



Review Article

Presurgical naso-alveolar molding in cleft lip and palate patients - a critical review

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ABSTRACT

Purpose: To evaluate and assess the current scientific evidence about the efficiency and usefulness of Presurgical Naso-alveolar molding (PSNAM) in cleft lip and cleft palate patients.

Methods: A comprehensive scientific literature search was carried out using the PUBMED electronic database which focuses on the current concept of PSNAM and those which critically analyze its long-term effects in the treatment of cleft lip, palate, and nasal deformity, using different terminologies like the 'presurgical nasoalveolar molding', 'nasal molding' and 'infant orthopedics' and documented articles over 30 years were selected for the critical review.

Results: Following a PUBMED search, 58 articles were retrieved. These 58 articles were investigations about the effect of PSNAM on different aspects of cleft including effects of PSNAM on facial growth, maxillary arch, dentition and occlusion, its effects on nasal symmetry and nasolabial appearance, and speech.

Conclusions: Presurgical Naso-alveolar molding can be a useful adjunctive treatment modality for managing cleft lip and palate patients. This cost-effective technique is more beneficial in reducing the number of future surgeries required in the management of cleft lip and palate patients.

Keywords: PSNAM, Cleft lip and Palate, Naso-alveolar molding, Upper Lip

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INTRODUCTION

Cleft lip and palate (CLAP) is the most frequently encountered congenital orofacial deformity in day-to-day life due to abnormal facial development caused by embryological defects during the formation of the face. This anomaly not only affects the cosmesis but also affects speech and hearing.^{1,2} In these patients, the alar cartilage on the cleft side is flattened or concave and protruded out by the alveolar gap, resulting in depression and displacement of the nasal tip towards the side of the cleft.³ Reconstruction of the symmetrical lip and a natural-looking nose in these patients is a great challenge and has revolutionized dramatically in recent years. Two schools of thought exist about the treatment of CLAP. One hypothesis suggests surgical treatment and other schools of thought advocate for some sort of orthopedic molding of the defect before surgery.^{3,4} Although the outcome is improved over the years because of better surgical techniques, many authors suggest that even after multiple surgical corrections the final acceptable result remains questionable.⁵ As a result, the quest over the concern for the final nasal form led to the introduction of a new treatment approach called pre-surgical naso-alveolar molding (PSNAM).⁶ As the literature search revealed a paucity of scientific evidence of the benefits and concepts of PSNAM in the treatment of CLAP patients, this critical review was designed to evaluate the same.

METHODS

A literature search was conducted in the PUBMED database using the terms ‘presurgical nasoalveolar molding,’ ‘nasal molding’ and ‘infant orthopedics’. Related articles on these topics that focus on the current concept of PSNAM and those that critically analyze its long-term effects in the treatment of both unilateral and bilateral CLAP were selected for the critical review. Individual case presentations and case series were excluded from the review.

RESULTS

Following the PUBMED search using the appropriate keywords of PSNAM, a total of 58 articles were retrieved. These 58 articles were investigations of the effect of PSNAM on different aspects of cleft including effects of PSNAM on facial growth, maxillary arch, dentition, and occlusion, its effects on nasal symmetry and nasolabial appearance, and speech (Table 1).

Sl. No.	Author	Year	Type of the study/Objectives	Results/Conclusions
1.	Smahel et al ¹	1988	Cross-sectional cohort study.	Significant reduction in alveolar gap width
2.	Karling et al ²	1993	Evaluated speech	No significant difference in articulation or resonance was found between groups.
3.	Ross and MacNamera ³	1994	Evaluated facial appearance	PSNAM has no lasting effect on the esthetics of lip and nose and facial aesthetics and does not alter the need for subsequent revisionary surgery.
4.	Santiago et al ⁴	1998	Compared PSNAM and primary gingivoperioplasty.	Reduced need for alveolar bone grafting in the PSNAM group.
5.	Bennun ⁵	1999	Evaluated nasal symmetry.	Better and permanent nasal symmetry, increased columellar length and no alar cartilage luxation.

6.	Grayson et al ⁹	1999	Studied long-term effects of PSNAM on the 3-dimensional shape of the nose.	Significantly increased symmetry of the nose.
7.	Mauil et al ¹⁰	1999	Retrospective study	PSNAM statistically improved the nasal symmetry.
8.	Mishima et al ¹¹	2000	Evaluation of maxillary arch dimension	No difference was noticed in alveolar arch form, degree of palatal surface curvature, and anteroposterior distance of palate between the two groups at 4 years of age.
9.	Konst et al ¹²	2003	Assessed speech	No effects on language development
10.	Lee CT et al ¹³	2004	Retrospective study	Midface growth in sagittal or vertical planes was not affected.
11.	Liou et al ¹⁴	2004	Assessed nasal symmetry	Improvement in the nasal symmetry after PSNAM and further corrected after cheiloplasty.
12.	Deng et al ¹⁵	2005	Evaluated nasal symmetry	Obtained better nostril height and nasal profile.
13.	Pai et al ¹⁶	2005	Prospective study	PSNAM improved the symmetry of the nose in width, height, and columella angle.
14.	Singh GD et al ¹⁷	2005	Prospective longitudinal study	PSNAM significantly increased the nasal symmetry. However slight overcorrection of the alar dome on the cleft side was recommended to maintain the PSNAM results.
15.	Spengler et al ¹⁸	2006	Prospective study	Significant decrease in the premaxillary protrusion and deviation. A significant reduction in the width of the larger cleft was also observed.
16.	Baek & Son ¹⁹	2006	Prospective study	Alveolar molding effects took place mainly in the anterior alveolar segment and growth took place mainly in the posterior alveolar segment and palatal segment.
17.	Bongaarts et al ²⁰	2006	Prospective randomized controlled clinical trial	PSNAM does not have any influence on the maxillary arch dimensions.
18.	Suzuki et al ²¹	2006	Evaluated speech	Effective in preventing zed articulation

19.	Ezzat et al ²²	2007	Prospective study		Decrease in the intersegment alveolar cleft distance.
20.	Jaeger et al ²³	2007	Evaluated alveolar arch and nasal symmetry		Significant improvement in the nasal shape and reduction in alveolar gap.
21.	Liou EJ et al ²⁴	2007	Longitudinal study		Both PSNAM and primary cheiloplasty lengthened the columella in bilateral cleft lip-cleft palate patients.
22.	Lee et al ²⁵	2008	Evaluated nasolabial appearance		Elongation in the columella length.
23.	Bongaarts et al ²⁶	2009	Evaluated facial growth		No significant effect
24.	Barillas et al ²⁷	2009	Assessed nasal symmetry		The lower lateral and septal cartilages were more symmetric in PSNAM-treated patients compared to patients treated with surgery alone.
25.	Kecik D & Enacar A ²⁸	2009	Prospective study		Significantly helpful treatment for patients with unilateral CLAP. The reduction in the alveolar cleft region and the nasal reshaping are favorable.
26.	Nakamura N et al ²⁹	2009	Evaluated effectiveness of PSNAM	of	The nostril height and width ratio and the height of the top of the alar groove in the experimental group were significantly superior compared with those of the controls.
27.	Hsieh et al ³⁰	2010	Retrospective study		The sagittal growth of the maxilla would be affected more adversely in the group treated with gingivoperioplasty.
28.	Ijaj A et al ³¹	2010	Evaluated effectiveness of PSNAM of bilateral CLAP infants with orthopedic ring plate.		Caused significant retraction of the premaxillary segment without applying extraoral forces. It produced columellar elongation and an increase in prolabium length facilitating the primary cheiloplasty and rhinoplasty to be precise and without additional scarring.
29.	Mishra et al ³²	2010	Evaluated PSNAM in the correction of cleft lip nasal deformity		Significant improvement in the nostril width, columella lengthening and alar perimeter, and more reduction in alveolar gap.
30.	Clark et al ³³	2011	Evaluated the long-term effectiveness of PNAM in patients with unilateral CLAP.		A long-term clinical improvement in nasal and lip anatomy of unilateral complete cleft lip patients.

31.	Garfinkle JS et al ³⁴	2011	A longitudinal, retrospective study	Patients with bilateral CLAP treated with PSNAM and primary nasal reconstruction, performed at the time of their lip repair, attained nearly normal nasal morphology through 12.5 years of age.
32.	Hou YX ³⁵	2011	Evaluated PSNAM effectiveness	17 infants were treated successfully with the closure of the cleft lip and alveolar processes, repositioning of the deformed nasal cartilages, and increased length of the columella. The lip and nasal deformities of 9 infants were corrected partly, which was helpful for surgery.
33.	Nazarian-Mobin SS et al ³⁶	2011	Retrospective study	There are differences in efficacy between unilateral and bilateral CLAP patients undergoing PSNAM.
34.	Yu Q et al ³⁷	2011	Evaluated usefulness of PSNAM using computer-aided reverse engineering and rapid prototyping techniques in infants with unilateral CLAP.	The cleft was narrowed, and the malformation of nasoalveolar segments was aligned normally.
35.	Fedeles J Jr et al ³⁸	2012	Longitudinal study	No statistically significant difference in nostril height, width, columellar length, inter-alar distance, and nostril symmetry between unilateral complete cleft lip/palate patients undergoing PSNAM and incomplete cleft lip patients/palate with no need of presurgical molding, proving PSNAM combined with primary nasal correction is very efficient management for CLAP children with outstanding results
36.	Gomez DF et al ³⁹	2012	Evaluated nasal changes after PSNAM treatment in unilateral cleft lip and nose patients using photogeometric analysis.	Significant reduction of cleft columella deviation with an increase in columella length, nostril height, and axial inclination on the cleft side was recorded. This increased the projection of the nasal tip. The non-cleft measurements remained without significant changes. The cleft nostril area increased significantly more than the non-cleft side by 90% with PSNAM treatment. Significant normal growth changes were observed in nasal width and nasal height.

37.	Shetty et al ⁴⁰	2012	Evaluated PSNAM treatment outcome in infants treated with different ages.	Younger infants treated at the age of 1 month benefited better than 1-5 month-old infants.
38.	Hak et al ⁴¹	2012	Assessed maxillary growth	The growth of the arch length was comparable to that observed in the non-cleft group.
39.	Lopez-Palacio et al ⁴²	2012	A longitudinal study	Improved nasal tip projection and alar cartilage depression and decreased partial columella deviation before rhinocheiloplasty.
40.	Sasaki et al ⁴³	2012	Evaluated the effects of PSNAM with an orthopedic appliance and compared them with a passive orthopedic method.	The width of the alveolar and palate cleft gap was significantly narrowed in the PSNAM group, and the cleft gap at the initiation of PSNAM correlated significantly with the Hausdorff distance after cheiloplasty. PSNAM improved the form of the naris after primary cheiloplasty and decreased the palate cleft gap more effectively than HP and that the width of the palate cleft gap was correlated with the surgical outcome of the naris.
41.	Dec et al ⁴⁴	2013	Retrospective study	PSNAM reduced the need for secondary alveolar bone grafting by 60% in patients with unilateral CLAP.
42.	Punga and Sharma ⁴⁵	2013	Comparative evaluation of cases done with and without nasal stents.	Nasal stents attached to the alveolar molding appliance, yield significant improvement of the nasal morphology and better nasal aesthetics presurgically.
43.	Sulaiman et al ⁴⁶	2013	Evaluated nasolabial appearance and nasal symmetry.	A significant improvement in the nostril height and width ratio and height of alar groove and maintained for 15 years.
44.	Chang et al ⁴⁷	2014	Compared modified Figueroa and modified Grayson nasoalveolar molding techniques.	Both techniques produced similar nasal outcomes.
45.	Li W et al ⁴⁸	2014	Evaluated a novel modified PSNAM device with a retraction screw.	The modified PSNAM device with a retraction screw can simultaneously correct nasolabial and palatal deformities and also rapidly retract and centralize the premaxilla.
46.	Liao et al ⁴⁹	2014	Compared modified Figueroa and modified	The Figueroa technique is associated with fewer oral mucosal complications and more efficiency.

		Grayson nasoalveolar molding techniques.		
47.	Zhong et al ⁵⁰	2014	Evaluated the effect of PSNAM devices on the palatal deformities in unilateral complete CLAP patients.	PNAM treatment is a non-surgical early treatment for the effective improvement of palatal primary deformities in unilateral CLAP patients.
48.	Mandwe et al ⁵¹	2015	Retrospective study	A statistically considerable rise in cleft nostril height and columellar width. Significant reduction in both intraoral cleft width and columellar deviation
49.	Rau et al ⁵²	2015	Evaluated PSNAM using 3 dimensional analyses.	Inter-segmental alveolar distance, inter-segmental lip distance, nostril height, nostril width and columella deviation angle were significantly changed in unilateral CLAP.
50.	Rubin et al ⁵³	2015	Retrospective study	PSNAM-prepared patients are more likely to have less severe clefts and to be less likely to need revision surgery when compared with patients not prepared with PSNAM.
51.	Shen et al ⁵⁴	2015	Efficacy of PSNAM using prefabricating sets of PSNAM appliances using three-dimensional technology.	Alveolar cleft widths narrowed significantly, soft-tissue volume of each segment expanded, and the arc of the alveolus became more contiguous across the cleft.
52.	Yu Q et al ⁵⁵	2015	Evaluated the effect of PSNAM based on computer-aided design technique.	Maxillary alveolar morphology could be improved in unilateral CLAP infants treated with computer-aided PSNAM. The width of the cleft could be reduced and the maxillary midline corrected effectively. However, the alveolar height decreased significantly after the treatment.
53.	Koya et al ⁵⁶	2016	Prospective study with blinded measurements	PSNAM therapy improved nasal asymmetry by columellar lengthening and effectively molded the maxillary alveolar arch.
54.	Leverde et al ⁵⁷	2016	Longitudinal study	Significant reduction in cleft width, increase in nostril height of cleft and reduction in facial asymmetry of nostril width. Also, nasal base width asymmetry was decreased from 64%.
55.	Zuhaib et al ⁵⁸	2016	Longitudinal study	Promising reduction in the cleft size, significant improvement in nasal

				symmetry including the columellar length on the cleft side.
56.	Hongyi et al ⁵⁹	2016	Retrospective study using 3 dimensional analysis (Cone Beam Computed Tomography).	PSNAM significantly corrected alveolar deformity and improved appearance.
57.	Shetty V. et al ⁶⁰	2017	A randomized controlled trial	PSNAM significantly reduced intersegment distance and thereby improved arch symmetry and stability, and thus may prevent arch collapse in the long term.
58.	Liang Z. et al ⁶¹	2017	Two-group, parallel, prospective, randomized clinical trial.	PSNAM is beneficial before primary cheiloplasty, but it is insufficient to maintain long-term nostril symmetry after primary cheiloplasty without nasal cartilage dissection.

Table 1: Review of published studies on PSNAM therapy in the management of Cleft Lip and Palate infants

DISCUSSION

PSNAM is a non-surgical treatment approach of reshaping or molding the alveolus, lips, and nostrils in infants born with CLAP before surgical therapy. This new technique was introduced by Grayson et al, in 1993.⁶ The design of this appliance is characterized by a removable alveolar molding acrylic plate made from an impression of the infant's maxilla. The nasal stent is bent at the end of a 0.032-inch stainless steel wire that is incorporated into the anterior part of the alveolar molding plate. The appliance is held in position with a combination of adhesive tapes applied to the cheeks and cleft lip segments. Both intraoral acrylic molding plate and nasal stent are adjusted weekly or biweekly throughout 4 to 6 months to gradually mold the nasal and alveolar deformities and to finally achieve nasal and alveolar symmetry, nasal tip projection, and approximation of the cleft segments.⁷⁻²¹

The rationale behind the concept of PSNAM is attributed to the Matsuo and Hirose hypothesis,⁷ which states that the amount of plasticity in neonatal cartilage, is highest after birth and gradually reduces as infants grow.²²⁻²⁹ This might be because of high levels of hyaluronic acid in estrogen hormone that was transferred from the mothers to the infants. Hyaluronic acid reduces cartilage, ligaments, and connective tissue elasticity by breaking down the intracellular matrix.³⁰⁻⁴² The cartilage subsequently loses its pliability at around 6 weeks. Therefore, PNAM is most successful during the first 3–4 months of life. One more school of thought is based on the chondral-modeling hypothesis,⁸ which hypothesized that PSNAM may be acting as a catalyst that stimulates the chondroblasts, producing interstitial expansion and improvements in nasal form.⁴³⁻⁴⁹

The main goals of PSNAM therapy are 1) facilitating intraoral feeding; 2) improving the projection of the nasal tip; 3) reducing nasal deformity; 4) improving maxillary growth; 5) retracting and repositioning the premaxilla posteriorly in bilateral cleft patients and 6) facilitating primary lip, alveolar and nasal surgeries.⁵⁰⁻⁵⁶ Apart from these, PSNAM treatment has various advantages. They are 1) requirement of less extensive orthodontic treatment at later ages; 2) reduces tongue interference with the palatal shelves which may encourage the normal growth of the palatal shelves, thus allowing a spontaneous reduction in the width of the cleft; 3) improved speech development due to improved physiological tongue function and position and finally 4) a positive psychological effect on the parents.⁵⁷ However, views of the opponents of PSNAM should also be considered which claim that PSNAM 1) is a complex and expensive therapy that is ineffective and unnecessary because parents are obliged to travel frequently to the treatment center and

endure an increased burden of care; 2) there is no significant improvement in parents satisfaction; 3) restricts maxillary development as a result of the molding process.⁵⁸⁻⁶⁰

Although various controversies and much debate exist with PSNAM in the field of CLAP surgery, different investigations have been done to study the effects of the appliance on different aspects of cleft including the effects of PSNAM on facial growth, maxillary arch, dentition, and occlusion, its effects on nasal symmetry and nasolabial appearance and speech.⁶¹ These researches have shown that PSNAM could manipulate the infant's oronasal complex, reduce cleft width, correct the anatomical position of the maxillary segment, and finally improve the angulation of the palatal shelves to a more horizontal position, correct the malpositioned nasal cartilages, columella, and philtrum, brings the columella toward the midsagittal plane; increases columella length, and improves the symmetry of the nostril apertures and reduces scar formation after cheiloplasty. It also decreases the need for alveolar bone grafts. The detailed review of PSNAM therapy in the treatment of CLAP is elaborated in Table 1.

CONCLUSIONS

Based on the current literature review, it was concluded that PSNAM appears to be a more beneficial adjunct in the treatment of CLAP. The PSNAM treatment is usually rendered either by a Pedodontist or an Orthodontist. Therefore, strong coordination among all the specialties of the CLAP care team is essential to render holistic therapy for the long-term benefit of these patients.

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Nil

CONFLICTS OF INTEREST

There are no conflicts of interest

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