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Presurgical Nasoalveolar Molding (PNAM) for a Unilateral Cleft Lip and Palate: A Clinical Report

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Keywords
Unilateral cleft lip and palate; nasal stent; extraoral retentive button; columella- philtrum.

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The authors deny any conflicts of interest.

Accepted February 25, 2012

doi: 10.1111/j.1532-849X.2012.00891.x

Abstract

Cleft lip and palate deformity is a congenital defect of the middle third of the face. Incidence varies from 1:500 to 1:2500 live births. Etiology depends upon hereditary and environmental factors. Restoration of these defects is important not only for functional and esthetic reasons, but also because there may be a positive psychological impact for the patient and parents. The goal of primary closure of the lip for unilateral cleft lip is to ensure a normal and symmetrical lip and nose. Presurgical infant orthopedics has been employed since the 1950s as an adjunctive neonatal therapy for the correction of cleft lip and palate. Presurgical nasoalveolar molding (PNAM) represents a paradigm shift from the traditional methods of presurgical infant orthopedics. PNAM consists of active molding of the alveolar segments as well as the surrounding soft tissues. This clinical report describes a new approach of PNAM therapy for an infant with complete unilateral cleft lip and palate showing significant reduction in cleft defect size and improved contour and topography of deformed surrounding soft tissues.

Cleft lip and palate deformity is a congenital defect of the middle third of the face. Incidence varies from 1:500 to 1:2500 live births. Etiology depends upon hereditary and environmental factors.[1] Cleft lip and palate can arise with considerable variation in severity and form. Wider and extensive clefts are associated with significant nasolabial deformity. The unilateral cleft lip deformity is characterized by a wide nostril base and separated lip segments on the cleft side. The affected lower lateral nasal cartilage is displaced laterally and inferiorly resulting in a depressed dome, an oblique columella, the appearance of increased alar rim, and an overhanging nostril apex.[2] If associated with cleft palate, the nasal septum deviates to the noncleft side with a shift of the nasal base.[2] Although advances in reconstructive surgery have significantly improved the quality of repair for clefts of the lip, alveolus, and palate, surgery alone cannot correct all aspects of the cleft defect. When standard surgical approaches are used to repair deficiencies in the lip, columella, and philtrum, the result is often severe scarring of the nasolabial complex. The unilateral cleft lip and palate defect will yield a less than ideal result when addressed only through surgical correction. The basic goal of any approach to cleft lip, alveolus, and palate repair is to restore its normal anatomy. Ideally, deficient tissues should be expanded, and malpositioned structures should be repositioned before surgical correction that will provide the foundation for a less-invasive surgical repair.[3] Grayson et al first developed presurgical nasoalveolar molding (PNAM) at the Institute of Reconstructive Plastic Surgery, New York University Medical Center. PNAM consists of selective repositioning by active molding of the alveolar segments and deformed nasal cartilages as well as lengthening of the deficient columella.[4] The original research on neonatal molding of nasal cartilage was performed by Matsuo et al.[5-8] The objective of PNAM is to reduce the severity of the intraoral cleft deformity and actively mold and position the surrounding tissues before surgical intervention. PNAM enables the surgeon and patient to enjoy the benefits associated with repair of the cleft deformity but results in less postsurgical scarring. The nasoalveolar molding technique has been shown to significantly improve the surgical outcome of the primary repair of cleft lip and palate compared to traditional approaches of presurgical orthopedic techniques.[9]

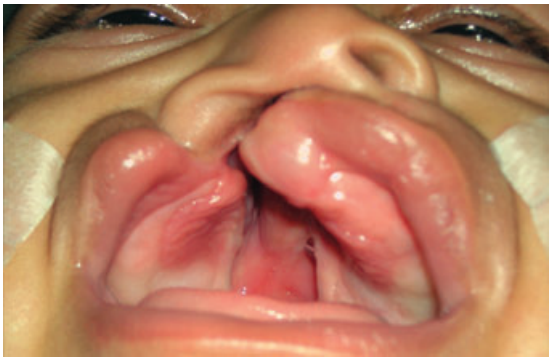

Figure 1 Pretreatment view (age: 2 days).

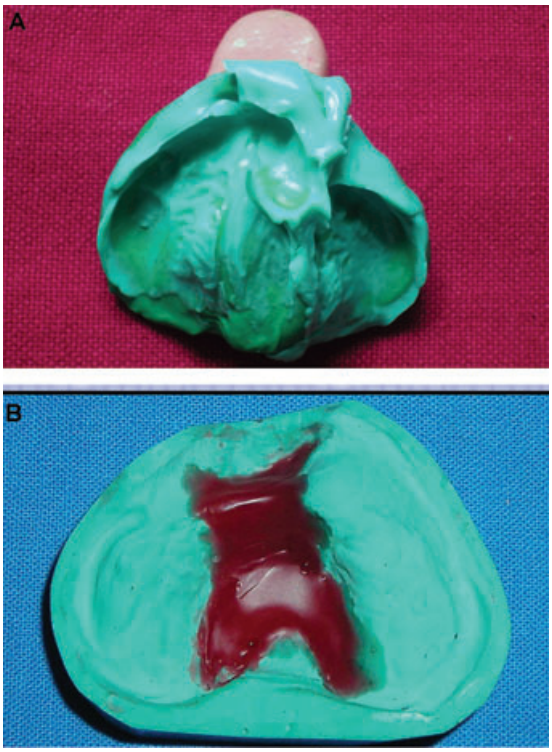

Figure 2 (A) Impression of unilateral cleft defect; (B) undercut block-outs and development of arch form in baseplate wax.

Clinical report

Case history, examination, and diagnosis

A 2-day-old infant suffering from complete unilateral cleft lip and palate (right side) was presented to the Department of Prosthodontics at Government Dental College and Hospital, Nagpur, India, for evaluation and treatment. A general physical examination was carried out under the supervision of the physician, and consent was obtained to start the molding procedure in the first week of birth. A cleft defect was examined for the presence of natal teeth, unusual undercuts, and other tissue abnormalities. The distance between the two alveolar segments was 12 mm (Fig 1).

Figure 3 Extraoral retentive button secured to labial flange of appliance at 40° angle to the occlusal plane.

Impression, working cast, and fabrication of oral molding appliance

Following evaluation and a thorough explanation of the treatment goals and the procedure to the parents, an impression of an intraoral cleft defect was made using a low-fusing impression compound (Aslate Soft Green Tracing Sticks; Asian Acrylates, Mumbai, India) followed by wash impression with light-body elastomeric impression material (Aquasil XLV; Dentsply, York, PA) in an acrylic tray (Fig 2A). With the infant fully awake and without any anesthesia in a clinical setting prepared to handle an airway emergency with a surgeon present as a part of the impression team, the impression was obtained.[10,11] The infant was held in an upside down position by the surgeon, and the impression tray was inserted into the oral cavity. The tray was seated until the impression material was observed just beginning to extrude past its posterior border. During impression making, the infant was held in an inverted position to keep the tongue forward and to allow fluids to drain out of the oral cavity. Once the impression material was set, the tray was removed, and the oral cavity examined for the residual impression material in the cleft region. An impression was carefully poured in type III gypsum product (Kalstone; Kalabhai Karson Pvt. Ltd, Mumbai, India), and the cast was recovered. The size of the cleft defect was measured at the base of the alveolus on the cast using a vernier caliper (Digital Vernier Calliper; Sealy Power Products, Suffolk, UK) and was found to be 12 mm. The cleft region of the palate and alveolus was filled in with baseplate wax (Modeling wax; Deepti Dental Products, Ratnagiri, India)

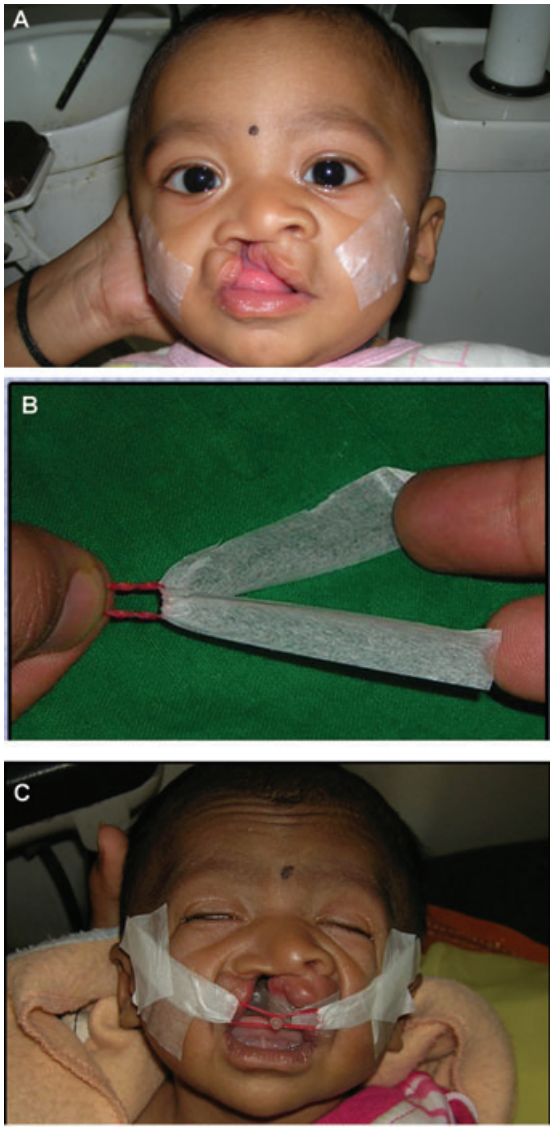

Figure 4 (A) Broader base tapes secured onto the infant's cheeks; (B) orthodontic elastics incorporated into loops of thinner tapes; (C) thinner tapes secured to the base tapes with backward and upward pull.

to approximate the contour and topography of an intact arch before the fabrication of the oral portion of the molding appliance (Fig 2B). The cast was duplicated in irreversible hydrocolloid (Neocolloid; Zhermack, Rovigo, Italy) to obtain a working cast on which two layers of baseplate wax were adapted and lab processed using clear heat-cure acrylic resin (Travelon Clear Denture Material, Dentsply India, Gurgaon, India) to fabricate the molding prosthesis of 2 to 3 mm thickness to provide structural integrity and to permit adjustments during the molding therapy. The appliance was finished and polished to ensure that all tissue borders were smooth and that the oral portion of the appliance that would be in contact with the dorsum of the tongue was given a high polish. At the insertion appointment, the appliance was carefully fitted in the infant's oral cavity and

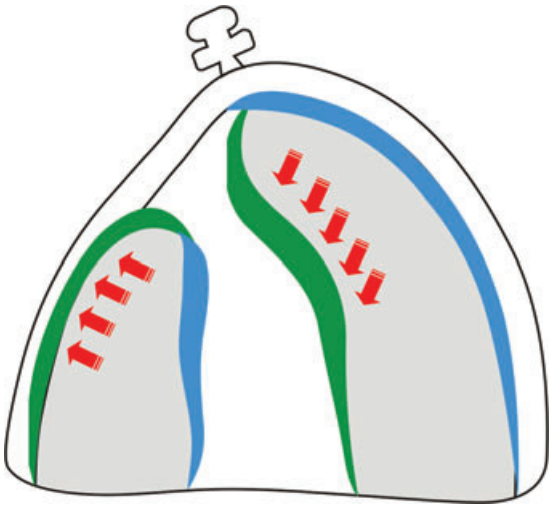

Figure 5 Schematic diagram of molding appliance: blue areas indicate soft liner application, and green areas indicate areas of relief. Red arrows indicate direction of force.

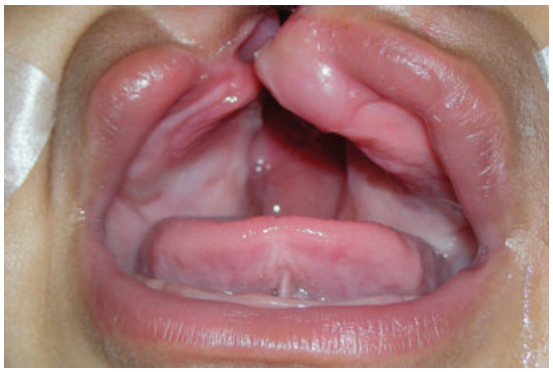

Figure 6 Close approximation of alveolar segments.

observed for few minutes. The infant was able to suckle without gagging or struggling.

Extraoral retentive button

An extraoral retentive button was fabricated with self-polymerizing clear acrylic resin (Rapid Repair; Dentsply) and positioned facing downward on the labial flange, at an angle 40° relative to the plate, allowing clearance for upper and lower lips that facilitated the positive seating of the appliance to the palatal tissues. The appliance was then secured extraorally to the cheeks and bilaterally by surgical tapes with orthodontic elastics at each end (Fig 3). The use of skin barrier dressing tapes (Tegaderm; 3M ESPE, St. Paul, MN) was advocated to reduce cheek irritation.

Retentive taping with adhesive tapes and orthodontic elastics

For proper retentive taping, a broader base tape of Suture-Strip (0.5 × 2 inch; Generic Laboratories Wound Care, St Paul, MN) was first applied to the infant's cheeks, lateral and superior to

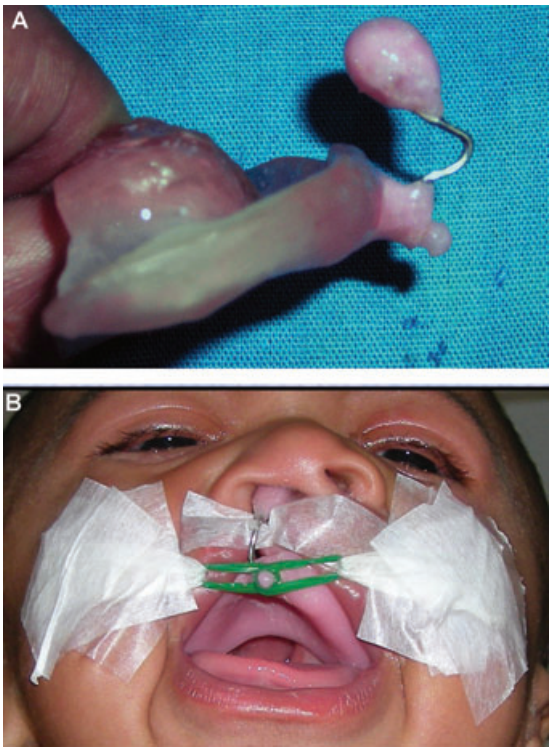

Figure 7 (A) Nasal Stent: 19 gauge SS wire covered with acrylic and soft liner; (B) nasal stent positioned in nostril aperture to support the nasal dome and pushing outward.

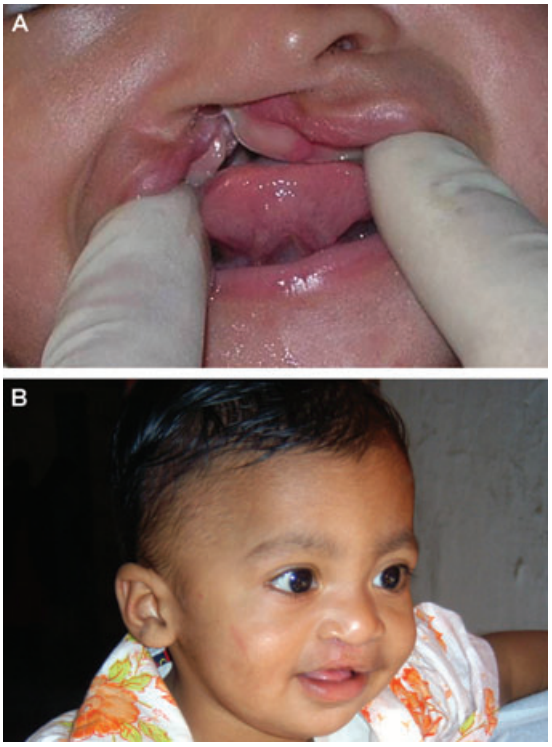

Figure 8 (A) Cleft nasal deformity after nasoalveolar molding just before surgery; (B) postsurgical view.

the commisures. These base tapes served to anchor the thinner (0.25 × 4 inch) base tapes of suture strips used to hold the appliance against the palate (Fig 4A). Small orthodontic elastics (Tru-force Latex Elastic System; TP Orthodontics Inc, La Porte, IN) were incorporated into the loops of thinner tapes folded over them (Fig 4B). The elastic band was placed over the retentive button, and thinner tapes were pulled and secured to the base tapes on the infant's cheeks posteriorly and superiorly (Fig 4C). An additional broader tape was applied over the ends of the thinner tapes to anchor suture strips and elastic bands to the base tapes. The elastics (inner diameter 0.25 inch, wall thickness heavy) were stretched to approximately two times their resting diameter for a proper activation force of about 100 g. The adhesive tapes and elastic bands were changed to allow continuous retention of the appliance. The parents were provided with detailed instructions on the proper method of lip taping along with taping materials and adhesive. The patient was recalled on a weekly basis for follow-up. At each recall appointment, the progress of the molding appliance was monitored. The oral cavity was examined for any possible sores or ulcerations, inflammation, and swelling because of active molding forces by the appliance. Before any adjustments, the appliance was cleaned with soap and water. Adhesive tapes and elastics were changed every week to maintain the proper activation force to mold the alveolar segments. Instructions were given to keep the appliance in the oral cavity for 24 hours except during cleaning. The tissue surface of the appliance was modified to allow selective pressure on the greater and lesser alveolar segments on either side of the cleft for correct alignment. A 1-mm thick layer of permanent soft liner (Permasoft, Dentsply Austenal, York, PA) was added to the inner surface of the labial aspect of the greater alveolar segment while reducing the acrylic from the palatal aspect of the appliance to direct the greater segment inward toward the cleft. The acrylic was selectively removed from the inner labial aspect of the lesser segment of the alveolus (1 mm) while adding an equal amount of permanent soft liner on the palatal aspect to direct the lesser segment outward from the cleft (Fig 5). The ultimate goal of this sequential addition and selective grinding away of material was carried out during recall appointments at 2- to 3-week intervals to reduce the size of the intraalveolar gap and to have the two alveolar segments contact with the configuration of a proper maxillary alveolar arch form.[3]

Nasal stent

The phase of active nasal cartilage molding began when the intraalveolar gap reduced to approximately 5 mm by incorporation of the nasal stent component (Fig 6).[3] The rationale behind delaying the addition of nasal stent was that with a reduced alveolar gap, the base of the nose and lip segment alignment was improved. At this stage, a second impression was made, and the procedure was repeated. The acrylic retentive button was removed and repositioned to accommodate the addition of the nasal stent. A nasal stent constructed from 0.019 inch round stainless steel wire (Smith SS wire; KC Smith, Monmouth, UK) was secured to the labial flange of the appliance. It was extended forward and then curved backward in the form

of a "swan neck" entering 3 to 4 mm past the nostril aperture (Fig 7A). The swan-neck shape provides access to tape the lip across the cleft.[2,10,11] The wire extending into the nostril was curved back on itself to create a small loop for retention of the intranasal hard acrylic component of the nasal stent to provide form and support to the tissues. This hard acrylic component was shaped into a bilobed form resembling a kidney. Finally, the superior aspect of the nasal stent was covered with a thin layer of soft liner to ensure positive elastic pressure to the internal tissues of the nasal dome (Fig 7B). The upper lobe was inserted into the nose and gently lifted toward the dome until a moderate amount of tissue blanching was evident. The lower lobe of the nasal stent lifted the nostril apex and defined the top of the columella. Aggressive lip taping was continued once the nasal stent was added to the appliance. Periodic examination of the tissues and adjustment of the appliance was continued every week to mold the nasoalveolar complex into the desired shape and position. After 4 months, the intraalveolar gap between the two segments at the crestal level was approximately 1.5 to 2 mm, ensuring a clinically desirable approximation of the alveolar segments. After completion of the PNAM procedure, the alveolar segments were aligned, and the nasal cartilages, columella, and philtrum were properly repositioned (Fig 8A). The infant was scheduled for surgical repair with the plastic surgeon after parents' consent.

Surgical procedure

The primary surgical closure of the lip and nose was performed at 4 months of age (Fig 8B).[12-14] The surgical technique was modified to take the advantage of the PNAM preparation. Because the alveolar segments were in approximation, a gingivoperiosteoplasty (GPP) made it simple for the plastic surgeon to perform palatal and alveolar closure.[15-18] The patient was followed regularly at 3-month intervals. Soft and hard tissue examination was carried out during each appointment. The palate was completely closed with a second surgery at 18 months of age, and no palatal perforation was observed. The lip and nose repair scars were minimal and less identifiable, giving the patient a normal facial esthetic appearance.

Discussion

The goals of PNAM in patients with unilateral cleft lip and palate are to align the intraoral alveolar segments and correct the nasal tip, alar base, philtrum, and columella. Presurgical infant molding is required to restore normal anatomy, to expand deficient tissues and to reposition the malpositioned structures before surgical correction. Historically, the use of presurgical infant orthopedic appliances,[19] or molding therapy, has aided significantly in reducing the cleft size of the alveolus and palate before surgery. Various techniques for molding intraoral alveolar segments closer together in unilateral and bilateral cleft situations have been described.[9,20] All these orthopedic appliances move only alveolar segments together but do not reposition the deformed surrounding soft tissues like the nasal dome and columella-philtrum region. PNAM includes not only the reduction in size of the intraoral alveolar cleft through the molding of the bony segments, but also the active molding and positioning of the surrounding soft tissues affected by the cleft, including the deformed soft tissue and cartilage in the cleft nose. This is accomplished through the use of a nasal stent that enters the nasal aperture. The nasal stent serves as a custom tissue expander that slowly corrects the flattening of the cleft lip nasal deformity and brings the columella into a more midline position. This nasal stent not only provides support and gives shape to the nasal dome and alar cartilages, but also exerts a reciprocal intraoral molding force against the alveolar segments.[20,21] Long-term studies of PNAM therapy indicate that the change in the nasal shape is stable with better lip and nasal form and minimal scar tissue. PNAM reduces the number of surgical revisions for excessive scar tissue, oronasal fistulas, and labial and nasal deformities. With alveolar segments in a better position and increased bony bridges across the cleft, the permanent teeth erupt in a good position with adequate periodontal support.[22] Studies have also demonstrated that 60% of patients who underwent PNAM and GPP did not require secondary bone grafting.[16]

Matsuo et al[5] showed that maternal estrogen level is highest immediately after birth. Maternal estrogen increases hyaluronic acid, a component of the proteoglycan intercellular matrix, found circulating in infants for several weeks after birth, in neonatal cartilage rendering a high degree of plasticity.[23] Therefore, active soft tissue and cartilage molding is successful in the first few months after birth. PNAM provides controlled repositioning of alveolar segments through active molding without need for lip adhesion surgery and repair of nose, lip, and alveolus in one surgery. It serves as an obturator to facilitate infant feeding and eliminates the need for columellar lengthening surgery. PNAM guides the development and growth of the alveolar segments and tongue position that improves the speech.

Lee et al studied the long-term effect of PNAM followed by GPP on midface growth at prepuberty and concluded that growth was not affected by a PNAM procedure.[24] Liou et al recommended nasal conformers that can be placed for 4 to 6 months to compensate for relapse and differential growth. A nasal stent plays an important role in reshaping the alar cartilages like a nasal conformer.[25] The swan-neck shape of the nasal stent provides access to tape the lip across the cleft and apply a forward and upward molding vector to the dome of the lower lateral alar cartilage and a reciprocal alveolar molding vector on the medial hemialveolar segment.[10,11] A study assessing the alveolar cleft width and nostril symmetry after PNAM showed that PNAM improved symmetry of the nose in height, width, and columella angle compared to presurgical status, with some relapse of nostril shape in width (10%), height (10%), and columella angle (4.7%) at 1 year of age.[26] Prahl et al studied the effect of infant orthopedics on maxillary arch form, alveolar segment position, and facial appearance and concluded that infant orthopedics does not prevent collapse and can be abandoned as a tool to improve maxillary arch form. Also, infant orthopedics have no effect on facial appearance; however, the effect of passive maxillary plates, instead of active tissue molding like PNAM, was evaluated.[27,28] Bongaarts et al evaluated the effect of infant orthopedics on maxillary arch dimensions in the deciduous dentition in unilateral cleft lip

and palate patients and concluded that infant orthopedics had no significant observable effect on maxillary arch dimensions or on the contact and collapse in deciduous dentition at 4 to 6 years of age.[29] Speech intelligibility is an important criterion to evaluate the early functional outcome in cleft lip and palate patients. Van Lierde et al conducted a study on speech intelligibility of children with unilateral cleft lip and palate who received Wardill-Kilner palatoplasty, as judged by their parents and concluded that there was no significant difference in speech intelligibility between normative data and children with a cleft defect.[30] An important benefit of PNAM is an opportunity for parents to take part actively in rehabilitation of their child. PNAM has evolved over the past decade into its present form through contributions made by clinicians and parents.

The locked-out segment, tissue ulceration, failure to retain appliance, failure to tape the lip segments, nostril expansion, and exposure of primary teeth are common complications that can be encountered throughout the molding procedure.[3] Limitations of the PNAM procedure are that the process needs to begin as soon as possible after birth, as cartilage gets less plastic as age progresses, and the patient learns to remove the appliance. Parental cooperation is a must for successful PNAM therapy.[3]

Conclusion

PNAM can be successfully employed in the early management of both unilateral and bilateral cleft anomalies in newborns. PNAM provides safe, effective, and lasting improvement in the esthetics of the nasolabial complex in infants with unilateral or bilateral cleft deformities. PNAM is an emerging technique that acts as a form of custom tissue expansion while correcting the nasal cartilage deformity nonsurgically and resolving the columellar length deficiency and alveolar segment malposition with minimal surgery. The result is an overall improvement in the esthetics of the nasolabial complex while minimizing the extent of surgery and number of surgical procedures, thus providing positive psychological impact to the parents.

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