Diversities in presurgical orthopedics: A review
S. Thabitha Rani, R.E. Rajendra, M. Manjula, N. Sreelakshmi, A. Rajesh
Department of Pedodontics and Preventive Dentistry, Kamineni Institute of Dental Sciences, Narketpally, Nalgonda, Telangana, India

Abstract
In children with cleft lip and palate, it is essential to maintain harmony among several aspects of treatment such as growth, esthetics, function and psychosocial development since birth. Treatment of infants with cleft lip and palate has been associated with many marked advances in recent years. To obtain the best possible results, these can and should be incorporated into the cleft team treatment protocols. Deformities in cleft lip and palate exhibit diversities in severity and form, as the wider and complete clefts show significant nasolabial deformity. This article reviews the literature on background of early maxillary orthopedics, various appliances, which have been proposed to reduce the initial alveolar cleft defect and molding of the deformed nasal cartilages, benefits, long-term effects of the same.

History of PSO
The concept of PSO/IO treatment was originated in 1500s. Before the modern school of thought began, extraoral approaches for retracting the protruded premaxilla like facial binding with headcap (Franco, 1951); headcap with arms extending to the face (Hoffman, 1686); bandages over the prolabium (Louis, 1768; Chaussier, 1776; Desault, 1790); facial adhesive strapping (Hullihen, 1844); use of rubberbands (Thiesch, 1875); elastic band attached to a headcap (Von Esmarch and Kowalzig, 1892) have been contributed to the development of this field. A modification to this external binding given by Brophy (1927), was wiring both the ends of the cleft alveolus together in order to reduce the cleft by tightening the wires, (after which lip surgery can be performed). The modern concept of neonatal maxillary orthopedics was introduced by McNeil, Scottish Prosthodontist, from Glasgow University, as an adjuvant that aimed at non-surgical resection to retraction of the premaxilla in bilateral cleft lip and palate (BCLP) infants. This therapy also known as presurgical or early orthopedic treatment, presurgical or infant orthopedics (PSO/IO), early maxillary orthopedics, or more recently nasoalveolar molding (NAM), was rapidly adopted by many centers around the world.

Introduction
Cleft is a congenital abnormal space or gap in the upper lip, alveolus or palate. Cleft palate can be defined as a “furrow in the palatal vault” or “breach in the continuity of the palate.” Huffman and Lierle described nasal deformity associated with unilateral cleft lip and palate (UCLP), includes dysmorphology of the columella, nasal tip, alar cartilage, and nasal sill; is complex and affects the shape of the nose in all three planes of space. The affected lower lateral nasal cartilages are displaced laterally and inferiorly, resulting in a depressed dome, increased alar rim, oblique columella, and an overhanging nostril apex, which effectively shortens the columella on the same side. The bilateral cleft lip deformity generally presents with a procumbent and rotated premaxilla. The alar base width is significantly increased, and the lip segments are widely separated.

The effect of unbridled growth of facial parts especially the septovomerine unit exaggerates the deformity which causes the cleft to widen and the unjointed premaxilla to rotate forward, while the lateral element without attachment to these forces lags behind.

During 16th, 17th, 18th and 19th centuries, various surgical approaches for these soft tissue disparities have been tried to achieve optimal lip repair. Considering the fact that neither of the surgical procedures alone achieved optimal results, the treatment modalities have been taken a paradigm shift from...
reduction of the cleft alveolar segments. In his technique, acrylic plates with “stimulator pads” were constructed from a series of modified plaster models in which the displacement of the palatal cleft segment was gradually reduced. He assumed that each successive plate when worn pressure would stimulate growth of the underlying bone, thus reducing the width of the hard palate defect.\[14\]

Passive plates along with delayed surgical procedures were introduced in Zurich, Switzerland in 1957 as an attempt to prevent irrevocable sequelae of primary surgery. Hotz,\[15\] Hotz and Gnoinski,\[16\] Hotz and Perko\[17\] devised an alveolar molding plate made of a hard and soft acrylic. The tissue surface of the acrylic plate was gradually altered such that the alveolar segments were gently pressed to grow and mold into the desired shape and position.

Burston,\[18-20\] advocated the use of a passive plate with “wings” and external strapping till 18 months of age, aiming at the treatment principle to establish early palatal arch symmetry, palatal growth, normal respiration, chewing and speech.

Rosenstein and Jacobson\[21\] and Monroe \etal\[22\] designed an acrylic obturator that extends into the alveolar undercut areas, predicting that this device would allow continued growth by a passive molding action without permitting medial movement of the buccal segments. The rationale of “maxillary orthopedics” described by McNiel, Burston and Rosenstein was that alignment of maxillary alveolar cleft segments at an early age will allow the maxillary halves to develop normally in spite of non-bony union.\[24\]

Voluminous literature exists on a wide array of appliances that have been designed for this purpose. Heubner and Liu\[55\] classified these appliances into presurgical or post-surgical, active or passive, and intraoral or extraoral. Active maxillary appliances (whether retained by surgically installed pins or not) delivers controlled forces to facilitate the movement of cleft alveolar segments in a predetermined manner with, whereas passive appliances simply act as a fulcrum upon which the forces generated by surgical lip closure enhances the contouring and molding of the alveolar segments in a predictable fashion.\[56\]

Earlier, the extra oral elastic traction to the premaxilla through a bonnet or facial taping;\[25-31\] Intra-oral traction through pins and pinned palatal devices;\[32-40\] springs;\[41,42\] and tissue supported palatal plates.\[43\]

These traditional presurgical infant orthopedic (TPSIO) approaches failed to address the deformity of the nasal cartilages and the columellar deficiency in both unilateral and bilateral clefts of the lip and palate.

### Presurgical Nasoalveolar Molding

Matsuo \etal\[46\] reported the reduced need for otoplasty with the use of a stent in the deformed neonatal auricular cartilage. Furthermore, later, Matsuo \etal\[45\] suggested the use of nasal conformers before and after cleft lip surgery to improve the nasal form but the only limitation of their nasal stent design is that it requires an intact nasal floor. This stent cannot be used in a complete cleft without a Simonart’s band, despite the fact that this deformity is usually more severe and would, therefore, benefit from nasal molding.

Evidence shows that increased plasticity of the tissues in neonates is due to increased levels of hyaluronic acid, a component of the proteoglycan matrix, which inhibits the linking of cartilage intercellular matrix. This linking allows ligaments, cartilages and connective tissues to relax.\[46\] The maternal levels of estrogen are high at the time of birth and begins to decline immediately after birth. Pre-surgical molding of cartilages during the first 2-3 months after birth would be most successful.\[11\]

Nasal stenting has been used primarily as a postsurgical means of maintaining the shape of the alar cartilages in clefts.\[47-51\] The dynamic presurgical nasal remodeling technique using an intraoral plate with a nasal extension to remodel the cleft nasal deformity was first published in 1991.\[52\]

Grayson \etal\[53\] Grayson and Santiago\[11\] and Cutting \etal\[54\] adopted the concept of molding cartilages of Matsuo’s, and described presurgical nasoalveolar molding (PNAM), as a new approach to the TPSIO for unilateral and BCLP infants in an attempt to approximate cleft alveolar segments, stretch the lip muscles, and reposition the deformed nasal cartilages as well as lengthen the deficient columella. In this technique, acrylic nasal stent is added to the passive acrylic intraoral molding plate, thus minimizing the need of intact nasal floor for retention of the appliance.\[55\] modified this acrylic nasal stent into a wire framework. Suri and Tompson\[56\] designed a modified muscle activated intraoral appliance along with external stainless steel wire outriggers to improve alveolar position and nasal septum symmetry.

Ever since Grayson \etal, 1993 introduced PNAM appliance, a wide range of new designs of the appliance have been advocated by many authors,\[41,45-55\] seeking and achieving different objectives.

### Objectives of PNAM\[57\]

- To decrease the severity of initial cleft deformity.
- Lip segments should contact at rest
- Symmetrical lower lateral alar cartilages
- Reduction in the width of the alveolar segments until the passive contact of gingival tissues is achieved
- Nonsurgical elongation of the columella
- Centering of the premaxilla along the midsagittal plane
- Retraction of the premaxilla
- Reduction in the width of the nasal tip
- Improved nasal tip projection
- Decrease in nasal alar base width.

### Alleged benefits\[58\]

PNAM technique has been reported to have a myriad of benefits which include facilitation of feeding, guidance of growth and development of the maxillary segments, normalization of tongue function, and facilitation of surgery, speech and positive
psychological effect of parents. In addition, it facilitates the surgeon in achieving a better and more expected outcome with less scar tissue formation, thereby reducing the number of surgical revisions for excessive scar tissues, oronasal fistulas, nasal and labial deformities.\(^{[77]}\)

**Discussion**

For more than three centuries, binding of facial clefts has been used.\(^{[78]}\) New PSO techniques have evolved from the original\(^{[14,18]}\) and adopted into cleft treatment protocols at national and international level. The original techniques claimed few benefits that include reduction of cleft width by stimulation of palatal shelf growth and therefore, facilitation of surgical closure.\(^{[14,79]}\) Additional claimed benefits were improved maxillary arch development,\(^{[40]}\) improved facial growth,\(^{[18,80]}\) occlusion of the dentition; improved feeding and growth of the infant;\(^{[15]}\) hearing, speech and language development; social benefits to the parents and infant.\(^{[81]}\)

Ross\(^{[82]}\) showed in a multicenter study that there was no difference in facial growth between cleft patients treated with or without PSO. Wood\(^{[83,84]}\) and Lee et al.\(^{[77]}\) showed that maxillary growth was not inhibited in these patients who underwent PSO closure of cleft alveolar gap followed by primary gingivoperiosteoplasty as described by Millard and Latham.\(^{[85]}\)

However, opponents of this approach state that PSO may lead to unfavorable changes in the arch form;\(^{[86]}\) they are ineffective and unnecessary;\(^{[76,80-87]}\) complex and expensive and might have an effect on maxillary growth. None of these claims are evidence based.\(^{[76,80-87]}\) However, the results of a multicentre, prospective randomized controlled clinical trial showed that PSO had no lasting effect on arch form after soft palate closure\(^{[91]}\) or at ages 4 and 6 years.\(^{[93]}\) PSO did not prevent the collapse of the maxillary arch\(^{[94]}\) or improve occlusion.\(^{[93,85]}\) Similarly, Adali et al., 2012 reported that PSO had no significant effect on arch dimensions.\(^{[95]}\)

Uzel and Alparslan, 2011 reported long-term effects of PSIO appliances with respect to treatment outcomes from a systematic review to assess the scientific evidence for the same in patients with cleft lip and palate. In their study, it was found that seven randomized controlled trials (Dutchcleft) assessed different treatment outcomes at different ages for a maximum follow-up of 6 years, where they observed no positive effects on feeding, speech, arch dimensions, facial growth, occlusion and nasolabial appearance using passive plates. In the literature, Eurocleft studies have the longest follow-up, i.e. for 17 years but could not compare between PSIO+ and PSIO− due to the differences in the treatment protocols. Thus, the effects in adults are still unclear, which lead to another debate on the type, timing of the cleft lip repair and its effects on clinical outcomes.\(^{[97]}\) PSIO treatment will not be efficient in long run unless it is coordinated with adequately timed, conservative, gentle surgery. Prediction accuracy may vary between groups of children with cleft according to different treatment methods.\(^{[98,99]}\) Santiago et al.,\(^{[100]}\) stated that treatment outcomes, favorable or unfavorable may be anticipated according to initial severity of the cleft deformity and less related to the treatment alone. More importantly, treatment protocol could vary according to the severity of the initial cleft deformity.

The major objective of NAM is to provide esthetic benefits by molding asymmetrical nasal cartilages, which makes it different from the TPSIO.\(^{[26,55,56,88-91]}\) Ross and McNamara, 1994\(^{[101]}\) reported that no difference in aesthetic scores was observed between PSIO+ and PSIO-groups, in their longest follow-up study (14-15 years). In contrast, Maull et al., 1999, evaluated 3-dimensional changes and reported that PNAM significantly increases the symmetry of the nasal cartilages, which is maintained long-term into early childhood. Spengler et al., 2006 reported that PNAM had significantly improved nasal symmetry.\(^{[97]}\) Bongaarts et al., 2008, reported that IO+ children were more attractive than IO-children. According to the systematic review published, there was evidence on the improvement of nasal symmetry in UCLP patients using NAM appliances.\(^{[102]}\) Similarly, Suri et al.\(^{[65]}\) reported that infants who received NAM presented more symmetric and more ideal alveolar segment approximation, a straighter columella, and greater columellar length than those who received IO only. Shetty et al.\(^{[103]}\) reported that cleft infants treated with NAM appliance within 1 month of life showed improvement in nasal dome height, columellar height and resembled non cleft patients at 18 months of age. William et al.,\(^{[104]}\) demonstrated short term, nasal molding with NAM appliance was effective in providing symmetrical nostril outcomes. Shetty et al.\(^{[105]}\) reported a significant decrease in alveolar cleft width, arch length, arch width and increase in inter tuberosity width and arch perimeter with the use NAM appliance. Rani et al.,\(^{[100]}\) reported that PNAM therapy was most efficient and effective way of treating cleft infants in failure to thrive condition. Initiation of the therapy even at the age of 2 months resulted in molding of the flattened cleft nasal cartilages and remarkable weight gain, which further facilitated the surgical lip repair with no postoperative complications.

**Conclusion**

The use of PSO/PNAM even today remains an ongoing battle in the terrain in providing the long-term treatment effects in the multidisciplinary management protocol for the infants with cleft lip and palate. Well-structured standardized, longitudinal studies done on similar cleft deformities using the same management protocols may give a conclusive information to resolve the existing controversy.

**References**

of the unilateral harelip nose. Plast Reconstr Surg (1946)
1949;4:225-34.
Bull 1959;23:367-75.
8. Pruzansky S. Presurgical Orthopedics and bone grafting for infants with cleft lip and palate: A dissent. Cleft Palate J
1964;1:164-86.
9. Prah-Andersen B, Meijer R. Preoperative orthodontic treatment in children with complete cleft, yes or no? Stomatol
10. Witzel MA. 47th Annual meeting of the american cleft palate craniofacial association, letter to the editor. Cleft Palate
16. Rutrick R. The specific interaction of hyaluronic acid with nonsurgical correction of nasal deformity in the early
22. Georgiade NG. The management of premaxillary and maxillary segments in the newborn cleft patient. Cleft Palate
27. Suri S, Tompson BD. A modified muscle-activated maxillary orthopedic appliance for presurgical nasoalveolar molding in infants with unilateral cleft lip and palate. Cleft Palate
34. Georgiade NG. The management of premaxillary and maxillary segments in the newborn cleft patient. Cleft Palate
37. Georgiade NG. The management of premaxillary and maxillary segments in the newborn cleft patient. Cleft Palate