Modified Presurgical Nasoalveolar Molding in the Infants with Complete Unilateral Cleft Lip and Palate: A Stepwise Approach

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Abstract Presurgical orthopedics in one or the other form has been an important part of the multidisciplinary approach towards the better cleft care. Presurgical nasoalveolar molding (PNAM) was described as a modified approach to the conventional form of orthopedics. PNAM not only reduces the severity of the alveolar defect before surgery, it also reduces the nasal deformity bringing it near to the normal. Nonsurgical nasal correction forms an important adjunct to the primary nasal repair at the time of primary lip repair. However, acceptance of nasoalveolar molding in Indian set-up has not been wide spread due to various reasons such as lack of the resources and inability of the parents to comply with the frequent adjustment schedule. At the Nitte Meenakshi Institute of Craniofacial surgery at the Nitte University, Mangalore, authors have developed a modification of the PNAM appliance previously described in the literature. The key modification is done at the time of fabrication of the occlusal prosthesis. This modification has made the overall procedure simpler

and at the same time helped to reduce the recall visits by half of the originally required. This article describes the fabrication procedure of the modified nasal alveolar molding appliance and the modified treatment protocol in a stepwise manner.

Keywords Nasoalveolar molding · Presurgical orthopedics · Malformation · Deformation

Classical cleft nasal deformity is a secondary deformation anomaly that arises in the fetal period secondary to the primary cleft lip and palate malformation. It presents itself in a typical abnormal form or position of the nasal structures. Although the nasal deformity follows a pattern, severity of the deformity depends upon the underlying soft and hard tissue defect.

Correction of the cleft nasal deformity has been the greatest challenge to the cleft surgeons. Nasal deformity increases with the time if left untreated [1]. Unrepaired nasal deformity also leaves the stigmata of cleft till the adolescence. Also secondary correction of the nasal deformity would lead to more surgical scarring and less than ideal results [2]. Thus, any form of the nonsurgical treatment to reduce the nasal deformity early in the life is highly desirable.

There have been attempts in the experimental animal models to reverse this deformation by in utero nasal molding [3]. This deformity also lends itself to the post-natal correction by nonsurgical means by virtue of its plasticity [4]. This property of the immature infant cartilage is best utilized with in the first 6 weeks of the birth [5]. First attempt at the presurgical nasal correction was made by Matsuo et al. [5, 6]. Grayson [7] conceptualized the combination of the presurgical nasal molding with the conventional form of the presurgical orthopedics.

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Since 2005, at The Nitte Meenakshi Institute of Craniofacial surgery, PNAM as described by Grayson [7] has been used for the patients with unilateral cleft lip and palate (UCLP). The PNAM requires weekly visits over a period of 3–5 months. Being a tertiary care center, it receives patients from the far off places. Many of these patients cannot afford weekly visits for the frequent adjustment as required by the original protocol.

Authors have utilized a modified appliance with increased interval of the recall period. This article describes the use of modified presurgical nasoalveolar molding appliance with a modified protocol.

Procedure

Treatment begins with the evaluation by the members of the multidisciplinary team. It is preferable to start the treatment as soon as possible to take advantage of the plasticity of the tissues. Immediate and long term goals and priorities are determined for the patient. Once the syndromic associations and systemic anomalies are ruled out, the patient is considered fit to undergo the presurgical treatment. Patients with the life threatening syndromes and respiratory difficulty are not considered for the presurgical treatment. Informed consent is obtained for every case.

Impression Making

Following the clinical examination, an impression of the intraoral cleft defect is made using a heavy bodied silicone elastomeric impression material (Speedex putty, Coltène/Whaledent AG, Altstätten/Switzerland) in an infant acrylic impression tray. Impression trays are chosen from a collection of variously sized trays made from previously obtained maxillary dental casts of the patients with unilateral cleft lip and palate. There are separate trays for the right and the left side clefts.

Fig. 1 Intra oral impression poured with dental stone to obtain accurate cast used for making appliance

Patient positioning is an important part of the overall procedure. The infant is held upside down in the mother's lap in such a way that the infant's neck can be extended for the maximum exposure for the operator. Care should be taken to support the infant's head. This positioning helps to visualize the posterior extent of the tray. Flow of the impression material should be controlled so that it does not go beyond the tray boundaries. Through-out the procedure it is made sure that the infant is actively crying. It helps to avoid the choking of infant's airway and also makes direct visualization of the cleft possible. In the initial stages impressions were made in the operation theatre in the presence of the anesthetist to handle any airway emergency. But as we have gained experience with the impression technique, all the impressions are made in the maxillofacial surgery unit outpatient department in the hospital. Special care is taken to prevent the airway obstruction in the neonates when obtaining intra oral impressions. Impression is poured with the dental stone to obtain an accurate cast (Fig. 1).

Fabrication of the PNAM Appliance

Occlusal Plate

A molding plate, made up of hard clear acrylic (RR cold cure, DPI, India), is fabricated on the dental stone model. The plate should have a thickness of 2–3 mm for the structural integrity. This molding plate differs from the conventional orthopedic plate as described by the Hotz [8]. Molding plate is fabricated in such a way that there are no extensions of the plate into the alveolar or palatal cleft space. All the undercuts and the cleft space is obliterated with the modelling wax (Cavex Holland BV) so that cast appears to have an intact alveolus (Fig. 2). At the same time two to three layers of the modelling wax is also added as a spacer in the region where the major segments has to move on the palatal side during the course of the treatment.

Fig. 2 Cleft space and undercuts obliterated with the modeling wax and spacer is added on to the palatal side of major segment

Obliteration of the cleft space and the addition of wax spacer is the key modification. This modification prevents any need for weekly trimming of the occlusal appliance as described by Grayson. Care is taken to smoothen the borders of the plate and relieve the labial frenum attachments sufficiently (Fig. 3).

Retention Arm

One retention arm is attached to the appliance in such a manner that it will allow for the approximation of the cleft lip segments and will not interfere with the resting position of the lower lip. The retention arm is made up of same material as the occlusal plate. Retention arm is around 15 mm long and 5 mm in diameter. The free end of the retention arm has a retention button which adequately secures the molding plate in the mouth with the help of orthodontic elastics and tapes. The exact location and angulation of the retention arm is determined during the try-in of the molding plate in the infant's mouth with the cleft lip segments approximated. The retention arm is positioned approximately at an angle of 30° to the occlusal plane.

Fig. 3 Occlusal plate is fabricated over the dental model, polished and properly relieved in the labial frenum region

Adjustments of the Molding Plate

The molding plate is adjusted to gradually approximate the cleft alveolar segments. It involves the addition of the soft acrylic liner (GC Tissue Conditioner, GC EUROPE N.V., Leuven) at the labial side of the major segment. Addition is done only medial to the labial frenum attachment. Alveolar molding and approximation is achieved only through the addition of soft acrylic at every follow-up visit. Thickness of soft acrylic added is 1 mm or less per visit. The amount of the soft acrylic added could vary depending on the clinical objective and the mucosal tolerance to ulceration. Selective removal of acrylic is usually not required from the palatal side. Whole procedure becomes less tedious as the selective trimming of the molding plate is not required. Also the adjustment period could be increased to 2–3 weeks because there is no interference with the movement of the greater segment as the space is provided by the addition of wax spacer during the fabrication of the appliance. This increased interval of follow up visits reduces the burden equally on the cleft team and the parents.

Insertion of the Appliance and Lip Taping

The appliance is secured extra-orally to the cheeks, bilaterally by the surgical adhesive tapes (1/2 inch Micropore Surgical tape, 3 M, US) that have orthodontic elastic bands (inner diameter—0.25 inch, wall thickness—heavy) at one end. The elastic band on the surgical tape is looped on the retention arm of the molding plate and the tapes are secured to the cheek bilaterally. The elastics are pulled approximately twice their resting diameter to achieve an activation force of approximately 100 g. The activation force can vary depending on the stage of the treatment and the clinical judgement.

At the same time cleft lip segments are approximated with the lip tapes to achieve a nonsurgical lip adhesion. Lip

taping is also helpful in stabilizing the plate in wider clefts (Fig. 4). Active movement of major segment is achieved by forces applied by stretched elastics and over build-up of soft liner on the labial flange of the appliance. At the same time both the segments passively grow into the cleft space. So this technique makes use of both the active application of the force and passive growth for the closure of cleft space. This form of treatment is best considered the semi-active form of the presurgical orthopedics.

The Nasal Stent

The nasal stent extends as a projection from the labial flange of the oral molding plate. It is made up of 0.9 mm round stainless steel wire (3 M Unitek, India) (Fig. 5). The free end of the nasal stent extends into the nostril in such a way that it supports the deformed nasal alar cartilage adequately after the lip segments are approximated by the lip taping (Fig. 6). Hard acrylic is added to the nasal end of the stent to form 7–8 mm long oval form, part of which remains outside the nose. A layer of the soft acrylic liner is added over the hard acrylic core to prevent the mucosal ulcerations.

Nasal molding is best begun as early as possible. Nasal stent is added to the occlusal plate at the beginning of the treatment when the cleft is 12 mm or less than that. If the cleft is wider than 12 mm, then it is preferable to reduce the alveolar cleft deformity before the nasal stent is added. Nasal molding can begin as the nasal cartilage becomes lax with reduction of the severity of underlying skeletal base deformity.

Adjustment of Nasal Stent

Adjustments of the nasal stent is done to gradually modify the abnormal curvature of the cleft nasal cartilage to a gentle round curvature that resembles the normal shape. Gradual adjustments are done by addition of soft liner at

Fig. 4 Occlusal appliance in place with lip taping

Fig. 5 PNAM appliance with a nasal stent attached to the retention arm

Fig. 6 PNAM appliance in place with nasal stent adequately supporting the cleft nasal cartilage

nasal end of the stent. Nasal molding is more effective when child is fed with the plate in place. Lip taping brings the stretched cleft alar margin closer to its normal position and helps in the nasal molding by thus making the cartilage lax.

Conclusion of Nasoalveolar Molding

Once the alveolar segments are approximated and the nose is molded as desired, there is no further activation of the appliance. The appliance is passively kept in place for 2–3 weeks for stabilization of the results achieved as the nasal correction is especially prone for relapse [9]. The goals are, initially, to reduce the severity of alveolar cleft and to reposition the apex of the alar cartilages toward the

tip of the nose and, later, to maintain the achieved morphologic changes.

Parents Instructions

The appliance is worn continuously except for cleansing after feeding. The retention tapes and lip tapes are changed as soon as they become loose. Some infants actively suck on the handle of the plate and resist the removal of the plate from mouth. While some infants may take more time to get used to the presence of the plate in the mouth.

Primary Cheilorhinoplasty

The primary lip repair can usually be performed at approximately 4–6 months of the age. A primary nasal correction is an important part of the overall treatment to achieve ideal results with the nasolabial molding.

Discussion

Use of the presurgical orthopedics in cleft lip and palate has been controversial since its inception in 1950s. Recent prospective studies have clearly shown the questionable benefit of conventional presurgical orthopedics in the unilateral cleft lip and palate patients [10, 11]. Presurgical nasolabial molding was described in the last decade

which conceptualized the combination of nasal cartilage molding along with the conventional form of alveolar orthopedics [7]. However, the critiques of the presurgical treatment have described it as unnecessary, tedious and costly procedure [12].

Presurgical nasolabial molding not only reduces the severity of the defect before surgery, it also reduces the nasal deformity bringing it near to the normal. Nonsurgical nasal correction forms an important adjunct to the primary nasal repair at the time of primary lip repair.

Acceptance for the nasolabial molding has been slow in the Indian scenario. Reason for it is twofold. There is lack of sufficient resources and poor background of the parents further limits the efficacy of the cleft team. We have modified the original protocol and appliance for the presurgical nasolabial molding originally described by the Grayson. This modified procedure becomes more time efficient and less tedious. This helps to increase the parents' compliance. Also these modifications have worked well for us (Fig. 7). Our experience with this protocol and modified appliance has further convinced us that this method can be utilized effectively in the Indian set-up. Further longitudinal studies with long term follow-up will provide more evidence. Motivation and teaching of the parents is extremely important for the overall success of the treatment. Parents' compliance makes an important contribution towards the achievement of good results.

Fig. 7 An infant with right unilateral cleft lip and palate treated with the modified appliance and the modified treatment protocol. **a** Patient at 5 days of age showing stretched cleft nasal cartilage over widely separated cleft lip segments. **b** Same patient after completion of nasolabial molding showing approximation of cleft lip segments and improved symmetry of the nose. **c** Typical cleft nasal deformity

with lateral splaying of the lower lateral nasal cartilage and caudal displacement of the medial crus of the cartilage. **d** Improved nasal cartilage morphology and elongation of columella on the cleft side. **e** Alveolar cleft gap in the beginning of the treatment. **f** Alveolar cleft segments have approximated by alveolar molding. **g** Same patient after the primary lip-nasal repair showing symmetrical nostrils

References

1. Converse JM, Hogan VM, Borton FE (1977) Secondary deformities of cleft lip, cleft lip and nose, and cleft palate. In: Converse JM (ed) *Reconstructive Plastic Surgery*, vol 4, 2nd edn. Saunders, Philadelphia
2. Bennum RD, Perandones C, Sepiarsky VA, Chantiri SN, Aguirre MI, Dogliotti PL (1999) Nonsurgical correction of nasal deformity in unilateral complete cleft lip: a six-year follow-up. *Plast Reconstr Surg* 104:616
3. Levine JP, Bradely JP, Shahinian HK et al (1999) Nasal expansion in the fetal lamb: a first step toward management of cleft nasal deformity in utero. *Plast Reconstr Surg* 104:607
4. Matsuo K, Hirose T, Tonomo T (1984) Nonsurgical correction of congenital auricular deformities in the early neonates: a preliminary report. *Plast Reconstr Surg* 73:38–50
5. Matsuo K, Hirose T, Otagiri T, Norose N (1989) Repair of cleft lip with nonsurgical correction of nasal deformity in the early neonatal period. *Plast Reconstr Surg* 83:25
6. Matsuo K, Hirose T (1991) Preoperative non-surgical over-correction of cleft lip nasal deformity. *Br J Plast Surg* 44:5
7. Grayson BH, Santiago PE, Brecht LL, Cutting CB (1999) Pre-surgical nasoalveolar molding in infants with cleft lip and palate. *Cleft Palate Craniofac J* 36:486
8. Hotz M (1969) Pre- and Early postoperative growth-guidance in cleft lip and palate cases by maxillary orthopedics (an alternative procedure to primary bone grafting). *Cleft Palate J* 6:368–372
9. Liou EJ, Subramanian M, Chen PK (2004) Huang CS: The progressive changes of nasal symmetry and growth after nasoalveolar molding: a three-year follow-up study. *Plast Reconstr Surg* 114:858–864
10. Prah C, Kuijpers-Jagatman AM, van't Hof MA, Prah-Andersen B (2001) A randomized prospective clinical trial into the effect of infant orthopedics on the maxillary arch dimensions in unilateral cleft lip and palate (Dutchcleft). *Eur J Oral Sci* 109:297–305
11. Prah C, Kuijpers-Jagatman AM, van't Hof MA, Prah-Andersen B (2003) A randomized prospective clinical trial of the effect of infant orthopedics in unilateral cleft lip and palate: Prevention of collapse of alveolar segments (Dutchcleft). *Cleft Palate Craniofac J* 40:337–342
12. Salyer KE (2004) Unilateral cleft lip-nose repair—long-term outcome. *Clin Plast Surg* 31:191–208