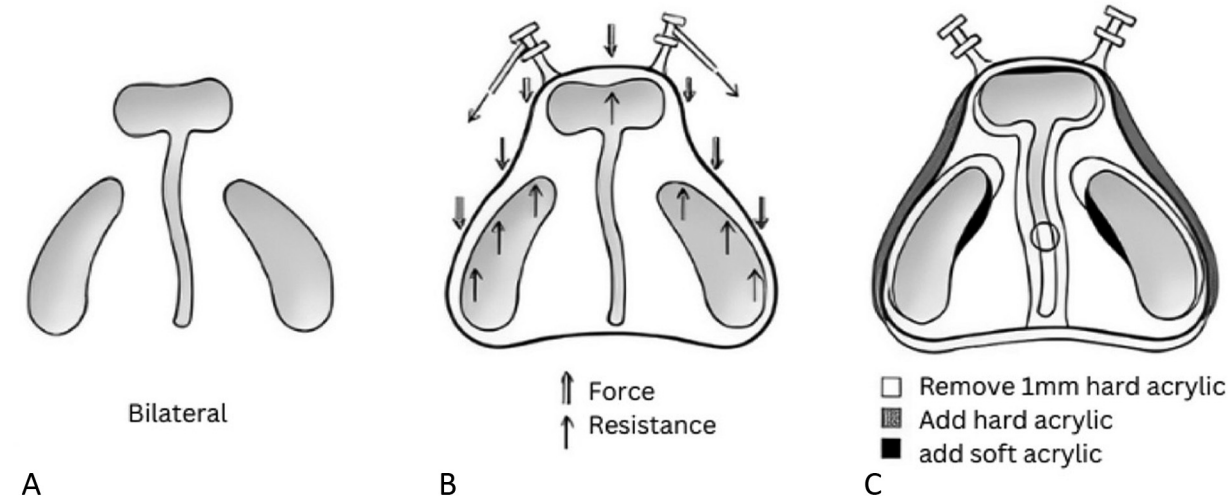

Fig. 4 (**A-C**) Biomechanics of bilateral cleft lip and palate (BCLP). (Reproduced with permission of Steven and Goudy).[33]

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Conflict of Interest
None declared.

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