**Plastic and Aesthetic Research**

Perspective



# Nasoalveolar molding: benefits and burdens

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## Abstract
Nasoalveolar molding (NAM) has been glorified and maligned. Supporters argue that NAM improves cleft outcomes and reduces secondary procedures. Critics highlight the expense, labor intensity, and inconsistent or transient results. We offer NAM to our patients and have been doing so for over a decade; nevertheless, our benefits assessments are nuanced. In the following paper, we present our rationale, evolution, technique, and outcomes of NAM, augmented with an analysis of the literature. We offer another perspective in this ever-evolving area of evidence-based cleft palate care.

**Keywords:** Cleft lip and palate, nasoalveolar molding, cleft nasal deformity

## INTRODUCTION
The primary objective of presurgical infant orthopedics (PSIO) is reducing deformities. The modern PSIO was born in 1950 when Scottish prosthodontist C. Kerr McNeil introduced his palatal appliance[1]. Nevertheless, acceptance has not been universal; 60 years later, the use of PSIO in cleft care is debated.

## EVOLUTION
Ambrose Pare described a cleft lip repair technique using cleft pins in 1575. In 1686, Hoffmann described using a head cap and facial binding (arms extending from the cap) to narrow the defect and prevent

postsurgical dehiscence[2]. Retracting the maxilla actively in bilateral cleft lip and palate was first documented by Desault in 1790[3]. The concept of a made-to-fit maxillary plate placed to reposition the cleft alveolar segments is attributed to McNeil[1]. In this method, acrylic plates are sequentially fabricated as the infant grows, and the segments are actively molded into the desired position. In 1975, Georgiade and Latham introduced a device anchored by pins designed to concurrently retract the protuberant premaxilla and expand the posterior segments over a few days[4]. This quick and vigorous retraction of the premaxilla initiated significant controversy; in response, Hotz introduced a passive appliance that "passively aligned" the cleft segments[5,6].

The history of PSIO thus far constitutes the "alveolar cleft era", where attention is placed on narrowing the alveolar distance, and the primary benefit is the ease of surgical repair. The nasal deformity remained unaddressed.

In 1984, Matsuo *et al.* postulated that neonatal cartilage is highly plastic and amenable to manipulation due to the high levels of hyaluronic acid-brought about by elevated levels of maternal estrogen circulating in the infant[7]. This increased level of hyaluronic acid inhibits the intercellular matrix, enables the relaxation of connective tissue, cartilage, and ligaments, and helps ease the passage of the fetus through the birth canal. Neonatal levels of maternally derived estrogen are maximal perinatally and fall to baseline levels in the subsequent 6-8 weeks. Utilizing this window, Matsuo *et al.* molded and corrected deformed auricular cartilage[8,9]; the same principle was then extended to the cleft nasal cartilage by Nakajima *et al.* and Matsuo *et al.*[8,9,10]. In 1993, Grayson *et al.* went a step further and combined maxillary molding plates and nasal cartilage shaping; they described a technique to simultaneously correct the alveolus (with acrylic maxillary plates), lip (by soft-tissue taping), and nose (with nasal stents to mold the highly pliable neonatal nose)[3,8,9]. Though popularized by Grayson and colleagues, Bennun claims that his colleague Dogliotti used very similar principles by designing a small nasal stent to the McNeil palatal plate as far back as 1987, and they published their results on 80 patients in Spanish in 1991[11,12].

## MATERIAL AND METHODS

The primary objective [Figures 1 and 2] of NAM is a reduction in the severity of the deformity. This procedure entails the following elements [Table 1]:

NAM's goals, as envisioned by its pioneers, Grayson and Cutting[13], are (i) improved nasal form that persists; (ii) reduction in secondary nasal procedures; (iii) minimizing the need for secondary alveolar bone grafting; (iv) achieving these results with minimal effects on midface growth; and (v) an overall decrease in the number of revision procedures.

### Why do we do it?

Our team uses nasoalveolar molding in all cleft cases whenever possible. Most often, the reason for not offering NAM before surgical treatment is the infant being brought in late (i.e., more than ten weeks after birth). Since 2010, consistent use of NAM has been an integral part of our cleft protocol. We faced early challenges regarding learning curves for the team's orthodontists, minor complications, issues due to the therapy itself, frequent appointments, and distances traveled by our patients and parents. Over the years, we refined our NAM protocols and techniques, facilitated the training and continuing education of the NAM providers, and have reduced the financial and emotional burdens to the parents by providing financial assistance (we are a Smile Train-supported cleft unit), constant follow-up via telemedicine, and reducing visits by combining consults.

**Table 1. Objectives of nasoalveolar molding in unilateral and bilateral clefts**

| Unilateral cleft lip and palate | Bilateral cleft lip and palate |
| --- | --- |
| Approximating lip elements that are almost in contact at rest | Achieving congruity of the premaxilla and lip elements |
| Symmetrical lower lateral alar cartilage | Gentle retraction of the premaxilla [Figure 3] |
| Stretching of the nasal mucosal lining, which eases surgical repair | Midsagittal centering of premaxilla [Figure 4] |
| Near approximation of the bony alveolar segments, which indirectly aligns the base of the lip and nose | Non-surgical elongation of columella in bilateral deformity [Figure 5] |
| Lengthening and up-righting of the inclined columella | Achieving congruity of the bony premaxilla and alveolar segments [Figure 6] |
| The stretched ala in the unilateral cleft, during NAM, shows some laxity which can then be elevated into a symmetric, convex form | Narrowing of alar base width |
| Nasal tip overcorrection on the cleft side | ● Nasal tip narrowing<br>● Improved tip projection |

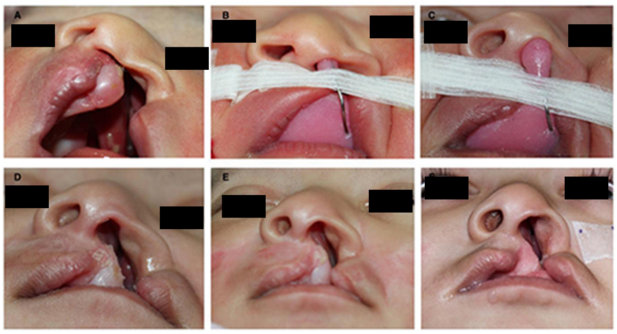

**Figure 1.** Objectives of NAM achieved in Unilateral complete cleft clip and palate (UCLP). (A) and (D) at presentation. (B) and (E) midway through NAM. (C) and (F) before surgery. The columella is upright, the ala is domed, the nasal lining is stretched, and the alveolus is approximated.

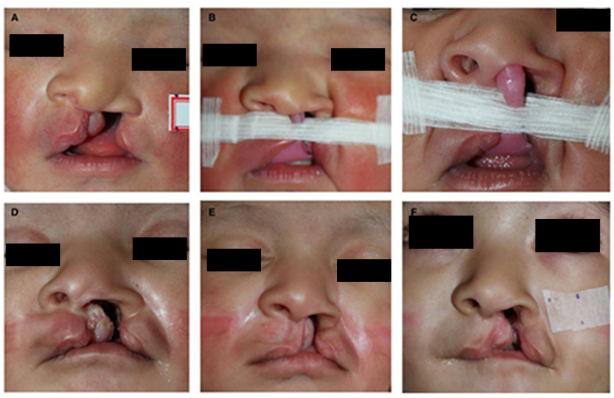

**Figure 2.** Objectives of NAM achieved in Unilateral complete cleft clip and palate (UCLP). (A) and (D) at presentation. (B) and (E) midway through NAM. (C) and (F) before surgery. Significant amelioration in deformity is apparent.

Currently, all surgeons and parents find the results satisfactory. From a purely surgical standpoint, NAM lessens the severity of the deformity and aids in the ease of the procedure. Immediate surgical results appear far more aesthetic. These are purely anecdotal statements and do not hold scientific value; for this reason, we analyzed our outcomes methodically[14].

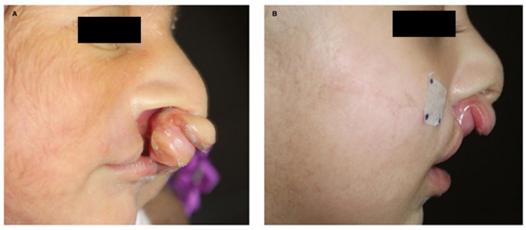

**Figure 3.** Objectives of NAM in BCLP. (A) at the start. (B) after gentle retraction and centering of the premaxilla.

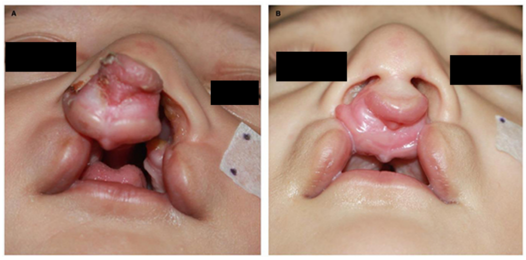

**Figure 4.** (A) deviated, rotated premaxilla at presentation. (B) derotated, centered premaxilla.

**Figure 5.** (A) complete lack of columella at presentation. (B) non-surgical lengthening of columella achieved after NAM.

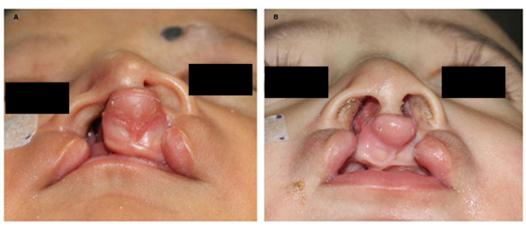

**Figure 6.** (A) deviated premaxilla, flattened alae. (B) premaxilla brought domed lower lateral cartilages, a columella, and congruent lip elements to the center.

Most of our early NAM cases are now in their late-mixed-dentition age or early teens. We are, at best, wishing for improved long-term nasal aesthetics and fewer secondary operations, and at worst, we hope there are no detrimental growth effects and that we have not inadvertently introduced iatrogenic defects into the existing deformity. At the 5-year follow-up, our unilateral CLP NAM patients had better objective scores on the Asher-McDade Scale. However, they were not statistically significant compared to the non-NAM group. However, they showed statistically significant better subjective evaluation scores.

Furthermore, lip revisions were significantly higher in the non-NAM group[15]. These are early results; the patients will be followed until adulthood to assess outcomes. Therefore, until the evidence suggests otherwise, we will continue to provide NAM to all patients, as our goals are routinely achieved with minimal morbidity and a reasonable degree of parent and surgeon satisfaction.

### How we do it

Our NAM technique has evolved. In the past decade and a half, we have incorporated elements from the Grayson technique[13] and the Figueroa method[12]. We commence the nasal molding at the outset and do not use retentive tags on the maxillary plate unless it is a particularly severe case. Our nasal stent is unilobed and fashioned as a bulb rather than the bi-lobed Grayson stent. Our cutoff for not providing NAM is ten weeks. On average, the treatment duration is between 12-16 weeks. For the unilateral deformity, our goals at the completion point are an alveolar approximation to within 3-4 mm (we do not advocate or perform gingivoperiosteoplasty), contact of lip elements, columella straightening, and mild overcorrection of cleft side ala of the nose. The greater segment is molded by curving inwards and centering the frenal attachment. The lesser segment is manipulated by trimming the anterior part of the plate and loading the posterior region.

In bilateral clefts, we aim for premaxillary centering, congruency with the lip elements in all dimensions, columellar lengthening, vertical positioning of the premaxilla in the same plane as the alveolar segments, lip approximation to pro-labial elements and laxity, and doming of the lower lateral cartilage of the ala.

The impressions are always made in the hospital setting with a high-evacuation suction on hand and anesthetic and surgical members of the cleft team [Figure 7] to manage any airway emergencies (we have not had one to date). Once the casts are poured, the undercuts are blocked out with beading wax. The molding plate is fabricated with self-cure acrylic resin and made about 2-3 mm thick. Retentive buttons are not routinely used [Figure 8]. The nasal stent holding wire is bent to lie 7-10 mm from the lip at a 45 degree angle [Figure 9]. The terminal loop rests at the lower border of the collapsed nostril, and a 5 mm diameter bulb-shaped, unilobed acrylic stent is fabricated on the loop. It is inserted 3-4 mm inside the nares on the cleft nose until the dome is gently lifted and there is a slight blanching of the skin [Figure 10]. Only one retentive arm is warranted in unilateral clefts, and its location is determined by stretching the lip elements together while centering the philtrum and columella [Figure 11]. In the case of the bilateral cleft lip and palate, two stents are required[15]. The rationale is lengthening the columella. Central taping between the two retentive arms that span the columella and abuts the nasolabial junction is crucial; over time, it lengthens the columella and defines the nasolabial angle. The twin nasal stents allow the lifting of the nasal domes and create a counterforce to facilitate the stretching of the premaxilla[16].

The entire appliance is secured bilaterally to the cheeks with orthodontic elastic bands. Surgical tape (micropore) is used, and skin tolerance is usually good. The use of aloe vera gel is demonstrated to caregivers for the same reason. The surgical tape elastic is looped onto the retention arm, and the tape is secured to the cheeks. The elastics are heavy, with an inner diameter of 0.25 inches, and they are stretched to twice their original length to achieve the proper activation force (though the literature describes this force as about 100 g. We do not need or use that much force unless it is a particularly severe case; for unilateral cases, we may use force less than half as much)[17]. Caregivers are instructed to change the tape once daily, remove the appliance and clean it with warm water. If present, they are to remove residues of old denture adhesive and any milk/formula debris. The tape is applied first to the non-cleft side, stretched to the cleft side, and adhered there.

The babies are then seen at weekly (early on) or biweekly appointments where the progress is evaluated. We are primarily concerned with approximating alveolar segments and nasal cartilage molding. Retention of the

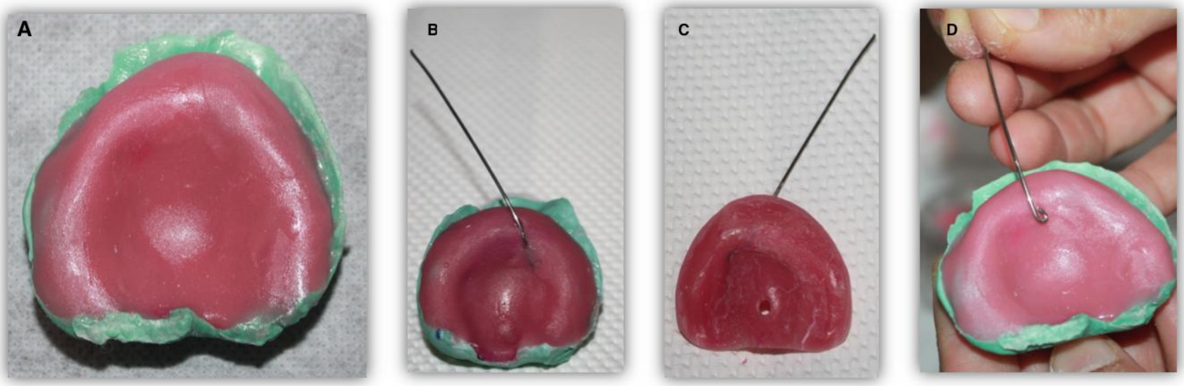


**Figure 7.** A) acrylic plate prepared on the cast. (B-D) 0.8 mm SS wire (12-14 cm length) is adapted over the waxed model with a retentive tag and is acrylized.

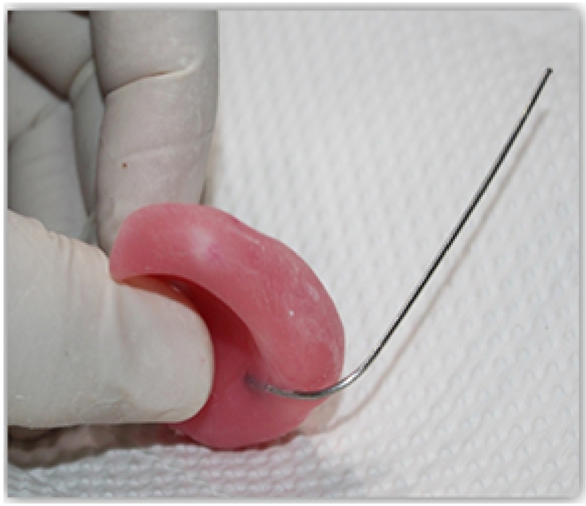

**Figure 8.** The wire extends out of the plate approximately 45 degrees and passes close to the columella of the nose on the cleft side.

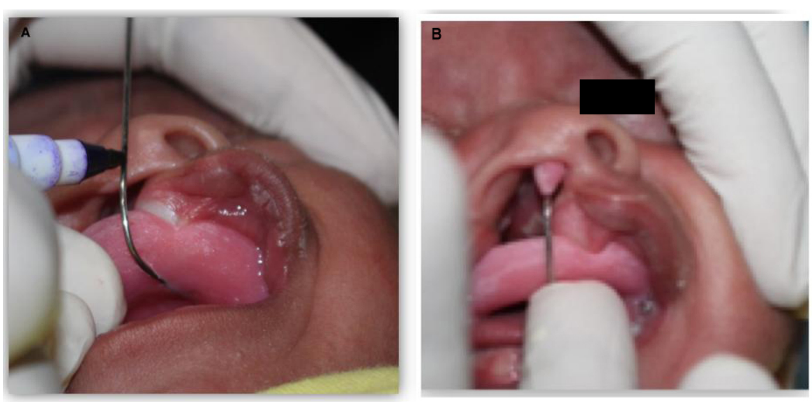


**Figure 9.** A) markings are made such that the stent wire lies 7-10 mm from the lip. (B) the nasal bends are checked in the mouth for inclination, with a terminal loop resting at the collapsed nostril's lower border. A 5 mm diameter acrylic stent is made on the loop.

**Figure 10.** (A) activation of the alveolus is performed by adding soft liner acrylic in the areas of pressure/relief. (B) micropore taping of the lip and plate insertion is performed using a denture adhesive. Thereafter the final tape is placed, and a nasal tape is applied.

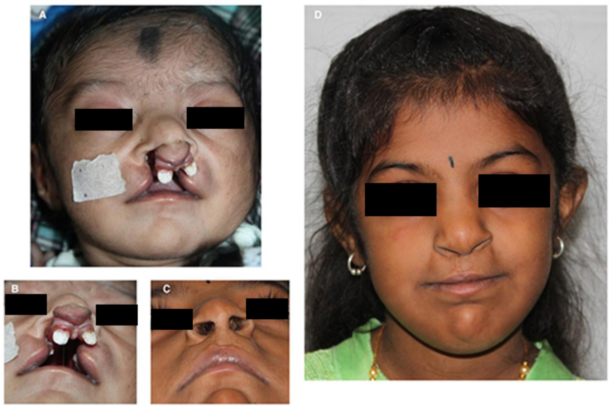

**Figure 11.** NAM results. (A) and (B) at presentation. (C) and (D) aged 8 years.

plate is evaluated, and the oral cavity is inspected for signs of over-extension, ulceration, or soft-tissue injury. The molding plate is modified by removing acrylic from the regions where one wishes the alveolar elements to move. Concurrently, the soft liner is also removed to guide the segments closer, i.e., we mold the pliable bone by selective "unloading" rather than loading. Transverse plane-palatal loading is performed for buccal outward movement and buccal loading for palatal movement. In the bilateral cleft, the premaxilla is first de-rotated, then pulled back into the same plane as the alveolar segments; finally, all three segments are congruent with selective molding [Figures 12-15].

## RESULTS

A modified Millard technique without perialar incisions. No surgical intervention was performed on the nose.

A modified Millard technique without any perialar incisions. No surgical intervention was done on the nose.

The weekly or biweekly appointments may appear burdensome; however, they allow us to monitor feeding and nutrition closely. Nutrition is a substantial challenge in most patients; babies brought in late and not provided NAM are often seen more than once a month to support feeding and nutrition.

**Figure 12.** NAM results. (A) at presentation. (B) 16 weeks later, before surgery. (C) aged 6 years.

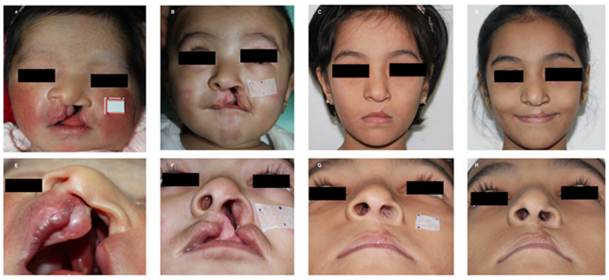

**Figure 13.** NAM results. (A) and (E) at presentation. (B) and (F) 12 weeks later, before surgery. (C) and (G) aged 10 years. (D) and (H) aged 12 years.

**Figure 14.** NAM results. (A) at presentation. (B) 12 weeks later, before surgery. (C) aged seven years.

Meazzini *et al.* compared the nasal shape of young adults with BCLP treated with primary surgical columellar lengthening and NAM with age and sex-matched non-cleft adults[18]. The authors concluded that NAM and primary rhinoplasty in patients with BCLP resulted in the near-normal length of the columella and nasal projection until young adulthood. Nevertheless, the widths of all nasal features were significantly wider than the non-cleft population and required secondary nasal correction in one-third of the sample[18].

### A flexible protocol

Occasionally, we attempt nasal molding (using nasal hooks, Figure 16); or premaxillary manipulation (in severe cases, Figure 17) even if the child presents late to our clinic. Shetty *et al.* followed 150 patients (50 each in age groups 0-1 month, 1-6 months, and 6 months-1 year) who underwent NAM and compared

**Figure 15.** UCLP with alveolar segments almost in approximation. Taping and nasal hooks are used for lip approximation and nasal molding. The results are shown in sequence.

**Figure 16.** BCLP presented at 8 weeks with severely protruded premaxilla. Taping was done for 16 weeks to manipulate it into a more amenable position.

**Figure 17.** The most common complication of NAM is skin and mucosal irritation and ulceration.

results by measuring linear anthropometric measurements on dentofacial models[19]. All three groups showed significant improvement with the NAM protocol. Although the authors admit that those who started therapy before one month of age benefited most, surprisingly, the other two groups benefited almost equally. Such studies are relevant to our patient cohort as many patients report at 8 weeks of age and thereafter (even 6 months of age and older is relatively common).

We do not hesitate to use nasal molding in incomplete cleft lips with a nasal deformity or only lip taping and nasal hooks in cases where alveolar molding is not warranted. In brief, our nasoalveolar molding protocol is not rigid; instead, it is fluid and individually catered to the severity of the deformity and the patient's circumstance. We focus more on the “nasal aspect” of the deformity than on the alveolar approximation, as gingivoperiosteoplasty to avoid a secondary bone graft is not part of our protocol.

This was a modified Millard technique without perialar incisions. No surgical intervention was done on the nose.

## Complications

In our clinical experience, we have had no severe complications with NAM.

1. The most common issue we have faced is irritation and sometimes ulceration of the delicate oral tissues. This most commonly occurs due to over-extension of the molding plate. Problem areas are the areas under frenal attachments, the premaxillary element, and the posterior fauces[20]. These are generally minor and are easily rectified (by relieving pressure areas) once identified.

2. Skin irritation/ulceration [Figure 18] and pigmentation. Generally not reported in the Western literature, temporary hypopigmentation of the midface in areas of taping is common in darker-skinned children [Figure 19]. It is temporary and resolves when the child reports for palate surgery. Skin irritation from repeated application of tapes is dealt with by teaching the caregivers to gently handle the delicate infant skin (using warm water to remove the tapes and not ripping them), dressing tape underneath, and aloe vera gel.

3. The nasal lining can become inflamed and rarely notched [Figure 20] if the nasal stent applies undue pressure or the bulb is not fabricated or placed correctly.

4. The pro-labial skin can become ulcerated if the central band is too tight.

5. Creation of mega-nostrils, i.e., over-expansion of the nares and a distended nasal aperture created from excessive tension on the flexible lower alar cartilage [Figure 21]. This may occur from improper stent positioning or over-contouring such that the forces are applied on the rim rather than the nasal dome[21]. It has also been suggested that this occurs when the nasal stent is applied before the cleft gap is less than 5 mm[13]. Close monitoring of the forces applied is the key to avoiding such adverse outcomes.

6. There is a theoretical risk of the plate dislodging and obstructing the airway. Inadequate horizontal taping pressure may cause the molding plate to drop onto the tongue[22]. In anticipation of such an event, we place a 3-4 mm hole on the palatal aspect of the maxillary plate so that, in the worst-case scenario, the infant's airway is not completely blocked.

7. Poor monitoring and over-enthusiastic molding by the NAM provider or poor compliance from the caregiver can cause the greater segment to move too quickly, and the lesser segment gets "locked out" behind, the greater segment; therefore, the arch form collapses. Occasionally, the lesser segment might rotate excessively to approach the major segment perpendicularly, resulting in an asymmetric T-shaped configuration. When such a scenario occurs, the segment relationship should be restored by expanding the alveolar segments and redirecting proper gap closure

8. The NAM appliance is meant to be worn full-time. Furthermore, a candidal infection may result if not removed daily and cleaned thoroughly[20]. Fungal infestation is treated with nystatin or amphotericin ointment. Therapy continues while the fungal infection is treated.

9. Bleeding and columellar tearing. In unilateral cases, bleeding can occur due to a rough nasal stent[20], but it is less common than the overstretching, tearing, and bleeding that occurs over the thin columella in bilateral clefts. In these cases, the pressure exerted by the pro-labium tape and the excessive superior and

**Figure 18.** Not often reported in Western literature, we often face the problem of hypopigmentation in taping. Resolves spontaneously in a few weeks after cessation of NAM.

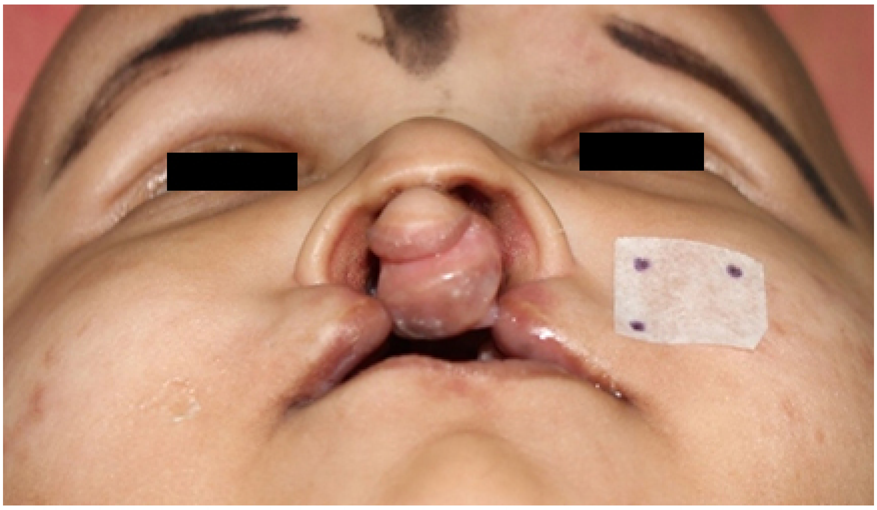

**Figure 19.** Mild notching is apparent in this BCLP patient who underwent NAM.

lateral forces from overactivated nasal stents can exceed tissue thresholds, leading to tearing at the base and resulting in associated bleeding. If the tissue breaks down, therapy is suspended for 1-2 weeks until the tissue heals.

**Figure 20.** We occasionally encounter nostrils that are larger than intended, the “meganostril”.

**Figure 21.** Relapse is real. (A) and (E) at presentation (2 weeks old). (B) and (F) post-NAM, before primary repair. (C) and (G) at palate repair, 6 months after primary lip repair. (D) and (H) a slight reduction in nostril height and widening of the alar base are apparent 18 months later.

10. An additional complication of the hard tissues involves the premature eruption of primary maxillary incisors through overlying gingival tissue due to the pressure exerted by the molding plate[22]. A previous study suggested that extraction is indicated to prevent aspiration if the erupting tooth is ectopic or supernumerary[23,24]. Extraction is also indicated if the erupting tooth is mobile or interferes with the proper activation of the appliance.

Despite the various adverse effects that may occur from NAM, the most significant challenge remains caregiver compliance and consistency. An excellently made device, with the best providers and the most detailed instructions, is in vain if the caregivers cannot use the device as intended, follow instructions, and turn up for the follow-up appointments at times specified. The only solution to this, as we have found the hard way, is intensive and repeated counseling. Counsel, counsel again, and repeat. We also try to club appointments so that a caregiver just starting on their NAM journey gets to interact with a caregiver who is just about done. This allows them to see first-hand what their troubles can accomplish and the end goal. No amount of physician counseling can replace the camaraderie and kinship that cleft caregiver interaction can.

## DISCUSSION

As of 2012, over one-third of US cleft centers offer nasoalveolar molding. About half of the surveyed centers in Europe used some form of presurgical orthopedics (mostly passive plates)[25]. The cost of treatment for CLP is high, and any PSIO adds to it. In the West, the estimated cost of interventions and habilitation average more than $100,000 per individual[26]. These figures do not represent the immeasurable costs incurred in the psychosocial realms (e.g., multiple appointments, various doctor consults, caregiver anxieties, and losses incurred due to missed workdays, lost wages, and possibly childcare for siblings). We do not have such estimates of comprehensive cleft care or nasoalveolar molding therapy in India. (We estimate the cost of nasoalveolar molding alone to cost about $350 to $400 per child.)

As evidence-based outcomes become the standard of care, much of medicine has moved toward new treatment advances in technology, techniques, and medications[27]. Comprehensive cleft care is now considered on-par treatment, and the focus of these multi-disciplinary teams is not individual procedures or simply survival; the emphasis has shifted toward thriving and providing the best quality of life possible to these children - in infancy, through childhood, and into their adult lives as fully functioning members of society with minimal to no stigmata of their birth condition. Therefore, all therapeutic burdens have to judge against this backdrop.

The critique of NAM can be summarized as arduous and expensive, and the clinical benefit is transient. The biggest drawback of the therapy, as mentioned in literature, time and again, is the unavoidable caregiver reliance and compliance[28]. Infants with unilateral deformity are in the NAM provider office an average of 13-14 times prior to primary surgery, and this number is about 20-22 in children who suffer from bilateral clefts[29-31]. Add to this the distances traveled, the times spent in waiting rooms, the money spent, and the wages lost; the burden starts to mount reasonably quickly. As a pilot study looking to develop a NAM-specific burden of care questionnaire, we interviewed 120 families whose children underwent NAM. We wished to perceive their experience. Surprisingly, despite the challenges involved, more than 70% were satisfied with the process and the outcome; 90% said they would recommend this presurgical treatment to others despite the added "burden." Similarly, in a systematic review performed by Alfonso *et al*., the authors attempted to evaluate NAM in the context of burdens of care (psychosocial, physical, and financial)[29]. Though the existing evidence is marred by bias (aggregating all PSIOs under one category) and lack of scientific quality, the authors lament the indiscriminate association of NAM and the increased burden of care. They admit that it may not be for everyone, but the quality of life and psychosocial advantages are evident.

On the other side of the argument, Wlodarczyk *et al.* report that the direct cumulative cost of NAM alone is a staggering $2,132 in indirect lost income per family; average direct charges for NAM totaled $12,290 for the hospital, physician, and appliance costs[30]. Over the entire study period, the cumulative direct cost of NAM, separate from the lip's surgical repair, was $970,910[30]. If possible, early primary lip repair, without any presurgical therapy, is more cost-effective. Offset this with arguments made by researchers who conclude that despite the added burden, many caregivers used this period of therapy as a problem-focused strategy to deal with their child's condition, and completing it is often associated with a sense of empowerment and self-esteem[32]. We witnessed this phenomenon, which is challenging to quantify.

The burden of care, when looked at from a broader perspective, should also include the anticipated cost of future surgeries. We compared 38 children with UCLP who underwent NAM to 48 children who did not. All patients received identical treatment except for NAM. The cleft severity index was used to record preoperative cleft severity. Despite the greater severity of deformity in the NAM group, at 5-year follow-up, the non-NAM group had a significantly higher rate of secondary surgeries with a wider variety of defects than the NAM group, i.e., there was a higher surgical burden of care[33].

### Limitations

Numerous studies consistently demonstrated that NAM improves nasolabial aesthetic outcomes[34,35]. As a presurgical therapy, it improves predicted and actual postsurgical outcomes[36]. The evidence suggests an overall reduced total cost of care[37] due to decreased rates of secondary procedures[38,39].

Despite the large number of cleft units worldwide offering and practicing presurgical NAM[40], its efficacy is challenging to evaluate[41]. The plethora of low-level evidence of the efficacy of NAM is challenging to use in systematic reviews or meta-analyses; the samples are either too small or too heterogeneous. The techniques and follow-up periods are too varied. Furthermore, there are individual patient characteristics and surgical variables (type of surgery, technique of repair, and surgeon expertise). Therefore, the evidence has always been shrouded in uncertainty. The call for more unified, standardized research is valid; however, until then, the debates shall continue.

Rather than the immediate peri-surgical period, the focus is on long-benefits, i.e., NAM's permanence[42]. The literature suggests relapse is apparent in the first postoperative years[43-45]. Practitioners believe that primary rhinoplasty is warranted as an adjunct to NAM. NAM does not address the blunting of the cleft nose, primarily attributed to the fibrofatty deposition between the domes of the lower alar cartilages[34]. Without suspension suturing, the nasal deformity is believed to worsen over time. The immediate improvement in the nasal deformity post-NAM and primary surgery is uncontested; however, reports suggest a 10%-20% relapse in height and width in the first few years[46,47]. Proponents of NAM and primary cheilo-rhinoplasty suggest the following three-pronged approach to address the relapse: (1) presurgical NAM; (2) overcorrection of the cleft side nasal dome[16]; and (3) postoperative nasal retainer use[10].

Assessing nasolabial aesthetics in BCLP patients using the anatomic subunit scale, we found that the immediate (6-month) aesthetic results were significantly better in those who had nasoalveolar molding[44]. Unfortunately, this was not a randomized study, and there was no power calculation to determine the sample size.

Following our unilateral NAM cases, the results are equivocal. At 5-year follow-up, NAM-treated patients had improved nasolabial aesthetics and fewer revision operations[46]. However, there appears to be an element of relapse [Figure 21]. By the fifth post-primary repair year, there was a gradual loss of nasal height and columella length and an increase in nasal width and alar base width. We can only speculate whether it is the unequal growth of the cleft and non-cleft sides, the inconsistent use of postoperative nasal conformers, or the actual deformity "relapse".

Any therapy/procedure performed on a child with cleft lip and palate is always weighed against its effect on mid-face growth. Our earliest NAM-treated children are yet to reach adulthood. However, looking at growth outcomes has not revealed any cause for alarm. Because bilateral cases are more challenging in, we analyzed them first. We compared hard tissue and dental cephalometric values in 42 NAM-treated 7-year-olds (20 in the NAM group and 22 in the no-NAM group) to 7-year-old controls with no clefts. None of the measured variables differed significantly between the NAM and no-NAM groups. Presurgical NAM during infancy in BCLP patients does not appear to have adverse effects on skeletal development after craniofacial growth compared to those treated without NAM[38,43]. Other authors report similar mixed-dentition period results. Rubin *et al.* analyzed data from 56 consecutive NAM-treated UCLP patients and concluded that there appears to be an impact on skeletal or soft-tissue facial growth in school-aged children with non-syndromic clefts[47]. Other studies from India, Turkey, and the Middle East[40] also suggest that NAM does not hamper midface growth, at least in school children. We are retrospectively auditing our outcomes as our patients grow and are studying our NAM protocol prospectively in a randomized fashion.

## CONCLUSION

The traditional method of delivering NAM is labor- and time-intensive for the family and the healthcare provider. It also demands the clinician's significant clinical experience and expertise to guide bony movement appropriately, accommodate the infant's growth, and alleviate undue pressure application[48]. Furthermore, few trained teams provide NAM. For these and other reasons, cleft care providers are motivated to investigate the role of digital workflows in NAM therapy to increase treatment efficacy and enhance the potential reach of care[49,50]. CAD-CAM-led NAM therapy has been explored by practitioners[49], and most workflows involve acquiring a digital model (either via direct intraoral scanning or by scanning a traditional impression/model), virtual planning and designing-finally, 3D printing serial devices (or even manufacture using milling machines). Virtual designing and fabrication of NAM appliances hopefully will be accessible to all NAM providing units as it overcomes issues of access to care, multiple visits for adjustments, tricky cleft impressions[51,52], risk of airway compromise during impressions, lack of expertise, extensive laboratory work, and increased chairside time. It would indeed be a grand day when an infant can be brought in for an intraoral scan, and the family can leave later with a set of serial appliances, which would require minimal or no alteration. Patients could then be followed virtually for complications and report to the clinic if warranted.

## DECLARATIONS

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### Authors' contributions

Conception and drafting of article, search, review, and interpretation of literature, collection and editing of patient photographs, and final compilation of paper: Jalil J

Providing insight into the topic and overseeing the overall direction of the manuscript and substantial material revision: Bonanthaya K

Writing section on "technique of NAM" and contributing to the rationale. Providing photographs and insight into clinical problems and complications: Parmar R, Bijapur SU

### Availability of data and materials

Not applicable.

### Financial support and sponsorship

None.

### Conflicts of interest

All authors declare that there are no conflicts of interest.

### Ethical approval and consent to participate

Not applicable.

### Consent for publication
Written informed consent (from parent/legal guardians) was obtained for publishing patient details and photographs.



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