

Nasal Changes Post Presurgical Nasoalveolar Moulding: A Systematic Review

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Abstract

Objective: The objective of this study is to review articles, which have comprehensively studied changes in nasal morphology and function in patients with unilateral cleft lip and palate defects, after undergoing Pre-surgical Naso-alveolar (NAM) moulding therapy.

Methods: A retrospective systematic review was conducted on twelve study articles. Inclusion criteria comprised of unilateral cleft lip and palate, pre-surgical nasoalveolar moulding, changes in nasal morphology and function. Exclusion criteria included age more than 4 months, patients having undergone surgical treatment, bilateral cleft lip and palate. The articles were reviewed using odds ratio.

Results: Parameters included in the study were changes in the nasal height and nasal width; changes in nostril height; changes in alar base width on cleft side; columella displacement, length and deviation. As deduced from the articles under review, patients having undergone NAM along with surgical treatment had significantly better nasal morphology as compared to patients having undergone surgical therapy alone.

Conclusion: The use of NAM can significantly improve nasal morphology at the time of nasal maturity as compared to individuals with no-NAM.

Keywords: Nasal morphology, Presurgical nasoalveolar moulding, Unilateral cleft lip, Unilateral cleft palate.

Introduction

Cleft lip and palate is one of the most common congenital craniofacial disorders estimated to 24.5 million births per year in the Indian subcontinent alone, along with the birth prevalence of clefts between 27 to 33 thousand per year, with higher prevalence in males over females as it is a sex linked recessive disorder.^[1] It is caused by embryological defects (failure of fusion of frontonasal processes with the maxillary component of the first brachial arch) encountered at the process of the formation and development of the facial structures between the fourth and eighth weeks of embryological development. Deficiency and disharmony of the mid face due to cleft lip, alveolus and palate deformity is observed in all 3 planes of space^[2]. The increased use of transabdominal ultrasound (3D) during the second trimester leads to an increased frequency of oral clefts being diagnosed antenatally. Important techniques such as the 3D-reverse view, reverse face view and flipped face view technique and improved ultrasonography equipment and probes aid in better visualization and diagnosis of the defect.^[3] Unilateral cleft lip is associated with typical deformities like rotation and distortion of the vermillion border with loss of cupid's bow and philtral landmarks on the cleft side caused by asymmetric forces on the premaxilla during facial growth. Orbicularis Oris muscle fibers, that may be continuous across Simonart's band in milder forms, are oriented asymmetrically along the cleft margins.^[4] The lower lateral nasal cartilage is depressed and concave resulting in depression and displacement of the nasal tip as well as overhanging of the nasal apex. The columella and nasal septum are inclined towards the cleft with base deviated towards the non-cleft side.^[5] Restoration of normal form and function post operatively with little to no

tendency of relapse dictates a need for therapy that provides rehabilitation of form as well as esthetics.

Presurgical orthopedics started with McNeil's studies followed by Matson, Matsua and Hirose who placed a silicone stent inside the nostril. The PNAM protocol was suggested by Grayson et al. (1993), Brecht et al. (1995), Grayson and Santiago (1997), Cutting et al. (1998). The treatment modality includes active moulding and repositioning of the deformed nasal cartilages and alveolar processes as well as lengthening of the deficient columella.^[5] The technique includes an impression, obtained using an elastomeric impression material in an infant acrylic impression tray, followed by fabrication of an acrylic plate secured to the palate and maxillary process and taping of the cleft lip segments for alignment of the nasal base. Nasal stents may be added to the moulding plate once alveolar cleft width has reduced to 6mm. ^[5] Parameters like alar cartilage morphology, bilateral symmetry can be achieved without additional soft tissue surgery or scarring. ^[6]

Newer techniques like Figueroa's NAM included simultaneous alveolar moulding and nasal moulding using an acrylic plate with rigid acrylic, nasal extension along with rubber bands and a soft resin ball attached to the acrylic plate. A modified version of the traditional Figueroa NAM states that the acquired maternal estrogen before birth results in a decrease in elasticity and increase in plasticity of cartilages. It has also been assessed by Matsua et al. that the temporary plasticity of nasal cartilage is believed to be caused by high levels of hyaluronic acid.^[7] Different electronic databases (PubMed and Google scholar)

The main objective of this study is to evaluate the outcome of Presurgical Nasoalveolar Moulding Therapy,

as effective on nasal morphology and esthetics, in infants diagnosed with unilateral cleft lip and cleft palate (CLCP).

Method and Methodology

This systematic review was carried out using the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).^[8] MEDLINE and Google search were searched from 1999 to 2021 for articles. Search included keywords and subject headings pertaining to cleft lip and/or palate and Presurgical Naso-Alveolar Moulding and infants. An example of the search strategy and concepts as applied to PubMed/MEDLINE is available in Fig. 1.

A) Selection Criteria

All resulting articles were compiled, and duplicate titles were removed. Two independent reviewers screened the remaining titles and abstracts in PubMed indexed journals and PubMed Central using predetermined eligibility criteria, which included all clinical papers on NAM and all cleft types and infants of age 0-4 months for full text review. Final inclusion criteria were unilateral cleft lip and palate, presurgical nasopalveolar moulding, and changes in nasal morphology. Exclusion criteria were non-English articles, abstracts, presentations, case reports, review articles, correspondences, editorials and duplicates, languages other than English, and not NAM articles. Cleft

surgery studies not in the context of NAM or exploring infant orthopedics other than NAM, and those studies only referring to surgical outcomes were also excluded

Fig. 1 shows the PRISMA flow diagram with tallied reasons for study exclusion.

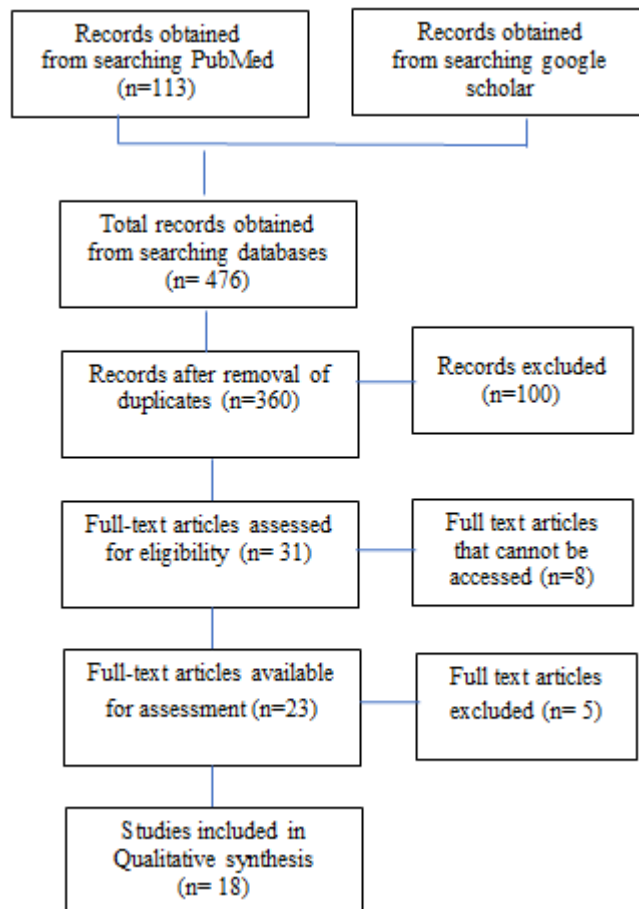


Fig. 1: PRISMA flow diagram with tallied reasons for study exclusion

Table 1

Sn.	Study	Design	No. of patients	Age starting for NAM	Patient intervention	Duration of treatment	Nasal height and width	Columella displacement, length and deviation	Outcome measure
1.	Maull in 1999 ^[10]	Retrospective study	10 patients presurgical nasal moulding in conjunction with alveolar	4 years 6 months for NAM and 9 years 1 month for control group	Orthopaedic treatment till 4 months of age	Treatment done at 4 months of the age, follow up done at 4 years 6 months for	Significant improvement in nasal symmetry	Improvement in columella deviation	Presurgical NAM significantly increases the symmetry of the nose. Depressed dome, wide alar width, deficient columella, and deviation of nasal septum was greatly reduced

			moulding and 10 patients only pre surgical alveolar moulding			PNAM group and 9 years 1 month for control group			
2.	Pai et al. in 2005 ^[16]	Prospective study	Fifty-seven new born (37 boys and 20 girls)	New born patients 0 years	Presurgical NAM before primary lip repair around 3 to 4 months of age	1 year	Infants with presurgical naso-alveolar moulding improved symmetry of the nose in width, height	There was some relapse of nostril shape in width (10%), Height (20%), and angle of columella (4.7%) at 1 year of age.	Infants with presurgical naso-alveolar moulding improved symmetry of the nose in width, height and columella angle, as compared to their presurgical status.
3.	Singh et al. in 2005 ^[30]	Prospective longitudinal study	10	28 days	All subjects underwent naso-alveolar moulding till 4 months of age	140 days	Relative size increases were found on the noncleft side, involving the upper nose (30%), alar depth (20%), alar dome (30%), and lateral wall of the nostril (17%). On the cleft side, the following showed a size increase: upper nose (8%), alar dome (5%) and lateral wall of the nostril (30%)	Relative size increases were found on the noncleft side columella height (30%), On the cleft side, the following showed a size increase: columella height (30%)	NAM significantly increased the nasal symmetry. However slight overcorrection of the alar dome on the cleft side was recommended to maintain the NAM results
4.	Spengler et al. in 2005 ^[18]	Prospective study with blinded measurement	8	34 days	PNAM appliance followed by intraoral moulding plate with nasal stent	212.5 days	Significant increase in the bi-alar width and in the columellar length and width	Increase in the bi-alar width and columellar length and width. Improvement in columellar deviation was	Significant reduction in the width of the larger cleft was also observed.

								observed, reduction in the premaxillary protrusion and deviation.	
5.	Baek et al in 2006 [21]	Prospective study	16 UCLP infants	37 days	PNAM appliances and rotation-advancement cheiloplasty	13 weeks	Not evaluated	Not evaluated	Alveolar moulding effects took place mainly in the anterior alveolar segment and growth took place mainly in posterior alveolar segment and palatal segment
6.	Bongaa rts et al. in 2006 [31]	Prospective two-arm randomized controlled clinical trial	54	2 weeks	Infant orthopedics performed with passive plate which were adjusted every 3 weeks. The appliance was continued till the soft palate surgery	52 weeks	Not evaluated	Not evaluated	Infant orthopedics does not have any influence on the maxillary arch dimensions.
7.	Ezzat et al. in 2007 [13]	Prospective study	Twelve patients with UCLP	26 days	The PNAM appliance	110 days	Increase in cleft nostril height, maxillary width	Increase in columella width	Decrease in both intersegment alveolar cleft distance and columellar deviation
8.	Singh in 2007 [14]	Finite element studies	The sample comprised 15 patients with left UCLP and 10 matched control subjects	At age 37 weeks	Successfully completed a course of NAM (4). At a mean age of 37 weeks, all infants underwent lip repair and primary rhinoplasty by the same surgeon (MY).	41 weeks	Reductions in facial surface area were found in the UCLP group, involving the columella (29%), labial tubercle (51%), lower lip (29%) and lateral aspects of the face (19%). However, the UCLP group also showed increases in size above the tip of	Not evaluated	Following surgical repair of UCLP in patients previously treated with NAM, 3D facial morphology was virtually indistinguishable from the non-cleft mean

							the nose (25%) and laterally to the columella directly below the nares (29%).		
9.	Barilla s in 2009 [22]	Retrospective review	25	3-4 months	Fifteen patients were treated with presurgical nasoalveolar moulding for 3 months before surgical correction, and 10 patients were treated by surgical correction alone. The average age at the time of follow-up was 9 years.	Mean age of 9 years (range, 7 to 11 years)	Nasal symmetry demonstrated a greater degree of cleft-side and non-cleft-side equality in the nasoalveolar moulding with surgery treated patients compared with the patients treated with surgery alone	Not mentioned	Lower lateral and septal cartilages are more symmetric in the nasoalveolar moulding patients compared with the surgery-alone patients. Improved symmetry observed in nasoalveolar moulding-treated noses during the time of the primary surgery is maintained at 9 years of age
10.	Hsieh et al. in 2010 [26]	Retrospective study	62	3months	PNAM therapy was followed by Gingivo-perioplasty	3-6 months	Not evaluated	Not evaluated	In unilateral cleft lip and palate patients, the sagittal growth of the maxilla would be affected more adversely in the group treated with gingiva-perioplasty
11.	Isogawa N, Ochiai S, Mito T, Kindai chi J, Ishibas hi N, Takagi Y, Ishika wa M.	Prospective Study	15.	Infants	Modified Hotz's plate, nasal stent, modified PNAM appliance	6weeks	Not evaluated	Not evaluated	The PNAM group is smaller on the lateral deviation of the incisal point than the modified Hotz's group. The decreased average width of the palatal cleft and curvature of the palate, was almost the same in both the modified Hotz's and PNAM groups. In comparison with the modified Hotz's plate, the

	in 2010 ^[28]								modified PNAM appliance also improves the moulding of the alveolar segments and reduces cleft width.
12.	Simanc a in 2011 ^[33]	Pilot study	5 infants	Aged 0 to 3 months	Presurgical NAM and taping	10 weeks	Decrease of the nostril floor on the noncleft side were observed in all subjects	Increase in columellar length on the cleft side	Increase in columellar length on the cleft side and decrease of the nostril floor on the noncleft side were observed in all subjects. Progressive changes were observed most significant.
13.	Clark SL, Teichg raeber JF, Fleshm an RG, Shaw JD, Chavar ria C, Kau CH, Gateno J, Xia JJ.in 2011 ^[34]	Prospect ive Study	25	0.8 months (range, 0.5–1.2 months the median length of the therapy was 3.6 months (range, 2.3–4.9 months), and the median time for surgery was 5.5 months (range, 2.8–6.2 months). The follow-up time was 5.1 years (range, 2.6–10.0 years). For the non-PNAM group, the median time for the surgery was 5.0 months (range, 2.6–6.4 months). The follow-up time was 6.0 years (range, 4.9–7.6 years).	PNAM and non PNAM	6 years	40% of the patients in the PNAM group achieved normal nasal morphology, whereas this was achieved only in 20% of the non-PNAM group. Normal alar width and nasal projection were seen in 60% and 65% of the PNAM group but only in 20% and 40% of the non- PNAM group	Not evaluated	The improvement in the PNAM group was most evident in nasal and lip anatomy.

Results

Study Characteristics: The database search results identified 476 articles. After removing duplicates, 360 unique abstracts remained for title and abstract screening for relevance. The screening procedure excluded 100 articles, leaving 260 articles for full text screening. Following this full text review, 242 additional articles were excluded, 18 studies were included for qualitative

analysis in this 6 were retrospective and 10 were prospective studies 1 was a finite element study and 1 was a pilot study.

Discussion

PNAM is a non-surgical method to minimize the severity of the cleft deformity by reshaping the cleft lip, alveolus, palate and the nose, before primary cheiloplasty and palatoplasty surgeries. In this context, a valuable asset in

the management of unilateral CLCP is proven to be PNAM.^[9] The main objectives of PNAM appliances are improving nasal symmetry and lip esthetics while elongating the columella and correcting the nasal cartilage (Grayson et al, 1999^[10]; Grayson et al, 2001^[11]; Liou et al, 2004^[12]; Ezzat et al, 2007^[13]; Singh et al., 2007^[14]; Lee et al., 2008^[15]). Unless coordinated with adequately timed, conservative and gentle surgery, it is known that Presurgical Infant Orthopedics (PSIO) treatment will not be efficient in the long run.

Effects of Traditional Presurgical Infant Orthopedics (PSIO) within different surgical techniques are not easy to differentiate, whether there are positive or negative results, due to the PSIO or to the surgical technique itself.^[16]

The concept of NAM works on Matsuo's principle^[17]; that the nasal cartilage could be moulded due to increased plasticity concurrent to increased levels of maternal estrogen and hyaluronic acid, if treatment is initiated within the first 6 weeks of life. Presurgical nasoalveolar moulding (PNAM) appliances have been in use as a new approach to Traditional Presurgical Infant Orthopedics (TPSIO). The alveolar ridge and nasal cartilage are moulded concurrently using the NAM appliance, which consists of an intraoral moulding plate with nasal stents.^[10, 18]

Advocates of the PNAM technique have stated that, besides other advantages of traditional plates, the main objectives of PNAM appliances are improving nasal symmetry and lip esthetics while elongating the columella and correcting nasal cartilage deformity.^[16,11] Alternatively, all types of (PSIO) approaches are complex and expensive, as stated by opponents, and might have an adverse effect on maxillary growth. None of these claims are evidence based.^[13,14]

A) Long term effects

In a 6-year follow-up by Bennun et al.^[19] to compare growth and cosmetic results of 97 UCLP patients using plaster models by using surface impressions of the babies revealed a much better and permanent nostril symmetry, no alar cartilage luxation and increase in the columellar length in patient with nasal component.^[19] It was concluded that there were no positive effects on factors like maxillary arch dimension, facial growth or occlusion, until the age of 6 years, when use of passive Infant Orthopaedic (IO) appliances were included in the treatment. However, it was stated that the review yielded a result that nasal symmetry was improved with NAM after a distinction was made between PSIO and NAM appliances by the authors^[20].

Nasal splints helped maintain the alar cartilage height and prevent collapse during scar healing post-surgery. The nasal, facial anatomy and texture corresponding to ethnic descent, could be an important factor for remodelling a nose in the desired shape accordingly.^[21,22]

B) Effect on feeding

Masarei et al. (2007)^[23] noted consistency in patients evaluated for isolated cleft, besides UCLP. There was no positive effect on feeding or consequent nutritional status, from the use of PSIO with passive and active appliances, in patients with UCLP based on the results of the two RCTs (Prahl et al., 2005; Masarei et al., 2007)^[23,24]

C) Language

Early positive effects of PSIO change over time, and no notable differences were found in language development between the two groups at the age of 6 years.^[17]

D) Facial Growth, Maxillary Arch and Occlusion

The centers that practice PSIO did not show demonstrable advantages in terms of the facial growth and the occlusion in patients with UCLP treated with different types of PSIO

appliances (Ross, 1987; Mars et al., 1992; Mølsted et al., 1992; Brattstrom et al., 2005; Mølsted et al., 2005).^[20,25,26,27]

E) Nasal Symmetry and Nasolabial Appearance

It is suggested that the main differences of NAM from TPSIO is the reshaping of the nasal cartilage and providing esthetic benefits in terms of nasal tip and alar symmetry (Grayson et al., 1999; Maull et al., 1999; Grayson et al., 2001; Suri and Tompson, 2004; Singh et al., 2005).^[8,9,28,29,30] Bongaarts et al. (2008)^[31] assessed patients with UCLP at ages 4 and 6 years. At 4 years of age, the full-face pictures of (IO+) children were scored to be more attractive than those of (IO-) children; however, at the age of 6 years, a positive effect of IO was seen by professionals on the nasolabial photographs. The difference in evaluation within the 2-year period also shows the importance and the necessity of long-term assessment on facial esthetics in particular treatment outcomes.

F) Complications of Presurgical Naso alveolar Moulding

Presurgical naso-alveolar moulding is most effective with full time wear. However, full time wear can be associated with certain complications like ulceration, tissue irritation leading to inflammation, fungal infections and bleeding. Soft tissue ulcerations can be due to excessive activation or due to the pressure from the moulding plate. After selective trimming of the moulding plate, the ulcerations are noticed to heal overtime. Improper maintenance of the hygiene with full time wear of the moulding plate can also result in residual fungal infections. This can be treated by topical Nystatin or Amphotericin. However, the Naso-alveolar moulding therapy should continue during the selected treatment phase. Another common complaint with naso-alveolar moulding is a rash like area of

erythema and chafing on the zygomatic process areas due to extra-oral taping. These are generally self-limiting. The best way to prevent these rashes is to wet the tape thoroughly before removal or by the application of a medical dressing under the tape and the skin.^[32]

Mega nostril may result due to excessive pressure on the nasal cartilage which occurs due to improper stent positioning or nasal over contouring resulting in excessive increase in the circumference of the nostril. Controversies exist stating compensation of relapse by overcorrection. One group suggests slight orthopaedic over correction of the alar dome (Singh et al; 2005)^[27] while the other group suggested vertical surgical nasal overcorrection (Liou E et al; 2004)^[10]. However, external bruising or petechiae maybe seen clinically in the area of insult causing reason for avoidance for application of over activation.

Hard tissues complications associated with NAM include excessive rotation of the lesser segment to meet the greater segment in a perpendicular manner, resulting in an asymmetric 'T' shaped configuration. Hence proper care should be taken to modify and monitor the segmental movement with 7-day follow-up. Eruption of teeth mid treatment is another hard tissue complication which could arise by the moulding appliance due to the pressure exerted on the gingival tissues. The appliance may be modified for favourable eruption of teeth. Moreover, a comparison of every single aspect of treatment seems impossible as a unique combination of population and treatment duration was used in each study.

In addition, this systematic review has not taken into account the different techniques of PSIO, timings of surgery and surgical techniques; which would have made comparison of the results even more difficult. All these aspects together have made conclusions of the results of

the studies by means of the intended systematic review impossible^[20]

Conclusion

Though surgical procedures have been the key element in cleft lip and palate rehabilitation, the NAM techniques aid and have made the rehabilitation much more reliable and physiologically appropriate. The use of NAM techniques by selectively controlling the growth patterns utilizes the malleability of para oral structures at an early age. Better esthetics and reliable long term results are observed as approaches of moulding the nasal cartilage, alveolar ridges and premaxilla (in the neonatal period) adjuncts the surgical procedures. Based on the review, better long term results with more benefits and efficacy are seen with nasal moulding. However, the effect of alveolar moulding needs to be studied further to assess the same. More favourable results were obtained when gingivo- periosteoplasty was performed along with primary lip repair. Therefore, in conclusion not only thorough knowledge of the changing concepts of the NAM technique but also interdisciplinary approach and timing of the initiation of NAM is considered essential for successful and early rehabilitation of CLCP.^[32]

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