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Changing paradigms in early cleft lip and palate rehabilitation by presurgical nasoalveolar moulding therapy in a newborn infant: A review

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Abstract
Cleft lip and palate is one of the most common congenital anomalies requiring multidisciplinary care. Cleft of the lip and palate is one such condition that occurs at such a strategic place in the orofacial region and at such a crucial time that it becomes a complex congenital deformity. The nasoalveolar moulding (NAM) technique is a new approach to presurgical infant orthopedics that reduces the severity of the initial cleft alveolar and nasal deformity. This technique facilitates the primary surgical repair of the nose and lip to heal under minimal tension, thereby reducing scar formation and improving the esthetic result. Pediatric dentist has a vital role to play right from the neonatal period up to phase of permanent dentition. This paper reviews the basic principles of NAM therapy, appliances used in this therapy and the protocol followed in this technique. In the present review article we carried an extensive review of the literature found in Index Copernicus, SCOPUS, PubMed, and Cochrane Library.

Keywords: Cleft lip, cleft palate, nasoalveolar moulding, infant orthopedics and orofacial health

Introduction
Cleft lip and palate though treatable; it has a great negative social impact on the patient as well as his/her family. So, it is high time to get involved and to provide complete rehabilitation to such children as every child had the fundamental right to his total oral health and every pedodontist has an obligation to fulfill this faith. The incidence of cleft lip and palate varies from 0.5 to 3.63 per 1000 live births and factors responsible for development of cleft lip and palate are genetic, environmental and geno-environmental interactions. In addition to this, infections during pregnancy and parental age play a vital role in etiology of CLCP [1]. Out of the several genes discovered recently, three of them, namely, the T-box transcription factor-22 gene, poliovirus receptor-like-1 gene, and interferon regulatory factor-6 (IRF6) gene are responsible for causing X-linked cleft palate (syndromic cleft), cleft lip/palate (CL/P)-ectodermal dysplasia syndrome, Van der Woude syndrome (VWS), and popliteal pterygium syndrome, respectively. These genes are also implied in nonsyndromic CLCP. Nonsyndromic cleft lip with or without cleft palate is seen with highest prevalence rate in Asian races and lowest in African populations [2]. Shaw *et al*. presented evidence that women above the age of 35 had a doubled risk of having a child with CLCP, above 39 had a tripled risk. Consanguineous marriages have an increased risk of CLCP in children [3]. Cleft lip can be easily diagnosed by performing ultrasonography in the second trimester. Detection rates in cleft lip in low-risk populations vary between 16% and 75% with two-dimensional ultrasound. The use of three-dimensional ultrasound of the face improves detection rate significantly [4]. Once CLCP is identified, family should be referred for genetic counseling to discuss other tests including amniocentesis.

Children may have hyper nasal speech which is difficult to understand as a result of velopharyngeal insufficiency. Many young children with clefts will exhibit shy, nervous, or uncooperative behavior. Bone support for these teeth is generally poor. Teeth that are present may be malformed and prone to caries. Parents appreciate education about teeth present or missing, surrounding a cleft. Simple explanations about the variability of teeth at the cleft site

may allay concerns. Panoramic and/or Occlusal radiographs are indicated to monitor development. The majority of children with a cleft palate will require orthodontics. Orthodontic treatment may be required in the primary, mixed, and permanent dentition [5].

The concept of presurgical orthopedic cleft molding was developed to further improve the esthetic result of lip repair. Use of presurgical orthopedics is recorded as early as the 18th century. The 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 CL patients. It is on this principle that the concept of nasoalveolar molding (NAM) works [6]. It is also suggested that NAM stimulated immature nasal chondroblasts, producing an interstitial expansion that is associated with improvement in the nasal morphology (Chondral Modeling Hypothesis, Hamrick 1999). Grayson and Shetye developed the concept of NAM, which combined a nasal molding stent with a passive, presurgical molding appliance in treating CLCP infants [7].

Development

By the end of the 4th week in gestational period of human embryo, bilateral swellings and nasal placodes develop on the lower part of the frontonasal prominence. The medial and lateral nasal prominences develop as peripheral thickenings of the mesenchymal tissue of the nasal placodes, producing two central depressions, and the nasal pits. Failure of the nose to develop completely is associated with failure of the nasal placodes to develop. Between the 4th and 8th weeks, the paired medial nasal prominences fuse with each other, with the paired lateral nasal prominences, and with cells in the maxillary prominences. Successful fusion of the medial nasal and maxillary prominences is essential for continuity of the upper lip and primary palate. Failure of fusion of one or both medial nasal and maxillary prominences results in unilateral or bilateral CL, respectively. As the face nears the completion of the "developmental critical period", from approximately the end of the 6th-8th intrauterine week, the lateral palatine processes grow out from the walls of the still common oronasal cavity. Growth of these paired processes is initially medial, but continues inferolaterally to lie on either side of the developing tongue. Nearing the 8th week, palatal shelf elevation begins while the tongue is depressed downward and forward. Once in contact, epithelial cells of the palatal shelves degenerate by programmed cell death uniting the paired processes in a process known as fusion. Once fusion of the shelves of the secondary palate occurs, the mesenchymal cells differentiate, and become osteogenic cells contributing to the bony development of the premaxillary, maxillary, and palatine portions of the palate. CP results from the failure of fusion of these paired lateral palatine processes as a result of a defect in any of the three major stages of palatal formation — palatal shelf outgrowth, elevation, or fusion [8].

Unilateral complete clefts are characterized by disruption of the lip, nostril sill, and alveolus (Complete primary palate). The deformities seen in relation to CL in these cases are cupids bow more or less clearly defined, philtral ridge is ill-defined if not absent, abnormal shortness of the lip compared with its height on the normal side, fernum of the vermilion is often hypertrophied, depth of vestibular sulcus can be outlined only on noncleft side, the cutaneous portion of the lip is often convex in both vertical and horizontal directions as the underlying muscles which have lost their medial insertion tend to draw up into ball of fibers. Nasal deformities associated are flattening and widening of the nostril aperture on cleft side, the columella is slanted towards the affected side, the alar base is slightly everted, the anterior nasal spine deviated towards normal side, and tip of the nose is slightly asymmetrical.

In bilateral CLP cases, the cupid's bow is generally absent and the cutaneous portion often appears as a convex surface shaped like a lens. There is no trace of philtral ridge and the prolabium is usually devoid of properly developed muscle fibers. The nasal deformities seen are nasal tip flattened and widened, the columella seems too short, and septal cartilage is often underdeveloped. At the time of birth, the premaxilla protrudes on a vomerine stem. Uncontrolled growth at the premaxillary suture results in over projection of the premaxilla, with or without rotation, and angulation of the segment. Just as the premaxilla is not reined back by the lateral palatal shelves, the lateral palatal shelves are not pulled forward by their attachment to the premaxilla. Without the intervening premaxilla to maintain arch width, the lateral palatal shelves collapse toward the midline [9]. The severity of this disruption of arch morphology varies and will dictate the tension on the repair, the degree of dissection required, and ultimately, the final esthetic result unless it is corrected with presurgical orthopedics.

Role of pedodontists

- Nasoalveolar moulding,
- Provide assistance to maintain healthy dentition and gums,
- Monitor the craniofacial growth & development,
- To correct jaw relationship & dental occlusion and
- Finally to achieve optimal functional occlusion, appearance & stability.

Objectives of NAM

Presurgical NAM works on the principle of 'negative sculpturing' and 'passive molding' of the alveolus and adjacent soft tissues. In passive molding, a custom-made molding plate of acrylic is used to gently direct the growth of the alveolus to get the desired result later on. While in negative sculpturing serial modifications are made to the internal surfaces of the molding appliance with addition or deletion of material in certain areas to get desired shape of the alveolus and nose.

Principal objective of presurgical NAM is to reduce the severity of the initial cleft deformity which is achieved by active molding and repositioning of the deformed nasal cartilages and alveolar processes.

- Nonsurgical lengthening of the columella.
- Approximation of lip segments to reduce tension in the tissues after lip repair and thus reduce scarring.
- Presurgical NAM is recommended to produce more favorable bone formation by reducing the size of the cleft and improving nasal esthetics.
- Reduces the need for secondary alveolar bone grafts.

Treatment phases

Phase 1	Pre anesthetic evaluation and Impression making
Phase 2	Fabrication and delivery of NAM plate Proper instruction to parents
Phase 3	Activation of the plate followed by stent fabrication
Phase 4	Activation of appliance until PNAM objectives are achieved
Phase 5	Surgical phase

Impression making

The parents are councilled about the procedure before starting the NAM. It has been reported that various impression techniques were followed in presurgical NAM therapy. Grayson and Shetyon held the infant upside down while taking the impression. The impression is made by loading the tray with a thick mix of tissue conditioning material and inserted intraorally, while the baby is held with face towards the floor, in order to prevent aspiration in the event of vomiting and asphyxia due to airway obstruction. Monitor the baby's oxygen level throughout and ensure that the baby is making suckling motions, for this will create the desired border molding, and ensure the baby's ability to perform nasal breathing. Before impressions, child is kept nil orally for about 4 hours. Prasanth *et al*, and Retnakumari *et al*., used heavy body silicone impression material for taking impression, and the infant was kept in supine position during the procedure. Dubey *et al*., kept the baby in mother's lap with head facing downward and her hands supporting baby's chest and lap region while making the impression. Yang *et al*, took alginate impressions using a pretrimmed customized pediatric tray. Utility wax was employed to avoid any sharp edges on the tray and to better adapt to the newborn's mouth. The impression was taken with the baby in the most upright position, being held by one of the parents Karimi *et al*., using red impression compound to take the preliminary impression. Splengler *et al*., took intraoral and extraoral alginate impression with the patient under general anesthesia. This method is generally not recommended as the patient is subjected to hospitalization for an impression procedure [10].

Councilling of parents

Impression making

Steps for making impression trays

- Make the first impression by moulding impression compound in baby's mouth.
- Make holes in impression compound.
- Take the primary impression by rubber base.
- Pour cast and make an accurately fitting impression tray.

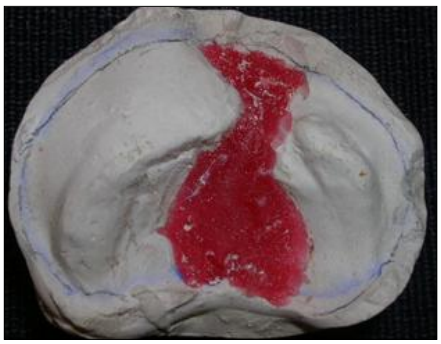
Primary Impression

Alternate method

- Once you have a set of trays
- Select an approximately fitting tray make the primary of rough impression.
- Pour cast and make the final impression tray.
- Take final impression

Making Models and Blocking the Undercuts

The moulding plate is fabricated on the dental stone model. All the undercuts and the cleft space are blocked with and the cleft space are blocked with wax. The plate is made up of clear selfcure acrylic. The plate must be 2-3 mm in thickness to provide structural integrity and to permit adjustments during the process of molding.



Stone model with blocked undercuts

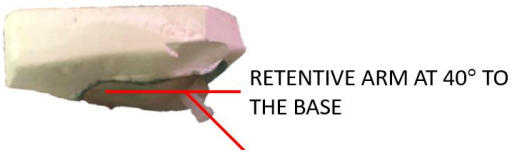
Armamentarium for the fabrication of NAM plate:

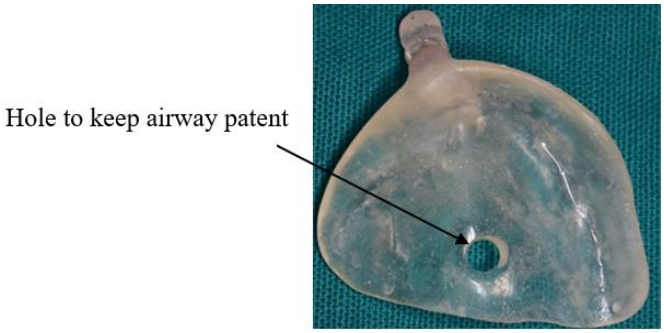
- Self-Cure Acrylic
- GC Relining Resin
- Steristrip Tapes ¼ X4inch

- Steristrip Tapes ½ X4 inch
- Tegaderm or Micropore Tapes.
- Three Prong Plier
- Universal Plier
- 3/16 Settling Elastics (RED)
- 0.8 Mm Or 0.9 Mm Hard Wire
- Straight Bur For Acrylic Trimming

The NAM plate described by Grayson is made up of hard, clear self-cure acrylic and is trimmed with a denture soft material. A retention button is fabricated and positioned anteriorly at an angle of 40 degree to the plate.

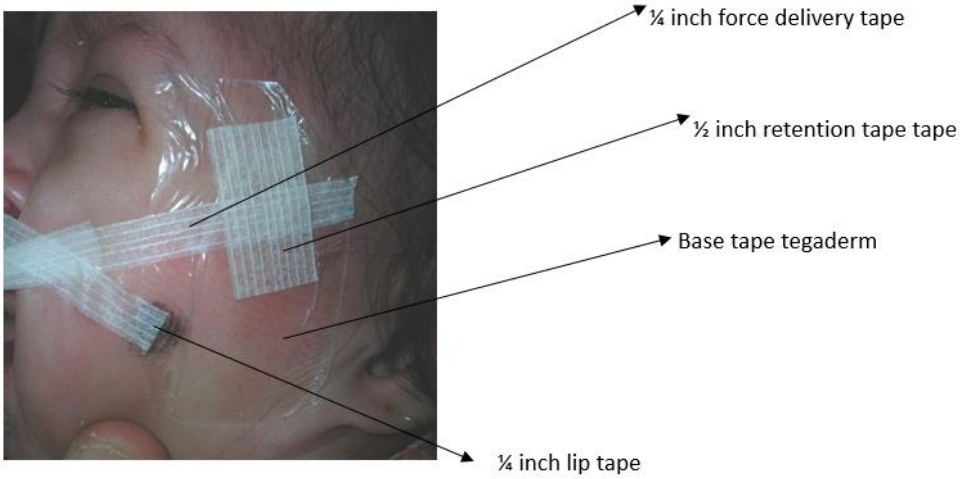
The vertical position of the retention arm should be at the junction of the upper and lower lip. The retention button adequately secures the molding plate in the mouth with the help of orthodontic elastics and tapes. A small opening measuring 6-8 mm in diameter is made on the palatal surface of the molding plate to provide an airway in the event that the plate drops down posteriorly [11].





Insertion of Nam appliance

The NAM appliance is secured extraorally to the cheeks and bilaterally by surgical tapes with orthodontic elastic bands at one end. The elastic on the surgical tape is looped on the retention arm of the molding plate and the tape is secured to the cheeks. The elastics (inner diameter 0.25 inch, wall thickness heavy) should be stretched approximately two times their resting diameter for proper activation force of about 100 g. The amount of force could vary depending on clinical objective and the mucosal tolerance to ulceration. Additional tapes may be necessary to secure the horizontal tape to the cheeks [12].



It is worn 24 hours a day and is removed only for feeding. The desired movement can usually be accomplished within 6 to 8 weeks. The infant may require time to adjust to feeding with the NAM appliance in the first few days. The baby is seen weekly to make adjustments to the molding plate. These adjustments are made by selectively removing the hard acrylic and adding the soft denture base material to the molding plate. At one visit not more than 1 mm of modification of the molding plate should be made.

Incorporation of nasal stent

A silicone nasal conformer suggested by Matsuo and Hirose can be used as a tool for presurgical nasal molding. The height of the conformer can be adjusted by gradually adding some soft resin or flat silicone sheets on the domes. It can be used for presurgical elongation of the columella in incomplete clefts or postoperative maintenance of the nostril configuration. Blanching occurs at the nasal tip as infant suckles and activates the appliance. It also exerts a reciprocal intraoral molding force against the alveolar segments [7]. There are some limitations in this method. These include the need for an intact nasal floor (Simonart's band or lip adhesion) and the inability to direct the force because the stent expands circumferentially. Grayson and Shetye adapted nasal stent to extend from the anterior flange of an intraoral molding plate. The greatest advantage of NAM is that it enables the practitioner to apply force skillfully to shape the nasal cartilage.

The stent is made up of 0.36 inch, round stainless steel wire, and takes the shape of a 'Swan Neck'. The hard acrylic component is shaped into a bilobed form that resembles a kidney. A layer of soft denture liner is added to the hard acrylic for comfort. The upper lobe enters the nose and gently lifts forward the dome until a moderate amount of tissue blanching is evident. The lower lobe of the stent lifts the nostril apex and defines the top of the columella. The nasal stent component of the NAM appliance is incorporated when the width of the alveolar gap is reduced to about 5 mm. The rationale for delaying the addition of the nasal stent is that as the alveolar gap is reduced, the base of the nose and the lip segment alignment is also improved. The alar rim, which at birth was stretched over a wide alveolar cleft deformity, will show some laxity; and with the nasal stent, this can be elevated into a symmetrical and convex form.

In Figueroa's technique, alveolar and nasal molding are performed simultaneously using an acrylic plate with rigid

acrylic nasal extension. Rubber bands are connected to the acrylic plate for gentle retraction of the premaxilla backward [14-18]. A soft resin ball attaching to the acrylic plate across the prolabium is sometimes used to maintain the nasolabial angle. In bilateral cases, there is a need for two retention arms as well as two nasal stents which are similar in shape to the unilateral stent [19-21].

Shetty *et al*., used the following protocol for presurgical NAM therapy:

First visit:

Parent education and counseling: Use of audiovisual aids and live demonstrations

- Interaction with parents of older NAM patients
- Diet counseling

Detailed documentation:

- Photographs — standard 1:1 ratio frontal and basilar view
- Dentofacial impressions
- Medical evaluation of patients

Demonstration of Home Care Instructions

- Daily appliance care
- Awareness about possible complications and their management

Telephonic correspondence after 2 days to ascertain parent and patient compliance.

Second visit (1 week subsequent to first visit): Evaluation of patient and parent compliance.

Detailed documentation

- Photographs-standard 1:1 ratio frontal and basilar view
- Dentofacial impressions
- Compatibility of appliance and required modifications
- <8-10 mm intersegment distance - initiate NAM
- >8-10 mm intersegment distance - aggressive alveolar molding

Recall visits every 3 weeks: Evaluation of patient and parent compliance.

Detailed documentation

- Photographs - standard 1:1 ratio frontal and basilar view
- Alveolar surface impressions.
- Dentofacial impressions recorded prior to primary lip repair

Treatment outcome and assessment

- Compatibility of appliance and required modifications
- Nasal molding started at the earliest and continued till completion
- Active alveolar molding continued till completion
- Passive alveolar molding started once complete approximation of alveolar segment achieved
- Fabrication of new appliance every 2 months
- Parents participation in periodic NAM workshops

Care and instructions

- Washing of plate should be with warm water
- Never use brush to clean the plate that will damage the resin
- Never drop the plate.
- Clean after every feeding to avoid fungal infection
- Feed the baby at upright position not sleeping

Trouble shooting for parents

- In case of rash –discontinue plate –apply cream – continue plate wearing
- In case of gag inform doctor
- In case of incessant crying –discontinue plate
- In case of bleeding areas discontinue plate –inform doctor

Problems

- Gag – trim posterior ends
- Bleeding—trim sharp ends
- Bleeding from skin– stop wear of plate –use soothing lotions
- Plate gets dislodged – reduce force or change direction of tapes change angulations of handle.
- Baby dislodges the plate by tongue – flatten the palatal surface so that the tongue does not get a grip.

Conclusion

NAM technique has been significantly shown to improve the surgical outcome of CLP patients compared with other techniques of presurgical orthopedics. NAM should be considered soon after birth to promote a physiological pattern of function, which eventually sets the course for the functional patterns in later life. PNAM, when performed prior to primary lip repair, will give psychological reassurance to parents, enhance surgical outcome, reduce the need for soft-tissue revision surgeries later and also reduce the overall cost of treatment.

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