Nasoalveolar molding appliance: a necessary pre-surgical treatment method for congenital cleft lip and palate

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Summary

Cleft lip and palate (CLP) are among the most common congenital defects in the craniofacial region, significantly impacting aesthetics, function, and the psychosocial well-being of both patients and their families. Particularly in cases of wide clefts, the anatomical structures on either side of the cleft are often severely deficient and deformed, complicating surgical procedures. Pre-surgical orthodontic treatment, especially with the Nasoalveolar Molding (NAM) appliance, has gained increased attention recently due to its ability to improve the position and shape of facial structures, facilitating optimal surgical outcomes. The goal of pre-surgical NAM treatment is to reduce the width and enhance the symmetry of the structures on both sides of the cleft, including the lip, nose, and alveolar ridge. Given its benefits, NAM treatment is increasingly encouraged and emphasized for newborns with cleft lip and palate.

Keywords: *Cleft lip and palate, Nasoalveolar Molding (NAM), pre-surgical orthodontics.*

1. OVERVIEW

Cleft lip and palate are among the most common defects in the craniofacial region. The prevalence of this condition varies across countries worldwide, influenced by socioeconomic status, environmental factors, geography, and differences in genetics and race. The causes of cleft lip and palate are believed to be multifactorial and polygenic [1], with various genetic variants, as well as environmental factors such as smoking and alcohol [2-4] and the use of certain medications, as well as nutritional deficiencies [5, 6].

The care and treatment of craniofacial defects require multidisciplinary collaboration. Among these, surgery plays a crucial role in restoring the facial structure to as normal a condition as possible. As Brophy emphasized nearly a century ago: *"It is a rule that a reliable foundation is essential to all dependable superstructures. The lip is no exception to this rule in cleft lip"* (Brophy, 1927). Therefore, the alveolar ridge, premaxilla, and maxilla form a foundation for the lips and nose that are situated above [7]. These are deformed in patients with cleft lip and palate, making surgery more challenging. This necessitates pre-surgical intervention, especially with the Nasoalveolar Molding (NAM) device, which has been proven to significantly improve the outcomes of the first repair in patients with cleft lip and palate compared to other pre-surgical orthodontic techniques. This includes reducing the severity of the cleft, reshaping the position of the lips, nose, and alveolar ridge to facilitate easier and fewer surgical interventions [8].

1.1. Historical development

Throughout history, various pre-surgical devices have been used with the goal of reducing the complexity of cleft lip and palate (CLP) surgeries. Franco developed a head cap as an external means to reduce the gap. In 1686, Hoffman designed a head cap that extended to the face via the cheeks and lips to retract the premaxilla backward. In 1776, Chausier designed a cheek compression bandage to treat cleft lip as a treatment method for a large number of patients "despite the continuous movement of young children". In 1790, PJ Desault invented a rather complex compression fabric bandage that he applied to prevent the protrusion of the premaxilla for 11 days before surgery to create a constant backward pressure"… [9]. In the modern era, in 1950, McNeil described the first pre-surgical orthodontic device capable of stimulating tissue growth and reducing the width of the cleft in the alveolar ridge and palate [10]. Subsequently, physicians recommended a pre-surgical device to adjust the alveolar ridge and reduce the width of the cleft lip and palate. The first was the Hotz appliance, a passive device consisting of a simple base that helps guide the development of the alveolar ridge's shape without the need for external force [11]. In 1976, Latam et al. described the Latam device, which uses a pin placed in the palate to stimulate the development of the premaxilla and expand the posterior part of the upper jaw [12].

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In 1993, Grayson et al. first described the Nasoalveolar Molding (NAM) device, an appliance that affects the lips, nose, and alveolar ridge in newborns [13]. By 1999, Grayson et al. had made improvements that made the NAM device lighter and simpler [14]. According to Grayson, the nasal stent is attached to the base when the width of the cleft is reduced to 5mm. However, Figueroa et al., as well as Liou et al., incorporated the nasal stent from then.A. beginning [15, 16]. Since then, various improvements have been proposed by different authors.

1.2. Objective

The primary objective of the pre-surgical NAM device is to reduce the severity and deformation of the structures on either side of the cleft. This facilitates the surgeons during subsequent repairs, thereby yielding optimal treatment outcomes for the patient. These objectives include:

- Reducing the width of the cleft in the alveolar ridge and repositioning the alveolar segments to their normal positions, thus helping to form the alveolar arch and thereby reducing the need for alveolar bone grafting [17].

- Reducing the width of the cleft in the alveolar ridge while simultaneously reducing the lip cleft, thus decreasing the tension in the lip area before and after lip reconstruction surgery [18].

- Increasing the symmetry of the nose and the length of the nasal columella, improving the long-term aesthetic appearance of the nose [19-21].

- Acts as a shield that helps the child avoid aspiration when breastfeeding and prevents the tongue from invading the cleft during swallowing [18, 22].

- Regular follow-up visits help to reduce anxiety for the family [23, 24].

- Saves costs for patients and society through the reduction of surgical interventions [25].

1.3. Principle

The NAM device operates on the principles of *"Negative sculpturing"* and *"Passive molding"* of the alveolar ridge and surrounding soft tissues. The base is cast from the patient's upper dental impression using acrylic that is adjusted and selectively added to after each follow-up visit to guide the development of the alveolar ridge." [26].

1.4. Timing of implementation

According to Matsuo (1984), in the first 15 days after birth, the increased levels of pregnancy Estrogen stimulate the production of Hyaluronic acid. Hyaluronic acid breaks down extracellular matrices, reducing the elasticity of connective tissue, ligaments, and cartilage. The flexibility of nasal cartilage is higher in the postnatal period compared to when the child grows older. Cartilage typically loses its flexibility within about 6 weeks, so the NAM device is most effective on soft tissue and cartilage for children aged 3-4 months [27].

2. TECHNOLOGY

2.1. Technique for maxillary impression taking

The child is impressioned while fully awake, without anesthesia. The impression taking must be performed very carefully and always conducted with an anesthesia team on standby to manage any emergencies promptly. Before the impression, the child must fast for about 2 hours. The impression is taken on a dental chair, with the child placed in the parent's lap in an upright position, with the head slightly tilted forward. After selecting the correct size of the impression tray, the evenly mixed Silicone compound is placed into the tray and inserted into the mouth with positive pressure. Immediately following this step, a portion of the Silicone is pushed upwards to take the nasal impression. [28, 29]. During the impression taking, the dentist uses a mirror (or the left thumb) to push the patient's lower jaw down and back to prevent the impression material from falling into the oral cavity. During this time, the child is allowed to cry freely [29]. After the procedure, the impression of the nasal cavity, lip, and alveolar bone is removed simultaneously. The criteria for a good rubber impression are clarity, capturing all details, no tearing or deformation upon removal from the mouth, and maintaining three-dimensional stability. Finally, the nasal and oral cavities are cleaned to ensure no impression material remains [30]. After taking the impression, proceed to pour the model using hard plaster.

2.2. Technique for fabricating the denture base and nasal stent

On the plaster model, use wax to fill the cleft areas in the palate and alveolar ridge to recreate the desired shape of the palate and dental arch. Eliminating the cleft and adding a wax cushion is a critical modification step. Use a pencil to draw the border of the denture base, avoiding the labial and buccal frenula, with the posterior limit being the boundary between the hard and soft palate. Proceed to press the denture base using 1.5mm thick acrylic resin. Trim and polish the denture base. Test the denture base in the patient's mouth, ensuring that it does not exert excessive pressure or obstruct lip and cheek movements.

Bend the nasal stent wire using stainless steel

with a diameter of 0.91mm (0.036 inches), forming it into a swan-neck shape. One end is attached to the denture base between the cleft, and the other end is shaped like a pea, made of acrylic and lined with a layer of soft plastic for comfort. The upper lobe is inserted into the nostril approximately 3-4mm, gently lifting the nose until the upper part of the nose appears slightly white. The lower lobe is used to support the nasal tip and extend the columella.

The Steri-strip lip tape measures 6x100mm (0.25x4 inches) and the orthodontic elastic band measures 6mm (0.25 inches), stretched to double its length (approximately 100 grams of force). This force can be adjusted according to clinical objectives and the degree of cheek skin irritation. To reduce cheek skin irritation, it is recommended to use DuoDERM or Tegaderm™ patches and change the adhesive position each time the tape is replaced [31].

3. COMPLICATIONS

The most common issues encountered during treatment with NAM are irritation of the oral mucosa, gums, or nasal mucosa. The tissues inside the mouth can become ulcerated due to excessive pressure from the device or from sharp, rough edges of the device. The child needs to be carefully examined at each follow-up visit to detect any ulcers and adjust the device accordingly. The nasal mucosa can become ulcerated if the nasal stent exerts excessive force.

Another frequently irritated area is the skin on both cheeks. Care must be taken when removing adhesive tape to avoid skin irritation. Using aloe vera gel or warm water to moisten the adhesive can make tape removal easier. It is recommended to use protective skin patches such as DuoDERM or Tegaderm™ and to change the adhesive position each time the tape is replaced, allowing the cheek skin to recover from irritation.

Wearing the device can cause the affected side of the maxillary arch to rotate excessively and become perpendicular to the healthy side, creating a T-shaped arch. In this case, it is necessary to expand the arch and adjust both sides of the arch to the correct relative position.

Another complication is the early eruption of maxillary teeth, which can interfere with wearing the device. In this case, extraction of the teeth may be indicated, or removing the acrylic in the area of eruption if the teeth are erupting in the correct position.

There is a risk of the denture base dislodging and obstructing the airway; therefore, a hole approximately 5mm in diameter is often created in the center of the denture base to allow air to pass through. [31].

Additionally, parental cooperation plays a crucial role in the successful completion of the NAM treatment process. Parents are responsible for daily changing of the tapes and cleaning the device for their child, as well as bringing the child for regular follow-up appointments. Lack of good cooperation can result in the loss of valuable treatment time for the child.

4. DISCUSSION

All preoperative orthopedic techniques overlook addressing nasal deformities during the pliable cartilage stage, which can be easily molded. This often leads to more surgical corrections. The use of preoperative orthopedic devices retained by pins, such as the Lactam device, has the additional disadvantage of increasing treatment costs and the invasiveness of device installation and removal, which must be performed under anesthesia. Simple lip adhesion cannot control the shape of the nose or the premaxillary segments on either side of the cleft. Uncontrolled premaxillary segments, especially when one segment is excessively rotated inward or outward, make it difficult to close the cleft, resulting in an imbalance of the lip and nose specifically, and the entire face generally, and easily form fistulas after surgery in the palate due to overly strained wound edges. A fistula in the palate affects speech when airflow escapes through the nose. Treatment with the N.A.M. device addresses most of these issues. Both short-term and long-term studies have shown that N.A.M. is an excellent treatment method to reduce the complexity of defects, improve the shape of the lip and nose, and achieve surgical results with less scar tissue, finer scars, and symmetrical, aesthetically pleasing lip and nose shapes. The study by Kinouchi et al. in 2018 compared two groups of patients: those treated with N.A.M (Nasoalveolar Molding) and a control group that used only the palatal plate without the nasal stent. The results showed that the N.A.M treatment group significantly improved nasal symmetry, including: Nasal shape, Columellar angle, Nasal tip/ala ratio, Nasal base angle. This study demonstrates that N.A.M treatment markedly enhances nasal symmetry compared to using only the palatal plate without the nasal stent [32].

The two premaxillary segments are aligned to a more symmetrical position, reducing the width of the alveolar cleft, increasing bone bridging across the cleft, decreasing the need for future bone

grafting, and creating a better opportunity for teeth to erupt in a more favorable position. In the study by Santiago et al., of the 20 sites in 18 patients treated with NAM, 12 sites did not require bone grafting. Among the 8 sites that did require grafting, 4 required only minimal grafting. In comparison, all 14 patients in the control group needed bone grafts. [17].

All of these factors reduce the number of future corrective surgeries, thereby lowering treatment costs [33]. Several studies have been conducted to evaluate the overall treatment costs and the level of parental satisfaction when treated with preoperative orthopedic devices. Shen et al. [34] and Chen et al. [35] have demonstrated that NAM is an effective treatment method and reduces treatment costs. The study by Shay et al. in 2015 [36] showed that the treatment costs for the group of patients treated with NAM ($3550.24 ± $667.27) were significantly lower than those for the group of patients who underwent surgery with only lip adhesion, including hospital and surgery costs ($9370.55 ± $1691.79).

Additionally, the palatal plate and lip adhesion prevent the tongue from entering the cleft during swallowing, allowing the mucosa and alveolar bone to develop toward the cleft without obstruction, and reducing the risk of milk aspiration during feeding. This helps the child eat and develop normally.

An important issue is the psychological impact of NAM on the patient's family. Regular follow-up visits reassure parents that their child is receiving ongoing care but can sometimes be a burden for some families. Caregiver cooperation during treatment is crucial for achieving successful outcomes with NAM. Parents are responsible for removing, fitting, and cleaning the device daily, so their positive attitude is essential for the success of the treatment. Poor compliance from parents can waste valuable treatment time for the child. Additionally, follow-up visits are a significant concern. Most families with children who have cleft lip and palate defects live far from medical facilities. Each visit requires traveling long distances, consuming a lot of time, and posing challenges in arranging schedules and work. This can make them feel exhausted and anxious, especially when their young child has to travel far, and missing follow-up appointments can lead to reduced treatment effectiveness.

Complications such as cheek skin irritation, oral mucosa irritation, or device dislodgment or breakage increase caregiver anxiety. Regular check-ups and communication between caregivers and doctors via social media platforms help doctors detect complications early and guide caregivers in adjusting the device directly. The initial design with a nasal stent helps reduce the number of follow-up visits, thereby lessening the burden on the family.

Furthermore, there has been considerable interest from clinicians regarding the long-term impact of NAM on midfacial development. Dr. Bruce Ross published a study in 1987 on preoperative orthopedic devices, which included 1,600 cephalometric records of 538 patients from 15 centers worldwide. He concluded that preoperative orthopedics did not affect facial development. In a study by Lee et al. in 2004, examining the long-term effects of NAM on midfacial development during adolescence, the results showed that midfacial development (up to ages 9-13) was not affected by NAM [37]. In 2018, Nayak et al. conducted a study to evaluate and compare the maxillary development in two groups of 7-year-old patients with bilateral cleft lip and palate, who had undergone surgery with and without NAM treatment during infancy. They concluded that NAM had no impact on the development of the maxilla at the early stage of the mixed dentition period [38]. In the study by Dec et al. in 2013, it was shown that the palatal cleft results from the movement of alveolar bone tissue and a tissue deficiency. This indicates that patients with cleft lip and palate inherently have hypoplastic maxillary and midfacial regions. [39]. Therefore, based on the studies, NAM cannot be considered to have any long-term positive or negative effects on the development of facial bone and soft tissue. A review of the literature indicates that N.A.M. does not alter facial bone development when compared to samples not treated with preoperative orthopedic devices. However, published studies on N.A.M. have provided evidence of benefits for patients, caregivers, surgeons, and society. [40]. Therefore, NAM remains a necessary preoperative treatment option for children with cleft lip and palate defects.

5. THE EMERGENCE AND DEVELOPMENT OF 3D TECHNOLOGY

Today, technological processes and digitalization are continuously evolving and are widely used in medicine, gradually replacing outdated traditional procedures while providing higher precision and efficiency. Computer-aided design (CAD) allows for digital stereoscopic imaging through laser scanning, providing highly accurate measurements. 3D models offer more information, enabling measurements and image inspection at any time, thus avoiding errors associated with manual measurements. Computer-

aided manufacturing (CAM) enables the printing of a set of devices designed through treatment planning software. However, as of now, 3D scanners cannot be used intraorally in infants. According to Quan Yu's study in 2011 [41], dental models of infants were recorded using three-dimensional laser scanners. Treatment planning and device design were based on computer-assisted simulations of the movement of structures. A complete treatment process, including pre- and post-treatment results, could be displayed directly on the computer, which is very helpful and simplifies communication between doctors and the patient's family. Subsequently, a series of devices were produced simultaneously, saving the doctor's time in the clinic by reducing chair-side adjustment time. Additionally, caregivers could replace the NAM device weekly and require fewer visits to the treatment facility until the child undergoes lip repair surgery. In 2015, Shen et al.[34] concluded that three-dimensional technology could accurately represent the anatomical structures in the cleft of an infant. The treatment outcomes of the authors were comparable to those of traditional treatment methods. However, the number of clinic visits and chair-side adjustments decreased. This technology is also more reliable, allowing visualization of treatment goals, assessment of improvements, and adaptation of the device, thereby reducing treatment costs and manufacturing time. This reduces the burden on healthcare staff, patients, and families. In 2016, a study by Ritschl et al. [42] showed no significant difference in treatment efficacy and complication rates between conventional techniques and N.A.M. fabrication using CAD/CAM technology.

However, the N.A.M. system still requires the nasal stent to be retained using conventional methods. Each time the plate is changed, a new nasal stent must be created or the stent must be removed from the old plate and attached to the new one. This process consumes significant time for both the patient and the doctor. Recognizing this drawback, in 2018, Grill et al. developed a new nasal stent retention system called RapidNAM based on a semi-automated production process for the intraoral plate [43]. Four objectives were set: compactness, stability, user-friendliness, and functional efficacy. All RapidNAM plates were designed with retention locks of the same size, allowing the nasal stent from the previous plate to be quickly removed and attached to the next plate with minimal adjustments, thus reducing treatment time during each follow-up visit.

Therefore, the development of three-dimensional technology in the treatment planning and design of NAM devices helps address the challenges associated with traditional NAM treatment and ensures that preoperative orthopedic treatment remains indispensable for children with cleft lip and palate.

6. CONCLUSION

The NAM device significantly improves surgical outcomes in patients with cleft lip and palate. The success of NAM requires the cooperation of the family, the age of the child at the start of treatment, the severity of the cleft, and the expertise of the treating physician. The deformities of the cleft are significantly reduced in size and the symmetry of related structures is increased before surgery, making surgeries on the lip, nose, and alveolar bone easier. Long-term studies in patients treated with NAM show more stable lip and nose shapes, less scar tissue, better-positioned alveolar bone segments, reduced need for alveolar bone grafting, and improved chances for the eruption of permanent teeth. The NAM device has demonstrated tremendous benefits for patients with cleft lip and palate as well as for surgeons.

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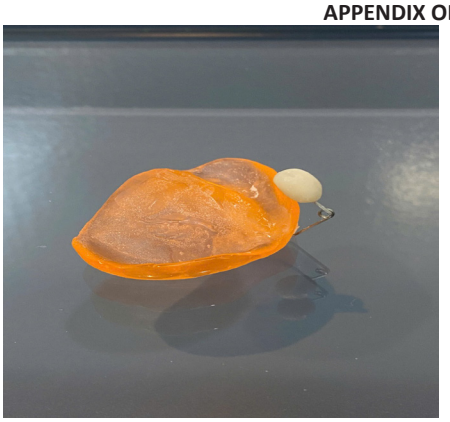
APPENDIX OF THE ARTICLE



The NAM appliances

Before treatment with NAM appliances

During treatment with NAM appliances

After treatment with NAM appliances