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Bridging the Gap: Nasoalveolar Moulding in Early Cleft Palate Rehabilitation

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Abstract

Orofacial clefts (OFC) are among the commonest birth defect in developed and developing countries alike. In underdeveloped and developing countries, babies born with oral clefts are generally anaemic with low birth weight and may be unfit for surgery. The surgical reconstruction is also challenging and the aesthetic outcome cannot be guaranteed by the surgeon. Presurgical nasoalveolar moulding (PNAM) has been suggested to bridge the gap between the clefted segments before surgical repair. It is a simple yet effective technique that needs to be initiated at the right time and age to achieve ideal functional and aesthetic outcomes. This chapter highlights the effectiveness of the nasoalveolar moulding technique and details the manner in which the appliance is fabricated and activated.

Keywords: presurgical nasoalveolar moulding, feeder plate, cleft lip and palate

1. Introduction

Each year, around 250,000 babies are born with some form of orofacial clefts [1]. Worldwide, the incidence of cleft is reported in one of every 600–800 newborns [2]. A vast majority of these babies are born in underdeveloped or developing countries. This already deplorable situation is aggravated by the fact that most of these cases are concentrated in rural areas where access to health care is severely inadequate or unavailable as compared to urban cities [3, 4].

In developed countries, cleft lip/palate (CL/P) is identified before birth by ultrasonography, which gives the parents much needed time for education and counselling regarding the additional care needed after birth. Consequently, due to the widespread access to medical care and scientific data, aetiology is scientifically understood to be due to a combination of genetic and environmental factors. In contrast, in developing countries prenatal care is less advanced or limited, a CL/P is usually unexpected and families rely less on medical explanations for the cleft and rely more on religion and folklore to explain the deformity [5].

Veau [6] classified clefts into (**Figure 1**).

Group I: Cleft involving the soft palate alone.

Group II: Cleft involving the hard and soft palate up to the incisive foramen.

Figure 1.
Veau's classification.

Group III: Complete unilateral cleft involving the soft and hard palate, the lip and alveolar ridge on one side.

Group IV: Complete bilateral cleft involving the soft and hard palate, the lip and alveolar ridge on both sides.

Successful rehabilitation of all these cases requires a multidisciplinary approach. Patients with orofacial clefts need to be treated at the right time and age to achieve functional and aesthetic well-being. The management of the child born with a cleft lip and palate requires coordinated care provided by a cleft care team [7], comprising of different individuals belonging to several specialities in:

1. Dental specialities (orthodontics, oral surgery, paediatric dentistry and prosthodontics),
2. Medical specialities (genetics, otolaryngology, paediatrics, plastic surgery and psychiatry),
3. Allied health care fields (audiology, nursing, psychology, social work and speech pathology)

In many developing countries, there are several unrepaired cleft patients due to the mismatch between the volume of patients and resources. Furthermore, babies who are born underweight or anaemic are not suitable for surgery. There is also an acute shortage of qualified surgeons available to treat them [8]. This results in patients who cannot reach their full social and economic potential [9]. Surgical repair alone cannot address the multiple issues encountered in patients with cleft lip and palate. One specific task is the aesthetic recreation of the deficient columella. The earliest mention of

presurgical infant orthopaedics was in the 1950s. This adjunctive therapy reduced the severity of the initial cleft deformity before surgery. This enabled the surgeon to enjoy the benefits associated with surgical repair in an infant with a minimal cleft deformity and reduced the need for a secondary surgery [10].

This chapter describes the technique of presurgical nasoalveolar moulding (PNAM), which was first described by Grayson et al. [11] in 1993 and had several modifications made over the years by Brecht et al. [12] in 1995, Grayson and Santiago [13] in 1997 and Cutting et al. [14] in 1998. This approach involves the active moulding and repositioning of the deformed nasal cartilages and alveolar process and lengthening the deficient columella, using the NAM appliance which consists of nasal stents attached to an intraoral moulding plate to aid in the moulding of the clefted alveolar ridge and nasal cartilage. The primary goal of PNAM is to achieve good arch form and eventually stabilisation.

The concept of NAM works on Matsuo's principle that a high degree of plasticity is seen in the cartilages of infants in the first few months after birth. A high amount of circulating maternal oestrogen causes an increase in the amount of hyaluronic acid in the fetal cartilage, rendering it plastic. Hence, active soft tissue and cartilage moulding are most successful if initiated within the first 6 weeks of life [15].

2. Unilateral orofacial cleft lip and palate

Clinical examinations of babies born with unilateral cleft lip and palate often show significant nasal deformities. The lower lateral alar cartilage is concave and

Figure 2.
Unilateral orofacial cleft lip and palate.

depressed in the alar rim and separated from the contralateral cartilage. This results in a depressed nasal tip and possibly an overhang of the apex of the nostril. The columella and nasal septum are deviated towards the cleft, and the base towards the non-cleft side. Furthermore, the orbicularis oris muscle in the lateral lip segments contracts into a bulge with some fibres running superiorly along the margins of the cleft towards the nasal tip (**Figure 2**) [16, 17].

3. Bilateral orofacial cleft lip and palate

Babies born with bilateral cleft lip and palate often present a challenge to the cleft care team. In these cases, the alar cartilages have failed to migrate up into the nasal tip and stretch the columella. So, the cartilages are positioned along the alar margins and are stretched over the cleft as flaring alae. The prolabium also lacks muscle tissue and is positioned directly on the end of the shortened columella. In the complete bilateral cleft, the premaxilla is suspended from the tip of the nasal septum, while the clefted alveolar segments stay behind (**Figure 3**) [18, 19]. The primary issue in these cases is that the premaxilla is unattached laterally and is positioned far too anteriorly by the time lip surgery is scheduled. Secondly, in some cases, the lateral width of the premaxilla exceeds the anterior space between the two lateral maxillary segments. A combination of these two challenges may also exist.

Figure 3.
Bilateral orofacial cleft lip and palate.

4. Procedure

Before commencing any treatment procedures, the parents/caregivers are counselled about PNAM therapy. The procedure, goals, possible complications and their role is explained to them.

5. Impressions

Several impression materials and techniques have been advocated for making the impression of the clefted alveolar segments. Grayson and Shetye [20] advised keeping the child nil orally for about 4 hours and making the impression while holding the baby upside down to prevent aspiration in the event of vomiting and asphyxia due to airway obstruction. A thick mix of tissue conditioning material was loaded onto the tray and inserted intraorally. The impression is allowed to set while the baby is making suckling actions in order to create the desired border seal and ensure the baby's ability to perform nasal breathing. The baby's oxygen level was monitored during the entire duration of impression making.

Retnakumari et al. [21] used heavy body silicone impression material with the baby in a supine position during the procedure. Dubey et al. [22] kept the baby in the mother's lap with the head facing downward and her hands supporting the baby's chest and lap region while making the impression. Yang et al. [23] advised alginate impressions using a beaded pretrimmed paediatric tray. Splengler et al. [24] made intraoral and extraoral alginate impressions with the baby under general anaesthesia. This method is generally not recommended as the patient is subjected to hospitalisation for an impression procedure.

Irrespective of the material and technique used, the sole objective of including all the available undercuts in the dental cast should be met. An ideal impression material must be rigid and set fairly quickly in the baby's mouth. The baby is positioned in an upright position, fully awake on the caregiver's lap. It is preferable if the baby is crying, as it allows better visuals of the extent of the cleft. The entire clefted palate should be recorded (**Figure 4**) and the size of the cleft should be determined on the resultant cast using a Vernier calliper.

Figure 4.
Impression of the clefted segments in a unilateral cleft (A) and a bilateral cleft (B).

6. Appliance fabrication and design

The moulding plate is fabricated on the dental stone cast obtained from the impression. All the undercuts and the cleft space are blocked with wax. The moulding plate is made up of clear acrylic. A 5 mm hole is incorporated to facilitate breathing in case of accidental dislodgement (**Figure 5**). The plate must be 2–3 mm in thickness to provide structural integrity and permit adjustments during the process of moulding.

Figure 5.
On the obtained cast (A), cleft space is blocked out with wax (B) and the moulding plate is fabricated with a breathing hole (C).

Figure 6.
Two retentive arms are incorporated in bilateral cases.

A retentive acrylic arm is fabricated and positioned labially at an angle of 40 degrees to the plate. It should be placed at the junction of the upper and lower lip. The retentive arm adequately secures the moulding plate in the mouth with the help of orthodontic elastics and tapes. In bilateral cases, there is a need for two retentive arms (**Figure 6**) [13]. The appliance has to be finished and polished ensuring that no sharp borders are present.

7. Appliance insertion and moulding

The NAM appliance was tried on the baby. The intaglio surface of the plate was then modified to allow for selective pressure on the two segments of the arch using tissue conditioner. There is selective removal of acrylic in the region into which the movement of alveolar bone is desired; and tissue conditioner was added to regions from which, the alveolar bone needed to be reduced. Selective pressure was applied on the greater and lesser alveolar segments to permit moulding. 1 mm thickness of tissue conditioner was applied onto the outer surface in the region of the greater

segment and the inner surface was relieved by 1 mm. Tissue conditioner was also applied on the inner surface in the region of the lesser segment and the outer region was relieved by 1 mm (**Figure 7**). This caused a force that was directed inward on the greater segment and outward on the lesser segment that would cause approximation of alveolar tissue [25].

The NAM appliance is secured extra orally to the cheeks and bilaterally by surgical tapes with orthodontic elastic bands at one end. A muslin head cap with Velcro strips at the side is tailor-made for the baby (**Figure 8**). The Velcro strips provided attachment of the elastic bands, as well as facilitated their placement and removal. The elastic band is looped on the retentive arm of the moulding plate and secured with tape to the cheeks. The elastics with an inner diameter of 0.25 inch, and heavy wall thickness, should be stretched to about twice their resting diameter in order to achieve an ideal activation force of about 100 g. The amount of force could vary depending on the clinical objective and the mucosal tolerance to ulceration. Additional tapes may be necessary to secure the horizontal tape to the cheeks.

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 moulding plate. These adjustments are made by selectively removing the hard acrylic and adding the

Figure 7.
Selective pressure applied on the clefted alveolar segments.

Figure 8.
A custom made muslin head cap used to secure the NAM appliance.

soft tissue conditioner to the moulding plate. No more than 1 mm of modification of the moulding plate should be made per visit. The desired movement can usually be accomplished within 6 to 8 weeks.

The NAM appliance needs to be worn 24 hours a day and removed only for daily cleaning, and needs to be inserted back soon afterwards. Even after 3 weeks, most cases did not show any clinical evidence of tissue irritation or accumulation of debris.

The effectiveness of the selective moulding is enhanced by adequately supporting the appliance against the palatal tissues and taping the lip segments across the cheek. This tight apposition of the lip segments provides the same benefit of traditional lip adhesion, but without the consequent scarring. It also serves to improve the alignment of the nasal base by bringing the columella towards the midsagittal plane, thereby improving the symmetry of the nostrils. Lip adhesion in isolation produces an uncontrolled orthopaedic movement. However, if carried out along with the moulding plate, the movements can be more precise and controlled.

8. Nasal stent

The nasal stent is added to the NAM appliance when the width of the cleft is reduced to a size of ≥ 6 mm. The reasoning behind delaying the addition of the nasal stent is that when the cleft size reduces, the alignment of the base of the nose and the lip segment also improves. The alar rim, which was initially stretched over the clefted segments at birth, will show some laxity, now that the cleft size has reduced and thus can be elevated into a symmetrical and convex form with the nasal stent. Any attempt to correct this deformity before reducing the cleft size may result in an undesirable increase in the lateral alar wall [26].

Matsuo and Hirose [27] suggested a silicone nasal conformer, which can be used for presurgical nasal moulding. The height of the conformer is 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 moulding force against the clefted alveolar segments.

Grayson and Shetye [20] adapted nasal stent to extend from the anterior flange of an intraoral moulding plate. The greatest advantage of NAM is that it enables the practitioner to apply force skilfully to shape the nasal cartilage. Figueroa's technique [28] involves the simultaneous moulding of the alveolar cleft and nasal cartilage using a rigid acrylic nasal extension attached to an acrylic plate. Elastics are attached to the acrylic plate to allow gentle retraction of the premaxilla. A soft resin ball may also be attached to the acrylic plate across the prolabium in order to maintain the nasolabial angle. In bilateral cases, there is a need for two retentive arms as well as two nasal stents which are similar in shape to the unilateral stent.

The nasal stent is made from 19 gauge (0.36 inch), round stainless-steel wire, in the shape of a 'Swan Neck' (**Figure 9**). The base of the stent should be located midway between the clefted lip segments. The superior loop is adjusted to fit passively in the nostril on the cleft side. The nasal portion of the wire is then covered with self-cure clear acrylic and then by a layer of the tissue conditioner until mild blanching is evident. This superior lobe gently lifts the nasal dome forward, while the lower lobe lifts the tip of the nose and defines the top of the columella.

Figure 9.
Nasal stent.

Through gradual increments of tissue conditioner, the nostril on the cleft side is lifted to achieve acceptable elevation, and symmetry moulding continued until the desired nasal cartilage and alveolar shape is achieved.

Shetty et al [29] used the following protocol for presurgical NAM therapy:

1. First visit:

- Parent education and counselling: Use of audiovisual aids and live demonstrations
- Interaction with parents of older NAM patients
- Diet counselling
- Detailed documentation: Photographs and Dentofacial impressions
- Medical evaluation of patients
- Demonstration of daily appliance care
- Awareness and management of possible complications

2. Second visit (1 week after the first visit):

- Evaluation of patient and parent compliance
- Detailed documentation
- Evaluation of fit of the appliance and required modifications
- About 8–10 mm gap between the clefted segments—aggressive alveolar moulding

3. Periodic 3 weeks recall visits:

- Evaluation of patient and parent compliance
- Detailed documentation

- Comparison of dentofacial impressions recorded before treatment outcome and assessment.
- Fit of the appliance and required modifications
- Nasal moulding
- Active alveolar moulding continued till completion
- Passive alveolar moulding started once complete approximation of alveolar segment achieved
- Fabrication of new appliance every 2 months
- Parents participation in periodic NAM workshops

4. Care and instructions

- Washing of plate should be with warm water
- Never use a 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 an upright position not sleeping

5. Troubleshooting 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 the doctor

6. Troubleshooting for cleft care team:

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

9. Lip and nose surgery

The success of PNAM depends upon the surgical procedure and the treating surgeon's skill. The surgical procedure, most commonly recommended is the modified gingivoperiosteoplasty (GPP), described by Millard and Lantham [30] carried out usually within 12–16 weeks of age. The surgery may be delayed in cases where additional weeks of PNAM therapy is needed. The surgical procedure involves a first stage primary lip nose repair to close the alveolar defect followed by one-stage palatal repair at 11–13 months of age when speech begins to develop (Figure 10) [31].

Figure 10.
Lip and nose surgery.

10. Extraoral nasal stent

Postsurgery, an additional external nasal stent can be given for 1 year to improve the nasal morphology if it did not resemble the unaffected side and also maintain the nasal correction if needed. The postsurgical external nasal stent is fabricated by making an impression of the unaffected nostril using tissue conditioner, and using it to mould the nasal contour on the cleft side [32].

11. Complications

The most common complication with the NAM therapy is irritation of the oral mucosa, gingival tissue and nasal mucosa. These issues arise due to the forces applied by the appliance [20]. They can be avoided by careful examination and modification of the extent and fit of the appliance. Fungal infection is another complication that can occur due to poor oral hygiene and continuous wear of the appliance. This can be avoided by following a meticulous oral hygiene routine and following the wash care instructions for the NAM plate. In severe cases, local nystatin or systemic amphotericin can be used [33].

12. Conclusion

Presurgical infant orthopaedics by means of nasoalveolar moulding enables the surgeon to carry out gingivoperiosteoplasty, which decreases the need for a second

surgery. Bilateral cases, especially benefit as columella lengthening is carried out nonsurgically. It also minimises scar tissue formation and provides for more consistent outcomes. PNAM is most successful when initiated early and through meticulous planning and collaboration between the various disciplines.

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