REVIEW ARTICLE

# Pre Surgical Nasoalveolar Molding: Changing Paradigms in Early Cleft Lip and Palate Rehabilitation

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**ABSTRACT**

**Background:** Alveolar and nasal reconstruction for patients with cleft lip and palate is a challenge for the reconstructive surgeon. Various procedures have been attempted to reduce the cleft gap so as to obtain esthetic results post surgically. Yet there is need of continuous exploration of newer and better methods. Rehabilitation of cleft lip and palate generally requires a team approach with paedodontists playing a major role of performing nasoalveolar molding. Presurgical Nasoalveolar Molding (PNAM) was introduced to reshape the alveolar and nasal segments prior to surgical repair. Over the time there have been changes in the concepts of the same.

To assess these changing concepts a pubmed search was performed with different related terminologies and articles over a period of 30 years were obtained. Among the articles retrieved, studies performed over different concepts in early management of cleft lip and palate was selected for the systematic review.

**Aims:** This paper describes the changing paradigms in the management of patients with cleft lip and palate, focuses on the current concept of Presurgical nasoalveolar molding(PNAM) and discusses the long term benefits of the same.

**Conclusion:** The concept of the management of cleft lip and palate has changed over the time with more emphasis on the nasal and alveolar molding prior to the primary lip repair. This molding reduces the number reconstructive surgeries performed later for the purpose of esthetics.

**Keywords:** Cleft lip and palate, Nasal molding, Gingivoperiosteoplasty, Infant Orthopedics.

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## Background

Cleft lip and palate is one of the common facial deformities that not only affect the cosmesis but also affect the speech and hearing. Facial clefting is the second most common congenital deformity. Over the years various treatment modalities have been attempted in these patients so as to achieve satisfactory outcome. Surgical treatment of cleft lip and palate has been documented since 317AD, when Chinese General Wei Yang Chi had his cleft lip corrected by cutting and stitching the edges together. Since then various authors described the different surgical techniques for correction of cleft lip (Pierre Franco 1556, Ambroise Pare 1575, Tennison 1952, Millard's technique 1960). To further improve the esthetic result of lip repair, the concept of presurgical infant orthopedics was

developed. Presurgical infant orthopedics plays a significant role in neonatal cleft lip and palate treatment. Mc Neil articulated the modern concept of presurgical maxillary orthopedics in 1950 when he described the use of serial appliances to approximate alveolar cleft segment.

From Mc Neil's concept of alveolar molding to concept of nasoalveolar molding many changes have taken place in appliance designs. These appliances could be classified as – Active or Passive; Presurgical or Post surgical; and Intra oral or Extra oral (Huener and Liu 1993). Active appliances move alveolar cleft segments in a predetermined manner with controlled forces whereas passive appliances deliver no force but act as a fulcrum upon which forces created by surgical lip closure, contour and mold the alveolar segments in predictable fashion.

**Matsuo's concept**

According to Matsuo et al auricular cartilage could be molded with permanent results if treatment was started within 6 weeks of life. During this period there are high levels of maternal estrogen in the fetal circulation which triggers an increase in the hyaluronic acid. Hyaluronic acid alters the cartilage, ligament and connective tissue elasticity by breaking down intercellular matrix. Levels of estrogen start dropping at 6 weeks of age. Matsuo applied this concept for the correction of nasal deformities in cleft lip patients. It is on this principle that the concept of nasoalveolar molding works. It is also suggested that nasolaveolar molding stimulated immature nasal chondroblasts, producing an interstitial expansion that is associated with improvement in the nasal morphology (Chondral Modeling hypothesis, Hamrick 1999)[1,2].

**Objectives of Presurgical nasoalveolar molding:**

- Active molding and repositioning of the deformed nasal cartilages and alveolar processes.
- Lengthening of the columella
- Placement of the lip segments in a more anatomically correct position facilitating lip repair without scarring.
- Favors nasal correction. Forces exerted on nasal structures while performing alveolar molding permit straightening of columella and correction of alar cartilage displacement. Thereby reducing the number of nasal surgical procedures and improving nasal esthetics[3].
- It has also been suggested by Pritchard (1946) that bone healing was inversely proportional to the size of cleft viz larger the cleft slower is the bone healing. Hence presurgical naso alveolar molding is recommended to produce more favorable bone formation by reducing the size of the cleft[4].
- Reduces the need for secondary alveolar bone grafts

**Clinical characterization of the cleft area:**

The cleft lip and palate deformities are complex with the involvement of not only the palate and lip but also the nose. The shape of the nose gets affected in all the 3 planes of space. The deformity appears as distortion, displacement and tissue deficiency of nasal and maxillary structures. As quoted by Millard *"When the actual platform of the nose is cleft, the projection and the outward rotation of premaxilla and retroposition of the lateral maxillary element certainly guarantee that the nose will sit askew. Even when there is no bony cleft, the discrepancies in maxillary contour are responsible for some degree of nasal asymmetry. This is an architectural fact, for any structure, with one of its key legs shortened or pulled out from under, it must tilt."*

As a result following features can be seen clinically in Unilateral Cleft lip and palate:

- Premaxilla on the non cleft side is turned out.
- Lower lateral alar cartilages on the cleft side are abnormally stretched with inferior and medial rotation.
- Horizontal nostril aperture on the cleft side.
- Depressed cleft nasal dome.
- Distorted and short cleft columella
- Septum deviated towards the non cleft side.
- Orbicularis oris muscle in the lateral lip segments contracts into a bulge with some fibers running superiorly along the margin of cleft towards nasal tip.

Bilateral cleft lip and palate are typically characterized by shortened columella, premaxilla remaining suspended from the tip of the nasal septum with alveolar segments remaining behind and presence of stretched alar cartilages over the cleft[5].

**Concept of Gingivoperioplasty**

The surgical bridging of the cleft alveolar process with periosteal flap was initially described by Skoog (1965) as a means of stabilizing the separated segments of the maxilla. It has been suggested by Skoog that repair of the cleft lip is incomplete without the simultaneous reconstruction of bone defect of the maxilla by gingivoperioplasty, as there will be risk of collapse of the lateral segments of the maxilla due to the pressure exerted by the repaired lip. Furthermore it is suggested that it coordinates the growth at the growth centers as the maxillary discontinuity is restored[6,7]. However, controversies exist regarding the conduct of gingivoperioplasty in cleft patients because of its potential to impair maxillary growth. It is important to recognize that the state of art of gingivoperioplasty has changed since the time of its introduction by Skoog in 1967.

Skoog's technique necessitated wide mucoperiosteal dissection to mobilize the flaps enough to allow for approximation of cleft alveolus as he did not perform pre surgical nasoalveolar molding. Current technique of gingivoperioplasty introduced by Millard and Latham (1990) is performed after the patients undergo presurgical orthopedic closure of the cleft alveolar gap. Strict association of presurgical nasoalveolar molding and alveolar gap closure allow gingivoperioplasty to be performed. Studies have indicated that there is no need for alveolar bone graft if gingivoperioplasty is performed in the infancy. Also it has been indicated that there is greater cost savings in patients undergoing nasoalveolar molding combined with gingivoperioplasty as there is no need for further bone and nasal revision surgeries [Pfeifer et al 2002][8]. Several studies have shown high osteogenic potential of periosteum depositing bone without subsequent resorption in the patients undergoing gingivoperioplasty procedure [Ritsila et al 1972, Smith et al 1995][9,10]. However some other studies have quoted higher frequency of anterior crossbite in patients treated with gingivoperioplasty. Anterio posterior distance was also found to be reduced in maxilla[11]. Similar results were obtained by Berkowitz et al [12] and Hsieh et al [13]. Hence more long term studies might be required to assess the effect of gingivoperioplasty in cleft patients. However the following advantages of gingivoperioplasty exists:

- Provides stability for the jaw as a whole and provides more anatomical conditions for growth.
- Helps in fistula closure.
- Establishes intact maxillary dental arch at an early age.

- Facilitates correct eruption path of the permanent teeth
- Avoidance of bone graft hence avoidance of traumatic injury of the donor site.

**Concept of Nasal Molding**

In the treatment of cleft lip nasal deformity, the correction of nose continues to be the greatest challenge. In patients with unilateral cleft lip/ palate, the nasolabial defect influences the physical appearance of the child. Hence it is recommended to perform nasal molding prior to primary lip repair. Considering that nose is an important component of facial esthetics, correction of nasal symmetry and nasolabial fold is an important objective of nasoalveolar molding. According to Millard (1984) clefting is due to disturbance of embryogenesis and proper closure of all involved structures should be achieved as soon as possible to favor normal growth of the face. Several approaches have been used in order to reduce the nasal asymmetry early in life using surgery alone or in conjunction with other approaches. Matsuo et al designed a nasal stent for the correction of the nasal deformity. However a drawback of this stent was that it required an intact nostril floor. In the cases without nasal floor, Matsuo performed primary lip adhesion to make stenting possible. Another modification as suggested by Grayson was addition of nasal stent in the alveolar molding plate. This did not require the presence of intact nasal floor and as the stent was added to the plate, controlled force could be exerted. Modified extra oral nasal molding appliance was suggested by Doruk C et al (2005). The advantage of this appliance was that there was no need for nasal impressions and same appliance could be used for different patients after sterilization[14].

Various studies have been conducted to assess the nasal changes after presurgical nasoalveolar molding. Studies performed by evaluating the casts after nasoalveolar molding revealed that this therapy significantly improved the nasal symmetry. Columella deviation, length and width were also significantly improved (Spengler AL et al 2006)[15]. Similar results were obtained by Pai et al who performed the evaluation based on the photographs of the patient. However some amount of relapse of the nostril width, height and angle of columella were observed at 1yr of age[16]. Study conducted by Maull et al (1999) to determine changes in three dimensional shape of the nose after nasoalveolar molding also showed improved symmetry of the nose[2]. However, early primary rhinoplasty procedures initially yielded good results, but return of original deformity soon followed. This was due to the inherent dysmorphology of the nasal cartilages and due to the contractures after surgical repair. Hence to prevent this post surgical nasal stents have been recommended. Koken nasal splints which are commercially available can be used to prevent post surgical relapse. Modification of this splint has been suggested by Cobley et al (2000)[17] which could allow the stent to be removed and cleaned to maintain hygiene and also maintain the airway patent.

However very young patients have difficulty in tolerating such devices in which cases nasal splints can be recommended at the age of 4 or 5years when the child is more cooperative. One such appliance is dynamic nasal splint suggested by Cenzi R and Guarda L. This splint acts by applying gradual orthopaedic action. This splint consists of an expansion screw which is to be worn for 40 – 60 days for 15-18hours/day. Later the appliance is kept inactive without activating for a period of 3-4months. This is generally recommended after 4-5yrs of age when the patient is cooperative and accepts the nasal splint[18].

**Concept of Alveolar Molding**

The presurgical alveolar molding protocol for cleft patients has been described by Grayson et al (1993). In this protocol a conventional intra oral molding plate is fabricated after making the intra oral impressions. The molding plate is modified at weekly intervals. The modification is done by 0.5 – 1mm increments. The appliance is selectively grinded in the areas were movement is expected at the same time soft denture liner is added in the region which require molding. This is similar to Zurich type of molding device described by Hotz (1969). The soft denture liner applies pressure on the alveolar ridge. The effectiveness is enhanced by lip taping. The lip taping produces controlled orthopaedic force which helps the molding plate to guide the alveolar segments in position. Various studies have been conducted to evaluate the effect of nasoalveolar molding. Study conducted by Ezzat et al has shown statistically significant reduction in the intersegmental distance i.e in the cleft gap. At the same time it was found that the arch was not collapsed as there was an increase in maxillary arch width[19]. Bongaarts et al[20] reported Infant orthopedics does not have any influence on the maxillary arch dimensions. Study conducted by Spengler et al on bilateral cleft lip and palate patients has shown that there significant improvement in the nasal symmetry. It was also found that nasoalveolar molding forces the protruded premaxillary segment into alignment with dentoalveolar segments, thereby improving the shape of the arch[14]. Three dimensional analysis of effect of alveolar molding was done by Baek et al (2006). The results of the study suggested that the cleft gap was significantly reduced. It was also found that alveolar molding took place mainly in the anterior alveolar segment and growth occurred mainly in the posterior alveolar segment[21]. Table 1 describes the review of the various studies conducted.

The timing of repair of the defect also plays an essential role. As described by Matsuo, the earlier the intervention is initiated the better are the results. A study was conducted by Shetty V to evaluate the effect of nasoalveolar molding at different ages. The results of the study indicated that favorable outcome was obtained when the treatement was intiated within 1 month of life however positive outcome was also achieved when the treatment was initiated within 5months of life but to a lesser extent[22].

Although all studies evaluating the effect of nasoalveolar molding have shown significant improvement in the result, but the drawbacks of these studies are that they are performed on a smaller population group and they lack a control group i.e the subjects who do not undergo alveolar molding. Also long term effects of nasolaveolar molding have not been evaluated. Hence further studies are required to conform the long term effects of naso alveolar molding.

**Complications of Pre Surgical Naso Alveolar Molding**

Pre surgical naso alveolar molding is most effective with full time wear. However, full time wear can be associated with certain complications like ulceration, tissue irritation and fungal infections and bleeding. Soft tissue ulcerations can be due to excessive activation or due to pressure from the molding plate. These ulcerations heal with the selective trimming of the molding plate. Improper maintenance of the hygiene with the full time wear of molding plate can also result in fungal infection. This can be treated by Nystatin or Amphotericin. However the Nasoalveolar molding therapy should continue during the treatment phase. Another common complaint with nasoalveolar molding is rash like area of erythema and chafing on the zygomatic process areas due to extraoral taping. These are generally self limiting. The best way to prevent these rashes

is to wet the tape thoroughly before removal of the same.

Excessive pressure on the nasal cartilage can result in meganostril. This occurs due to excessive increase in the circumference of the nostril due to improper stent positioning or nasal overcontour-

**Table 1: Review of studies of cleft lip and palate treated with Pre Surgical Nasoalveolar Appliance**

| Author | Year | Design of Study | Aim of Study | PNAM | Effect of Nasal Molding | Effect of Alveolar Molding |
|---|---|---|---|---|---|---|
| Smahel et al[7] | 1988 | Cross sectional cohort | Growth and development of face at 10 yrs of age treated with primary cheiloplasty with periosteoplasty and palatoplasty. This group was compared with children treated without periosteoplasty but with bone grafting and children treated without periosteoplasty and bone grafting. | Not performed | Not evaluated | Comparison of the 3 techniques disclosed that subsequent jaw development was more advantageous with after primary periosteoplasty and least favorable after bone grafting. Facial changes consisted of milder retrusion of upper jaw, maintenance of overjet and more satisfactory prominence of upper lip. |
| Maull et al[1] | 1999 | Retrospective study. | Effect of presurgical molding on long term nasal shape in complete unilateral cleft lip and palate | All subjects underwent presurgical orthopedic treatment for 4 months | Presurgical nasoalveolar molding statistically increases the nasal symmetry | Not evaluated |

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|---|---|---|---|---|---|---|
| Pai et al[16] | 2005 | Prospective study | Assess nostril symmetry and alveolar cleft width in infants with unilateral cleft lip and palate | All subjects underwent naso alveolar molding till 4 months of age | PNAM improved symmetry of nose in width, height and columella angle as compared to presurgical status. | Not evaluated |
| Singh et al[3] | 2005 | Prospective longitudinal study | Evaluate 3Dimensional changes in nasal morphology in patients with unilateral cleft lip and palate | All subjects underwent naso alveolar molding till 4 months of age | NAM significantly increased the nasal symmetry. However slight overcorrection of the alar dome on the cleft side was recommended to maintain the NAM results. | Not evaluated |
| Spengler et al [15] | 2005 | Prospective study with blinded measurement | Evaluate the effect of PNAM in bilateral cleft lip and palate patients. | PNAM was started at 34 days and the average length of the treatment was 212 days | Significant increase in the bialar width and columellar length and width. Significant improvement in columellar deviation was also observed. | Significant reduction in the premaxillary protrusion and deviation. Significant reduction in the width of the larger cleft was also observed. |

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|---|---|---|---|---|---|---|
| Baek et al[21] | 2006 | Prospective study | Evaluate alveolar molding effect and growth in unilateral cleft lip and palate patients using 3D analysis | Average duration of PNAM therapy was 13 weeks | Not evaluated | Alveolar molding effects took place mainly in the anterior alveolar segment and growth took place mainly in posterior alveolar segment and palatal segment. |
| Bongaarts et al[20] | 2006 | Prospective two-arm randomized controlled clinical trial | Evaluation of effect of infant orthopedics on maxillary arch dimensions | Infant orthopedics performed with passive plate which were adjusted every 3weeks. The appliance was continued till the soft palate surgery | Not evaluated | Infant orthopedics does not have any influence on the maxillary arch dimensions. |
| Ezzat et al[19] | 2007 | Prospective study with blinded measurement | Evaluate the effect of PNAM in non syndromic patients | PNAM therapy started at 26th day and continued for 110 days. | Nasal symmetry was increased by decreasing columellar deviation, increasing nostril height, maintaining bialar width of the nose, and increasing columellar width | Decrease in the intersegment alveolar cleft distance while permitting an increase in posterior arch width |

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|---|---|---|---|---|---|---|
| Hsieh et al[13] | 2010 | Retrospective study | Evaluate the effect of gingivoperioplasty on facial growth | PNAM therapy was followed by Gingivoperio-plasty | `Not evaluated | In unilateral cleft lip and palate patients, the saggittal growth of the maxilla would be affected more adversely in the group treated with gingivoperiopl-asty. |
| Shetty V et al[22] | 2012 | Longitudinal follow up | Evaluate the effect of timing of initiation of the nasoalveolar molding | In one group NAM was initiated within 1 month and in another group NAM was initiated within 1-5 months | Performed | The study concluded that the effect of NAM on nasoalveolar morphology were more significant before 1 month of age. However the patients who presented late for the treatment also benefitted but to a lesser extent. |

-ing. Controversies exists over the correction to compensate for the relapse. One group suggests slight orthopedic over correction of the alar dome (Singh et al 2005)[3] while other group suggested vertical surgical nasal overcorrection (Liou E et al 2004)[23]. However application of over activation should be avoided which may be seen clinically as external bruising or petechiae in the area of insult. Hard tissues complications associated with nasoalveolar molding include excessive rotation of the lesser segment to meet the greater segment in a perpendicular manner, resulting in asymmetric T shaped configuration. Hence proper care should be taken to modify and monitor the segment movement. Another hard tissue complication involves eruption of the teeth. This could be due to the pressure exerted on the gingival tissues by the molding appliance. Modification of the appliance can be done to allow for favorable eruption of the teeth.

**Conclusion**

Though surgical procedures have been the key element in cleft lip and palate rehabilitation, the nasoalveolar molding techniques have made the rehabilitation much more reliable and physiologically apt. The malleability of the para oral structures are utilized by selectively controlling their growth patterns at an early age with the use of naso alveolar molding techniques. Such approaches of molding the nasal cartilage, premaxilla and alveolar ridges in the neonatal period adjuncts the surgical procedures and results in better esthetics and reliable long term results. Based on the literature review, the nasal molding seems to be more beneficial and effective with better long term results. However the effect of alveolar molding needs to be studied further to assess the long term beneficial effects. More favorable results were obtained when gingivoperiosteoplasty was performed along with primary lip repair. Hence it can be concluded not only interdisciplinary approach but also thorough knowledge of the changing concepts of the nasoalveolar molding and timing of the initiation of the same is essential for early and successful rehabilitation of the cleft lip and palate.

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