Pre-Surgical Infant Orthopedics with the NasoAlveolar Molding (NAM) Device for Unilateral and Bilateral Cleft Lip and Palate: Case Series

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ABSTRACT

Management of infants born with cleft lip and palate entails an interdisciplinary team effort that begins from infancy to adulthood. The goal of pre-surgical infant orthopedics is to reduce the severity of the cleft deformity before surgery. However, traditional methods do not address the deformity of the nasal cartilages and alveolar ridges simultaneously.

The Nasoalveolar Molding (NAM) technique takes advantage of the malleability of immature nasal cartilage and its ability to maintain a permanent correction of its form. The NAM device is used to actively mold the alar dome, nasal cartilages, premaxilla, and alveolar ridges into a more normal anatomic form and position. It permits non-surgical elongation of the columella through application of tissue expansion principles. This results in better facial aesthetics and may help reduce the extent, number and cost of surgeries.

The three cases presented illustrate the application of the NAM device for the pre-surgical infant orthopedics in unilateral and bilateral cleft lip and palate patients treated at the Philippine Children's Medical Center-Pediatric Dentistry Division (PCMC-PDD).

Key Words: nasoalveolar molding, unilateral cleft lip and palate, bilateral cleft lip and palate, pre-surgical orthopedics

Introduction

Cleft lip and cleft palate are two main types of oral clefts which reflect disorders in fusion of the midfacial skeleton.[1] The incidence of cleft lip with or without cleft palate varies worldwide with an estimate of one in every 700 live births[2] making cleft lip and cleft palate one of the most common types of birth defects. The highest risk for oral clefts is found among Asians (1.4/1000 live births), followed by Caucasians (1/1000) then African Americans (0.4/1000).[3] Among Asians, the risk for oral clefts is higher among Far East Asians (Japanese, Chinese, and Korean) and Filipinos.[4] In the Philippines, the birth prevalence is 1.94 per 1000 live births or one in every 500.[5] Offspring of patients with a cleft lip have an increased risk (1 in 20) of having clefting conditions. If other siblings or other close relatives have clefts, the frequency is 1 in 6.[6]

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Etiology and Risk Factors

Human facial development begins by the end of the fourth week in utero as the area beneath the forebrain becomes segmented into five branchial arches. At the sixth to seventh week, the upper lip is formed by fusion of the medial nasal and maxillary processes. Palatal shelf fusion takes place between the eighth to twelfth weeks as the two palatal shelves shift from a vertical to a horizontal position over the tongue. Fusion progresses from an anterior to posterior direction. A cleft results when any of these tissues fail to meet.[2]

While the exact cause of cleft lip and palate is unknown, the most widely accepted view seems to be the multifactorial theory in which genetic predisposition to clefting is acted upon by environmental factors, although to a lesser extent.[7,8]

Oral clefts may occur as an isolated anomaly.[9] However, approximately as much as 50% of children born with clefts may have one or more associated anomalies,[10] which are more likely to be linked with chromosomal abnormalities and syndromes.[11] There are over 300 different syndromes associated with oral cleft,[9] such as amniotic band anomalad, Apert syndrome, Crouzon syndrome, hemifacial microsomia, Meckel syndrome, Pierre Robin syndrome or sequence, Stickler syndrome, Treacher-Collins syndrome, trisomy 13, van der Woude syndrome and Velocardiofacial syndrome, to name a few.[2,10,12]

An increased risk of bearing offspring with oral clefts has been associated with maternal exposure to certain drugs or chemicals, maternal smoking and alcohol intake, maternal infections and faulty metabolism of nutritional elements as well as advanced maternal age.[10,12]

Cleft Lip and Palate (CL/P)

Clefts of the lip and palate may be categorized as unilateral, bilateral, complete or incomplete and can present itself in varying degrees of severity and combinations.[1]

Unilateral cleft lip and palate (CL/P) presents as a cleft involving the palate, alveolar ridge and process, and upper lip.[1,2] On the affected side, the nasal base is wide and is separated by the lip segment; while the alar rim appears concave as the lower lateral nasal cartilage is displaced laterally and inferiorly. The nasal base, nasal septum and columella deviate obliquely to the non-cleft side.[13]

Different variations of bilateral CL/P exist ranging from both right and left sides, presenting as complete cleft to a combination of a complete cleft on one side to incomplete on the other side.[14,15] Characteristic features are deformed nasal structures with a wide alar base, depressed alar rims and flat nasal tip. The prolabium is attached to the nasal tip by a very short or absent columella. The palatal processes are separated from each other and from the premaxilla which is permitted to rotate upward and outward by the separated upper lip segments.[1,2,13]

Need for Treatment

Aside from the apparent physical deformity, infants born with CL/P are faced with other challenges. Maintenance of adequate nutrition is often a problem. Feeding is difficult and takes longer due to the lack of intraoral pressure.[1,16] Excessive air intake, nasal discharge/regurgitation and choking are common occurrences.[16] Eustachian tube dysfunction can cause chronic middle ear problems which can impair hearing. This can lead to speech and intellectual disabilities. Poor velopharyngeal closure, malocclusion and deformed lip anatomy can likewise result in faulty speech.[1]

Increased incidence of dental caries and malocclusion is observed in cleft patients due to anomalies in the number, size and shape of teeth, delayed tooth eruption, lack of alveolar bone support in the cleft area(s), collapsed dental arches, crossbites, and disruption of skeletal facial growth due to surgical intervention.[1]

Finally, it is not uncommon for children with clefts to suffer from psychological and emotional trauma since they are prone to teasing and bullying by peers, while some may lack family support and acceptance.[14]

Therefore, an interdisciplinary approach to management of CL/P patients requires the involvement of individuals from three fields: (1) dentistry (pediatric dentistry, orthodontics, oral surgery and prosthodontics); (2) medicine (genetics, otolaryngology, pediatrics, maxillo-facial surgery, plastic surgery, and psychiatry); and (3) allied health care (audiology, nursing, psychology, social work, and speech pathology).[1,15,16]

Pre-surgical Infant Orthopedics

As early as 1686, attempts were made by Hoffman to retract the protruding premaxilla and narrow the cleft using a head cap with arms extended to the face.[17] Since then, the method of using the head as extraoral anchorage[18] has undergone modifications. The use of intraoral appliances for early maxillary orthopedic treatment began in 1954 when McNeil[19] used an acrylic appliance to reduce both the size of the alveolar cleft gap and hard palate cleft. This marked the beginning of the era of modern pre-surgical orthopedic appliances. Over the next 40 years both active and passive appliances were developed with the aim of molding the cleft segments prior to surgery.

It was the pioneering work of Matsuo et al. in 1984 on molding neonatal auricular cartilage[20,21] that paved the way for his attempts at nasal molding on CL/P infants in 1991. Matsuo used a stent in the form of a pair of silicone tubes to shape the nostrils. However, this technique had some disadvantages such as the need to have an intact nasal floor and the inability to direct the force because the stent expands circumferentially.

In 1993, a technique that enabled correction of the alveolus, as well as the lip and nose was described by Grayson et al.[22] The premaxilla and alveolus are first molded using a passive orthopedic appliance and lip taping. With the arches aligned and the width of the alveolar gap reduced, nasal molding can commence in order to improve the shape of the alar dome and increase the length of the columella. Grayson achieved this by adapting the nasal stent to extend from the anterior flange of an intraoral molding plate.[19,23,24] Lip taping is again added to help decrease the width of the base of the nose and approximate the lip segments. This method also eliminated the need for an intact nasal floor.

Figueroa and Liou separately introduced modifications to the Grayson technique[14] in which alveolar and nasal molding are done simultaneously. Figueroa achieves premaxilla retraction using rubber bands attached to the acrylic plate. The nasolabial angle is maintained by attaching a soft resin ball across the prolabium to the acrylic plate. In Liou's method, lip taping is also employed for premaxilla retraction. Nasal molding bulbs made of soft resin are attached to the ends of 0.028 inch stainless steel wires embedded in the dental plate. Denture adhesive is used to attach the dental plate portion of the device to the maxillary lateral segments.

The aim of this paper is to discuss the early pre-surgical management of unilateral and bilateral CL/P using a nasoalveolar molding (NAM) device. It also presents three cases treated at the Philippine Children's' Medical Center-Pediatric Dentistry Division (PCMC-PDD).

Patient A

Patient A, male, 25 days old, was referred to PCMC-PDD for management of bilateral CL/P (Figures 1A and B). Medical history revealed prior history of pneumonia and intake of Clarithromycin, no previous hospitalization and no known allergies to medicine or food. Patient A at the time of consult was being given a vitamin supplement (Nutrillin®).

Clinical examination showed that the premaxilla was displaced anteriorly and towards the right, the left alar rim was depressed and there was a wide gap between the maxillary alveolar segments (Figure 1C). Options for pre-surgical CL/P management were explained to the mother who opted for the nasoalveolar molding (NAM) device. Patient A was then referred to a pediatrician for check-up and medical clearance.

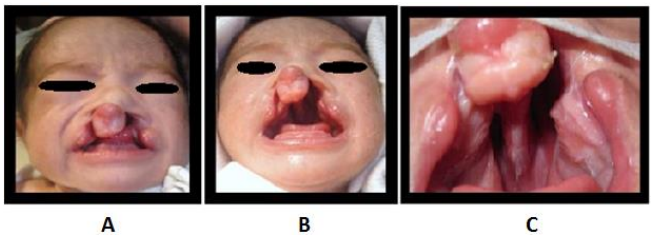

Figure 1. (A and B) Patient A showing extent of bilateral cleft. (C) Intraoral view.

A week later, with the necessary medical clearances, an impression was taken using a custom-made acrylic impression tray (Figure 2A) and vinyl polysiloxane impression material (Exaflex® type O putty, GC America Inc.) (Figure 2B). The impression was poured in yellow cast stone (Figure 2C). The cleft area on the working cast (Figure 2D) was blocked out with pink wax. Separating medium was applied to the cast and clear auto polymerizing acrylic (Duracryl, SMI London) was used to make the obturator portion of the NAM device. Only one nasal stent was made for the left nostril which showed more severe depression as compared to the right nostril. Furthermore, approximation of the lip segments showed that the right nostril presented a more normal shape and form so it was decided to do nasal molding of only the left nostril. The nasal stent was made with auto polymerizing acrylic and .036" stainless steel orthodontic wire (Ormco, Glendora Ca.). This was embedded within the obturator. (Figure 3)

The appliance was tried-on to check the fit and extension of the obturator and nasal stent. Lip taping/ strapping was done by attaching white medical tape (3M™ Transpore™, USA) to the hydrocolloid dressing patches (DuoDERM CGF dressings, ConvaTec, USA) placed on the cheeks. The medical tape was attached from right to left to reposition the displaced premaxilla (Figures 4A, B and C). A small amount of denture adhesive cream (Polident®, GlaxoSmithKline) was applied to the tissue surface of the obturator and then seated into the patient's mouth. The ability of the patient to bottle feed properly was observed. Proper handling of the NAM device and lip taping procedures were demonstrated to the mother, the primary caregiver of the patient. The mother was then asked to do return-demonstration to ensure that proper home care will be done. The mother was given home care instructions and was strongly advised to return with the patient for check-up and NAM device adjustment at weekly intervals.

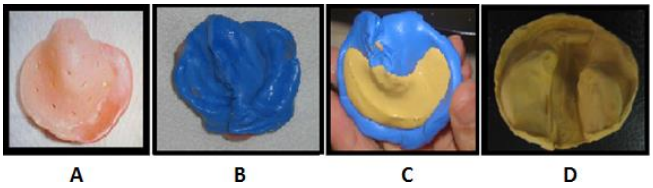

Figure 2. (A) Custom made acrylic impression tray. (B) Impression taken with vinyl poly-siloxane impression material. (C) Impression poured in dental stone. (D) Working cast.

Figure 3. NAM device with one nasal stent.

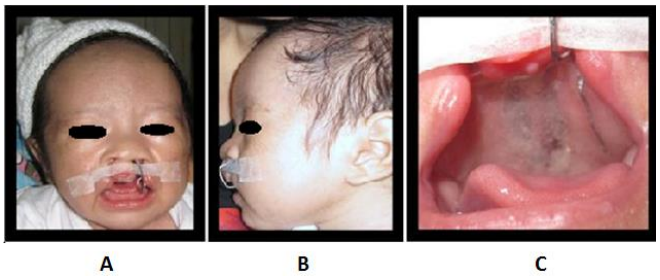

Figure 4. (A and B) Patient A with NAM device installed (one nasal stent) and lip taping. (C) Intraoral view of NAM device.

On the first follow-up appointment, pressure spots or mucosal ulcerations were noted on the raphe area. The portion of the obturator opposite this was adjusted by trimming. The size of the nasal stent was increased by adding one millimeter (mm.) thickness of acrylic on its anterior portion. Lip-strapping was reinforced to the mother. By the second recall visit, the left ala was almost symmetrical with the right ala. Use of hydrocolloid dressing on the cheeks was discontinued due to skin irritation but lip taping was continued with the medical tape directly attached to the cheeks. The third and fourth recall visits consisted of enlargement of the nasal stent and trimming the anterior part of the obturator by one mm. increments to accommodate the downward and backward rotation of the premaxilla.

Six weeks after the NAM device was installed, symmetry of the right and left ala had been achieved. The shape of the left ala was stable even without the nasal stent. The pre-maxilla had moved down and back. Active adjustments were discontinued and the NAM device was maintained passively until prior to the time of lip surgery. The mother was instructed to continue the lip-strapping at home.

A month later, it was observed that the soft tissue edges of the premaxilla and anterior portion of the two halves of the maxilla were more co-aptated. In preparation for lip surgery, the nasal stent was removed and the obturator portion was left to maintain the position of the maxillary segments. A piece of dental floss was tied through a hole drilled in the anterior flange of the obturator and then secured to the patient's cheek with medical tape to ensure easy retrieval of the obturator should it accidentally come loose. Lip-strapping was continued.

Patient A and his mother left for New York, USA shortly after his last check-up. They had obtained sponsorship for lip surgery from the Little Babyface Foundation. Lip surgery was performed approximately four months after initial consult.

Patient A returned to our unit for follow-up three months after his lip surgery. He was then eight months and twenty days old and weighing 7.5 kilograms. Clinical examination showed a symmetric nose, a flat upper lip on profile view (Figures 5A, B and C), a premaxilla in contact with the palatal halves, and a palatal defect (still open) (Figure 5D).

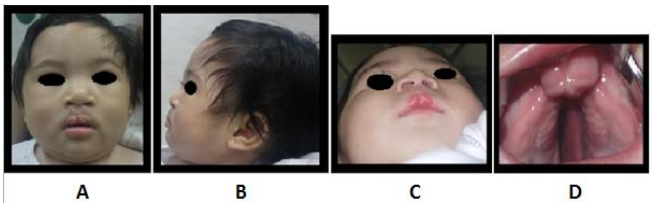

Figure 5. (A, B and C) Patient A after lip surgery showing good symmetry of the nose and adequate nasal tip projection. (D) Intraoral view showing improved arch form, premaxillary segment closer to the two maxillary halves.

Two weeks later an obturator was fabricated and installed to help in feeding and to maintain the width and position of the palatal halves. Post-operative instructions were given to the mother who was advised to return for regular monthly check-ups until the time Patient A is ready for palate closure.

Patient B

Patient B, male, 3 days old was diagnosed to have bilateral CL/P (Figures 6A and B). He was referred to the PCMC-PDD for fabrication of a NAM device to aid in feeding. Medical history at the time of consult revealed that the patient was taking cefuroxime (Zinnat®), as prescribed by the attending pediatrician upon discharge from the neonatal intensive care unit (NICU) for treatment of lower respiratory tract infection. Clinical examination showed an anteriorly displaced premaxilla, elongated and depressed alar rims, and a wide cleft gap (Figure 6C). The parents were requested to obtain a medical clearance. The preoperative treatment plan was discussed and treatment consent was obtained from the parents.

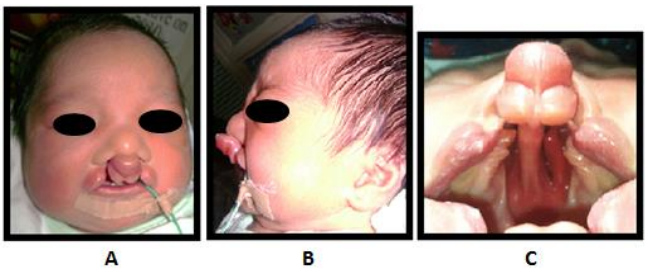

Figure 6. (A and B) Patient B showing bilateral CL/P. (C) Intraoral view showing protruded premaxilla and large cleft gap.

The following week, Patient B returned for impression-taking and NAM device fabrication with two nasal stents (Figures 7A and B). White medical tape (3M™ Transpore™, USA) was used for lip taping (Figures 8A, B and C). The parents and grandmother were instructed on proper handling and care of the NAM appliance as well as the lip taping procedure. Trial feeding followed to check whether the patient was able to feed adequately without regurgitation of milk through the nose. Home-care instructions were given and a reminder that weekly adjustments are necessary.

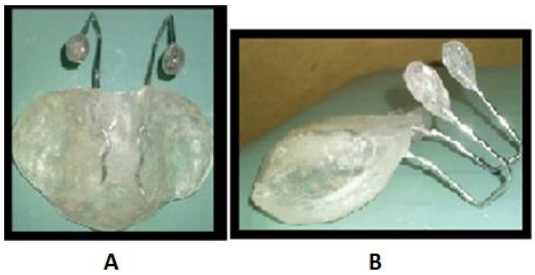

Figure 7. NAM device with two nasal stents: (A) top view. (B) side view.

Initial adjustments were made on the first recall visit. The position of the nasal stents were adjusted to align the right and left alar rims. The anterior part of the obturator was trimmed to create space for retraction of the premaxilla. No sore spots were noted. Proper cleaning of the appliance and oral cavity needed to be reinforced to the parents.

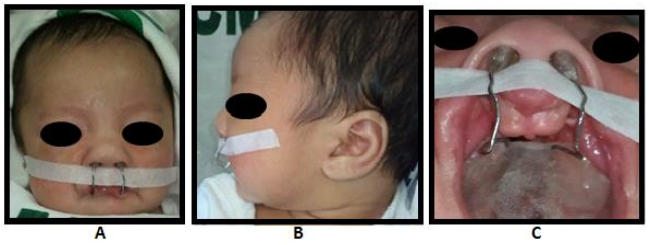

Figure 8. (A and B) Patient B with NAM device installed (two nasal stents) and lip taping. (C) Intraoral view of NAM device.

On the second recall visit, the presence of mucosal ulceration on the anterior portion of the left maxillary ridge was noted. The obturator was adjusted accordingly. On the succeeding visits, it was noted that the mucosal ulceration was decreasing in size but continued to be present in the next five visits even if there was no contact with the obturator. Weekly adjustments of the nasal stents involved gradual addition of acrylic to the bulb of the nasal stent to increase its size. The acrylic was trimmed from the anterior part of the obturator as the premaxilla was gradually retracted.

By the fourth recall visit, lip strapping was discontinued because of worsening of contact dermatitis on Patient B's cheeks. Slight skin rashes on the forehead and eye brow areas were noted. The parents were advised to seek consult with a dermatologist. On the following visit, the parents reported that the dermatologist informed them that the skin rashes on the forehead and eyebrow are normal, and advised the parents to switch from using Micropore (3M™ Microspore™, USA) to Transpore (3M™ Transpore™, USA) to minimize contact dermatitis.

Eight weeks after installation of the NAM device, adjustments of the nasal stents and obturator were discontinued in preparation for lip surgery. Lip strapping was resumed and continued until just before the lip surgery.

The parents were advised that weekly visits were still necessary and that after lip surgery Patient B would still need an obturator. However, after the last visit, the patient failed to return despite repeated attempts for recall because the patient's grandmother had some apprehensions about him undergoing another procedure for the obturator. The patient finally returned three months after lip surgery. By this time Patient B was already 7 months old (Figures 9A, B, C and D). The parents were again reminded of the importance of an obturator. They finally agreed and Patient B was scheduled for obturator fabrication.

Patient C

Patient C, male, 37 days old (Figures 10A and B) was referred to PCMC-PDD by the mother of Patient A. Patient C's mother reported difficulty in feeding and wanted to have a NAM device fabricated. Medical history was unremarkable. Clinical examination revealed incomplete unilateral left cleft lip, incomplete cleft palate (Figure 10C). The preoperative treatment plan was discussed with the parents. The parents were requested to obtain a medical clearance.

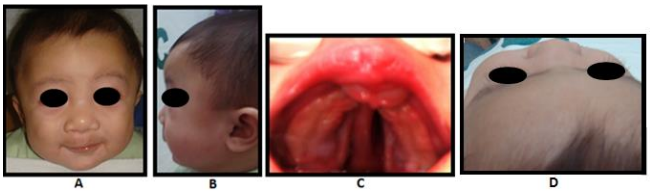

Figure 9. (A and B) Patient B after lip surgery showing good symmetry of the nose, adequate nasal tip projection. (C) Intraoral view showing premaxillary segment closer to the two maxillary halves. (D) Top view showing nasal symmetry.

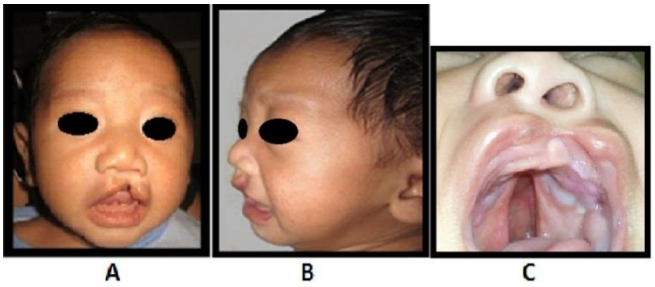

Figure 10. (A and B) Patient C showing incomplete unilateral cleft lip (left), slightly depressed left alar rim. (C) Intraoral view incomplete cleft palate.

Two weeks later the parents returned with a medical clearance in which the physician noted a "moderate operative risk with a history of upper respiratory tract infection." Preoperative treatment plan was again discussed with the parents for which they gave a signed treatment consent.

Figure 11. (A and B) Patient C with NAM device (left nasal stent) installed. (C) After lip surgery showing good nasal form. (D) Intraoral view.

An impression was taken and the NAM device was fabricated with a nasal stent for the left nostril (Figure 11A and B). The parents were given instructions for the proper

handling and care of the NAM device. Proper feeding with the NAM device was observed before the patient was dismissed.

Patient C returned for a total of four weekly recall visits during which the nasal stent was adjusted by increasing its size by adding auto polymerizing acrylic and adjusting its position in an attempt to achieve symmetry between the left and right ala. By the third recall visit, a mucosal ulceration on the posterior portion of the soft palate was noted so the posterior extension of the obturator was reduced by 2 mm.

Patient C underwent lip surgery a month after his last adjustment and returned for post-operative follow-up two months later (Figures 11C and D). The parents reported that Patient C was confined for one week due to pneumonia and also complained that when the patient feeds, milk comes out of his nose. They came back to PCMC-PDD to have an obturator fabricated to aid in the patient's feeding. Patient C had doubled his weight from 3.6 kilograms on the initial visit to 7.2 kilograms during the follow-up appointment.

In preparation for obturator fabrication, intraoral and extraoral photographs were taken. Medical clearance was secured by the father wherein a "moderate operative risk with a history of upper respiratory tract infection" was again indicated. The following week, an obturator was fabricated and installed on Patient C.

Results

The three patients we treated with the NAM device all showed significant improvements both extraorally and intraorally. Patient A and B both showed retraction and centering of the protruded premaxilla resulting in improved arch form and improved nasal height and nasal symmetry after NAM therapy; Patient A had better nasal tip projection than Patient B. A marked increase in columellar length was also observed in Patients A and B. Nasal symmetry for Patient C was improved but not completely achieved with the NAM device. However, nasal symmetry was further improved and achieved after lip surgery.

A common complication observed among the three patients was tissue irritation in the form of mucosal ulcerations. This was easily managed by selective grinding of the appliance. However, the mucosal ulceration of Patient B continued to persist for several weeks even when no apparent contact could be observed with the obturator portion of the appliance. Contact dermatitis was observed in both Patients A and B while Patient B also developed skin rashes on the forehead and eyebrow areas. This necessitated referral of Patient B to a dermatologist who recommended a change in medical tape used for lip strapping. For all patients, it was necessary to reinforce proper oral hygiene measures to the parents particularly during the initial stages of treatment.

Discussion

The main goal of pre-surgical infant orthopedics is to improve hard and soft tissue relationships in order to reduce the severity of the cleft deformity. This entails the following: (1) aligning and approximating the separate alveolar segments while achieving passive contact of the gingival tissues; (2) correcting the nasal tip and improving symmetry of the lower alar cartilages; (3) centering the philtrum; (4) lengthening the columella and; (5) approximation of the lip segments at rest.[15] Approximately one to two months of active treatment is needed to accomplish these movements.

Pre-surgical infant orthopedic treatment is indicated in patients with a wide unilateral CL/P and bilateral CL/P with an anteriorly and superiorly displaced premaxilla. Early management is crucial and should begin preferably within the first two weeks of life.[25] Matsuo[20] believed that the increase in maternal estrogen levels at the time of birth stimulates an increase in hyaluronic acid levels in the neonate. This prevents the linking of cartilage intercellular matrix which results in a decrease in elasticity of ligaments, soft tissue and cartilage necessary to facilitate safe passage of the baby through the birth canal. The cartilage tissues become more malleable and are highly moldable especially during the first six weeks of life. The greatest benefit from active soft tissue and cartilage molding can be achieved during the first two to three months after birth.[23] After this time, the cartilage becomes less malleable.

Improved outcomes with the use of the NAM device have been reported by various authors. Among the changes noted were the following: 1) a significant decrease in alveolar cleft width[26,27,28] and columellar deviation;[26,28,29,30] 2) a significant increase in columellar length;[27,28,29,31,] and 3) a statistically significant improvement of nasal symmetry,[27,28] nostril height,[26,27] nasal angle and nasal tip projection.[27,30] More significant improvements were observed in unilateral CL/P patients, particularly in columellar deviation and length, along with nostril height when compared with the bilateral CL/P group.[32] Deng et al.[33] measured a greater decrease in alveolar cleft width among unilateral CL/P patients (average of 5.3 mm) as compared to the bilateral CL/P patients (average of 4.7 mm on the left and 4.2 on the right), while nasal profile was improved in 76 percent (%) of the unilateral CL/P cases as compared to 66% in bilateral CL/P cases. In unilateral CL/P patients, a decrease in the width of the alveolar cleft gap allowed for an increase in posterior maxillary arch width.[26] A reduction in protrusion of the premaxilla and concomitant improvement in arch form was found to be significant among bilateral CL/P patients.[27]

The importance of early management of CL/P patients and its effect on the level of success of treatment outcomes with the NAM device cannot be overemphasized. Patients A and B, both bilateral CL/P patients, achieved significant

amounts of improvement of both the nasal and alveolar deformities. Only one nasal stent was used for patient A since it was only his left nostril that was severely depressed while patient B required two nasal stents. The use of the NAM device, in conjunction with the lip taping, resulted in significant retraction and centering of the protruded premaxilla and lengthening of the columella for both patients A and B. These corrections were achieved within six to eight regular weekly adjustments. For patient C, symmetry of the nasal cartilages was not completely achieved because treatment started late (at seven weeks of age) and adjustments lasted only for four weeks.

Stability of the corrections achieved with the use of the NAM device followed by primary lip surgery was investigated in other studies. Relapse tendencies were observed to be greatest within one year post-op.[34] Relapse rates of 10% for nasal height, 20% for nasal width and 5% for columella angle were reported at 1 year of age. Columella length was seen to decrease by an average of 1.9 mm. during the first two years following lip surgery but increased by the third year.[29] Significant relapse of nasal symmetry was attributed to differential growth rates between the cleft and non-cleft sides, while differential growth of the nose and columella resulted in significant changes in columella length.[34] In view of these observations, the following recommendations have been proposed: narrowing of the alveolar cleft gap with the NAM; overcorrection of the vertical dimension of the nasal dome with the nasal stent; and maintenance of the nasal shape following surgery with a nasal conformer.[34,35]

NAM therapy in Patients A and B resulted in good nasal symmetry between the right and left nostrils. Since only the left nostril of Patient A was molded, it is possible that some relapse in the height of the left nasal dome will be evident one year post-surgery. For Patient B who had bilateral nasal molding, some degree of relapse is also expected and may even be unequal if the right and left nostrils experience different growth rates. Secondary nasal procedures at a later time may still be indicated in all three patients, particularly in Patient C where nasal symmetry was not completely achieved with NAM therapy, to address significant relapse and in order to further improve aesthetics. Use of a nasal conformer to maintain nasal form post-surgically was not recommended by the attending surgeons for any of our three patients.

Still, achieving good alignment of soft and hard tissues prior to primary lip and nasal repair has been shown to result in improved long-term nasal aesthetics. Other studies of long term follow-up of patients after one,[36] three[29] and nine[37] years showed significant maintenance of corrections obtained at one year post-op. An additional benefit is a reduced number of nasal and labial surgical procedures. This is because the outcome of the surgery is improved and more predictable with less scar tissue formation.[38,39] There is also less need for secondary alveolar bone grafts in the majority of patients especially when gingivoperiosteoplasty is included in the protocol.[13,40] Less number of surgeries[27,41] and hospitalization translates into savings in cost for the patient and the family.[28,42,43] Furthermore, the parents are directly involved in the treatment so it gives them the opportunity to take an active role in the rehabilitation of their child.[13]

The success of NAM therapy, to a large extent, depends on obtaining excellent cooperation and a firm commitment from both parents and/ or caregivers since the NAM therapy is both labor and time intensive. Other studies showed that issues on compliance account for an estimated 56% of complications (30% due to broken appointments; 26% due to removal of the NAM by the tongue) encountered with the NAM therapy.[44] It is imperative that the parents are made aware not only of the potential benefits but, more importantly, of their responsibilities in the therapy and the difficulties that they and their child may encounter during the entire length of treatment.[15,44] The NAM device must be worn at all times and removed only for cleaning. The parents need to develop the manual skills involved in positioning the device and lip taping which can prove to be challenging particularly if the infant is crying and uncooperative. They also have to learn how to tolerate their child's apparent discomfort which can prove to be quite difficult and frustrating.[15] Otherwise, if the parents cannot comply with their responsibilities (cleaning of the NAM device and the infants' mouth, lip taping, returning for the weekly adjustments for the duration of the treatment), it may be more prudent to decide against using the NAM device.

Other complications commonly encountered with NAM therapy as reported in other studies are mucosal irritation or ulcerations, which accounts for an estimated incidence of 10%;[44] intraoral bleeding; fungal infections; over-enlargement of the nostril; nasal bleeding; and over-stretching of the columella. Contact dermatitis can also occur due to repeated removal of the tapes. Protective tapes can be used to avoid tissue irritation. Over-activation of the nasal stent may cause bruising or petechiae in the dome area and primary maxillary incisors may erupt prematurely if excessive pressure is exerted by the molding plate.[44]

Only minor complications were encountered with our three patients and these consisted mainly of mucosal ulcerations. The parents/caregivers were generally cooperative. The treatment procedures were thoroughly discussed with the parents/caregivers. Their responsibilities, particularly with home-care duties, were explained in detail and compliance was checked periodically. We also found it helpful to encourage the parents/caregivers particularly during the start of treatment.

Complications can lead to increased treatment time as well as compromised aesthetic outcomes. Regular weekly

check-up and adjustment can ensure that complications are minimized.

Conclusion

Pre-surgical infant orthopedics with the NAM device has proven to be beneficial for both unilateral and bilateral CL/P patients, provided that therapy begins early, ideally within the first two weeks after birth.

In addition, adequate molding of the hard and soft tissues is also dependent on the proper handling and adjustment of the NAM device by the operator. When used correctly, NAM therapy can decrease the width of the cleft defects and help mold the premaxilla and alveolar segments into a more normal arch form. This ultimately affords a more ideal base for lip closure and avoids excessive tension at the surgical site. With the nasal stent(s), the alar cartilages can be molded into a more normal and symmetric shape, simultaneous with the premaxillary and alveolar correction, and often avoiding the need for additional surgery for the nose. The obturator portion aids in feeding, prevents nasal regurgitation and excessive intake of air and allows better maxillary growth before surgery.

Our experience with Patients A, B, and C treated at the PCMC-PDD showed favorable results with the NAM device. For Patients A and B, nasal symmetry was achieved after six to eight weeks of activation. Nasal symmetry for Patient C was further improved after lip surgery.

Good parent or caregiver compliance can be expected if the parents are properly educated on the benefits of the NAM therapy, their responsibilities and what to expect during treatment. Regular follow-up and positive reinforcement also has a beneficial effect on both treatment outcome and cooperation of the parents/ caregiver.

The benefits of the NAM therapy clearly outweigh the risks. The NAM therapy is, however, not without its complications. Most complications, such as mucosal ulcerations, can be easily resolved and minimized, if not prevented, with regular weekly check-ups and adjustments.

It is recommended that long-term assessment and follow up be carried out to further investigate the stability of the results of the NAM therapy in our institution, to determine the need for future surgeries and to assess changes brought about by age.

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