

### **Presurgical Nasoalveolar Moulding In Cleft Lip and Palate Patients: An Overview**

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**Citation of this Article:** Dr. Bhuvanewari Mani, Dr. Sangeetha Duraisamy, Dr. Edeinton Arumugam, Dr. Poornima R Jnaneshwar, Dr. Muralidharan Dhanasekaran, Dr. Pavithra Mani, "Presurgical Nasoalveolar Moulding In Cleft Lip and Palate Patients: An Overview", IJDSIR- August - 2020, Vol. – 3, Issue -4, P. No. 448– 457.

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**Type of Publication:** Review Article

**Conflicts of Interest:** Nil

#### **Abstract**

Cleft lip and palate is one of the most common congenital defects of the craniofacial region. Patients with cleft lip and palate face a variety of problems including difficulty in feeding, repeated middle ear infections leading to hearing impairment, dental problems like missing of teeth in the cleft region or twinning of teeth, dental or skeletal malocclusion, speech difficulties with nasal twang in the speech and nasal deformity. The management of cleft lip and palate begins from birth and requires multidisciplinary approach with the participation of plastic surgeon,

pediatrician, social workers and nurses, oral and maxillofacial surgeon, speech therapist, orthodontist and prosthodontist. Presurgical infant orthopedics has been advocated as an adjunctive to the cleft lip & palate surgery for many years. This technique focused on retraction or binding of the protruding premaxilla and they did not address the nasal cartilage deformity or deficiency of columella seen in bilateral cleft cases. The presurgical naso alveolar molding (PNAM) which reduces the nasal deformity by molding nasal alar cartilages to normal form. There are several controversies surrounding this clinical

procedure despite long term studies establishing the benefits of presurgical nasoalveolar molding. This objective of this article is to present an overview of the history, basic principles of PNAM, the various types of techniques used, their modification and to discuss the value of using PNAM in early cleft management.

**Keywords:** Cleft lip and palate, Presurgical orthopaedics, Nasoalveolar moulding

### **Introduction**

Orofacial clefts including cleft lip (CL), cleft lip with cleft palate (CLP) and isolated cleft palate (CP) are the most common congenital birth defects of the head and neck region.<sup>1</sup> In India with a population of 1.21 billion and 24.5 million births per year, the incidence of cleft lip & palate is reported between 27,000 to 33,000.<sup>2,3</sup> Cleft lip and palate is more common in male whereas isolated cleft palate is more common in females<sup>4</sup>. The aetiology is multifactorial involving both genetical and environmental factor<sup>5</sup>

Patients with cleft lip and palate faces problems like feeding difficulty, repeated ear infections, loss of hearing, congenitally missing or malformed teeth, difficult in pronunciation and psychological impairment with low self-esteem and poor social interaction<sup>6</sup>. The management of cleft lip and palate begins from birth and requires a multidisciplinary team involving plastic surgeon, pediatrician, social workers and nurses, oral and maxillofacial surgeon, speech therapist, orthodontist and prosthodontist.

Presurgical orthopaedics has been advocated as an adjunctive to the cleft lip and palate surgery for many years in several cleft centres. These techniques focused primarily on retraction or binding of the protruding premaxilla and lips reducing the cleft width before surgery. They prevented the soft tissue dehiscence but did

not address the nasal cartilage deformity and deficiency of columella in bilateral cleft cases.

The presurgical Nasoalveolar molding (PNAM) was first introduced by Dr. Berry H. Grayson as a new presurgical technique that involves the passive moulding of lip, alveolus and nasal cartilage prior to the cleft lip surgical procedure. The presurgical Nasoalveolar molding approximates the alveolar segments, moulds the nasal cartilage and develop the contour of columella -philtrum region and nostrils.<sup>8</sup>

Long term studies have proved that including PNAM in the cleft lip and palate treatment protocol reduced the labial deformities, oronasal fistulas, need for secondary alveolar bone grafting and the need for reconstruction of the columella and hence the resultant scar formation. PNAM procedures are usually initiated within first 14 days of child birth and completed before 6 months of age to exploit the effect of raised hyaluronic acid and maternal circulating oestrogen levels in moulding the tissues effectively.<sup>9-10</sup>

Though PNAM created a paradigm shift from the traditional methods of presurgical orthopaedics there are many controversies surrounding its use in the early cleft management. The aim of the article is to provide an overview of the history, basic principles of PNAM, the various types of techniques used, their modification and to discuss the value of using PNAM in early cleft management.

### **History**

The presurgical orthopaedics evolved as a desire to improve the outcomes in the early surgical management of cleft lip and cleft palate. Several techniques such as facial binding, Lip strapping, Silver wires, Lip adhesion, Latham device and Maxillary plates were used in the earlier years for reduction in cleft width and approximation of the protruding premaxilla before

surgery. (Tab. 1)<sup>7,10,11-19</sup> The patients still required correction of the deficient columella and nasal deformity at a later stage and these procedures resulted in a scar in the base of nose and the tip of the nose remains uncorrected despite additional surgeries.

Matuso et al in 1984 described a non surgical management of auricular defects by exploiting the plasticity of auricular cartilage and extended the same technique in moulding the nasal cartilage in cleft cases<sup>10</sup>. Their earlier attempt was limited to cases with intact nasal floor and later they demonstrated the use of silicone tubes in moulding the nostrils in bilateral cleft cases<sup>19</sup>.

With this understanding of plasticity & the ability to mould the cartilage the concept of Nasoalveolar moulding was created by Grayson. A Typical PNAM appliance is a removable maxillary alveolar moulding appliance with nasal stents embedded in the alveolar portion. The appliance is adjusted weekly or biweekly to correct the nasal and alveolar deformities. In the later years several modification were included in the basic appliance design and long term studies were carried out to evaluate the merits of NAM.

1689	Hoffmann	Used facial binding to reduce the width of the cleft before surgery. <sup>11</sup>
1790	Desault	Demonstrated retraction of premaxilla segment in bilateral cleft patients before surgery. <sup>11</sup>
1844	Hullihen SP	Presurgical orthopaedics with adhesive tape binding. <sup>12</sup>
	Esmarch & Kowalzig	Introduced a Bonnet and elastic strap binding for premaxilla before surgery. <sup>13</sup>
1927	Brophy	Used silver wires to approximate the ends of alveolus before surgery. <sup>14</sup>

1950	McNeil	Used acrylic plates to mould the alveolar segments before surgery. <sup>15</sup>
1958	Burston WR	Modified McNeil's technique <sup>16</sup>
1975	Georgiade NG & Latham RA	Pin retained coaxial screw device to retract the premaxillary segment. <sup>17</sup>
1987	Holtz M	Passive orthopaedic plates for stabilization of premaxillary segment in complete bilateral cleft lip & palate cases. <sup>18</sup>
1984	Matsuo et al	Described a technique to mould the nasal cartilage by exploiting its plasticity in patients with intact nasal floor. <sup>10</sup>
1988	Matsuo and Hirose T	Moulding of the nostril using silicone tubes. <sup>19</sup>
1993	Grayson BH	Described a new technique to mould the lip alveolus and nostrils that produced preoperative columella lengthening in Bilateral cleft lip & palate cases <sup>7</sup> .

Tab.1. various techniques used in the early presurgical management of cleft lip and cleft palate.<sup>7,10,11-19</sup>

In this article we describe pre surgical nasoalveolar moulding ,a new method to traditional pre surgical infant orthopedics for patient with unilateral or bilateral cleft lip and palate. The PNAM treatment protocol was described by Grayson et al in 1993,Brechet et al in 1995, Grayson and Santiago in 1997 ,cutting et al in 1998.The main objective of PNAM is repositioning of deformed nasal cartilage and alveolar processes and lengthening of columella

## Principle

Nasoalveolar moulding works on the principle of Passive molding and negative sculpting of the alveolus and adjacent hard and soft tissue including the nasal cartilage with the help of acrylic molding plates and nasal stents. The acrylic plates are used mould the alveolar segments and approximate them before the surgery. In case of bilateral cleft lip and palate, nasal molding helps to push the alar domes anteriorly in a sagittal path for increasing columella length<sup>20</sup>.

## Objectives

The objectives of PNAM are to provide symmetry to severely deformed nasal cartilages to promote the additional bone formation and achieve projection of the flattened nasal tip, promote lengthening of the columella, produce approximation lip segments to decrease tissue tension after lip repair and thus lessen scar formation, improve the alignment of the alveolar ridges and reduce the distance between the cleft lip segments and reduce the need for secondary alveolar bone grafting at a later stage<sup>21-26</sup>.

## Procedure For Pnam Therapy

The various clinical steps involved in the Nasoalveolar molding are obtaining a good impression, fabrication of the maxillary plate, insertion and adjustment of appliance, incorporation of the nasal stents and it requires weekly or biweekly adjustments to obtain the desired objectives.

## Impression Technique

Many researchers reported different method of impression techniques for PNAM for infants. Impression of cleft lip and palate for infant is achieved within the first week of birth when cartilage is plastic and moldable.

Grayson and Shetye held infants in an inverted position in order to prevent tongue from falling back and it helps to allow fluids to drain out of the oral cavity<sup>27</sup>. The tray is properly seated until the impression material sufficiently

covers the upper gum pads. Once the impression material is set, then impression tray is removed. The impression is then poured with the help of dental stone to get an accurate dental cast of an infant.

Yang et al used to take impression in erect position using a pre-trimmed customized pediatric tray. Utility wax is used to avoid any sharp edges on the tray and to enhance proper adaption to the infant's mouth<sup>28</sup>. Mishra B et al conducted study in north India during the period of May 2004 to May 2006 using cleft patient less than 1 year of age. Impressions were taken without any anesthesia. The patient's parents are instructed to hold the infant in prone position in his /her parents lap on dental chair<sup>29</sup>. Dubey RK et al obtained primary impression using ice cream stick and impression compound. He made the baby to sit in parents's lap with head facing downward and parent hands supporting baby's chest and lap region while creating the impression. Dental cast poured from impression and it was used to fabricate special tray for final impression. Putty consistency polyvinyl elastomeric impression material used to make final impression with the support of special tray<sup>20</sup>.

Radhakrishnan V et al illustrated impression technique for bilateral cleft cases. Infant was made to lie down on the operation theatre in supine position. Impression achieved using heavy body rubber base impression material<sup>26</sup>. Splengler et al took intraoral and extraoral alginate impression with the patient under general anesthesia<sup>23</sup>.

## Fabrication of Appliance

Moulding plate is fabricated on the dental stone model. moulding plate is made up of hard clear acrylic and is lined with a thin soft denture material. Reduction of border of the moulding plate has to be done in the area of the labial frenum and other sulcus areas to prevent ulceration. The retention arm is placed approximately 40 degree down from the horizontal for proper activation and

to prevent dislodgement from the palate. The pencil mark is placed at the junction of the clefted segment, and the vertical position of retention arm is attached at the junction of upper and lower lips at rest. Various materials have been used for fabrication of PNAM appliance like heat-cure polymerizing material<sup>30,31</sup>, light-cure polymerizing material<sup>28</sup> and 2 mm thermoplastic base plate<sup>32</sup>

### Appliance Insertion

The retention arms are engaged by the tape elastic system, the elastics (inner diameter 0.25 inch, wall thickness heavy) should be stretched approximately two times the resting diameter for proper activation force (2 oz). The amount of force may vary depending on the clinical objective and the mucosal tolerance of pressure. Pre maxilla retraction requires greater elastic traction force than is required for closure of a unilateral alveolar gap. Yang et al suggest to use liquid adhesive such as Mastisol painted with a cotton-tipped applicator horizontally on the cheeks where the Steri Strips will be placed<sup>28</sup>. The plate can be kept in the mouth for full time and parents are instructed only to remove it for daily cleaning.

### Appliance Adjustment

The appliance is kept in the mouth for 24 hours and instruction has to be given to parents. After 24 hours, patients is asked to report back for evaluating any presence of sore spot or any other problem associated with the 3appliance. Every weekly appointments are scheduled in order to modify acrylic plate by adding resin or selective trimming till it achieve desired union of alveolar fragments. Addition of Nasal stent should be delayed till laxity of the alar rim is achieved because it may result in the enlarged circumference of the nostril.

### Nasal Stents

The nasal stent is recommended when the alveolar gap width is decreased to 5mm. The stent is 0.36 inch long in the shape of a “swan neck” which is made up of round stainless steel wire. It is adhered to the labial flange of the molding plate, near the bottom of the retention arm. The upper lobe enters the nose and carefully brings forward the dome until a modest amount of tissue blanching is apparent. The necessary length to do the molding therapy is dependent on the degree of the initial cleft defect<sup>27</sup>

### Modifications

#### 1. The modified muscle-activated maxillary orthopaedic

**Appliance-** Infant orthopaedic plate contain stainless steel wire are fabricated for an infant with a wide complete unilateral cleft lip and palate<sup>33</sup>. It prevents the cleft-widening effect of the tongue, helps with tongue tip placement and uses the functional movements of the musculature to guide and relocate segment medially to its normal position.(Figure 1)



Figure 1:- Sunjay Suri et al ,2004 Infant orthopedic plate with the nasal stent attached<sup>33</sup>.

### Nasal Elevators

The nasal alar elevator consists of a thin, stainless steel wire covered with a silicone tube made up of plastic. It usually exerts its force on the cleft side of the nose. If

needed, it may be designed to exert force on both sides of the nose. They are produced in various sizes to ensure a perfect fit for each individual nose. (Figure 2)

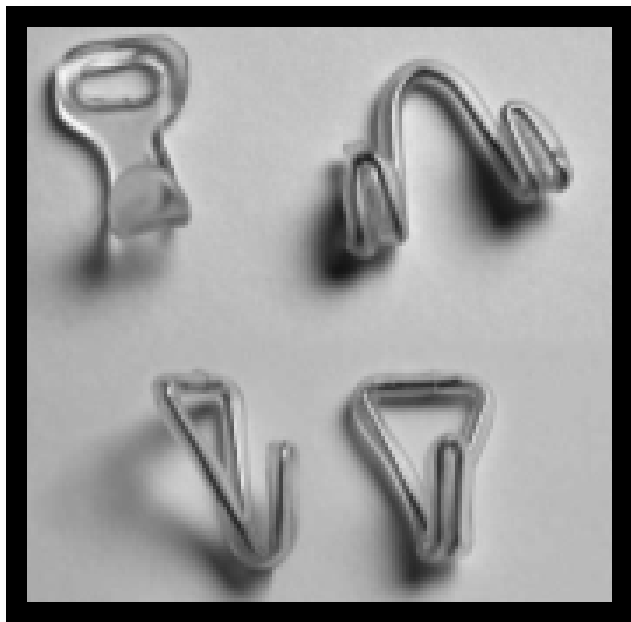


Figure 2: Nasal Elevators- AVNI ABDIU et al<sup>34</sup>

### Extraoral Nasal Molding

The nasal stent and soft denture lining were added to the preoperative orthopedic plate. The stability needed for the modified nasoalveolar molding appliance was obtained with adhesive and elastic tapes applied to the cheeks. (Figure 3)



Figure 3: Doruk C et al<sup>35</sup> Extraoral nasal molding appliance (ENMA)

### Ring plate with modified wire nasal stents

A custom made self-retentive appliance with anterior acrylic ring that surrounds the premaxillary segment was introduced by the Abida Ijaz, which is especially designed for PNAM of neonates born with bilateral cleft of the lip

and palate. The objective of this innovative device with anterior acrylic ring was to retract and align the protruded and rotated pre-maxillary segment without using extraoral forces such as head caps, bonnet, elastics or adhesive tapes. (Figure 4)

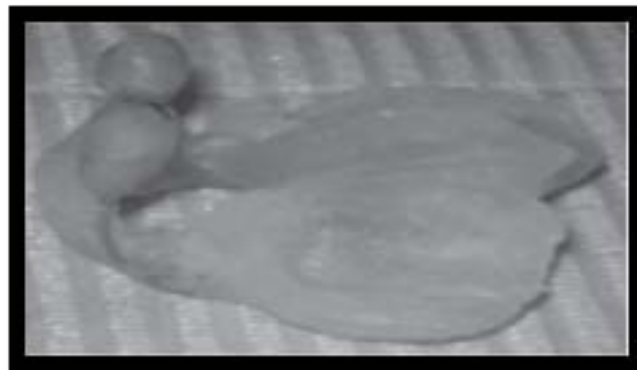


Figure 4: Abida Ijaz , Ring plate with modified wire nasal stents<sup>36</sup>

### Complications

1. Irritation of oral mucosa
2. Inflammation of intranasal lining of the nasal tip due to upper lobe of nasal stents
3. The risk of dislodgement of the molding plate which may obstruct the airway
4. Pressure from molding plate may cause premature eruption of maxillary deciduous central incisors.

### Discussion

The pre surgical nasoalveolar moulding which helps to reduce the severity of the original cleft deformity and it enables the surgeon to achieve good outcome related to repair of the alveolus, lip and nose. The NAM technique has also eliminated surgical reconstruction of columella and the resultant scar tissue formation in bilateral cleft lip and palate<sup>9</sup>The nasoalveolar moulding technique has been shown to considerably increase the surgical outcome of the initial repair in cleft lip and palate patients compared to other techniques of presurgical orthopaedics<sup>37</sup>. The concept of PNAM was established with the consideration

of the plasticity of infant's cartilage as a result of elevated levels of circulating maternal oestrogen in bloodstream which has ability to everlastingly modify its shape. The plasticity of the cartilage fades over the first 6 months of age, elasticity lastly sets in and finally helps to maintaining the shape of the nasal cartilage. Contrary, sometimes there is a failure to correct the severe nasal cartilage deformity often results in the need to make more surgical revisions. Major disadvantage regarding bilateral cleft lip and palate is lip taping or surgical lip adhesion. If control of the alveolar segments is failed to achieve, the premaxilla can descend vertically and the anterior aspect of the posterior alveolar segments can lead to collapse palatally. This can result in an impinging deepbite of the premaxilla, arch form collapse. These conditions hold challenges for surgical reconstruction, orthodontic management and speech therapy<sup>38,39</sup>. Maull DJ et al in 1991 conducted long-term studies have indicated that the change in nasal shape is stable with less scar tissue and better lip and nasal form<sup>40</sup>. This advances reduces the complication of excessive scar tissue, oronasal fistulas and nasal and labial deformities<sup>41</sup>. The alveolar segments in a better position and increased bone bridges across the cleft region helps to reduce the need for secondary bone grafting while giving a better chance for the teeth to erupt in a good position with sufficient periodontal support<sup>42</sup>. Thus, PNAM might also reduce the overall cost of cleft care by reducing the number of secondary nasal revisions. Studies have also demonstrated 40% who did need bone grafts showed more bone remaining in the graft site compared to patients who have had no gingivoperiosteoplasty<sup>43</sup> and 60% of patients who underwent NAM and gingivoperiosteoplasty did not require secondary bone grafting<sup>44</sup>. Lee *et al.* demonstrated that midfacial growth in the sagittal and vertical plane was not affected by NAM and gingivoperiosteoplasty<sup>45</sup>.

Bongaarts et al conducted study regarding the effect of Infant Orthopedics on Facial Appearance of Toddlers With Complete Unilateral cleft Lip and palate by using facial appearance at 4 and 6 years of age assessed on full face photographs showing only nose and mouth. As a result of the study concluded that at the age of 4 years full face picture of children treated with infant orthopedics were more attractive than full face picture of children treated without infant orthopedics, however difference were disappeared at the age of 6 where only professionals saw a significant difference on nasolabial photographs at the age of 6 years<sup>46</sup>. Thus, presurgical nasoalveolar molding (PNAM) can be an adjunct to facilitate surgical repair in infants with CLP.

### Conclusion

The current review article is an attempt to critically analyse the literature regarding the effects of NAM. NAM therapy is useful not only for the initiation of dental alveolar growth but also as a presurgical orthodontic treatment to establish the nasal shape and better treatment results after the initial lip surgery. Lack of parent or caregivers' compliance and commitment results in less than ideal clinical outcomes. Since the beginning of NAM, there has been a significant difference in the positive outcome of the primary surgical cleft repair. With adequate clinical skills, NAM has added incredible value to the cleft patients as well as to the surgeon for accomplishing the primary repair.

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