EFFECT OF PRESURGICAL NASOALVEOLAR MOLDING ON COLUMELLA LENGTH.

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Abstract

Introduction: Presurgical nasoalveolar molding is a procdure to minimze the extent of nasaoalveolar deformity prior to surgery in order to achieve more esthetic and stable post surgical results. This study was aimed to assess changes in collumellar length before and after presurgical nasoalveolar molding.

Materials and Method: This quasi-experimental study was carried out at Department of Orthodontics, Karachi Medical and Dental College Hospital. Duration of the study was six months. Study included 50 neonates. Selection criteria was 1) New born to 3 month-old. 2) Either sex. 3) Unilateral or bilateral CLP diagnosed by history and clinical examination on inspection. A proforma was used to record the extra-oral measurements of columellar length before and after nasoalveolar molding. SPSS 14.0 was used for statistical analyses

Results: There was a statistically significant increase in the columellar length shown by paired t test ($P < 0.01$)

Conclusion: Infants show increase in columella length and improved nasal tip projection in unilateral and bilateral cleft lip and palate patients after PNAM.

Key Words: Cleft Lip and Palate, Presurgical Nasoalveolar Molding, Columella.

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INTRODUCTION

Cleft lip and/or cleft palate is among the most frequent birth defect, with prevalence of 1 in 700 -1000 births worldwide.[1] Incidence varies according to the type of cleft, racial group and sex. Cleft lip with or without cleft palate ranges from 3.6/1000 births for Indians, 0.5/1000 for Negroes and 1/1000 birth for Caucassians.[2] There are many exceptions to these summaries, with some particular geographic areas having high frequencies related to founder effects or environmental triggers.[3] In Pakistan incidence for CLP was 1.91 per 1000 births (one per 523 births). [4] According to WHO statistics, Pakistan is on fourth number with largest population of cleft lip and cleft palate .According to rough estimate, there are around 1.2 million unoperated cleft patients in the world, out of which, around 2-300,000 are in Pakistan. In Sindh, there are around 50-60 thousand. [5]

Growth and development in children with cleft lip or palate CLP is affected by morphology of the facial defect and the necessary treatment.[6] Patients with large clefts and small arch circumference, arch length, or

both demonstrated less favorable maxillary growth than those with small clefts and large arch circumference or arch length at birth. While the cleft deformity is associated with some abnormal facial growth, the surgical procedures performed to repair the cleft appear to play the greatest role in abnormal facial growth. Repair of the cleft palate has greater effects on future growth than repair of the lip. Earlier cleft repair causes more inhibited facial growth producing midface retrusion. [7]

Cleft management is multidisciplinary and involves other than plastic and paediatric surgeon, many other specialities like pediatricians, ENT Surgeons, maxillofacial surgeons, orthodontists, prosthodontists, speech therapists, psychologists and social workers are also involved. [8]

Presurgical infant orthopedics is an adjunctive neonatal therapy for the correction of cleft lip and palate. It helps in minimizing the severity of deformity prior to surgery thus allowing more esthetic and stable result post surgical. This technique takes advantage of the malleability of immature cartilage and its ability to maintain a permanent correction of its form and nonsurgically construct the columella through the application of tissue expansion principles. [5] Grayson designed the first presurgical nasoalveolar molding appliance with a stent extended from the anterior flange of an acrylic plate to correct the nostril shape as well as to mold the cleft alveolar segments. [9] Nasal alveolar molding is used effectively to reshape the nasal cartilage and mold the maxillary arch before cleft lip repair and primary rhinoplasty. It provides aesthetic and functional benefits of nasal tip and alar symmetry and improved dental arch form. [10] As a result, the changes associated with presurgical nasoalveolar molding therapy help decrease the complexity of subsequent surgeries.[11] Infants with presurgical orthopedics become more similar to noncleft contemporaries than those without presurgical orthopedics.[12]

Presurgical NAM produce more consistent and esthetic postoperative results by decrease the need for alveolar bone graft, minimizing the extent of the primary nasal surgery required, minimizing lip tension reducing scar formation, and saving patients from psychological trauma. It allows for positive growth of the alveolar ridges into an improved arch. [9] The purpose of this study was to assess the effect of NAM in terms of increase in length of columella.

MATERIALS AND METHODS

Setting: Department of Orthodontics, Karachi Medical and Dental College Hospital [KMDC]

Duration: Six months.

Sample size: 50 cases

Sampling technique: Convenience, non-probability sampling used.

Sample selection:

Inclusion criteria:

- New born to 3 month-old infants.
- Patients of either sex.
- Unilateral or bilateral cleft lip/ palate diagnosed by history and clinical examination specifically on inspection.

Exclusion criteria:

- Other craniofacial malformations or systemic diseases e.g. Treacher-Collins malformation.
- Previously surgically treated.

Study design: Quasi-experimental.

Data collection procedures:

Data was collected from patients coming to the department of Orthodontics, Karachi Medical and Dental College Hospital, referred by gynaecologists, pediatricians and plastic surgeons using proforma. After taking consent from the patient's parents, history was taken and clinical examination done. An initial impression taken by a heavy-bodied silicone impression material as soon after birth as possible. The infant was held upside down by the surgeon to keep the tongue forward and allow fluids to drain out of the oral cavity. A cast or model of the alveolar anatomy was made by filling the impression with a dense plaster material [dental stone], which was used for fabricating a molding plate using acrylic resin and was lined with a thin layer of soft denture material. The initial columlla length $\mathbf{T_1}$ were directly measured intra-orally using a Boley gauge with 0.1mm precision. This procedure was repeated after nasoalveolar molding was completed and measurements were taken $\mathbf{T_2}$. All measurements were taken by the same observer, under the supervision of the same orthodontist, with the same Boley gauge. The appliance was secured extra-orally to the cheeks and bilaterally by surgical tapes, which had an orthodontic elastic band at one end. The elastics looped over a retentive arm extending from the anterior flange of the plate. The retentive arm was positioned approximately 40^o down from the horizontal to achieve proper activation and to prevent unseating of the appliance from the palate. Adhesive strip 1/4x 4 inches was applied extraorally to facilitate approximation of the cleft lip and alveolar segments. The tapes were changed once a day. The nasal stent was made of 0.036-gauge round stainless steel wire were added when alveolar cleft remain approximately 5-6mm. A horizontal prolabial band was placed across the base of the columella at the nasolabial fold. Weekly visits were required to modify the appliance by trimming and

adding acrylic to specific areas on the fitting surface to guide the controlled repositioning of the alveolar cleft segments into the desired position. By modifying the PNAM plate and the external forces applied by the taping and elastics, the premaxilla was repositioned between the lateral alveolar segments. The advancement of the alar cartilages into the nasal tip was accomplished by adding acrylic to the nasal stents. Columellar lengthening was achieved by the combined force of the nasal stents and the horizontal prolabial band. All parents were instructed on how to insert and remove the PNAM appliance, which was worn at all times except for routine cleaning. This slow movement continued until the tissue and cartilage reached the position required for surgery.

Data Analysis: Statistical analysis was performed with statistical software ***SPSS 14.0.*** All numeric response variables including sex, type of cleft and pre and post treatment were presented by mean ± standard deviation [SD]. Paired T-test was applied to get the standard error mean (table-I).Correlation between the paired samples (pre treatment and post treatment records) were attained at the significance level of <0.01 (table-II).The paired differences were then evaluated at 2 –tailed significance level (table-III). Male to female ratio [M:F] was calculated for sex distribution.

RESULTS

Fifty patients with cleft lip and palate underwent PNAM. Of these patients, 23 were unilateral and 27 were bilateral 28 were males and 22 were females with a mean age of 20.06 days.

The columellar length (pre treatment 0.61mm, SD 0.91; post molding 5.65 mm SD 0.73) showed an increase of 5.04mm (SD 0.668) which was calculated as very highly significant (P<0.01) at 2-tailed

Table I: Paired Sample Statistics

	Mean	N	SD.	SEM
Columella after NAM	5.65	50	0.73	0.10
Columella before NAM	0.61	50	0.91	0.13

Table II: Paired Sample Correlations

Paired Samples Correlations			
	N	(r)	Sig.
Columella after NAM & Columella before NAM	50	0.69	3.34E-08

Table III: Paired Sample Test

	Paired Differences					t	Sig.
	Mean	SD	SEM	95% CI			
				L	U		
Columella after NAM – Columella before NAM	5.04	0.67	0.095	4.85	5.23	53.28	.000

Significance level. (table1, table2, table3) P<0.01

Discussion

Even though a universal goal of treatment for cleft patients is to restore symmetry, anatomy, and function, nasal morphology remains distorted and asymmetric to varying degrees after treatment. Columella plays an important role in cleft nose deformity. In bilateral cleft columella is underdeveloped, and is almost negligible. Patients born with unilateral cleft lip and palate are characterized by nasal asymmetry due to a shortened columella on the cleft side that deflects the nose to the unaffected side [13].

It is difficult to correct short columella and straightened lower lateral cartilage surgically in UCLP. The postoperative result will be horizontal axis of nostril looking like a tear drop with tip pointed medially. In addition scar tissue contraction can lead to increased relapse and interfere with the nasal growth [14]. In BCLP correction of deficient columella is performed as secondry procedure after lip repair, by advancing skin up from the lip or nasal floor into the columella. This is done by the age of 5-7 yrs, by that time the typical deformity of nose becomes firmly established

and confluence of tight secondary scar at the lip columella junction is necessary consequence [15].

Most surgeons would agree that their chance of achieving a finer surgical scar, good nasal tip projection, and a more symmetrical and precisely defined nasolabial complex would be better in an infant that presents with a minor cleft deformity. It is traditional surgical experience that a finer scar forms when a surgical incision heals under less rather then more tension [16].

Thus, persistent problems with associated nasal deformities have given rise to the use of presurgical nasoalveolar molding (PNAM) in cleft-treatment protocols. The theory of PNAM treatment is based on Matsuo's research that the nasal cartilage is still developing and is subject to repositioning within the first 6 weeks of life. Grayson et al. described the first treatment protocol for PNAM. It has been recognized that primary nasal correction for unilateral cleft lip nasal deformities simultaneous with lip repair can significantly improve nasal appearance and primary nose surgery does not influence subsequent growth or development of the nose as the earlier studies indicated [17,18].

Principle objectives of molding are to correct the malpositioned nasal cartilages, columella, and philtrum; to bring the columella toward the midsagittal plane; improved nasal symmetry and columellar lengthening. The nasal septal and columellar deviation seen in unilateral cleft lip and palate can also be improved. Presurgical nasal alveolar molding in children with cleft lip and palate also allows repositioning of the maxillary alveolus and surrounding soft tissues in hopes of reducing wound tension and improving results. [19].

In our study, history of cleft in the family was found in 7% of the subjects. Relevant to socio economic status, 64% of the subjects belonged to lower class and 26% belonged to middle class. We used records of 50 patients for our study in which 22(44%) were female and 28 (56%) were male; 23 (46%) were unilateral cleft lip and palate and 27(54%) were bilateral cleft lip and palate. Male female and unilateral bilateral distribution are shown in Fig 1 and Fig 2 respectively. Male to female ratio was 1.72:1. The frequency of age distribution of the cleft babies is shown in Fig. 3. The average age at which PNAM was begun was 20.06 days (table 4). The average length of therapy was 101 days, with a range of 86 to 120 days. The ideal cartilage-molding period, which was determined by Matsuo and Hirose is within the first 6 weeks of life.

We retract the premaxilla and lengthen the columella using Grayson's technique. In this technique the premaxilla is retracted before lengthening of the columella in bilateral cleft. In unilateral cleft nasal stent is added when alveolar cleft reduce to 5mm to allow laxity of alar cartilage thus avoiding over expansion of nostils. Lip taping was used that helps in increasing length of columella and its also cause its uprighting towards midsaggital plane in UCLP [20].

The molding plate is modified at weekly intervals to gradually approximate the alveolar segments and to reduce the size of the intraoral cleft gap.
Grinding is done in places where alveolus is required to move while soft denture liner is added to the appliance in the region from which one desires the bone to be reduced .Columella length was improved through the application of tissue expansion principles. Columella is stretched with an stainless steel wire stents and prolabial band, attached to a palatal molding plate, and secured to the cheeks with tapes [5].

Preoperative expansion of nasal lining is important for columellar elongation because it facilitates interdomal suturing without tension and minimizes widening of the nose [21].

Use of the NAM technique has eliminated surgical columella reconstruction and the resultant scar [5].We mold the nasal cartilage and narrow down the alveolar cleft so that primary cheiloplasty would be easier. We did not attempt to approximate the alveolar cleft for gingivoperiosteoplasty. The nasal stent was fabricated of 0.036 round stainless steel orthodontic wire, a modification to the original acrylic resin stent, as proper control of direction and force of an acrylic stent is difficult. These wire stents are easy to make, repair and keep clean [10].

Evaluation of the measurement reveals that PNAM therapy cause significant increase in columellar length. The columellar length (pre treatment 0.61mm, SD 0.91; post molding 5.65 mm SD 0.73) showed an increase of 5.04mm (SD 0.668) which was calculated as very highly significant ($P<0.01$) Columellar deviation and width were also significantly improved. Combination of columellar lengthening and repositioning with nostril lengthening helped improve the nasal symmetry. The width of the cleft in this study was reduced and the results where found to be dependent on the duration of appliance worn and application of pressure by taping.

The results of PNAM in the patient presented are consistent almost with cases treated in previous studies. Lee et al in their study reported an increase in columellar length by 4.08+/-0.14 mm in 13 patient who

underwent PNAM. They suggested that nonsurgical columellar elongation with nasoalveolar molding followed by primary retrograde nasal reconstruction restored columellar length to normal by 3 years and significantly reduced the need for secondary nasal surgery [22]. Ijaz.A in her study of 32 pakistani childern showed an increase of 2.156 mm in columellar length [23]. Spengler et al .in their study of 8 children with BCLP reported an increase in columellar length of 1.46 mm [11]. Liou, Subramanian and Chen in their study of 22 BCLP patient reported an increase in columellar length of 2.0+/-1.1mm [24]. Singh, Levy-Bercowski and Santiago in their study of 10 pateint of UCLP reported an increase in columella of 30% [25].

The principal objective of presurgical nasoalveolar molding (NAM) increase the surface area of the nasal mucosal lining, up righting of the columealla , and achieving close approximation of the cleft lip segments at rest result from gentle application of forces through the NAM appliance and lip taping. Preservation of these presurgical changes is achieved through the coordinated and modified surgical technique of the primary cleft repair[20].

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Some regression of improvement is often seen in the previous studies due to differential growth patterns within the nasal subunits [19]. As indicated in previous studies nasal symmetry significantly relapse in 1st yr of life then remain stable for 2nd and 3rd yr [24]. The relapse has been reported to be due to tissue scarring, Soft elasticity of the deformed alar cartilage, or differential growth between the cleft and non-cleft sides [18]. A relative relapse was seen in columella length because of the differential growth between the columella and the rest of the nose in the first and second years postoperatively [24].

To compensate for the relapse resulting from the differential growth in the first year maintaining the surgical results by using a nasal conformer. It is advised to overcorrect the columella length by at least 2 mm presurgical nasoalveolare molding and surgery and that the nasal conformer made of silastic be used for the first year postoperatively [24].

In the method of nasoalveolar molding and columella elongation, the posterior lateral alveolar ridges are molded to an appropriate width to accept the premaxilla. The combination of presurgical nasoalveolar molding and nonsurgical columella elongation allows bilateral cleft lip and nose correction in a single stage[26].

Lip adhesion and a passive alveolar molding appliance can be used together to achieve a normal position of alveolar arch and stabilize it in a symmetrical platform. Lip adhesion alone is more expensive than presurgical molding, wounds the lip elements, retracts the premaxilla in an uncontrolled fashion, and does not mold the nasal cartilages [5,27].

As with all plastic surgery, the timing and procedure of surgical repair should be predicated on the severity of the deformity [28]. Rotation advancement remains the most frequently used technique for unilateral cleft lip repair [29]. Cutting (i.e., retrograde) method have been most successful method. The retrograde method makes no external nasal incisions, but requires either preoperative or postoperative nasal molding to achieve maximum benefit [16].

Figure I Gender distribution

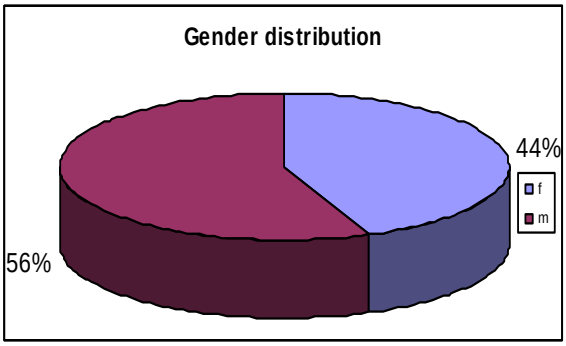


Figure II Type of cleft

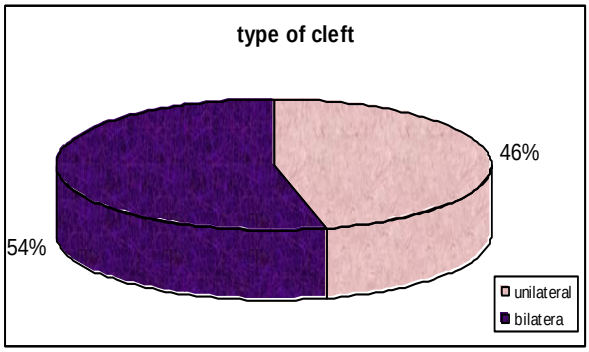


Figure III Frequency of age

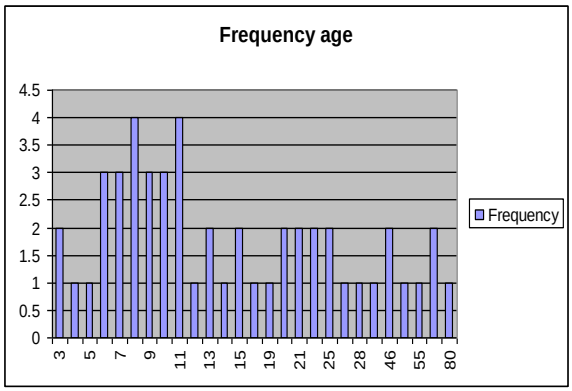


Table -IV Summary of statistics of variable

	Age	Coloumellla after NAM	Columella before NAM
Mean	20.06	5.65	0.61
Std. Error	2.72	0.10	0.12
of Mean	12.5	5.5	0
Median	8	5.5	0
Mode	19.27	0.73	0.91
Std	3	4.5	0
Deviation	80	7	4
Minimum			
Maximum			

Limitations:

Compliance is an essential factor with this method of treatment. Poor compliance by the parents can cause loss of valuable treatment time. Weekly follow up was required but few patients were not regular for their appointments, for whatever reasons, affecting the results of molding. Patient were also coming from a long distance, their parents feel it difficult to continue the follow up.

This treatment requires regular daily dressings at home and weekly visits at the hospital. Dressings, medication and equipment used are very expensive and some are not available in Pakistan [30]. We therefore, have to import these medicines like Mastisol (adhesive dressing for lip adhesion).

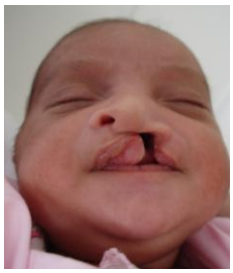
Complication like soft tissue breakdown results in patient being unable to wear the molding plate firmly. Intraoral ulcerations might occur where active molding pressure is applied and in frenal area [9]. Taping should be done firmly to approximate the lip segments as well as support the appliance [31]. There may be a tendency for the soft tissue to exert an opposing downward force that will dislodge a poorly taped appliance.

Few patients diagnosed of natal/neonatal teeth, which required extraction to facilitate the fabrication and placement of the device as tooth cause feeding difficulties and recurrent bleeding from mobility of tooth. There is risk of aspiration, trauma and ulceration on ventral surface of tongue too. These neonatal teeth must be extracted with caution because the tooth buds of neighboring teeth may be damaged and remnants of the dental papillae may be left behind. We did extractions in local anaesthesia [32].

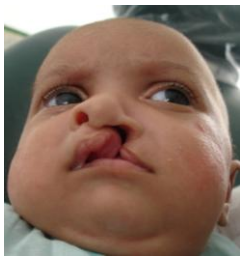
Problems also occur with wire stents like distortion or excessive control of wire stent sometimes result in instability of molding plate [33]. PSIO requires a significant expenditure in clinical and technical facilities and personnel.

Bilateral cleft Before PNAM repair

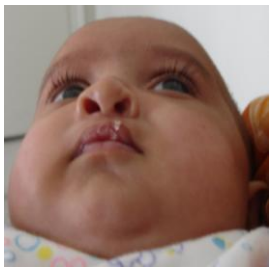
Bilateral Cleft after PNAM and surgical



Unilateral Cleft before PNAM



Unilateral Cleft after PNAM and surgical



Unilateral cleft Primary surgical repair

The subjects evaluated in this study are not fully grown. Long-term studies will need to be performed that analyze the overall risks and benefits of this

technique. NAM is a new therapy, and the subjects studied were representative of the earliest treated, therefore, further evaluation of changes with age is required when this group reaches adolescence and then adulthood [18].

As the child gets older tongue activity develop and baby is more likely to learn to dislodge the molding appliance that makes the process more difficult and the parents must monitor the child more closely. The plasticity of cartilage also decreased so its better to start procedure soon after birth.

The use of NAM in patients with complete unilateral cleft lip and palate, in combination with the primary lip surgery, might permit these patients to obtain similar nasal morphologies as healthy, noncleft infants. Nonetheless, in this study, PNAM therapy made the subsequent nasal and lip reconstruction easier to perform. It should be considered a routine procedure in the treatment protocol for CLP

Conclusion

Presurgical nasoalveolar molding therapy is an effective procedure having significant advantages in the treatment of cleft lip and palate patients. It improves nasal symmetry and nasal projection by non-surgical elongation of deficient columella through cartilage molding and tissue expansion. PNAM also forces the protruded premaxillary segment into alignment with the dental alveolar segments, improving the shape of the maxillary arch.

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