Presurgical Orthopaedic Nasoalveolar Molding in Cleft Lip and Palate Infants: A Comparative Evaluation of Cases Done With and Without Nasal Stents

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Abstract Addressing the craniofacial anomaly of cleft lip and palate presurgically has been done since more than 50 years now, with a constant improvisation of the treatment protocols from time to time. The present study deals with a modification of the technique devised 16 years ago. The effect of nasal stents attached to a pre-surgical naso-alveolar molding (PNAM) appliance on the nasal morphology achieved prior to primary surgical correction of the cleft lip was to be evaluated. Twenty subjects, infants with cleft lip and palate, less than 2 months of age were selected for pre-surgical nasoalveolar molding treatment. Impressions were recorded, casts made and PNAM appliance fabricated. Ten infants were given the appliance without nasal stents and to the other ten appliances nasal stents were added. The patients were recalled every 2–3 weeks and a series of 9 measurements were recorded every visit along with adjustments made to the appliance for desirable effects on the lip, alveolus and nose. This was carried out till the patient was taken up for lip repair. The final measurements obtained at the end of the presurgical treatment were recorded. Mann-Whitney test, between study and control group showed that the increase in the columella length was statistically significant ($p = 0.0001$ and $p = 0.033$) in the study group as compared

to the control group. Also the increase of the nasal tip projection (mean = 1.30 mm) in the study group was found to be statistically significant ($p = 0.006$) as compared to the control group. We concluded that nasal stents attached to the alveolar molding appliance, yield significant improvement of the nasal morphology and better nasal aesthetics presurgically.

Keywords Presurgical nasoalveolar molding · Cleft lip and palate · Cleft alveolus · Nasal stents · Nasal morphology · Columellar length

Introduction

Infants born with cleft lip, palate and alveolus undergoing primary correction of the lip or nose suffer from an unsightly broad scar due to the excessive amount of stretching of the skin, reduced nasal aesthetics because of decreased columella length and increased columella width. They also need a secondary alveolar bone grafting at a later date due to the widened alveolar cleft gap.

A simple and relatively inexpensive means of reducing the cleft alveolar gap thereby reducing the need for secondary alveolar bone grafting was evaluated. Also, efficacy of the lip tape in approximating the cleft lip segments was assessed.

Our study aimed to

1. Evaluate the improvement in nasal morphology prior to primary correction of cleft lip using a pre-surgical naso-alveolar molding (PNAM) appliance with a nasal stent and to compare the improvement in a similar group using a PNAM appliance without the nasal stent.
2. Evaluate the changes in the lip and alveolar cleft segments in both the groups.

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Fig. 1 Impressions of the cleft infants' alveolus and palate made using condensation silicone impression material

We relied on the following parameters in order to quantify our results in the technique practiced herein

1. The change in nasal morphology.
2. Nostril width/diameter and nasal tip projection.
3. The approximation of lip segments achieved pre-surgically.
4. The approximation of alveolar segments achieved pre-surgically

Materials and Methods

After obtaining the clearance from the ethical committee, infants with cleft lip and palate who reported for treatment were taken up for nasoalveolar molding after recording their impressions. The cleft space was blocked on the cast made of dental stone with modeling wax and an acrylic nasoalveolar molding appliance was made for these patients in the laboratory and delivered.

Fig. 2 a Cast poured with dental stone; b Block out of cleft space with modeling wax

Fig. 3 The presurgical nasoalveolar molding appliance with nasal stent for infants with unilateral cleft of lip, alveolus and palate fabricated and used in this study for each patient

Fig. 4 The presurgical nasoalveolar molding appliance with nasal stents for infants with bilateral cleft of lip, alveolus and palate fabricated and used in this study for each patient

Collection of Data

The study was planned, after obtaining ethical clearance, as follows:

1. Selection of subjects and recording of maxillary impressions
2. Appliance fabrication and delivery

Fig. 5 PNAM appliances in situ in an infant with unilateral cleft lip, alveolus and palate

Fig. 6 PNAM appliance in situ in an infant with bilateral cleft lip, alveolus and palate

3. Clinical evaluation of the effects of the appliance on the nose, lip and alveolus at subsequent visits along with time to time modification of the appliance
4. Comparison of the study group with the control group who were treated without the use of nasal stents.

Methodology

The comparative evaluation required two groups of patients.

Study Group

For 10 patients, maxillary impressions were made using heavy bodied impression material and casts were made from dental stone (Figs. 1, 2). The naso-alveolar molding appliance, in form of a molding plate covering the cleft alveolus and hard palate was then fabricated on these casts (Figs. 3, 4). The appliance was secured in the oral cavity using tape-elastic system attached to the acrylic retention arm extending from the anterior flange of the appliance (Figs. 5, 6). Parents were guided about the change of elastics and tape daily.

The patient kept the appliance in the secured position for the entire day (except when it is to be removed for cleaning) for 2 weeks after which the appliance was modified to achieve the desirable movements of the cleft alveolar segments.

At a later visit when the alveolar cleft gap reduced to 5–8 mm, a nasal stent made of 19 gauge stainless steel wire was incorporated in the appliance.

At each visit the effects were analyzed in the patient by measurement of certain readings including nasal tip projection, bialar width (BAW), right and left nostril diameter (RND and LND), left and right columella length (LCL and RCL) and Columellar width, cleft lip

Fig. 7 The initiation of movement as observed by the inward turning of the premaxillary segment on right side

Fig. 8 Landmarks for measurements

Fig. 9 Measurements used for our comparative study (1)

segment (CLS) and alveolar gap using vernier calipers. (Figs. 7–11).

Control Group

A group of 10 patients were treated as controls for whom molding had been done without the use of nasal stents. The results in these two groups were compared using the same set of measurements as stated above

Fig. 10 Measurements used for our comparative study (2)

Fig. 11 Measurements used for our comparative study (3)

Results

The difference between the changes in cleft lip segment, cleft alveolar gap and nasal morphology were apparent in cleft infants treated with Nasal Stents (Figs. 12–16, 19–24) and without them (Figs. 17, 18).

Mann–Whitney test (statistical analysis), between study and control group (Table 1) showed that the increase in

Fig. 12 Gradual closure of a unilateral cleft alveolus in 5 months with PNAM

Fig. 13 Gradual reduction of the cleft deformity in a bilateral cleft alveolus with PNAM

Fig. 14 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 1: study group)

Fig. 15 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 2: study group)

the columella length was statistically significant ($p = 0.0001$ and $p = 0.033$) in the study group as compared to the control group with a mean increase of 2.20 mm of the left columella and 0.95 mm increase in the right columella. However, Kruskal-Wallis test (Table 2) showed that there was no statistical significance related to the difference of right or left columella length

between left sided cleft, right sided cleft and bilateral cleft.

Also the increase of the nasal tip projection (mean = 1.30 mm) in the study group was found to be statistically significant ($p = 0.006$) as compared to the control group and the mean decrease in the cleft lip segment (mean = -5.3) and cleft alveolar gap (mean = -6.1) was

Fig. 16 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 3: study group)

Fig. 17 **a** Pre; **b** Post treatment: bilateral cleft infant treated presurgically with nasolabial molding appliance without nasal stents (patient 1 of control group)

also significant statistically when compared to the control group with $p = 0.004$ for cleft lip segment and $p = 0.037$ for the cleft alveolar gap (Graph 1).

No statistical significance could however be found for the decrease of the nostril diameter between the two groups. However it was observed that the decrease of

nostril diameter of the respective cleft side was present in almost all clefts except few in the control group. Kruskal-Wallis test (Table 2) also revealed that a mean decrease of -3.00 mm was observed in the right nostril diameter in right sided clefts and mean decrease of -1.929 mm was observed on the left side in left sided clefts.

Fig. 18 **a** Pre; **b** Post treatment: bilateral cleft infant treated presurgically with nasoalveolar molding appliance without nasal stents (patient 2 of control group)

Fig. 19 **a** Pre; **b** Post treatment: bilateral cleft infant treated presurgically with nasoalveolar molding appliance with nasal stents (patient 4: study group)

Discussion

The efficiency of presurgical orthopaedic treatment in infants with cleft lip and palate has been long discussed controversially. The points of controversy have been varied, related to not only the effectiveness of this treatment but also the timing of treatment and the type of force used [3].

In this study we found that there was a statistical significance between the study and control group in the columellar length as well as the nasal tip projection. In the group with nasal stents (study group) there was an increased improvement in the columellar length and nasal tip projection as compared to the control group. This was in concurrence with the studies of Maull et al. [16], Cutting et al. [5] and Grayson et al. [10]. We

Fig. 20 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 5: study group)

Fig. 21 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 6: study group)

also however found that the improvement of nasal aesthetics was also subject to the compliance of the patients' parents, the tolerance of an individual and even the gauge of the wire used. In few cases we started with a 21 gauge wire and found minimal improvement in the nasal morphology. All these cases were finally given an appliance with a 19 gauge wire which showed improvement in the nasal morphology in terms of improved columellar morphology which was statistically significant.

Few cases where the patients did not comply well with the instructions, did not show significant changes in the nasal esthetics, thereby highlighting the significance of the compliance on part of the parents of the patients.

This was also in concordance with Bercowski et al's article on complications [2] which includes compliance as one of the most important patient related complication

Fig. 22 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 7: study group)

Fig. 23 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasolabial molding appliance with nasal stents (patient 8: study group)

which becomes a hindrance to the successful presurgical nasolabial molding.

Matsuo et al. [15] stated that auricular cartilage is soft and plastic at birth, and hence congenital auricular deformities can easily be corrected non-surgically in the early neonatal period. However, as the infant grows older, the flexibility of the auricle decreases. Alar cartilage exhibits the same elasticity as auricular cartilage in the early neonate.

Cutting and Greyson [4] in one paper describe a one-stage reconstruction of the complete bilateral cleft lip, nose, and alveolus using an asymmetrically designed prolabial flap.

Smith et al. [21] described in their article, the growth and development of the premaxilla in both normal and cleft lip and palate subjects and discussed its relevance in surgery of the cleft alveolus.

Fig. 24 **a** Pre; **b** Post treatment: unilateral cleft infant treated presurgically with nasoalveolar molding appliance with nasal stents (patient 9: study group)

Table 1 Mann-Whitney test: comparison between study and control groups

Pre post molding diff	Group	N	Mean	Std. deviation	P
Bialar width	Study group	10	0.70	1.085	0.638
	Control group	10	0.70	0.632	
Right nostril diameter	Study group	10	−0.450	2.3028	0.845
	Control group	10	0.300	0.5869	
Left nostril diameter	Study group	10	−2.550	2.2663	0.071
	Control group	10	−0.850	1.0014	
Right columella length	Study group	10	0.95	0.926	0.033
	Control group	10	0.20	0.258	
Left columella length	Study group	10	2.20	1.033	0.0001
	Control group	10	0.30	0.350	
Columellar width	Study group	10	0.15	0.474	0.842
	Control group	10	0.10	0.211	
Alveolar cleft gap	Study group	10	−6.10	4.081	0.037
	Control group	10	−2.55	2.455	
Cleft lip segment	Study group	10	−5.300	2.1756	0.004
	Control group	10	−2.100	1.6125	
Nasal tip projection	Study group	10	1.30	1.229	0.006
	Control group	10	0.15	0.242	

Wood et al. [23] reported the effect of gingivoperiosteoplasty on growth of the midfacial skeleton 6 years following primary surgical repair. They were unable to demonstrate any clear impairment of the maxillary growth in the patients treated with GPP. Santiago et al. [19] conducted a study with the purpose of evaluating the extent to which presurgical infant orthopedics, when combined with gingivoperiosteoplasty, eliminated the need of alveolar bone grafting. They found that of the 20 sites 12 did not

require bone grafting when evaluated in the mixed dentition stage, 4 patients presented with minimal residual bony defects. However all patients of the control group required bone grafts [19]. Grayson and Cutting [11] presented the background of presurgical nasoalveolar orthopedic molding, the technique and the literature. A close comparison of the proposed benefits of earlier forms of presurgical orthopedics along with those of the current technique of nasoalveolar molding was presented.

Graph 1 Bar diagram representing difference between pre and post molding measurements in study and control groups

Pfeifer et al. [17] concluded that the treatment of unilateral cleft alveolus by nasoalveolar molding and gingivoperiosteoplasty resulted in substantial cost savings, compared with treatment by secondary alveolar bone graft.

Yamada et al. [24] concluded that presurgical orthopaedics reduces cleft width and makes subsequent surgery easier. Romero et al. [18] used an orthopaedic approach that combined Latham's appliance with a micropalate attached to the anterior surface of the premaxillary segment. An appliance was designed to have two hooks located anteriorly and a little lateral to the dental ridge. These were for the attachment of right and left elastic bands [18]. Grayson and Maull [8] describe that the principle objective of presurgical nasoalveolar molding (NAM) is to reduce the severity of the initial cleft deformity. Grayson et al. [9] described the complete impression technique and NAM appliance fabrication, adjustments and complications of NAM therapy. They stated that the objective of PNAM is to reduce the severity of the original deformity and thereby enable the surgeon to achieve better repair of the alveolus, lip and nose. Use of the NAM technique has also eliminated surgical columella reconstruction and the resultant scar tissue in bilateral cleft lip and palate. Ziai et al. [14] described two patients with cleft lip and palate and natal/neonatal teeth. They stated that in patients with cleft lip and palate with natal/neonatal teeth who require NAM, the teeth must be removed to facilitate

the fabrication and placement of the device. Singh et al. [20] evaluated the 3D facial morphology in patients surgically corrected for unilateral cleft lip and palate following presurgical NAM.

Grabowski et al. [7] presented an orthopaedic treatment protocol within the framework of complex rehabilitation of patients with clefts of lip, alveolus and palate. Presurgical orthopaedic treatment aimed at reduction of cleft size by guiding growth and functional rehabilitation.

Kirbschus et al. [12] reported the use of a device consisting of an acrylic pellote (attached to the maxillary plate with a wire) which lifted the nasal dome and was activated regularly thereby moving the cleft edges closer to each. Spengler et al. [22] have quantitatively shown that presurgical nasoalveolar molding therapy has significant advantages in the treatment of bilateral cleft lip and palate patients. Ezzat et al. [6] evaluated the outcome of PNAM therapy in the treatment of patients with non-syndromic unilateral cleft and palate. The improvement of the height of the cleft nostril was correlated with the time the appliance was applied. Liou et al. [13] concluded that both presurgical nasoalveolar molding and primary cheiloplasty lengthened the columella in bilateral cleft lip-cleft palate patients. Aminpour et al. [1] stated that molding can create improved nasal symmetry in unilateral cases and columellar lengthening in bilateral cases.

Table 2 Kruskal-Wallis Test between left, right and bilateral clefts showing pre and post molding difference

Pre-post molding diff	<i>N</i>	Mean	Std. deviation	<i>P</i>
Bialar width				
Left	14	0.75	0.915	0.319
Right	3	1.00	0.000	
Bilateral	3	0.17	1.041	
Total	20			
Right nostril diameter				
Left	14	0.607	0.4463	0.006
Right	3	−3.000	3.0000	
Bilateral	3	−0.333	0.5774	
Total	20			
Left nostril diameter				
Left	14	−1.929	1.6740	0.047
Right	3	0.333	0.5774	
Bilateral	3	−2.667	2.8868	
Total	20			
Right columella length				
Left	14	0.46	0.664	0.476
Right	3	1.33	1.258	
Bilateral	3	0.33	0.289	
Total	20			
Left columella length				
Left	14	1.46	1.308	0.519
Right	3	1.00	1.323	
Bilateral	3	0.50	0.500	
Total	20			
Columellar width				
Left	14	0.21	0.378	0.140
Right	3	−0.17	0.289	
Bilateral	3	0.00	0.000	
Total	20			
Alveolar cleft gap				
Left	14	−4.21	3.490	0.383
Right	3	−6.83	5.346	
Bilateral	3	−2.33	3.215	
Total	20			
Cleft lip segment				
Left	14	−3.571	2.2943	0.425
Right	3	−5.000	3.0000	
Bilateral	3	−3.000	3.4641	
Total	20			
Nasal tip projection				
Left	14	0.86	1.184	0.565
Right	3	0.17	0.289	
Bilateral	3	0.67	0.764	
Total	20

Fig. 25 Soft tissue ulceration on labial aspect of alveolus **Fig. 26** A week after antibiotics and temporary discontinuation of PNAM

From this study, it can be concluded that definitely there is a significant role of the presurgical nasoalveolar molding in the comprehensive treatment of cleft lip and palate.

When nasal stents are attached to the alveolar molding appliance, the benefits of nasal molding in an early age are evident from the significant improvement of the nasal morphology and better nasal esthetics presurgically.

Significant reduction of alveolar gap, the cleft lip segment and nostril diameter post molding in both groups, can also be concluded from this study.

Soft tissue irritation related complications may be encountered rarely (Fig. 25) but if judiciously managed, do not hinder the overall success of the treatment (Fig. 26).

Conclusion

Thus we can conclude that the reduction of the severity of the nasal deformity was found to be more in the study group, i.e., the group with nasal stents, as is also implicated by the statistically significant increase in the columellar length (or the projection of the columella) and the increase in the nasal tip projection post molding. Compliance of the patients' parents, which includes timely recall visits and following instructions religiously, plays a significant role in the success of presurgical nasoalveolar molding treatment.

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