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Original Research Article

A Hospital-Based Study to Assess the Presurgical Nasoalveolar Moulding in Unilateral Cleft Lip and Palate

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Abstract

Aim: The aim of the present study was to assess the presurgical nasoalveolar moulding in unilateral cleft lip and palate.

Methods: 100 infants (65 boys and 35 girls) with unilateral cleft lip and palate (UCLP) were recruited at department of Department of Burn & Plastic Surgery. A comprehensive clinical assessment, including facial and oral examination, was simultaneously performed by the standardized team. The study was conducted for the period of 1 year.

Results: The result showed significant increases in average nostril height (CNH) in cleft side (from 1.16 + 0.34 mm to 6.74 + 2.18 mm, $P < .001$) and significant decreases in average nostril width in cleft side (from 20.95 + 1.52 mm to 19.07 + 1.48 mm, $P < .001$). Significant changes were also seen in average CD in cleft side (from 62.76◦ + 7.33◦ to 33.84◦ + 8.32◦, $P < .001$). Infants with complete UCLP always have a missing nasal floor, the nasal cartilage on the cleft side tilted downward, and the tip of the nose tilted to the cleft side. This research found that the nostrils on the cleft side are slightly concave. The CD is always greater than 0◦.

Conclusion: PNAM has proved to be an effective adjunctive therapy for reducing hard and soft tissue cleft deformity before surgery. However, it is important that parents or caregivers become active members of the treatment plan. This study showed that PNAM therapy improved the nasal aesthetics, decreased the cleft size and aligned the maxillary arch with a reduction in cleft alveolus and palate size in UCLCP patients.

Keywords: presurgical nasoalveolar, unilateral cleft lip, unilateral cleft palate

Introduction

The primary aim of the surgical repair in cleft lip and palate is to restore the orofacial form to as normal as possible. As emphasized by Brophy around 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”. [1] Thus, the alveolar process, premaxillary and maxillary bones form a base for the overlying lip. These are distorted in patients with cleft lip and palate, making cleft repair difficult. If the primary surgical correction of cleft lip and palate is inadequate, the resultant nasal deformity that develops over due course of time is one of the most challenging reconstructive problems in rhinoplasty. [2] Further, the deficient/deviated columella and the deformity of nasal cartilages that persists after lip repair may result in nasal asymmetry, a flat nasal bridge, a wide soft tissue nose, a flat nasal tip, and deficient nasal tip protrusion. [3]

Clefts of lip and palate are the most common congenital defects involving the orofacial region. The primary goal of the treatment in the cleft patients is to restore normal anatomy and function. [4,5] Reconstruction of the symmetrical lip and a natural looking nose is a difficult challenge in unilateral clefts. [6] Over the last two decades, the surgical technique has been improved considerably through a better understanding of the primary pathology and an integrated multidisciplinary approach. [5,7]

PNAM addresses various problems associated with traditional methods of treating unilateral cleft lip and palate. It improves nasal asymmetry and deficient nasal tip. [8-10] It also moulds the protruded premaxillary segment into a more normal alignment with the alveolar segments, improving the shape of the maxillary arch and also reducing the size of cleft lip, palate and the alveolus. It decreases the complexity of subsequent surgeries and also gives a more aesthetic outcome. [11-13] Presurgical orthopaedics has been employed since 1950 as the adjunctive procedure for correction of protruding premaxilla in the cleft. However, the original research on the neonatal moulding of the nasal

cartilage was performed by Matsuo and Hirose. [14] In 1993, Grayson et al. described a new technique of presurgical moulding of the alveolus, lip and nose in infants born with cleft lip and palate. [15,16] At present, there are three different PNAM techniques routinely used, namely; Grayson's technique, [16] Figueroa's technique [17] and Liou's technique. [18]

The aim of the present study was to assess the presurgical nasoalveolar moulding in unilateral cleft lip and palate.

Materials and Methods

100 infants (65 boys and 35 girls) with unilateral cleft lip and palate (UCLP) were recruited at department of Department of Burn & Plastic Surgery, ESIC Medical College and Hospital, Bihta, Patna, Bihar, India. A comprehensive clinical assessment, including facial and oral examination, was simultaneously performed by the standardized team. The study was conducted for the period of 1 year (February 2022 to Jan 2023). Inclusion criteria included patients with a non-syndromic, complete UCLP and younger than 3 months at the start of NAM appliance. Exclusion criteria included patients with any known syndromes, bilateral cleft lip deformities, and incomplete or microform unilateral cleft lip deformities. All lost casts were excluded.

Research Design

A prospective longitudinal study was performed. There was a pre- and post-intervention comparison. There was no control group.

We used a passive type of presurgical infant orthopedics (NAM appliance) which had been developed by Odonto- Stomatology Department at Hospital 1. In our center, unlike the original descriptions of the technique, the NAM appliance involved placing nasal stent from the first day of therapy. All parents of participants provided written informed consent for their information and images to be published.

Research Procedure

A maxillary impression was taken by the Dentist aided by a surgeon at the first examination (before primary lip repair surgery). The impression was obtained with the infant fully awake and without any anesthesia. A properly sized and fitted infant acrylic tray was used in delivering the impression material. The parents were advised they could allow the infants to cry freely during the impression-making procedure. The Hospital 1 setting allowed for a rapid response by an airway team in case of an airway emergency. Impressions for the maxillary casts were taken using a fast-setting alginate. The plate was made with clear hard acrylic resin and then the soft denture lining material was added to that plate.

The 1-step impression of the cleft-lip-palate-nose complex was designed to save time, avoid harm to the child, and reproduce the complex intraoral and extraoral anatomy in one plaster model. The spaces were blocked with wax. We made a self-cure acrylic plate of 15-mm thickness which was lined with soft tissue liner 22-gauge stainless steel wire and was fabricated, positioned anteriorly at an angle of approximately 45◦ to 50◦ to the plate.

Patients were kept under observation, and every 14th day of visit the appliances were adjusted. An increase in nostril height and a decrease in columella deviation (CD) angle were achieved by combining force of the nasal stent and prolabial taping. Parents were educated on handling and wearing of appliances. They were also informed to add a thin layer of Vaseline on the nasal stent at the time of every insertion..

The registration accuracy of the individual coordinates from the measured points was +5 mm/100 mm, according to the manufacturer. Reference points were digitized 4 times at a 2-week interval by examiners. Intraclass correlation coefficients (ICCs) for reference point identification were computed to assess the inter examiner reliability as well as intra examiner reliability. Landmarks designs that indicate changes of nasal morphology, and the maxillary alveolar shape and position before and after treatment.

Statistical Analysis

Data analysis was performed in Stata version 12.0 (Stata Corp). Differences in all variables before and after treatment were tested by the paired samples t test. To reduce measurement error, one week after the first measurements, 3 cases were randomly selected and measured by the same examiner. A P value of less than .05 was set as statistically significant.

Results

Table 1: The Changes between Pre- and Post-NAM Appliance

Measurements	Before (T0)Mean±SD	After (T1) Mean ±SD	Changes	*P* value
Extraoral				
CNH	1.16 + 0.34 mm	6.74 + 2.18 mm	Increase	<.001
CNW	20.95 + 1.52 mm	19.07 + 1.48 mm	Decrease	<.001
CD	62.78 + 7.33°	33.84 + 8.32°	Decrease	<.001
Intraoral				
AA’	1372 + 304 mm	4.46 + 3.56 mm	Decrease	<.001

AX	8.24 + 2.56 mm	3.38 + 2.38 mm	Decrease	<.001
A'X	12.76 + 3.00 mm	3.54 + 3.52 mm	Decrease	<.001
CC'	32.96 + 2.58 mm	30.43 + 2.68 mm	Decrease	<.001
I/d	12.38 + 5.53 mm	3.68 + 2.56 mm	Decrease	<.001
IJ–d	31.84 + 11.29°	12.04 + 9.17°	Decrease	<.001
TT'	34.31 + 2.278 mm	36.26 + 2.36 mm	Increase	<.001
I–TT'	24.66 + 2.54 mm	25.45 + 2.15 mm	Increase	.004
A–TT'	26.28 + 2.14 mm	24.86 + 2.38 mm	Decrease	<.001
A'–TT'	18.44 + 2.06 mm	21.72 + 2.00 mm	Increase	<.001
ATT'	58.39 + 4.64°	48.76 + 4.88°	Decrease	<.001
A'T'T	67.83 + 4.76°	60.32 + 6.94°	Decrease	<.001

The result showed significant increases in average nostril height (CNH) in cleft side (from 1.16 + 0.34 mm to 6.74 + 2.18 mm, P < .001) and significant decreases in average nostril width in cleft side (from 20.95 + 1.52 mm to 19.07 + 1.48 mm, P < .001). Significant changes were also seen in average CD in cleft side (from 62.76◦ + 7.33◦ to 33.84◦ + 8.32◦, P < .001). Infants with complete UCLP always have a missing nasal floor, the nasal cartilage on the cleft side tilted downward, and the tip of the nose tilted to the cleft side. This research found that the nostrils on the cleft side are slightly concave. The CD is always greater than 0◦.

Discussion

Cleft lip and palate are among the most common congenital craniofacial anomalies in developing countries. The incidence of cleft lip and palate is approximately 1 per 700 newborns. [19] The disease can affect the entire life of patients including the appearance; difficulties in feeding, speech, and hearing; and dental problems. Treatment of cleft lip and palate starts from birth until adulthood and goes through a lifelong multidisciplinary care journey. The goals of presurgical nasoalveolar molding (NAM) are to align the intraoral alveolar segments and to correct the deformed cleft lower lateral cartilage. [20]

Millard [21] described the unilateral and bilateral cleft deformity as a failure of mesenchyme to migrate from the maxillary process into the nasomedial processes. As a result of this failure, the maxilla and premaxilla do not form a bony union, and the muscle fibres from the maxillary processes do not enter the prolabium. This presents a discrepancy and a displacement of the components of nasomaxillary complex that persist without any appreciable improvement during growth. The result showed significant increases in average nostril height (CNH) in cleft side (from 1.16 + 0.34 mm to 6.74 + 2.18 mm, P < .001) and significant decreases in average nostril width in cleft side (from 20.95 + 1.52 mm to 19.07 + 1.48 mm, P < .001). Significant changes were also seen in average CD in cleft side (from 62.76◦ + 7.33◦ to 33.84◦ + 8.32◦, P < .001). Infants with complete UCLP always have a missing nasal floor, the nasal cartilage on the cleft side tilted downward, and the tip of the nose tilted to the cleft side. This research found that the nostrils on the cleft side are slightly concave. The CD is always greater than 0◦. In the case of a unilateral cleft, there is projection and outward rotation of the premaxilla along with retro-positioning of the anterior maxillary wall on the affected side. This causes flattening of the nasal tip and inferior displacement of the soft triangle. [22] The nasal septum is twisted, slanted and dislocated out of the vomerine groove, resulting in a twist to the nasal tip. [23] The columella is deflected by the deviation of the nasal septum and is vertically deficient on the cleft side. The deformed alar cartilage is dislodged from its normal anatomical position. The medial crus is lower in the columella, with the junction curve of the medial and lateral crus separated from the opposite alar cartilage. It rest below the opposite cartilage and is flattened, spread and stretched across the cleft at an obtuse angle. [24.25]

Baek and Son (2006) [26] evaluated the effects of the NAM appliance and the growth of 16 children with complete unilateral 3- dimensional analysis (3D) models, by superimposing the film before and after the treatment. The authors concluded that alveolar molding effects took place mainly anteriorly during NAM treatment and the growth of the cleft segments occurred mainly posteriorly and after cheiloplasty. They found an increase in intertuberosity width after treatment (28.97 + 2.58 mm to 29.29+ 2.84 mm). The goal of PNAM is to align and approximate the alveolar cleft segments while at the same time achieving correction of the asymmetric nasal cartilage and soft tissue deformity. These corrections are achieved by adding a nasal stent to the labial vestibular flange of a conventional intraoral moulding plate. The nasal stent and alveolar moulding plate are adjusted gradually over a period of 5–6 months to achieve nasal and alveolar symmetry, nasal tip projection, and approximation of the cleft alveolar segments before primary lip, nasal, alveolar surgical repair. The nasoalveolar orthopaedic appliance is held in place with a combination of adhesive tapes applied to the cheeks and cleft lip segments. [27] The presurgical reduction in osseous and soft tissue cleft deformity considerably reduces the magnitude of the surgical

challenge, resulting in improved surgical outcomes. [28]

On evaluation, it was shown quantitatively that, PNAM therapy significantly reduced the alveolar and palatal gap, and deviation of columella. These, in combination, helped to align the maxillary arches. Nasal symmetry was significantly improved. Columellar length significantly improved, hence increasing the nasal aesthetics. Nostril height was significantly increased along with decreased in nostril width. All in combination improved the nasal tip projection.

Conclusion

PNAM has proved to be an effective adjunctive therapy for reducing hard and soft tissue cleft deformity before surgery. However, it is important that parents or caregivers become active members of the treatment plan. This study showed that PNAM therapy improved the nasal aesthetics, decreased the cleft size and aligned the maxillary arch with a reduction in cleft alveolus and palate size in UCLCP patients. Hence, this therapy should be advocated in all patients with UCLCP patients as a routine procedure in the treatment protocol, to improve the surgical results and enhance the aesthetics and function with minimal cost and surgeries

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