CHAPTER 4

The Role of Pediatric Dentists and Orthodontists in the Presurgical Treatment of Infants Born with Cleft Lip and Palate

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ABSTRACT

The concept of presurgical orthopedics has been employed in the treatment of cleft lip and palate (CLCP) patients for centuries. In 1993, Grayson et al[1] described a new technique to presurgically mold the alveolus, lip, and nose in infants born with cleft lip and palate. The objective of nasoalveolar molding (NAM) is to reduce the severity of CLCP deformities in the nose, lip, and alveolar processes prior to the initial surgical repair. NAM can achieve presurgical reduction in nasal cartilage deformity and size of the alveolar gap, approximate the lip segments at rest, increase the surface area of nasal mucosal lining, and provide nonsurgical elongation of the columella. It has been reported that there is a reduction in the number of secondary surgeries needed, especially if NAM is combined with gingivoperiosteoplasty.[2–4] The goals of NAM include improvement of long-term nasal aesthetics and reduction of cost and suffering to the patient and society by reducing the need for secondary bone grafts and number of secondary surgical revisions and hospital admissions. NAM is used by almost 40% of cleft palate teams in the United States.[5] The practice of NAM by pediatric dentists, orthodontists, and other dental specialists enables the treating provider to initiate the first stages of anticipatory guidance, create the foundation for oral prevention, and establish the "cleft dental" home. As a limited number of published resources exist explaining the role of the pediatric dentist and orthodontist in the treatment of the infant with NAM, this chapter will describe the role of NAM, its indications, appliance design, fabrication, biomechanics, complications, and patient management.

BACKGROUND

Cleft lip and palate can present with considerable variation in severity and form. Generally, the wider, more extensive clefts are associated with more significant nasolabial deformity. These clefts, deficient in hard and soft tissue elements, present a significant surgical challenge to achieve a functional and cosmetic outcome. Even the mildest incomplete unilateral cleft lip, in the absence of a cleft palate, can be associated with a nasal deformity that tends to worsen as nasal growth continues.[6]

The concept of presurgical orthopedics is not new; it has been employed in the treatment of cleft lip and palate patients for centuries. The earliest techniques focused on elastic retraction of the protruding premaxilla followed by stabilization after surgical repair. Hoffmann in 1689 demonstrated the use of facial binding to narrow the cleft and prevent postsurgical dehiscence of the soft tissue closure. Similarly, Desault in 1790 also used facial binding to retract the maxilla before surgical repair in patients with bilateral cleft repair.[7] In 1844, Hullihen stressed the importance of presurgical preparation of clefts using an adhesive tape binding.[8] Esmarch and Kowalzig used a bonnet and strapping to stabilize the premaxilla after surgical retraction.[9] In 1927, Brophy demonstrated the passing of a silver wire through both the ends of the cleft alveolus, and then progressively tightened the wire to approximate the ends of the alveolus before lip repair.[10]

In 1950, McNeil modernized presurgical infant orthopedics. He utilized a denture-like prosthesis that was delivered soon after birth, which brought about reduction of the alveolar arch deformity prior to surgical intervention.[11] His technique was further popularized by Burston.[12] Since then, a wide variety of appliances to control the presurgical alignment of the cleft maxillary arch segments have been described,[13–20] from the active pin retained appliance introduced by Georgiade and Latham in [21] to the passive orthopedic plate described by Hotz in 1987.[22]

In 1993, Grayson et al[1] described a new technique to presurgically mold the alveolus, lip, and nose in infants born with cleft lip and palate (Figure 4–1). Nasoalveolar molding (NAM) therapy placed emphasis on reducing the severity of deformity in the nasal soft tissue, the nasal cartilages, and the alveolar processes or gum pads. The molding of nasal cartilage was inspired by reports of pediatric auricular cartilage molding.[23] Matsuo described the cartilage in newborns as soft and lacking elasticity; hence, long-term correction of the ear deformity was possible if treatment started within 6 weeks of birth. Similarly, active molding and shape correction of the nasal cartilages take advantage of the plasticity of cartilage in the newborn infant. The temporary plasticity of cartilage is believed to be caused by high levels of estrogen at the time of birth, which correlates to increasing levels of hyaluronic acid, a component of the proteoglycan intercellular matrix found circulating in the infant for several weeks after birth.[24–26]

The objective of NAM is to reduce the severity of CLCP deformities in the nose, lip, and alveolar processes prior to the initial surgical repair. Most surgeons agree that a patient with a milder cleft deformity will obtain a better cosmetic surgical outcome than a patient with a more severe presurgical cleft deformity. NAM can achieve presurgical reduction in nasal cartilage deformity and size of the alveolar gap, approximate the lip segments at rest, increase the surface area of nasal mucosal lining, and provide nonsurgical elongation of the columella. It has been reported that there is a reduction in the number of secondary surgeries needed, especially if NAM is combined with gingivoperiosteoplasty.[2–4]

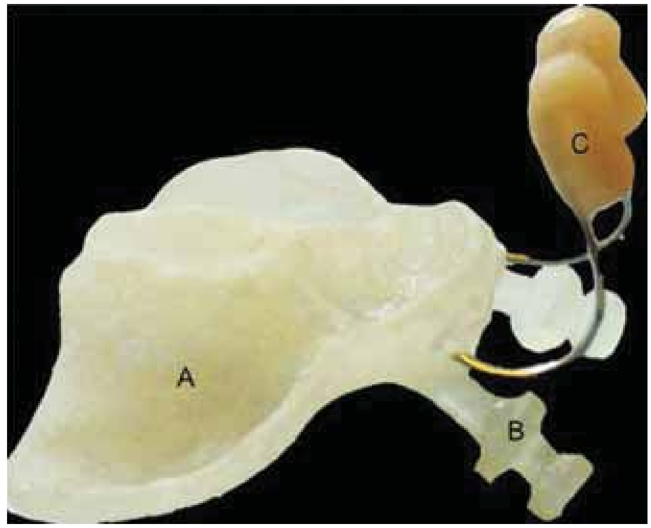


Figure 4–1. Nasoalveolar molding appliance (NAM). The appliance is made up of (*A*) an intraoral molding plate, (*B*) retention buttons, and (*C*) nasal stent, collectively forming the NAM appliance.

IMPRESSION TECHNIQUE (VIDEO OF NASOALVEOLAR MOLDING)

An impression of the infant with cleft lip and palate is routinely obtained within the first week of birth, provided the infant is in good health. The impression procedure can carry some risks to the infant if performed incorrectly; hence, meticulous precaution must be taken. The impression is performed in a clinical setting such as a hospital, where medical or dental personnel are prepared to handle an infant airway emergency. After fitting and selection of an appropriate-sized impression tray, the infant is held upside down by the surgeon and the impression performed. The infant is held in an inverted position to prevent the tongue from falling back to allow fluids to drain out of the oral cavity, and to provide optimal direct vision of the maxillary alveolar processes and cleft for the operator. A heavy-bodied silicone impression material is used to take the initial impression (Figure 4–2). Once the material is set (approximately 4 minutes), the tray is gently removed. Upon removal, the oral cavity is immediately examined for residual impression material and swabbed with wet gauze to ensure that no detached pieces of impression material are left behind. The impression is then poured with dental stone to create a model of the maxillary alveolar arches and palatal cleft.

APPLIANCE FABRICATION AND DESIGN

The molding plate is fabricated on the dental stone model. All undercuts around the alveolus and cleft spaces are blocked with wax. Separating medium is

A B

Figure 4–2. A. Illustrates the inverted infant position while impression is made to prevent the tongue from falling back and prevent fluid aspiration. **B.** Impression of a unilateral cleft patient using a custom tray and heavy-body silicone impression material.

applied to cover the entire arch. Hard self-cure acrylic (clear power + liquid) is mixed and then applied uniformly to a thickness of 2 to 3 mm to provide structural integrity and permit adjustment during visits. The dental stone with the applied hard acrylic is placed in a pressure pot and set on 27 psi for 20 minutes. After removal from the pressure pot, the hard acrylic plate is separated from the dental stone, finished, and polished. The borders of the plate are relieved by 1 mm, in addition to the areas corresponding to the labial and buccal frenal attachments, to ensure adequate clearance for the intraoral soft tissues. A retention button is fabricated and positioned anteriorly at an angle of 30° to 40° to the alveolar plane. In the unilateral appliance, only one retention button is used (Figure 4–3), whereas two are employed in the appliance for treatment of bilateral cleft (Figure 4–4). The exact location of the retention button(s) is determined at chair side. They are positioned so as not to interfere with approximation of the cleft lip segments. The vertical position of retention buttons should be at the junction of the upper and lower lips. When two buttons are employed, they must diverge to accommodate the nipple of a bottle or pacifier. The retention buttons adequately secure the molding plate to the roof of the mouth with the help of orthodontic elastics and surgical tapes.

A small opening measuring 6 to 8 mm in diameter is made on the palatal surface of the molding plate to provide a patent airway in the event of vertical entrapment of the plate intraorally. The nasal stent construction is delayed until the cleft of the alveolus is reduced to about 5 to 6 mm in width. As the alveoli are slowly molded toward one another, the soft tissue alar base on the cleft side becomes less tense and more able to be elevated with a nasal stent, without stretching and unnecessarily increasing its circumference.

APPLIANCE INSERTION AND TAPING

Before insertion, the molding plate appliance is checked for sharp or rough surfaces that may irritate the soft tissues. It is also examined for overextension in the area of the vestibular folds as well as along the posterior border. The appliance is then secured in the mouth

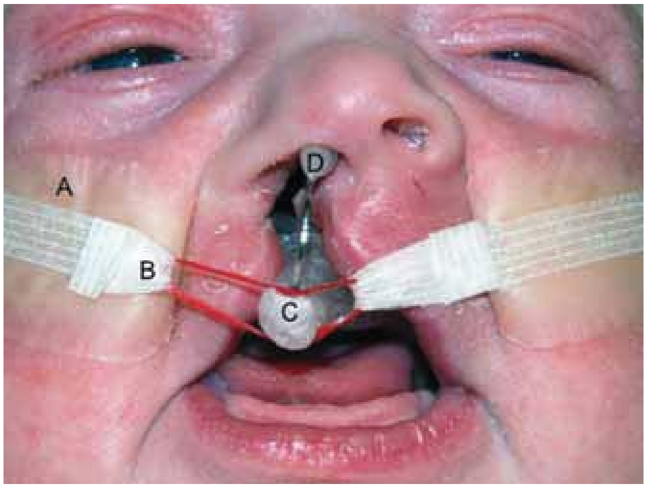


Figure 4–3. Unilateral NAM appliance. (*A*) Hydrocolloid base tapes. (*B*) 1/4-inch diameter surgical tapes attached to an orthodontic elastic that is engaged around the button. (*C*) Note the red elastic on patient's right is stretched to twice its resting diameter. This results in greater force to move the plate toward the cleft side (*patient right side*). (*D*) The lower lobe of the nasal stent is seen exiting at the nostril apex while the upper lobe of the nasal stent is within the nose and lifting the right nasal dome.

Figure 4–4. Bilateral NAM appliance. Note the two retention buttons that are used to engage the elastics and tape to the cheeks. (*A*) Columella band connecting the inferior lobes of the nasal stents and crossing the columella. Note the active stretching of the columella as the appliance is seated, which is further activated by the downward pull of the prolabium tape. (*B*) The prolabium tape is activated by its connection to the horizontal elastic (*arrow C*) that is suspended by the two retention buttons.

with the aid of surgical tapes that are adhered to the cheeks bilaterally. Orthodontic elastics are connected to the ends of the surgical tapes to engage the retention button(s) on the appliance. The use of skin barrier tapes on the cheeks, such as hydrocolloid base tape, is advocated to reduce irritation. 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 gms (see Figure 4–3). The amount of force could vary depending on clinical objective and the intraoral mucosal tolerance to pressure and resistance to ulceration. Additional "cover tapes" may be employed to secure and protect the elastic surgical tapes. Parents/caregivers are instructed to keep the plate in the infant's mouth continuously except for daily cleaning. The infant may require 1 or 2 days to adjust to feeding with the NAM appliance.

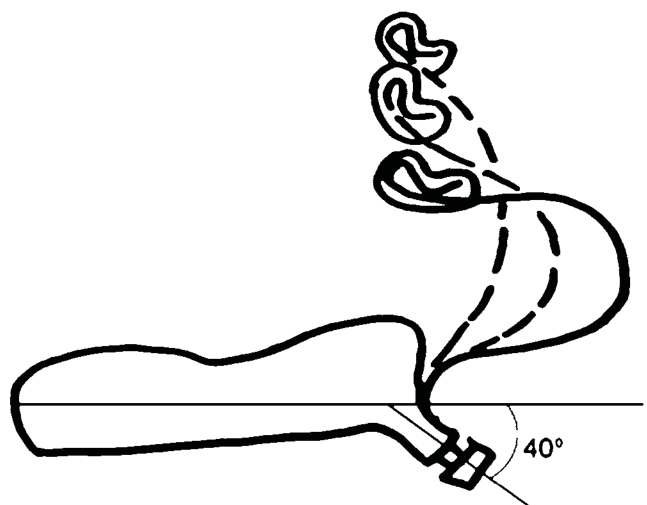
APPLIANCE ADJUSTMENTS

The adjustment of the appliance begins on the day of delivery by selectively removing hard acrylic from specific locations along the interior walls of the molding plate, while adding soft denture base material in corresponding proportions. This results in approximation of the position of alveolar segments. These modifications to the tissue facing surfaces of the molding plate should be restricted to 0.5 to 1.0-mm increments to prevent tissue irritation and ensure appliance seating/retention. The infant is seen weekly for incremental adjustments of the molding plate. The goal is to direct the alveolar segments into optimal position and form during the 3- to 6-month presurgical period. As this is achieved, there will be a corresponding reduction in the lip gap and alar base width. Care must be taken to prevent incomplete seating of the molding plate and potential deformation of the alveolus, by not allowing the soft denture material to build up on the interior of the molding plate in the region corresponding to the height of the alveolar crest.

INCORPORATION OF THE NASAL STENT

The nasal stent system is composed of a 0.36-round stainless steel wire, hard acrylic, and soft acrylic. The wire has a distinct curvature that projects outward from the appliance and then back into the nose. The appliance for the treatment of bilateral clefts has two stents projecting into the nostril apertures, whereas the appliance for a unilateral cleft defect utilizes one. The length of the curved wire allows flexibility for adjustment of the intranasal stent as the nose and face grow (Figure 4–5). The distal end of the nasal stent wire is shaped into a loop for retention of the hard acrylic, which acts as the core foundation of two nasal stent "lobes." 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 to form a barrier that protects the sensitive intranasal mucosa from irritation. The inferior nasal lobe is positioned adjacent to the columella and emerges from the nostril, pushing the nasal apex forward, medially, and slightly upward. The superior lobe is positioned inside the nose and converges medially, projecting the nasal tip (dome) forward. The elasticity of the soft denture liner also acts as a source of activation by stretching and expanding the nasal mucosal lining tissue with every 0.5 to 1.0 mm incremental addition.


A



B

Figure 4–5. A. Nasal stent seated in nose supporting and projecting the nasal dome in the direction of the arrow. **B.** Illustration describing how the length of the curved wire allows flexibility for adjustment of intranasal stent as the midface grows vertically.

NONSURGICAL COLUMELLA LENGTHENING IN BILATERAL CLEFT LIP AND PALATE

The nasal deformity in bilateral cleft lip and palate (BCLP) is unique from that of unilateral cleft lip and palate (UCLP). In BCLP, the flattened nasal tip is tethered directly to the prolabium by a severely deficient or absent columella. The lower lateral alar cartilages are flared and concave where they should be convex. The greatest challenge for aesthetic reconstruction is the absent or deficient columella.

The nasal stent components of NAM, specifically the columella band (see Figure 4–4) are used to nonsurgically elongate the deficient or absent columella. The forces generated when the nasal stent pushes up on the nostril apex and the medial crux of the nasal cartilages result in a reciprocal force directed downward by the columella band against the base of columella, allowing for its gradual elongation. The horizontal columella band is constructed from soft denture liner that joins the two inferior lobes of the nasal stent. It has a gentle curvature on the inferior surface that sits at the columella/philtral junction and defines this angle as the nasal tip continues to be lifted and projected forward. A second force is generated with prolabial tape that is adhered to the prolabium and stretches downward to engage the retention buttons with elastics (see Figure 4–4). Taping downward on the prolabium helps to lengthen the columella and vertically lengthen the often small prolabium.

PRIMARY SURGICAL REPAIR OF THE ALVEOLUS, LIP, AND NOSE

The objective of NAM therapy is accomplished before the primary surgical repair (Figures 4–6 and 4–7). Surgical closure of the lip and nose is performed from 3 to 4 months of age for UCL. Patients with bilateral cleft lip and palate tend to need 1 to 2 additional months to achieve the presurgical clinical objectives. Approximation of the alveolar segments permits the surgeon to perform gingivoperiosteoplasty. Reshaping of the deformed alar cartilage and stretching of the nasal mucosa can enhance the surgeon's ability to achieve a good surgical repair. The surgical technique should be modified to take advantage of the NAM outcomes.[27–29]

COMPLICATIONS

NAM complications can be characterized as soft tissue, hard tissue, and compliance-related.[30] Soft tissue complications include ulceration/irritation to the "pregingival" alveolar tissue and oral or nasal mucosa. They can be caused by rough internal surfaces of the molding appliance that were not properly contoured during adjustments or can be due to excessive pressure of the appliance against the mucosa. Relieving the acrylic plate corresponding to the areas of insult usually resolves the irritations or ulcerations. Another soft tissue complication is candida infection, which can arise if the molding plate is not cleaned regularly, especially since it is worn 24 hours a day. The intranasal lining of

Figure 4–6. Unilateral cleft lip and palate treated with NAM. **A.** Pre-NAM. Note the concave nasal cartilage on the cleft side, deviation of the columella to the noncleft side, and large alveolar gap. **B.** NAM appliance seated for 3 months. Note the nasal stent elevating and molding the nostril apex and nasal dome. The columella is taking a more upright position. **C.** Post-NAM. Note the nasal cartilages have retained a convex form on the cleft side, the columella is more upright, and the alveolar gap has been eliminated.

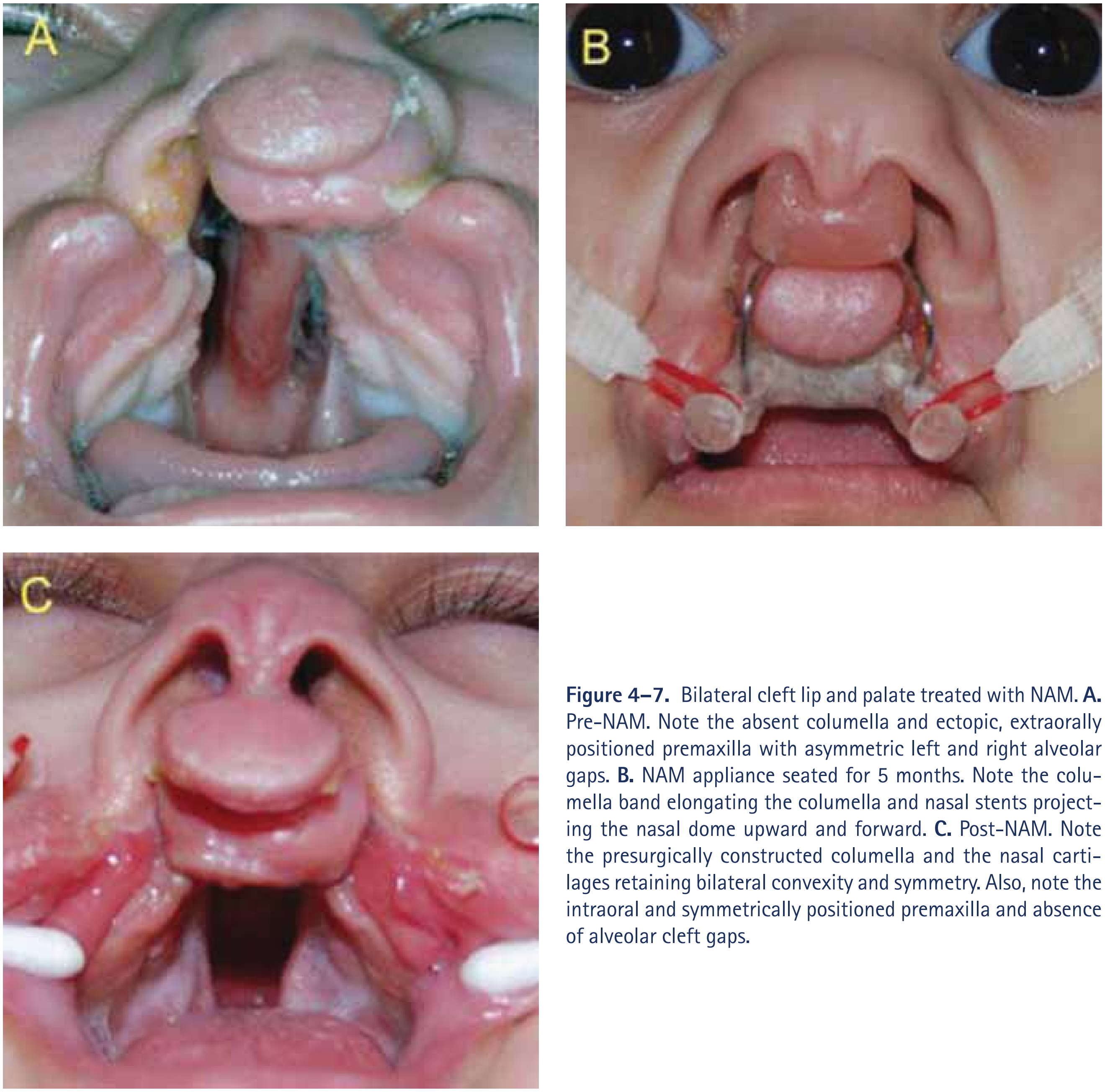


Figure 4–7. Bilateral cleft lip and palate treated with NAM. **A.** Pre-NAM. Note the absent columella and ectopic, extraorally positioned premaxilla with asymmetric left and right alveolar gaps. **B.** NAM appliance seated for 5 months. Note the columella band elongating the columella and nasal stents projecting the nasal dome upward and forward. **C.** Post-NAM. Note the presurgically constructed columella and the nasal cartilages retaining bilateral convexity and symmetry. Also, note the intraoral and symmetrically positioned premaxilla and absence of alveolar cleft gaps.

the nasal tip can become inflamed if the upper lobe of the nasal stent applies excessive force. The area under the horizontal columella band can become ulcerated if the band is too tight. Nasal stent complications can also arise if the stents are not positioned properly, which can lead to creation of an overexpanded nostril or petechiae in area of excessive pressure. The oral and nasal cavities of the infant should be carefully examined in each visit for these possible complications, which should subsequently be followed by the appropriate adjustments to the NAM appliance. The most common area of soft tissue irritations is the skin of the cheek. Extreme care should be taken while removing the cheek tape to avoid tearing or irritation of the skin.

Skin barriers, such as hydrocolloid tapes, are recommended to protect the skin. Slight relocation of the position of the tape during treatment can also provide rest and time for recovery of the skin.

One hard tissue complication of NAM is misalignment of the alveolar segments during the molding process. Careful molding plate adjustments made during the weekly visits ensure proper movement and alignment of the segments. Another common complication may be the premature eruption of primary maxillary incisors, sometimes resulting from pressure exerted by the molding plate.[31] In this case, relief of the NAM appliance can be made to accommodate the prematurely erupted tooth. The presence of a neonatal or ectopic tooth bud is usually managed by extraction if the tooth is mobile and presents the risk of aspiration.

An important factor that can result in complications during NAM treatment is caregiver/parental compliance. Failure to apply the recommended amount of elastic force can result in insufficient movement of the alveolar segments. Application of excessive force may result in soft tissue ulcerations and irritation. The removal of an appliance for extended periods of time (several hours per day or for several days) will result in an appliance that becomes maladapted to the patient's alveolar arch. Poor skin and appliance hygiene can lead to inflammation and discomfort. Failure to show up for regularly scheduled appointments will delay the progress of treatment. Successful treatment is dependent on complete commitment and compliance of the parents/caregivers. However, they must be provided with the knowledge and skills to deliver the appropriate home care, essential to the success of NAM.

BENEFITS OF NASOALVEOLAR MOLDING

NAM plays a significant role in reducing the extent of CLCP deformity in the period immediately prior to the primary cleft surgical repair. The literature has established that NAM improves nasal cartilage deformity and nasal symmetry, expands the nasal mucosal lining, and achieves nonsurgical elongation of the columella.[32–41] These presurgical enhancements have been found to reduce the need and number of surgical revisions due to excessive scar tissue, oronasal fistulas, and nasolabial deformities.[42] Moreover, if the alveolar segments are approximated and gingivoperiosteoplasty performed, the resultant formation of a bony bridge can improve the conditions for eruption and periodontal support of teeth along the former cleft margins. Santiago et al[43] reported that 60% of patients that underwent NAM and gingivoperiosteoplasty (GPP) did not require secondary bone grafting. Sato et al[44] found that in the remaining 40% that did need a bone graft, there was more bone remaining in the graft site compared with patients who did not previously undergo gingivoperiosteoplasty. Henkel reported that in 68% to 73% of patients in whom a Millard-type GPP was performed, a secondary bone graft was not required.[45]

CONCLUSION

Nasoalveolar molding in infants has aims that go beyond the traditional goals of presurgical orthopedics. These aims include improvement of long-term nasal aesthetics and reduction of cost and suffering to the patient and society by reducing the need for secondary alveolar bone grafts and the number of secondary surgical revisions and consequent hospital admissions.

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