Nasoalveolar Molding Prior to the Closure of Lip in Cleft Lip and Palate: A Clinical Study

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ORIGINAL ARTICLE

Nasoalveolar Molding Prior to the Closure of Lip in Cleft Lip and Palate: A Clinical Study

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ABSTRACT:

Aims and Objectives: To assess the efficacy of Nasoalveolar molding procedure in treating cleft lip and palate patients prior to surgical closure of the lip. Materials and methods: Nasoalveolar molding procedure was used in five infants suffering from cleft lip and palate and the results were evaluated as per the protocol for this study. Results: Nasoalveolar molding indeed proved to be helpful in reducing the size of the cleft and contouring of the nose before surgically closing the lip. Conclusion: Nasoalveolar molding helped in reducing the size of the clefts in cleft lip and palate patients and a better nasal contour was seen to be achieved with this procedure prior to the surgical closure of the lip.

Key words: cleft lip, cleft palate, Nasoalveolar molding, surgical closure.

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INTRODUCTION:

In orofacial region cleft lip and cleft palate is one of the commonest congenital defects found in humans..¹ Cleft lip with or without cleft palate occurs in approximately 1 in 1000 white births (range: 700-1300). The frequency in American Indians is the highest of any known group (3.6 per 1000 births). In Japan, the frequency is approximately 2.1 per 1000 births and in China the frequency is 1.7 per 1000 births where as the lowest rate is found in the black population (0.3 per 1000 births).²

The etiology of facial clefting is thought to be multifactorial, ie. an interplay between genetics and environmental factors. Due to the complex nature of embryogenesis, there are many potential areas for disruption in development which can result in clefting. These can occur as part of a syndrome or they can be nonsyndromic.²

In the early days of cleft management, congenital clefts were treated by simple coaptation of their surgically freshened borders then stabilized and joined together using trans-fixing needles around which sutures of linen or silk were tied. Presurgical orthopedic treatment, as it is understood today, is undertaken to prepare an infant with a cleft for surgical repair of the lip and later, for repair of the palate. A combination of active and passive appliances is used to achieve the best possible results in a patient.

METHODOLOGY:

The objective of this study was to assess the effectiveness of Presurgical Nasoalveolar molding in infants suffering from cleft lip and palate and to evaluate the amount of reduction in cleft width after this procedure.

A sample size of 5 patients of which 4 patients were of bilateral cleft lip and palate and 1 patient had an unilateral cleft lip and palate. The age of the infants ranged from 12 to 61 days with the average age being 26 days. Whereas the time duration of molding therapy ranged from 40-120 days with the average time being 80 days.

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Inclusion Criteria:

- The cleft lip and palate patients considered for the Nasoalveolar molding procedure were till 3 months of age only.
- Healthy babies with no other systemic or local complications other than the cleft lip and palate were included in this study.
- Infants suffering from unilateral and bilateral clefts were included.

Exclusion Criteria:

- 1) Patients who were more than 3 months old were not included in the study.
- Cleft lip and palate patients with any systemic problems or congenital diseases other than cleft lip and palate were excluded from the study.

A detailed case history was taken as per the case history proforma and the procedure started with the informed consent of the parents. Impression of the cleft (figure 1) was taken using medium body putty consistency material (figure 2). This material was selected as it can produce fine details of the cleft, sets quickly and has high viscosity. The high viscosity of the material acted as a safety factor as it did not flow into the pharynx, choking the infant. After the impression was taken, a cast was poured in dental stone (figure 3) and a hard acrylic resin plate was constructed (figure 4a, 4b).

On the tissue surface of this obturator plate a thin layer of resilient liner was used. Resilient liners⁴ are elastomeric polymers used mainly in prevention of chronic soreness form dentures and the preservation of the supporting structures. These elastomeric polymers are made of different materials mainly velum rubber, vinyl and vinyl-acrylic polymers, silicone or polyurethane. This property helps in the molding procedure wherein when placed in the oral cavity it softens and adapts to the cleft and hence helps in constantly molding the cleft area towards each other.

The intersegmental width between the cleft alveolus was measured in the anterior region; the measurements were taken on the casts which were poured after the impressions were taken. Measurements were taken on 2 different occasions - one at the beginning of the Nasoalveolar molding Procedure and a second measurement was taken on the cast poured after taking impression on the completion of the Molding Procedure. Statistical analysis was done with the obtained data. The mean width of the cleft on the right side is found to be 6.75 mm and on the left side 8.8 mm, while the reduction in the width of the cleft on the right side is found to be 4 mm while on the left side is 4.4 mm. The stent was positioned in such a way that the active end was near the columella and the stent was activated so that it applies outward pressure which helps

in elevating the depressed nose (figure 5). The whole apparatus was stabilized with Velcro strips and the nasal taping was done with the help of tissue plaster. After about 1 week when the infant got used to the plate with the soft liner on it, a nasal stent was added on the plate. A 21 gauge stainless steel wire was used for this purpose.

Initially the patient was recalled fortnightly for follow up to check whether the soft liner needed any additions or adjustments which were done accordingly (figure 6); subsequently monthly recalls were advised during which the nasoalveolar molding plate was adjusted allowing for passive orthopedic guidance for maxillary growth. The local compatibility of the plate was found to be excellent and the acceptance by the infants created no problems until tooth eruption³. The plate also acted as an obturator which helped in facilitating feeding. Figure 7 shows the post-operative picture of the same child after the surgery.



Figure 1- Preoperative picture of bilateral cleft lip and palate



Figure 2 - Impression taken using medium body silicone material



Figure 3.- cast poured using dental stone.



Figure 4a- Nasoalveolar molding appliance.



Figure 4b - Nasoalveolar molding appliance insitu.



Figure 5 - After nasal taping.

RESULTS:

The record of measurements of the cleft width before and after nasoalveolar molding were sent for statistical analysis.

Table 1 showed the distribution of premolding and postmolding width in unilateral cleft lip and palate whereas table 2 showed the same in cases of bilateral cleft lip and palate.

Summarizing the statistical analysis of mean cleft width before the Nasoalveolar molding therapy revealed 7.89 mm and the mean width for the post Nasoalveolar molding Therapy was found to be 4.22 mm with an average reduction of 3.66 mm as seen in Table 3.



Figure 6 - After one week of follow up.



Figure 7 - Post operative picture of child.

Table 4 shows the comparison of pre and post molding width values in left and right sides by using wilcoxon matched pair test. The average reduction of the cleft width when compared to the right and left side was that the mean reduction in the cleft width on the right side is 2.75 mm with a p-level of 0.0679 (<0.10) which is statistically significant and in the same way the mean reduction on the cleft width on the left side is 4.4 mm with a p-level of 0.0431 (<0.10) which is again statistically significant. This result was obtained by using the Wilcoxon matched pairs test.

Table 5 depicts the comparison of right and left sides with respect to pre and post Nasoalveolar molding by Mann Whitney U-test. The mean reduction of cleft width between the right and left side was seen to be

statistically non significant according to Mann Whitney U test which showed similar closure rates between the right and left side.

Table 1: Unilateral cleft lip and palate

Sl. No	Pre Nasoalveolar molding	Post Nasoalveolar Molding	Reduction in cleft width (in mm)	
Case 2	14 mm	6 mm	8 mm	

Table 2: Bilateral cleft lip and palate

Sl. No.	Pre Naso Molo		Post Nasoalveolar Molding		Total reduction in cleft width	
	Dight side	Left	Right	Left	Right	Left
	Right side	side	side	Side	side	Side
Case 1	8 mm	5 mm	4 mm	3 mm	4 mm	2 mm
Case 3	10 mm	6 mm	6 mm	3 mm	4 mm	3 mm
Case 4	4 mm	6 mm	3 mm	3 mm	1 mm	3 mm
Case 5	5 mm	13 mm	3 mm	7 mm	2 mm	6 mm

Table 3: Summary of the statistical analysis

Molding	Summary	Right side	Left side	Total
Pre	Means	6.7500	8.8000	7.8889
	Std.Dev.	2.7538	4.3243	3.6553
Post	Means	4.0000	4.4000	4.2222
	Std.Dev.	1.4142	1.9494	1.6415
Reduction	Means	2.7500	4.4000	3.6667
	Std.Dev.	1.5000	2.5100	2.1794

Table 4: Comparison of pre and post molding width values in left and right sides by using Wilcoxon matched pairs test

Side	Molding	Mean	SD	Reduction mean	T-value	Z-value	p-level	Significance
Right	Pre	6.7500	2.7538	2.7500	0.0000	1.8257	0.0679	S
	Post	4.0000	1.4142				< 0.10	
Left	Pre	8.8000	4.3243	4.4000	0.0000	2.0226	0.0431	S
	Post	4.4000	1.9494				< 0.05	
Total	Pre	7.8889	3.6553	3.6667	0.0000	2.6656	0.0077	S
	Post	4.2222	1.6415				< 0.05	

Table 5: Comparison of right and left sides with respect to pre and post Nasoalveolar molding by Mann Whitney U-test (NS – Non significant)

Molding	Side	Rank sum	U-value	Z-value	p-value	Significance.
Pre	Right	16.5000	6.5000	-0.8573	0.3913	NS
	Left	28.5000			>0.05	
Post	Right	19.5000	9.5000	-0.1225	0.9025	NS
	Left	25.5000			>0.05	
Reduction	Right	16.5000	6.5000	-0.8573	0.3913	NS
	Left	28.5000			>0.05	

DISCUSSION:

Examination of skulls found in archaeological explorations in Peru, revealed that cleft palate has existed since the origin of mankind, and it is safe to hypothesize that this observation applies to cleft lip also.

Usually the treatment protocol in most centers of the world is a single stage procedure when the baby is 10 pounds in weight with a minimum of 10 gm% hemoglobin. This protocol was found to be satisfactory in all but very wide unilateral and bilateral clefts with a severely protruding maxilla. In cases of the wide (as in unilateral clefts) and severely protruding premaxilla (bilateral clefts) there was a severe distortion of the nose and the symmetry of the upper lip was also lost due to the continual growth of the mid face¹.

In a quest for constant improvement in the field of treatment of cleft lip and palate, new methods and techniques are utilized. One such technique is Nasoalveolar molding Procedure, which helps in reducing the width of the clefts before primary cheiloplasty.

McNeil, a prosthetist, in 1947 found that fitting a special kind of obturator plate which had stimulation pads on its palatal aspect, in the oral cavity of older patients of cleft palate who had a residual fistula, often diminished the cleft in size. Great strides have been made in the molding of the clefts, with different authors describing different techniques for the fabrication of the appliance. Starting from Burston (1955), an orthodontist who improved on the techniques of McNeil to the many present authors and researchers like Grayson et al^{5,6,7,8}. who have improved this technique to the present standards where today it is possible to use the Nasoalveolar molding procedure effectively as an adjunct. Alternatively it may be used as a prerequisite, in cases of severe bilateral cleft lip and palate cases where the prolabium is protruding and where it becomes absolutely necessary to mold the processes and get the protruding prolabium back into alignment so that surgical correction is a lot easier with minimal recall of the patient for redoing the lip as shown in one of the studies conducted by Kozelj, Vesna⁹; and Pham, Annette M and Senders, Craig W².

Several studies have also shown that there is not much difference in growth pattern of the midface of the cleft palate patient who has undergone Nasoalveolar molding^{6,10}. On the other hand there are studies to show that patients who underwent cleft lip repair without Nasoalveolar molding had to undergo subsequent surgery for alveolar bone grafting which increased the patients overall time spent in the hospital as compared to those who underwent lip closure after Nasoalveolar molding. It would be pertinent to mention here that in the latter case very few patients actually required a second surgery for alveolar bone grafting. In addition it also results in reduced cost of treatment from the patient's point of

view also⁷. The prospect of reduction in the intersegment alveolar cleft distance using the Nasoalveolar molding technique is emphasized by another study done which shows statistically significant decrease in the intersegment cleft width¹¹.

The results of this particular study carried out are in agreement with studies conducted by Essat C. F, Chavarria Carmen, et al. 11

CONCLUSION:

This study concluded that Presurgical Nasoalveolar molding indeed reduces the size of the cleft prior to the surgical closure which is supported by other studies^{2,10,12,13} and there is columellar elongation in the cases of bilateral cleft lip and palates which helps in easy closure of the defect^{8,14,15}, and due to this procedure the nasal symmetry can be improved a lot before the surgical correction and studies have shown that the symmetry of the nose achieved by Nasoalveolar molding is stable up to 4 years⁹. Additional studies have also shown that Nasoalveolar molding Procedure does not affect the post pubertal growth in the sagittal or vertical planes⁸.

Although further research needs to be undertaken to authenticate these finding further, undeniably this procedure is a step in the right direction as not only does it drastically decrease the chances of a follow-up surgery thereby ruling out the additional stress associated with it but also reduces the cost factor⁸ making the treatment of cleft lip and palate far more accessible to the common man.

To sum up this study shows that the use of pressurgical Nasoalveolar molding in the treatment of cleft lip and palate cases in infants definitely helps in the final outcome of the result.

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