International Journal of Science and Research (IJSR)
ISSN: 2319-7064
Impact Factor 2024: 7.101

Nasoalveolar Morphological Changes Following Presurgical Nasoalveolar Molding in Non-Syndromic Complete Cleft Lip and Palate Infants: A Retrospective Study

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Abstract: ***Nasoalveolar molding (NAM) is a non-surgical approach used to aid in the correction of cleft lip and palate deformities in infants. It is non-invasive, enables early intervention, helps to guide growth and development of face and jaws, reduces need for repeated plastic surgeries, improves feeding, speech and aesthetic outcomes. Despite these advantages many parents and surgeons do not opt for PNAM because of frequent visits. The aim of the present study was to quantify the effects of PNAM in and around cleft area including nasal structure in non-syndromic complete CLP. Methods: A retrospective study on pre and post PNAM 1:1 basilar photograph and intra-oral models of 49 Non-syndromic Complete cleft lip palate infants that underwent NAM. Results: In 49 infants, significant decreases were observed in anterior alveolar cleft width, total alar base width, palatal gap, nostril widths and basal widths (cleft and non-cleft sides), and columella deviation. Significant increases were found in lengths of greater and lesser segments, columella length, nostril heights (cleft and non-cleft sides), and nasal dome heights (cleft and non-cleft sides) (all $p < 0.001$). Conclusion: NAM is promising in approximating the cleft tissues, the advantages outweigh the disadvantages, so it is highly recommended in the treatment of cleft lip and palate infants.***

Keywords: Cleft lip and palate, Nasoalveolar molding, Presurgical nasoalveolar molding, Presurgical infant orthopaedics, NAM, CLP

1. Introduction

Cleft lip with or without palate (CL/P) is a common congenital anomaly with multifactorial genetic and environmental causes, occurring in 1: 500–1: 2000 births worldwide[1] and in nearly 3,500 infants annually in India.[2] Unilateral clefts are nine times more common than bilateral, with a male-to-female ratio of 2: 1.[3] Clinical features include nasal asymmetry, columella deviation toward the unaffected side, widened nostril and depressed alar rim on the cleft side, and lateral displacement of maxillary alveolar segments.[4] These defects cause feeding, speech, and aesthetic challenges, as well as psychosocial impact, requiring staged multidisciplinary care.

Management often begins at birth with a feeding plate, followed by primary lip repair at 4–6 months and palatal closure at 12–18 months, though additional surgeries are common.[6] However, additional surgeries are not uncommon due to the severity and malalignment of the clefted shelves.

Pre-surgically nasoalveolar moulding is done to appropriate and align the tissues better prior to surgery so there is less scarring and lesser need for repeated plastic surgeries.[11,13] McNeil (1950) introduced pre-surgical infant orthopedics (PSIO) to approximate clefted segments.[7] Matsuo first described pre-surgical nasal cartilage molding in neonates[9,10], and Grayson et al. developed the pre-surgical nasoalveolar molding (PNAM) appliance for unilateral and bilateral clefts.[7,11] NAM techniques include Grayson, Figueroa, Liou's device, rapid NAM, modified NAM, and dynamic pre-surgical nasal remodeling (DPNR).

The objectives of nasoalveolar molding (NAM) are to improve cleft lip and palate appearance by aligning alveolar segments, reducing cleft gaps, molding nasal cartilage, and lengthening the columella, thereby optimizing facial growth, oral function, and aesthetics, reducing the need for secondary grafts, and improving quality of life.[14,15] NAM is non-invasive, enables early intervention, enhances surgical outcomes, improves feeding and speech, and can reduce secondary surgeries from as many as 20 procedures. Without NAM, patients often exhibit short columella, flattened nasal tip, broad nostril floor, and expanded alar bases.[16] Barriers to its use include frequent follow-up requirements, logistical challenges for rural families, and limited awareness.

The current retrospective study is aimed at evaluating the Pre NAM-treatment (T0) and Post NAM treatment (T1) study models and photographs for clinical changes to quantify the effects of NAM in and around cleft area including nasal structure in non-syndromic complete CLP.

2. Materials and Methods

This retrospective in-vitro study was conducted after obtaining ethical clearance and permission from the concerned authorities. The study included records of 49 non-syndromic complete cleft lip and palate (NSCLP) infants (Veau's class III and IV) who underwent pre-surgical nasoalveolar molding (PNAM) at Bhagwan Mahaveer Jain Hospital, Bangalore, prior to cheiloplasty, palatoplasty, and rhinoplasty. Inclusion criteria were: infants reporting before 6 weeks of age, with complete NSCLP, and complete pre- and post-PNAM records of adequate quality. Exclusion criteria were: infants older than

6 weeks, incomplete cleft palate, syndromic CLP, and refusal of PNAM therapy by parents/guardians. Records of infants whose parents did not consent to PNAM were excluded.

For each patient, 1:1 basilar photographs taken before the start of PNAM therapy (T0) and after completion (T1) were retrieved. Photographs were analyzed using VistaDent software (Dentsply Sirona), which calculates linear measurements based on pixel values. Intraoral models were prepared from impressions taken with putty impression material at both intervals and measured directly with a digital vernier caliper.

The parameters measured (in mm) included: anterior alveolar cleft width, total alar base width, length of greater palatal segment, length of lesser palatal segment, palatal gap, gap between premaxilla and right palatal segment, gap between premaxilla and left palatal segment, columella length, columella deviation, nostril height (cleft and non-cleft sides), nostril width (cleft and non-cleft sides), nostril basal width (cleft and non-cleft sides), and nasal dome height (cleft and non-cleft sides).

All measurements were tabulated and analyzed using SPSS software (IBM Corp., Armonk, NY, USA). Student's paired *t*-test was applied to compare T0 and T1 values, with a p value < 0.05 considered statistically significant.

3. Results

49 patients records were selected based on the inclusion criteria that involved 1:1 basilar photographs taken before and after the completion of NAM that were subjected to measurement based on pixels and the values were tabulated and models made out of impressions made before and after the completion of NAM and were measured using a digital Vernier calliper and the values were tabulated. The data was analysed using paired t test using SPSS software.

Of the 49 patient records selected 44 of unilateral cleft cases and 5 were unilateral cases (Table 1), 33 were of male infants and 16 were of female infants. (Table 2)

Table 1: Distribution of unilateral and bilateral cases

Type of cleft	Number	Percentage
Unilateral	44	89.8
Bilateral	5	10.2

Table 2: Distribution of males and females

Gender	Number	Percentage
Males	33	67.3
Females	16	32.7

In both bilateral and unilateral cases, all the parameters showed highly significant change post Nasoalveolar molding. (Table 3)

Table 3: PreNAM 2 dimensional measurements and corresponding post NAM values

Sr No	Measurement	Pre NAM Value(mm)	Post NAM Value(mm)	p-value
1	Anterior alveolar cleft width.	8.30±3.7	3.81±3.51	$1.46e^{-12}$
2	Total alar base width.	48.13±3.09	44.55±2.62	$2.77e^{-21}$
3	Length of greater palatal segment .	28.78±3.11	32.71±4.23	$3.27e^{-13}$
4	Length of lesser palatal segment .	20.63±2.28	23.72±2.60	$3.05e^{-10}$
5	Palatal gap.	14.47±4.13	8.81± 4.37	$2.37e^{-16}$
6	Nostril height on cleft side .	4.02± 0.90	7.12±1.60	$6.75e^{-24}$
7	Nostril height on non cleft side.	6.17±0.47	11.09±0.90	$1.11e^{-31}$
8	Nostril width on cleft side.	23.86±0.78	14.18±0.61	$4.02e^{-54}$
9	Nostril width on non cleft side.	8.00±0.611	7.60±0.54	$4.21e^{-21}$
10	Columella length.	5.261±0.65	6.99± 0.67	$1.32e^{-29}$
11	Columella deviation.	54.88± 6.08	25.25±6.04	$5.02e^{-34}$
12	Nostril basal width on cleft side .	28.11± 1.02	25.57± 0.83	$1.87e^{-26}$
13	Nostril basal width on non cleft side.	17.01±0.38	16.22±0.39	$1.21e^{-16}$
14	Nasal dome height on cleft side.	5.08± 1.09	14.72± 1.07	$6.9e^{-51}$
15	Nasal dome height on non cleft side.	10.96± 0.44	12.30± 0.47	$3.04\ e^{-20}$

4. Discussion

In this study, 49 cases of cleft lip and palate (CLP) were analyzed, of which only 10.2% were bilateral, consistent with the lower prevalence of bilateral cases, as unilateral clefts are nine times more common[3]. Records of infants reporting before 6 weeks were selected, as Matsuo et al. postulated that neonatal cartilage is highly moldable due to elevated maternal estrogen and hyaluronic acid[9,10].

Sex distribution revealed a male predominance (67.3%), in agreement with Shapira et al. who reported a male: female ratio of 60: 40[49]. This may also reflect sociocultural issues in India such as female feticide and reduced healthcare access for females[50].

Nasoalveolar molding (NAM) therapy showed significant improvement in nasal symmetry. Columella deviation reduced markedly (p=5.02e-34), consistent with studies by Ezzat et al., Jiayi Yin et al., Thao Thi Nhu et al., Pai et al., Gomez et al., and Spengler et al. Significant improvement in columella length (p=1.32e-29) was also seen, in agreement with Zuhaib et al., Liou et al., Gomez et al., and Ezzat et al., where average lengthening of 1.7 mm was reported. This effect is attributable to the nasal stent engaging the nostrils and pulling the columella centrally, while lip taping in severe cases enhances projection[51,52].

Nostril width decreased significantly on both cleft (p=4.02e-54) and non-cleft sides (p=4.21e-21), similar to findings by Gomez et al., Kecik et al., Zuhaib et al., and

Singh et al. This is explained by the active force of the stent reshaping the alar cartilage. Nostril basal width also reduced significantly on cleft (p=1.87e-26) and non-cleft (p=1.21e-16) sides, supporting Singh et al. (2005), Kecik & Enacar (2009), Ruiz-Escolano et al. (2016), Liou et al. (2004), and Zuhaib et al. (2016). However, other studies (Ezzat et al., Gomez et al., Koya et al.) reported increased width, likely due to technique variations.

Total alar base width decreased significantly (p=2.77e-21), aligning with Zuhaib et al., though Koya et al. reported an increase, possibly due to ineffective lip taping. Dome height improved on both cleft (p=6.9e-51) and non-cleft (p=3.04e-20) sides, consistent with Liou et al. (2004), Pai et al. (2005), Mishra et al. (2010), Chien-Jung (2005), Shetty et al. (2016), Rachwalski et al. (2017), and Singh et al. (2018). This results from the nasal stent lifting the collapsed dome and reshaping concave alar cartilage, aided by lip tape approximation.

Nostril height increased on both cleft (p=6.75e-24) and non-cleft (p=1.11e-31) sides, in accordance with Ezzat et al. and Baek & Son, attributed to stent-induced elevation of the collapsed nostril. Some authors (Kecik & Enacar, Gomez et al.) found insignificant changes on the non-cleft side, possibly because the stent primarily engages the cleft side.

A significant reduction in anterior alveolar cleft width (p=1.46e-12) was observed, comparable to Koya et al. (6.7 mm), Zuhaib et al. (4.07 mm), Patel & Goyal (7 mm), and Pai et al. (5.8 mm). Narrowing reduces lip tension, improves surgical ease, supports maxillary growth, and decreases bone graft requirements. Reduction is achieved through selective grinding of acrylic and use of soft liners for segmental approximation.

Greater (p=3.27e-13) and lesser (p=3.05e-10) alveolar segment lengths improved significantly, similar to Mishima et al. and Sabarinath et al. Approximation within 5 mm facilitates reduced alar base width and better surgical outcomes, without disturbing maxillary growth.

Palatal gap reduction (p=2.37e-16) was also significant, consistent with Rossell-Perry, Gong, Bhutiani, Liao, Wolff, El-Ashmawi, Aslan, and Spengler. Gap reduction lowers complication rates, decreases secondary surgeries, and improves long-term function.

In summary, PNAM effectively reduces columella deviation, nostril and alar base width, and cleft gaps, while significantly improving columella length, nostril height, dome height, alveolar segment alignment, and palatal gap. These outcomes enhance esthetics, simplify surgery, minimize scarring, and improve prognosis in CLP patients.

5. Conclusion

Nasoalveolar molding (NAM) is effective in improving post-surgical outcomes in cleft lip and palate, provided it is initiated early and supported by skilled operators and cooperative caregivers. This study confirmed NAM's efficiency in reducing anterior alveolar cleft width, palatal gap, columella deviation, and in improving nasal and alveolar morphology. Despite its proven efficacy, NAM is often associated with prolonged treatment, frequent visits, caregiver burden, and financial costs. However, as comprehensive cleft care now prioritizes long-term quality of life, NAM remains an important adjunct to surgical correction. Newer approaches such as Rapid NAM and CAD/CAM-assisted appliances aim to reduce treatment time and caregiver burden while maintaining therapeutic success.

6. Limitations of the study

The limitations of the study are that it only considered the 2-dimensional measures and not 3-dimensional measures. And did not include the post-surgical outcomes of NAM treated patients. And our study did not include a control group for better outcome measurement and was based on a single cleft center.

Scope for further studies: Comparison of the NAM groups with control group included 3-dimensional measurement studies based on samples from multiple cleft centres.

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