Presurgical Nasoalveolar Molding Assisted Primary Reconstruction in Complete Unilateral Cleft Lip Palate Infants

Vasant Radhakrishnan* / VP Sabarinath** / Pallavi Thombare*** / PV Hazarey**** / Raman Bonde***** / Anil Sheorain******

Background: *Various methods have been described for the primary surgical reconstruction of the unilateral cleft lip and palate deformity (UCLP) in infants. There have been several attempts at restoring the normal anatomy of the nose at the time of lip repair in the affected individuals with varying degrees of success. Presurgical nasoalveolar molding (PNAM) is a presurgical infant orthopedic procedure that attempts to target the nasal deformity leading to a more esthetic surgical repair.* ***Objective:*** *At our center we aimed to use PNAM to help in providing the surgical team with a better foundation for an easier and more esthetic single stage repair at the level of nose in addition to the lip and alveolus.* ***Method:*** *The infant nasal cartilages are amenable to correction in the first few weeks of life when they retain their plasticity. Three infants with complete unilateral cleft lip palate (CUCLP) were operated upon after a course of PNAM. No nasal stents were use after repair to retain the results.* ***Results:*** *PNAM reduced the extent of the cleft deformity and improved the anatomic relationship between the affected structures. Postoperative recovery was uneventful. Subjective evaluation immediate post surgery and at the time of palate repair reveals adequate nasolabial esthetics. Long term results of PNAM assisted repair are to be ascertained.* ***Conclusions:*** *The use of PNAM enables in reducing the severity of the deformity the surgical team has to tackle thereby enabling in a better and esthetic primary repair*

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INTRODUCTION

Clefts of the lip and palate are the most common congenital defect involving the orofacial region.[1] The aim of treatment is to restore normal anatomy. In complete unilateral cleft lip palate (CUCLP) in addition to the lip, alveolus and palate, the nose too presents with deformity. The nasal component in the unilateral cleft deformity is characterized by a columella that appears shorter on the cleft side and an oblique position with its base deviated to the non-cleft side. The ala is flattened; resulting in horizontally orientated and asymmetrically proportioned nostrils. The base of the ala is displaced laterally and/or posteriorly or inferiorly. The nasal tip is displaced in the frontal and horizontal planes. The lateral crus of the lower lateral cartilage and the adherent skin are drawn into an S-shaped fold. The lower lateral cartilage too is displaced in frontal and horizontal planes.[2] Interestingly studies have reported that there are no differences between the cleft and noncleft side lower lateral nasal cartilage histologically and in size. It has been reported that displacement of the alar cartilage rather than hypoplasia is the major factor in cleft nasal deformity associated with cleft lip.[3,4] The nasal component of the deformity poses challenges for a good esthetic correction. Presurgical nasoalveolar molding (PNAM) and early surgical nasal correction involving the manipulation of the lower lateral cartilages are emerging as standard in contemporary management of primary cleft lip palate (CLP) deformity repair at many centers. This integrated approach aims at a complete esthetic primary surgical correction of all areas of the deformity including the nose minimizing the need for secondary surgical interventions later in life.

Presurgical infant orthopedics (PSIO) involves any orthopedic manipulation of the segments of the clefted maxilla in

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a newborn with complete unilateral or bilateral CLP aiming at establishing a more normal maxillary alveolar arch form or at retracting a protruding premaxilla to facilitate the surgical repair of the lip.[5] PSIO may prove to be beneficial to the surgeon if a better alignment and closer approximation of the cleft segments is achieved before the actual surgical repair. Narrowing down of cleft width as a result of PSIO generally makes surgical repair easy. Maisels[6] suggested that, when cleft closure is easier then the results of surgical repair tend to be better. Several benefits have been claimed for the use of PSIO including normalization of feeding and tongue function, better speech development, reduced risk of aspiration, easier and more aesthetic lip repair and reduced severity of dental and skeletal deviations in future providing a positive psychological impact on parents.[7] Despite the controversy surrounding PSIO, it continues to remain an important modality of treatment for the cleft infant.

There are several approaches that have been described for PSIO with essentially the same aims. The different appliances that exist for infant maxillary orthopedics have been previously reviewed.[8] The Hotz plate of the Zurich approach[9] aims at aligning the alveolar segments in the cleft infant prior to surgery. Matsuoe[10] initially described the use of silicone stents for non-surgical correction of the nasal cartilages in infants before surgery. The use was however limited to infants with partial clefts. Grayson and co-workers combined the finest of both the worlds and extended the possibilities for use in infants with complete clefts as well, in their approach called presurgical nasoalveolar molding.[11-13] It is a staged procedure in which molding of the alveolar segments is undertaken followed by correction of the cleft nasal deformity at a time when amenable to correction using nasal stents. Correcting the displacement of the lower lateral nasal cartilages presurgically provides a better foundation for surgical reconstruction of the cleft nasal deformity. This presurgical approach leads to a reduction in the severity of the deformity in the three major anatomic regions (lip, alveolus and nose) that the surgeon has to tackle. PNAM is a relatively new addition to our armamentarium. Here we describe the primary surgical repair of three CUCLP infants assisted with a presurgical course of PNAM.

METHOD

After a team evaluation of the case the parents are explained the procedure of PNAM including the potential benefits and possible complications. Functional benefits to the infant such as better feeding without nasal regurgitation due to the presence of an intraoral acrylic plate are stressed upon. Complications like intraoral ulcerations due to rough areas on the plate or extraoral eryhtema on the cheeks due to improper tape removal are also explained. Most importantly the need for parental cooperation is highlighted during the first visit. This is followed by an intraoral maxillary impression made using the procedure previously outlined by the authors.[14] Two stone casts are obtained one of which serves as the working model and the other the study model. The alveolar cleft and any other undercut areas on the working models are blocked and cold cure acrylic resin (DPI-RR Cold Cure, India) is used to fabricate a plate not more than 2mm in thickness. Too thin a molding plate will lack adequate structural stability and will not permit trimming during the course of therapy. The plate is checked for smoothness and absence of any rough regions and a trial fit undertaken in the infant's oral cavity. Proper fit of the plate is evidenced by the infant making attempts at sucking on the plate or operators finger during the trial procedure. Choking or gagging during trial could mean an increase in posterior extension of the plate, which needs to be reduced. Deciding upon the proper position of the acrylic retentive button on the labial flange of the plate follows this step. The button needs to be positioned so that it does not prevent lip approximation and vertically it should lie in between the upper and lower lips. The correct position is marked and the retentive button is attached to the intraoral plate using cold cure resin. The retentive button connects the intraoral plate to the extraoral elastic tape force system (Fig1A). After a period of two days progress is evaluated and alveolar molding is actively undertaken by addition of soft liner (GC Corporation, Japan) and removal of acrylic from select areas of the plate. If the infant starts with PNAM early enough, then we wait for the alveolar defect to reduce to less than five millimetres before nasal stents are constructed for active nasal molding (Fig1B). Infants are seen at ten day intervals and with the use of Titanium Molybdenum alloy wire (TMA) for nasal stents this interval is increased even up to twenty days. PNAM is a procedure in which three anatomic areas are addressed.

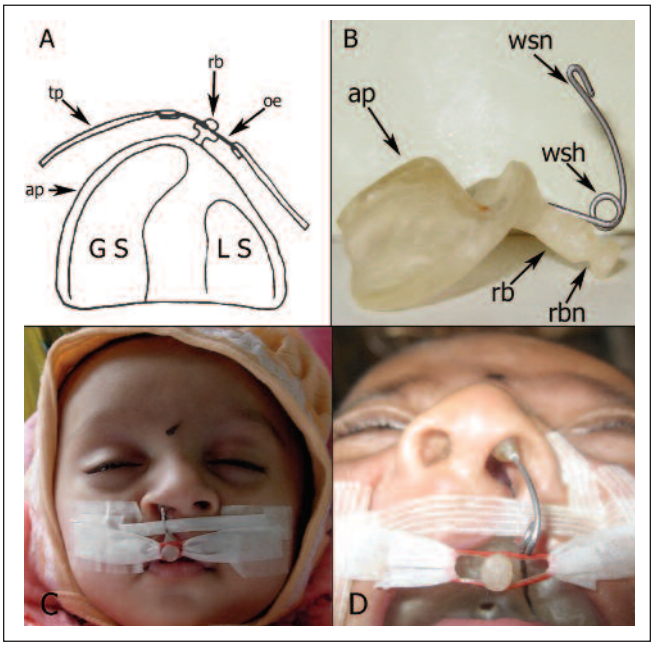

Fig 1A – Illustration of the occlusal view of the appliance showing the retentive button (**rb**) connecting the intraoral acrylic plate (**ap**) to the extraoral tape (**tp**)orthodontic elastic (**oe**) system. **GS** is greater segment on non cleft side and **LS** is lesser segment on cleft side **B** – Photograph of lateral view PNAM appliance with wire nasal stent with helix (**wsn**). Helix (**wsh**) acts as awire reservoir for adjustments. Acrylic palte (**ap**),retentive button (**rb**) and notch (**rbn**) for securing the orthodontic elastics (**oe**). **C** – Photograph of infant with PNAM appliance and Stainless steel nasal stent. **D** – Photograph of infant with PNAM appliance and TMA nasal stent

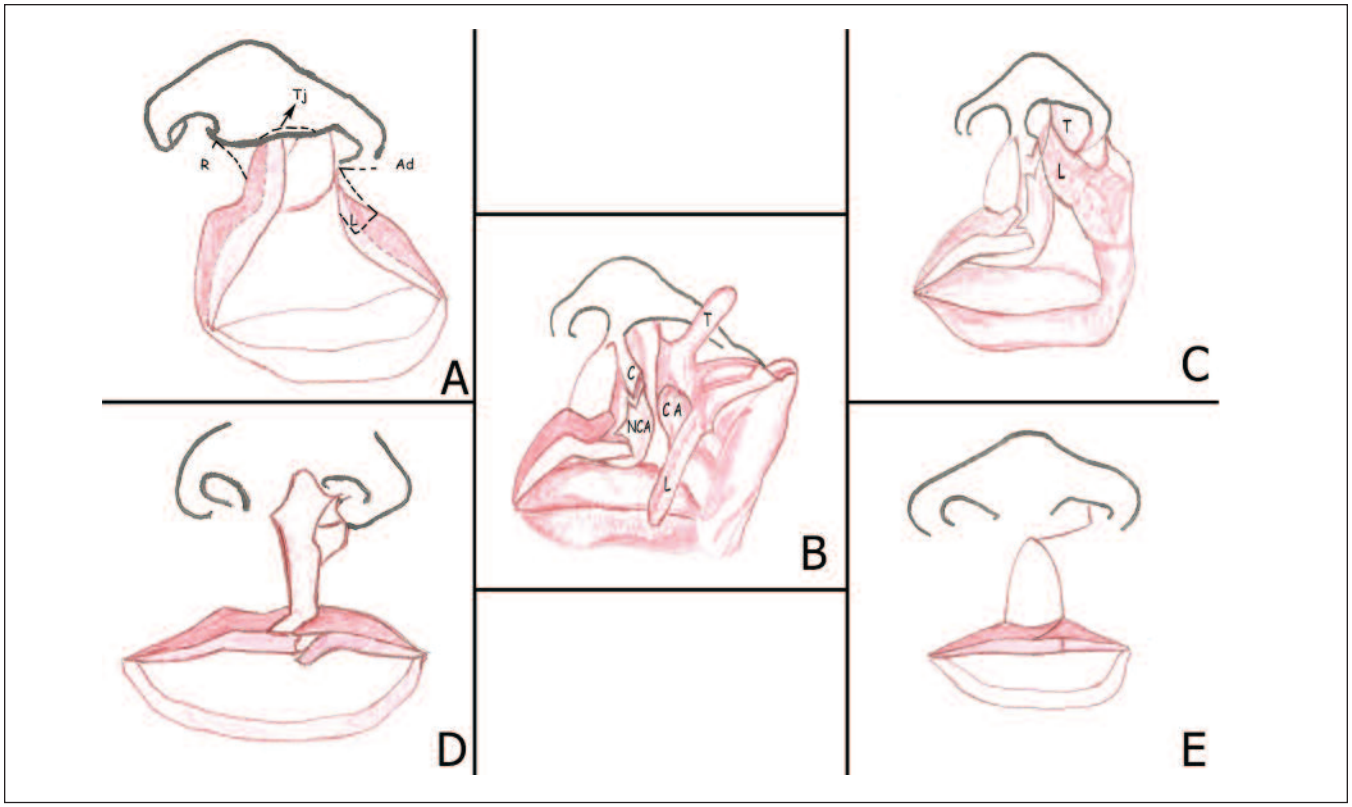

Fig 2 A - Illustration of surgical technique. Rotation (**R**), Advancement (**Ad**), L flap (**L**) and Tajima incision (**Tj**). **B** - Ilustration Turbinate flap (**T**). CA is cleft side alveolus, NCA is non cleft side alveolus. **C** - Ilustration of flap forming the floor of the nose. **D** – Ilustration of vermillion triangular flap. **E** – Illustration of final closure.

Lip

Hypoallergenic surgical wound closure strips are used for the purpose of nonsurgical lip adhesion to approximate the lip segments prior to definitive repair. At our center we use skin closure strips made of a porous, non-woven elastic material coated with a hypoallergenic adhesive (Steri-strip, 3M, USA). Benzoin Tincture is used on the cheeks prior to lip taping in order to boost the adhesiveness of the tapes. Care needs to be exercized especially at the time of removal of the tapes as improper handling may lead to skin erythema on the cheek of the infant. We advise parents to wet the tapes with luke warm water initially. After a two minute period the skin of the infant is stretched in the opposite direction of tape removal and tape atraumatically peeled off. The use of base tapes that are changed less frequently and application of aloe vera gel are other methods to reduce skin irritation. The site of application of the tapes may also changed periodically to reduce skin irritation

Alveolus

Controlled sequential addition of soft relining material to and removal of hard acrylic from select areas of the intraoral plate at the period of the infantile growth spurt help reduce the alveolar cleft and achieve contact of the alveolar segments. Parents are also advised on the additional benefits of a prone sleeping position of the infants to supplement the alveolar molding effect. Early and fast alveolar molding results are vital before embarking on nasal molding. Nasal molding begins as the alveolar defect reduces to five millimetres or less.

Nose

Molding of the nasal cartilages is possible in the infant owing to the high levels of maternal estrogen present. This is a time bound event and is possible in the crucial 4 to 6 weeks of life. The nasal extension from the intraoral molding plate has seen a progressive evolution. We previously adopted the use of round 36 mil stainless steel **(**Fig1C). Presently we use a 36 mil round TMA wire incorporating a helix with an intranasal acrylic bulb as described by Liou and co-workers (Fig1D).[15] The size and shape of the acrylic nasal bulb may also be modified to achieve proper nasal morphology.

Surgical repair

The surgical procedure was generally based on the outcome of the course of NAM. The surgical repair of the unilateral cleft lip and hard palate is done primarily with the Mohler modification of the Millard rotation and advancement technique[16] with the following few additional modifications. Unilateral Tajima incision (Fig2A) on the cleft side ala is made and dissection carried out above the lower lateral cartilages bilaterally through the incision. The L shaped vermillion mucosal flap (Fig 2A) is used to line the cleft space between the alveolar segments. The alar cartilages are freed from attachments on the lateral nasal wall and from the overlying skin. The skin of the roof of the nose is left attached to

Fig 3 A – F. Case 1 Pre NAM ,Post NAM and Post Surgical frontal and worms views

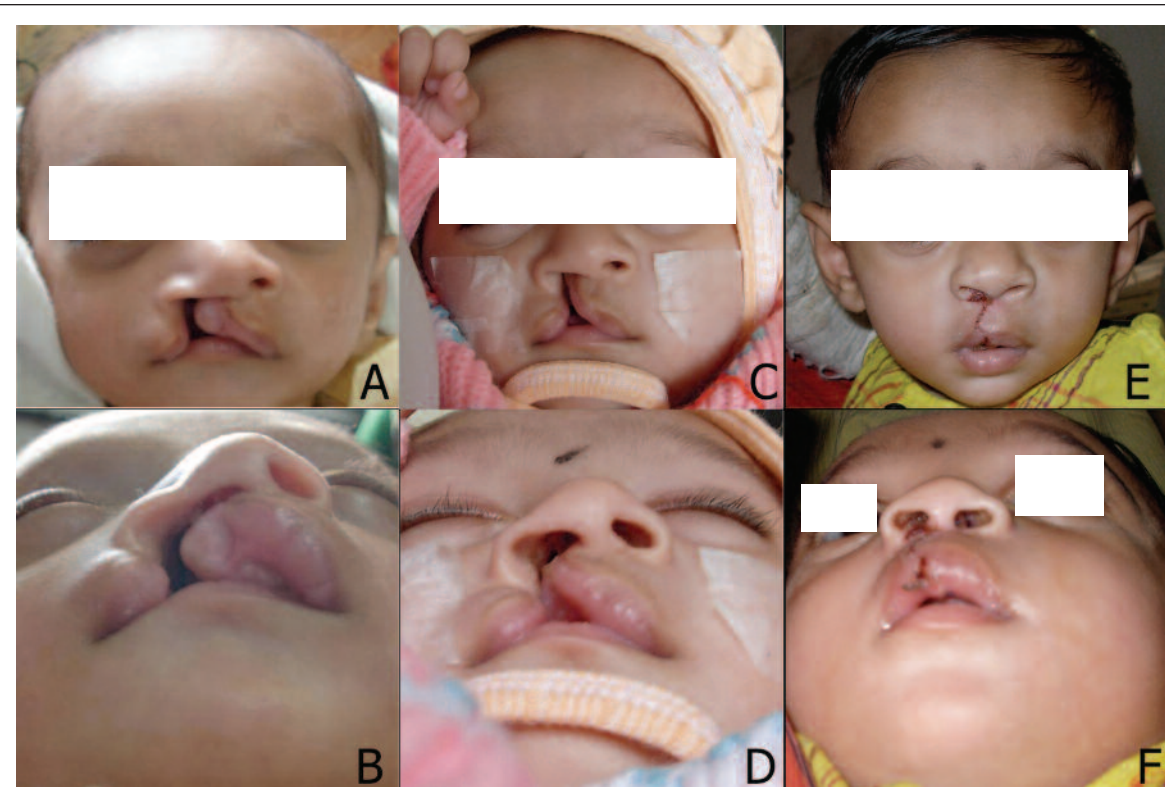

Fig 4 A – F. Case 2 Pre NAM, Post NAM and Post Surgical frontal and worms views

Fig 5 A – F. Case 3 Pre NAM, Post NAM and Post Surgical frontal and worms views

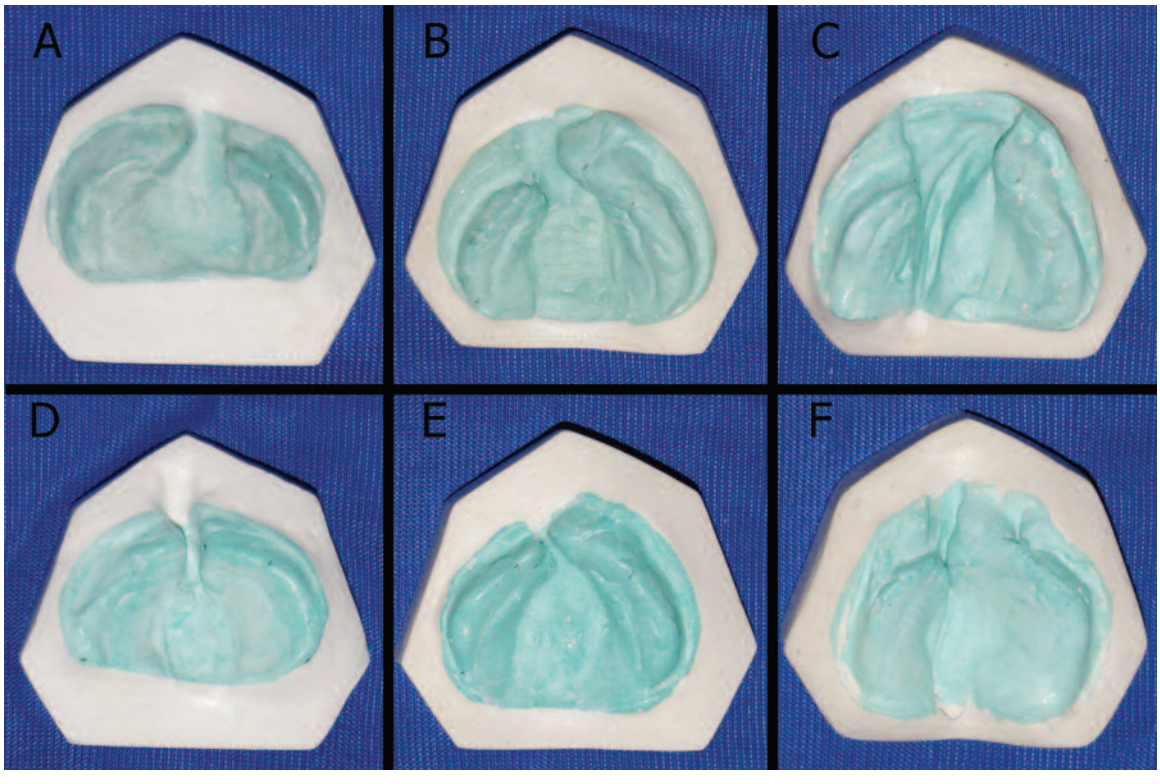

Fig 6 A-C. Dental study models of Pre NAM alevolar morphohlogy of Cases 1,2 and 3
D-F. Dental study models of Post NAM alevolar morphohlogy of Cases 1,2 and 3 showing significant reduction in alveolar cleft width

Fig 7A-C. Case 1,2 and 3 frontal view at follow up visit for palatoplasty.

the lower lateral cartilages. Two 5-0 PDS sutures are passed at the skin beginning at the skin over the cleft side ala cartilage passing through the nasal septum and alar cartilage of non cleft side and back again through the septum and cleft side alar cartilage and skin in a mattress fashion and sutured. A second suture is passed between the two cartilages just below the medial crus thereby defining the columella. A turbinate flap (Fig 2B) as described by Noordhoff[17] is raised and sutured to the mucosal flap of the nasal septum. The flap is used to form the floor of the nose (Fig2C). The hard palate cleft is repaired at the same time with a vomerine flap sutured to the oral mucosa of the cleft side. This leads to a single stage repair of the hard palate. A vermillion triangular flap (Fig2D) is used to correct the deficiency of vermillion present on the non cleft side. Suture removal is done on the fifth postoperative day. Post surgically no form of nostril retainer or stent is used to retain the results achieved.

RESULTS

PNAM helped in reducing the extent of the deformity in all the three infants from pre-treatment (Fig3A, Fig3B, Fig4A, Fig4B, Fig5A, Fig5B) at the level of nose and lip. There was significant improvement in nasal tip projection, columella size on cleft side and position of lower lateral cartilages as well as approximation of the lip segments (Fig3C-F, Fig4C-F, Fig5C-F).Additionally the alveolar defect was also reduced to a significant extent in the three infants from pre PNAM (Fig6A, Fig6B, Fig6C) to post PNAM (Fig6D, Fig6E, Fig6F). The postoperative recovery was uneventful in all the three cases. Ratings of nasolabial esthetics of photographs were done by two independent members one each from the surgical and orthodontic team immediate post NAM and at the time of suture removal as in an earlier study.[18] Nostril symmetry results for two of the infants was satisfactory and one was reasonable (Table1). Short term follow up (Fig7A, Fig7B, Fig7C) to the time of palatal surgery revealed retention of the results with minimal or no relapse in spite of not using nasal stents post surgically. Long-term results are yet to be ascertained.

DISCUSSION

Management of the cleft deformity aims at achieving normal anatomy and function. PSIO procedures serve as an adjunct to the surgical team. The underlying purpose of PSIO is achieving a near to normal anatomic relationship of the affected structures prior to surgery. PSIO aids in reducing the extent of distortion, deviation and displacement of the affected structures. This in turn reduces the extensive undermining of tissues during surgery helping the surgical team in an easier and more aesthetic repair.

Since the early 1990s many centers across the world have reported on the use of PSIO targeting the nasal component of the cleft deformity. In addition to Grayson; Liou, Figueroa, Dogliotti, Suri, Mitsuyoshi and Doruk have reported on different appliances to achieve the presurgical nasal objectives.[19-22] The intraoral acrylic plate is standard in almost all approaches and some involve sequential adjustments of select areas to achieve a normal alveolar arch form. Most methods also involve aggressive taping of the lip segments to bring them in close approximation. The modifications exist mainly in shape and composition of nasal stent and method of retention of the intraoral plates. Plates described by Liou and co-workers are held in place by suction and adhesion with denture adhesives to boost retention whereas Grayson's appliance makes use of extraorally anchored orthodontic elastics for the purpose. Figueroa *et al* prefer that the plate remains loose in the oral cavity to utilize the functional forces of swallowing and suction to aid in nasal molding. Suri and Thompson use extraoral steel outrigger loops with cheek tapes to secure their muscle activated maxillary orthopedic appliance in place. Nasal stents made of Titanium Molybdenum (TMA), Stainless steel (SS) and Cobalt Chromium alloys combined with intranasal acrylic bulbs and single piece acrylic nasal stents attached to the intraoral molding plate have all been described. TMA with an intranasal acrylic extension is the nasal stent we presently use. TMA has twice the range of action at only half the force of a similar dimension SS wire.[23] This is a boon to parents who have to cover large distances to report for treat-

ment as it has reduced the frequency of activation visits for the parents. Also, the helix acts as a wire reservoir which permits appropriate adjustments to the vector of nasal molding in all three dimensions. With nasal molding there is improvement in nasal morphology prior to repair, primarily the columella size and orientation, alar base and lower lateral cartilage position and nasal tip projection.

PNAM in addition to the nose also addresses the cleft deformity of the lip and alveolus. Presurgical lip taping is standard in most infant maxillary orthopedic approaches and ensures that there is reduced tension at the surgical site after repair and when combined with an intraoral plate leads to a controlled repositioning of the prolabium and premaxilla. Additionally it also enhances the cosmetic result as reduced tension contributes to minimal scarring. The extraoral force from lip taping contributes significantly to the reduction of the alveolar cleft gap. The objective of PNAM for the cleft of the alveolus is to achieve a normal and harmonious alveolar arch form with close contact of the two alveolar segments prior to surgery. To help achieve this objective sequential modifications to the intraoral plate are undertaken on a regular basis. Parents are also advised on the sleeping position of the infants as Huang *et al* have indicated that cleft and ridge widths decreased much faster in newborn cleft patients with a prone sleep position.[24]

As success in NAM is highly dependant on the age of commencement of therapy and parental cooperation results may not be consistent. The role of parents in ensuring success of PNAM needs to be emphasised here. Parents need to be motivated and explained the positive impact that PNAM can deliver prior to surgery, paving the way for easier and more aesthetic surgery. One of the contraindications to PNAM is lack of adequate compliance from parents in spite of repeated instructions. Increased age of the infant is another contraindication for PNAM as the plasticity of the cartilages begins to wane after the first two months of life. It is therefore important to have an aggressive referral system so that orthodontic intervention with PNAM can be initiated as early as possible. At our unit we do carry out PNAM even in older infants but mold both the alveolus and nose together.

Relapse after PNAM has been reported. Most of the centers have used nostril retainers to counteract this relapse. At our center in short term the nose has retained acceptable esthetics with no clinically significant relapse. Long term evaluation of the nose, lip and alveolar morphology is presently being undertaken at our unit and results are awaited.

Table 1.

Case	Cleft side	Sex	Start of PNAM (days)	Duration of PNAM (days)	Alveolar gap Pre PNAM (mm)	Alveolar gap Post PNAM (mm)	Rating Nasal morphology Post PNAM
1	L	M	8	180	6	2	S
2	R	M	50	190	7	1	S
3	R	M	2	133	13	0	R

Nostril symmetry was rated based on a earlier classification[18] as P–poor (flattened, typically cleft ala), R–reasonable (rounded but with indentation), and S–satisfactory (rounded, no indentation)

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