Presurgical nasoalveolar molding as an effective adjuvant therapy to aid rehabilitation cleft malformations in newborn

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ABSTRACT
Cleft lip and palate (CLP) is a congenital anomaly that commonly occurs in the mouth and maxilla. Cleft lip and/or cleft palate can alter a child's appearance, affect pronunciation, swallowing and chewing, and lead to varying degrees of psychological damage in growing children involving the upper lip, hard palate, soft palate and nose. The goal of primary closure of CLP is to ensure normal and symmetrical lips and nose. Presurgical nasoalveolar molding (PNAM) is a non-surgical method reshapes the lips, alveoli, cleft palate, and cleft nose to minimize the severity of cleft lip deformity prior to cleft palate and primary cleft palate surgery. This article is aimed to review management of CLP in newborn using PNAM. It is concluded that PNAM is an effective adjuvant therapy to reduce preoperative hard and soft tissue cleft malformations because helps improve nasal aesthetics, reduce cleft size, and correct the maxillary arch with reduction of alveolar size and cleft palate.
Keyword: cleft lip and palate presurgical nasoalveolar molding, nasoalveolar molding

INTRODUCTION

Cleft lip and palate (CLP) deformity is a congenital abnormality of the middle third of the face. The incidence ranges 1:500-1:2500 live births. The etiology depends on heredity and the environment.[1] The CLP can present with considerable variation in severity and shape. A wider cleft is associated with a significant nasolabial deformity.[2] Labiopalatoschisis or CLP, is a craniofacial congenital abnormality caused by abnormalities of facial development in the embryo. Teratogenic environmental factors and genetics play a role in the formation of labiopalatoschisis.[3,4] The CLP is a common birth defect. Both can affect several body systems and functions, including eating and drinking, facial development, teething, speech, and can have a social and psychological impact on children and parents[5] (Fig.1).[6]

Figure 1 Extraoral profile of CLP patient (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago: Quentessence Publishing Co; 2000.p.70)

Veau's classified CLP as type I, vermilion defect or red part of the lips; type 2, cleft covering the vermilion and part of the lip muscles up to but not including the base of the nostril on the affected side; type 3, unilateral CLP involving the entire thickness of the lip usually with nasal deformity; type 4, bilateral cleft lip, either partial, complete, or in combination.[7]

In the early of 17th century, Hoffman was the first scholar to use headgear as an anchor to retract the protruding anterior jaw and to narrow the cleft. Mc Neil used a palatal resin plate to move the fractured alveolar bone to its normal position. Hotz et al used an elastic resin material to make the maxillary palatal plate, which is worn from birth. After cleft lip surgery, it continues to be used until cleft palate surgery and eruption of the first primary molars. This appliance uses the maxillary growth itself to align the alveolar bone segments. The Latham appliance can retract the anterior portion of the protrusion, moving the affected alveolar bone segment forward and expanding the posterior alveolar bone segment. These methods can only correct serious alveolar bone displacement, but not nasal deformities.[8]

Preoperative orthopedics has been used since 1950 as an adjunct procedure for the correction of premaxillary protrusions in the cleft. Presurgical nasoalveolar molding (PNAM) was developed by Barry Grayson, Orthodontist in 1993, it assists in the reduction of intraoral alveolar cleft size, active molding and positioning, performed on newborns and reduction of the surgical area and the resulting scar tissue.[9]

Grayson et al describes a new technique of presurgical impressions of the alveoli, lips and nose in infants born with CLP. It has been shown that correction of nasal cartilage deformity and nonsurgical elongation of columella deficiency can be achieved in combination with impression of the alveolar process with premaxillary retraction via PNAM. This

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is possible because cartilage has a high degree of plasticity in the neonate. The transient plasticity of cartilage is caused by high levels of hyaluronic acid, a component of the proteoglycan intercellular matrix found circulating in infants for several weeks after birth. Matsuo dkk., Matsuo and Hirose are people first to use this plasticity to remove nasal cartilage.[10,11]

The main goal of treatment in cleft lip patients is to restore normal anatomy and function. Reconstruction of symmetrical lips and a natural-looking nose is a difficult challenge in unilateral clefts.[10] Advances in reconstructive surgery have significantly improved the quality of repair for cleft lip, alveolus, and palate; surgery alone cannot correct all aspects of cleft defects.[12]

Nasal deformities improve over time if left untreated. Uncorrected nasal deformities also leave cleft stigmata until adolescence. Also secondary correction of the nasal deformity will lead to more surgical scarring and less than ideal results. So, any form of non-surgical treatment to reduce nasal deformities early in life is highly desirable.[13]

The PNAM overcomes various problems associated with traditional methods for treating unilateral CLP. This increases the asymmetry of the nose and less nasal tip.[14] It also forms the protruding premaxillary segment into a more normal alignment with the alveolar segment, improves the shape of the maxillary arch and also reduces the size of the cleft lip, palate and alveolus. This reduces the complexity of subsequent surgery and also provides a more aesthetic result.[15] The aim of this literature review is to learn more about the management of CLP in newborns using PNAM.

LITERATURE REVIEW

The PNAM is an effective method to enhance the maxillary growth and development of CLP patients. PNAM is a new technique that acts as a specialized form of tissue expansion while correcting nasal cartilage deformities without surgery and resolving columella length deficiency and alveolar segment malposition with minimal surgery. The result is an overall improvement in the aesthetics of the nasolabial complex while minimizing the extent of surgery and the number of surgical procedures, thereby providing a positive psychological impact for the parents. Therefore, this literature review aims to find out more about the management of CLP in newborns using PNAM.

The PNAM is a non-surgical method of reshaping the alveolus, lips and nostrils prior to primary surgery for CLP.[5] PNAM technique consists of an intraoral plate that supports an acrylic nasal stent, which is joined with lip-band adhesion, shaping the nose, lips, and alveolar segments before surgery. The PNAM therapy has been used successfully in patients with bilateral and unilateral cleft lip[9] (Fig.2).[6]

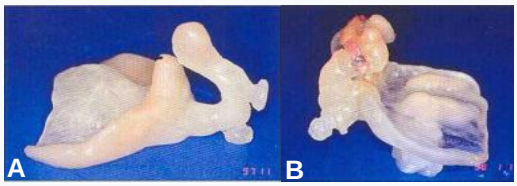

Figure 2 The PNAM prosthesis with nasal stent (lateral view); **A** unilateral NAM prostheses, **B** bilateral NAM prostheses (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.70)

The NAM process in the global protocol for the management of CLP has been approved for several years. It begins in the early neonatal phase, and continues after labioalveolar plastic surgery, usually starting at 6 months after birth. This parallel orthopedic therapy with surgical therapy ensures restoration of the cartilage that forms the collapsed nasal wing, the columella often tilts to the split side and contributes to the restoration of the lip relationship, which facilitates the surgical procedure. PNAM targets not only the labionasal soft tissues, but also the bone supporting tissues. Terminologically, the term *molding* has been used to describe soft tissue procedures and orthopedic procedures on bone. Nevertheless, it cannot be denied that soft tissue imprinting is also an *indirect orthopedic* due to the changes in muscle and cartilage brought about by the influence of modeling the underlying supporting bone. Thus, by ensuring lip approximation, this affects the centripetal action of the two jaw fragments adjacent to the cleft.[16]

The use of PNAM improves nasal symmetry before surgery. It appears that this change is beneficial after lip repair, as postoperative follow-up studies in patients treated with PNAM reporting improved symmetry when compared to patients treated without PNAM also suggest that PNAM may be a cost-effective technique by reducing the number and improving outcomes of secondary rhinoplasty procedures in future. In addition, a preoperative *symmetrical* nasal cleft with a narrower alveolar cleft is likely to simplify primary lip-nose repair. This can reduce surgical time, thereby reducing costs.[9]

Indications for the use of PNAM, especially for patients with unilateral or bilateral third degree CLP with severe cleft lip and alveolar process and nasal asymmetry, and mild unilateral or bilateral CLP. If accompanied by obvious nasal asymmetry, nose shaping treatment should also be considered; 7-14 days after birth is the best time to start nasal alveolus formation treatment. Because the plasticity of

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soft tissue and facial cartilage is best within three months after birth, especially nasal cartilage within 6 weeks after birth.[8]

The procedure for making PNAM according to Taylor,[6] that is 1) as soon as possible after birth, the infant is evaluated by all members of the interdisciplinary CLP team. Cleft defects are examined for the presence of natal teeth, Simonart bands, unusual undercuts, or other tissue abnormalities. If there is a tooth near the gap, it is often extracted because its presence will make healing difficult during the surgical treatment phase; 2) after thorough evaluation and explanation of the procedure and treatment goals to the parents, an impression of the intraoral cleft defect was made using an elastomeric material in an acrylic impression tray. Selected impreesion materials with very high consistency (Fig.3A); 3) the impression is done with the baby fully awake and without any anesthesia. The baby is held face down to prevent possible aspiration of regurgitated stomach contents. One person holds the baby securely around the chest, supporting the head and neck, while the other gets the impression (Fig.B,C)[6]; 4) the impression of the nasal

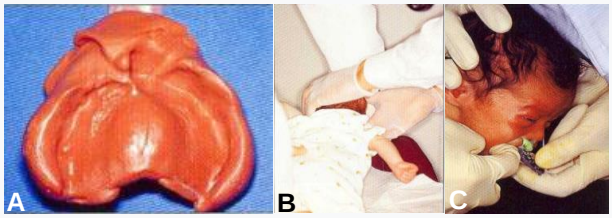

Figure 3A High-consistency elastomeric impression material on a special impression tray. Excess material on the back of the tray should be avoided; **B** techniques for obtaining intraoral impressions of cleft defects in newborns **C** the baby is carried on the stomach to prevent aspiration (Source:Taylor TD. Clinical Maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.71).

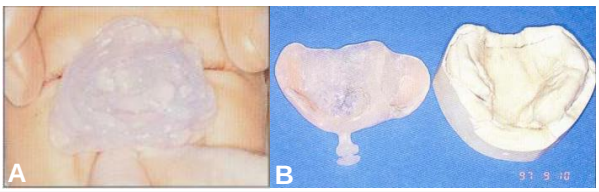

Figure 4A Clear PVS of nasal deformities can be obtained to study nose shape before and after imprinting. Nose molds are not used in the manufacture of nasal stents; **B** maxillary cast used to fabricate a unilateral intraoral impression of acrylic material (Source :Taylor TD. Clinical Maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.72)

area is not required but can be helpful in comparing the results of pre- and post-orthopedic impressions. Nasal impressions can be obtained using PVS which is expressed directly into the cleft nose from root to lip (Fig.4A).[6] Cotton plugs attached to dental floss are used to prevent material from entering deep into the nostrils. Nasal impressions are not used in the fabrication of the nasal stent portion of the nasoalveolar impression device; 5) when the material is fully set, about 2 minutes intraorally, the impression is removed and inspected to ensure all desired landmarks have been obtained; 6) the existing mold is then poured twice with gypsum impression material; one cast will be as a working model wherein an intraoral impression plate will be created while a second cast will be a record. The size of the defect at the alveolar level was measured on the cast impression and recorded. (Fig.4B)[6]; 7) the cleft palate and alveolus areas can be filled with wax to approximate the contour and topography of the intact arch prior to fabrication of the oral portion of the impression device. A small coating of petroleum jelly is then applied to lubricate the modified cast; 8) soft acrylic can be placed in the undercut area of the cast. The remainder of the plate molding was prepared from clear methyl methacrylate orthodontic resin using one of many acceptable techniques. Ideally, oral molding should be waxed from two layers of baseplate wax and then packaged and processed in the laboratory; 9) at the next visit, the molding device is carefully placed in the baby's mouth. Early attention was paid to device retention. A properly adjusted and properly constructed mold plate will usually hold up quite a bit on its own. After initially inserting the molding device, the infant should be observed for several minutes and the appliance stabilized on the roof of the mouth with the index finger by the doctor. Baby should be able to suckle easily without choking or struggling; 10) at this visit the tissue surface of the apparatus is also modified, through selective removal of acrylic from the desired movable area of the alveolar bone (Fig.5A).[6] Softliner is added to coat the appliance with a thickness of approximately 1-1.5 mm in areas where bone is desired to be reduced or removed (Fig.5B,C);[6]11) proper

Figure 5A Modifications were made to the internal surface of the molding tool with a bur along with the addition of hard acrylic and soft liner materials to direct the controlled movement of the alveolar segments to produce the desired arch shape and reduce the arch size of the alveolar cleft width; **B** internal surface of unilateral intraoral molding apparatus with acrylic retentive knob. Softliner material has been added; **C** diagram of weekly modifications to the internal surface of a unilateral mold tool to achieve a reduction in the gap width (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago, Quintessence Publishing Co; 2000, p.74)

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retentive adhesive between appointments is essential if the tool is to be maximally effective (Fig.6)[6]; 12) when the slit gap has been reduced to about 6 mm or less, a nasal stent can be added to the apparatus and the active nasal cartilage formation phase can be initiated. The nasal stent is an acrylic projection formed by the careful addition of a small amount of cold-cure acrylic resin until the stent is positioned within the nasal vault on the side of the nasal cleft (Fig.7);[6] 13) the nasal stent

Figure 6 Unilateral impression plate secured in the infant's oral cavity with surgical and elastic bandages (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago: Quentessence Publishing Co; 2000, p.75)

Figure 7A Initial nasal stent added in acrylic; **B** modified weekly to **C** final form (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.76)

can also be made of 0.036 inch stainless steel wire attached to the labial flange of the tool (Fig.8A).[6] When the wire is used for the stent, the wire is carefully bent at the nose tip of the stent to project passively into the nostril; 14) the stent base ei-

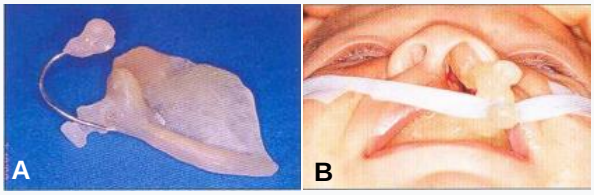

Figure 8A The nasal stent is made of 0.036 inch retentive wire, acrylic, and closed with a softliner; **B** nasal stent positioned in the nostril to support the dome and reposition the lower nasal cartilage at treatment week 13 (Source: Taylor TD. Clinical maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.77)

ther wire or acrylic, should be placed over the retaining button. The superior aspect of the acrylic nasal stent is covered with a thin layer of softliner material to ensure that positive elastic pressure is applied to the internal tissues of the nasal dome. The orientation of the nasal stent should be such that the tip of the nose and the dome on the cleft side protrude outward and toward the cleft side (Fig.8B)[6]; 15) the indentation is made with a wire, just below where the stent enters the nostril to make room for the edge of the nostril. The entire nasal extension of the stent wire is then covered with tough clear acrylic to provide shape and support to the tissue. Hard acrylic covered with softliner; 16) cleft nose deformity after nose shaping just before surgery. The alar base is now convex and the nasal tip cartilage has lifted. The lip segments are now closer to each other (Fig.9).[6]

Figure 9 Cleft nose deformity after nose shaping just before surgery (Source :Taylor TD. Clinical Maxillofacial prosthetics. Chicago, Quentessence Publishing Co; 2000, p.77).

Complications of using PNAM are: facial skin rash, which is reversible without tools and a very low incidence of mouth and nose ulcers. The preventive measure for facial skin rashes is the use of an anti-allergic baby breathable tape, a tape width of about 5 mm. After soaking in warm water, remove the tape and adjust the position of the tape. Meanwhile, preventive measures for mouth and nose ulcers are to ask parents to clean their child's mouth and utensils every day, and stop using the appliance after finding redness and swelling of the nasal cavity or oral mucosa and ulcers. The nose ball's surface is smooth. Before use, apply vaseline or baby oil on the surface to lubricate it. The volume of the nasal ball increases gradually without using too much force.[8]

DISCUSSION

The PNAM therapy significantly reduced the alveolar and palatal clefts, and columella deviation. In combination, it helps align the maxillary arch. The symmetry of the nose is significantly improved. The columellar length is significantly increased, thereby improving the aesthetics of the nose. Nostril height significantly increased as nostril width decreased. All in combination increase the projection of the tip of the nose[6] (Fig.10).[17]

Nasal alveolar contouring therapy can narrow the alveolar gap because 1) the prone position is used to change the shape of the dental arch; 2) the medial surface of the palatal plate is adjusted to guide the growth of the bone segment; 3) strength provided by lip adhesive tape.[8]

The research conducted by Bajaj et al was in 2011, with modifications from Grayson in the treat-treatment and tools. The PNAM from the Grayson

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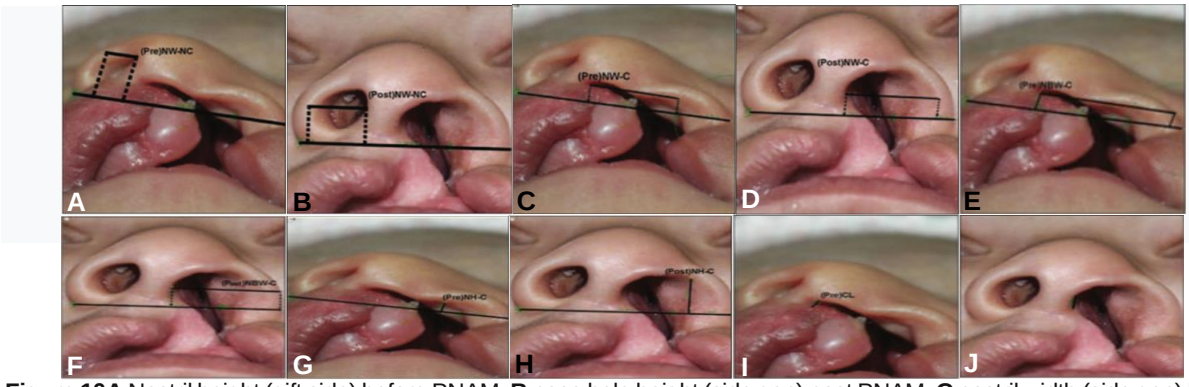

Figure 10A Nostril height (gift side) before PNAM, **B** nose hole height (side gap) post PNAM, **C** nostril width (side gap) before PNAM, **D** nostril width (side gap) post PNAM, **E** nostril basal width (side gap) before PNAM, **F** nostril basal width (side gap) post PNAM, **G** nose dome height (cleft side) before PNAM, **H** nose dome height (cleft side) post PNAM, **I** columella length (gift side) before PNAM, **J** columella length (gift side) post PNAM (Sumber: Zuhaib M, Bonathaya K. Parmar R. Presurgical nasoalveolar molding in unilateral cleft lip and palate. Indian J plastic Surg 2009;8(13):44-8)[17]

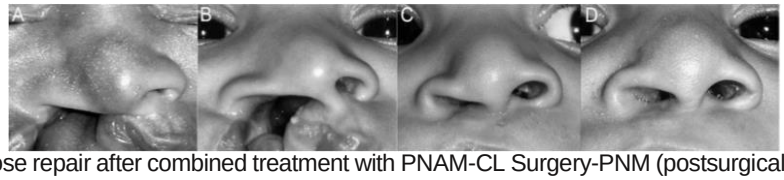

Figure 11 Cleft lip nose repair after combined treatment with PNAM-CL Surgery-PNM (postsurgical nasal molding). **A** before PNAM, **B** after PNAM, **C** after primary lip and nose repair. It seems that additional prints would be useful in this case, **D** after PNM, better nose contour was achieved after 1 month of treatment using a custom made acrylic nose conformer (Source: Gomez DF, Donohue ST, Figueroa AA. Nasal changes after PNAM in the unilateral cleft lip nose. Cleft Palate Craniofac J 2012; 11:699).

Technique requires weekly visits for 3-5 months, but in this study weekly visits were made up to 2-3 weeks. The molding plate, made of clear hard acrylic, is made on a dental stone model. The plate must be 2-3 mm thick for structural integrity. This mold plate is different from the conventional orthopedic plate as described by Hotz. The impression plate is made so that there is no extension of the plate into the alveolar or palatal cleft space. All undercuts and fissures are covered with wax so that the cast appears to have intact alveoli. At the same time two to three layers of wax are also added as spacers in the area of the main segment should move on the palatal side during treatment. The key to the modification is the removal of gaps and the addition of wax spacers. This modification prevents the need for weekly trimming of the occlusal apparatus as described by Grayson. This treatment is performed to smooth the plate boundaries and remove the attachment of the labial frenum sufficiently. Then the mold plate impression was adjusted to gradually approach the alveolar cleft segment, with the addition of an acrylic soft liner on the labial side of the main segment. The addition is made only medial to the attachment of the labial frenum. Alveolar impression and approximation were achieved only through the addition of soft acrylic at each follow-up visit. The thickness of the added soft acrylic was 1 mm or less per visit. The amount of soft acrylic added may vary depending on the clinical objective and the tolerance of the mucosa to ulceration. Selective removal of acrylic is usually not required from the palatal side. Also the adjustment period can be increased to 2-3 weeks as there is no interference with the movement of the larger segments due to the space provided by the addition of wax spacers during tool making. This increased follow-up visit interval reduced the burden equally on the cleft lip team and parents. Procedure is more time efficient and less tedious. This helps increase parental compliance. Parental motivation and teaching are critical to the overall success of treatment. Parental obedience makes an important contribution to achieving good results.[13]

A study was also conducted by Zuhaib et al in 2016 using the Liou technique, a modification of Grayson, involving 20 CLP patients. Through biweekly modification of the nasal bulb of the nasal mold and adjustment of the wire, the alar cartilage was carefully shaped to resemble its normal shape. The strength of the adhesive tape and the counterforce of the molded nasal bulb provide the necessary strength to bring the alveolus to its proper position. Furthermore, with regular selective lifting and the addition of a soft liner, the alveolus is molded. Significantly the results of these studies on evaluation, quantitatively demonstrated that PNAM therapy significantly reduced alveolar and palatal

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clefts, and columella deviation. In combination, it helps align the maxillary arch. The symmetry of the nose is significantly improved. The length of columellar is significantly increased, thereby improving the aesthetics of the nose. Nostril height significantly increased as nostril width decreased. They increase the projection of the nose tip.[17]

The research conducted by Alamsyah et al in 2022, by combining the Hotz plate design with the Kogo plate. The Hotz plate design is a passive type orthopedic plate that aligns the gap segment with the help of strapping using tape slowly. This tool is made with a combination of hard and soft acrylic. It covers the alveolar segment passively and extends posteriorly to the tip of the cleft in the uvula. Kogo plate design, 2 mm acrylic elevation is made on the posterior part of the plate. The modification of the Hotz-Kogo design is a combination of elevation of the posterior palatal mechanical surface and elongation to the cleft of the uvula, a nasal stent is placed to form the nasal cartilage. For unilateral CBL patients, the PNAM design used a single nasal stent, while for bilateral patients, a double nasal stent or prolabium box was used. This design is a combination of the Hotz plate that covers the alveoveolar segment and then extends posteriorly to the uvula will provide a good adaptation in creating a normal swallowing pattern, the addition of the Kogo plate design with a 2 mm elevation on the posterior plate which acts as a close box will increase retention on the plate, especially in infants with active soft palate movements and a high gag reflex. After observing and examining the patient, the reten-tion produced by the design proved to be good from the results of the device retention test with a light withdrawal method using a probe at one point in the anterior and two points at the posterior. The posterior close box also played a role in creating a normal swallowing pattern in this patient, characterized by good suction power, which was checked at each visit. The combination of the Hotz-Kogo modified PNAM design is seen in this case, the baby's sucking reflex is greater than the use of the Hotz plate. [18]

Pre-surgical nasoalveolar protocols and post-surgical nasal prints, should be used to improve the long-term outcome of this treatment approach taking into account 1) PNAM should endeavor to reduce and not increase the width of the alar base prior to surgery to facilitate future operations that shows *tapping* may be necessary to counter possible stretching of the tissue and/or changes in normal width growth; 2) PNAM treatment should be started as early as possible. This helps maintain the symmetry achieved. Neonatal hyaluronic acid, increased with a transient increase in estrogen levels, acts as a temporary barrier between intercellular material, giving cartilage a temporary lack of elasticity. If started later, the results will be less than satisfactory due to a decrease in the amount of estrogen and hyaluronic acid in the cartilage of the neonate. Consequently, the PNAM treatment in patients under 1 month of age is desirable and has led to higher subjective satisfaction than patients treated later; 3) PNAM treatment was extended as much as possible because longer treatment resulted in better nasal symmetry; 4) overtreatment of the patient to compensate for relapse and possible differential growth is a controversial aspect of the PNAM treatment. Caution should be exercised during PNAM not to increase the nostril circumference, *mega nostril*, and not excessively thin the nasal cartilage as a result of pressure. PNAM can cause an unstable nose; 5) the use of postoperative retention stents is highly recommended to improve the stability and shape of the nostrils. Postoperative use of acrylic or silicone stents has been recommended to maintain the surgical outcome achieved because recurrence is still a concern. In addition to commercially available stents, use an adjustable external nasal retainer to assist in the maintenance and enhancement of the postoperative nasal shape (Fig.11).[9]

It is concluded that PNAM has been shown to be an effective adjunct therapy for reducing hard and soft tissue cleft deformities before surgery. It is important that the parent or caregiver be an active member of the treatment plan. Studies show that PNAM therapy improves nasal esthetics, reduces cleft size and aligns the maxillary arch with a reduction in the size of the alveolar cleft and palate in patients. Therefore, PNAM therapy should be recommended in all patients with CLP as a routine procedure in treatment protocols, to improve surgical outcomes and improve aesthetics and function with minimal costs and operations.

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