Original Research Article

Evaluating the Role of Nasoalveolar Moulding in Pre-Surgical Intervention for Bilateral Cleft Lip and Palate

ABSTRACT

Introduction: Nasoalveolar Moulding (NAM) is a technique to pre-surgically mould the alveolus, lip and nose in infants born with cleft lip and palate. Objectives of Nasoalveolar Moulding for bilateral cleft lip and palate are retraction of the premaxilla with extraoral traction by lip taping, Maintenance of the arch form using passive appliance, create a clinically appreciable columellar tissue and harmonize the nasal tip projection.

Aim and objective: To access effectiveness of Naso-alveolar moulding on alveolus and nose in bilateral cleft lip and palate**.**

Study design : Prospective Cohort Study

Place and Duration of Study : IGIMS ,Patna. Between March 2022 and March 2024

Material and Method: This prospective study comprised 10 infants with bilateral cleft lip and palate (BCLP), undergoing nasoalveolar moulding (NAM). The mean age of the infants at the start of the study was <6 weeks, Impression was taken over which NAM appliance was fabricated and adjusted weekly depending upon progress of the treatment. Nasal stents were incorporated once the cleft width was reduced to 6mm. Duration of treatment extends to 25 to 29 weeks. Post NAM impression was taken, alveolar and nasal measurements were recorded.

Result: Right & left Alveolar cleft width, mid-palatal arch width decreases significantly.

Columellar length, right & left nasal height increase due to tissue elongation. Right & left nasal width and bialar width decreases significantly.

Conclusion: NAM therapy should be considered an integral part of the multidisciplinary approach to managing cleft lip and palate, improving not only the surgical outcomes but also the overall quality of life for affected infants

Key words: *Naso alveolar moulding, Bilateral cleft lip and palate*

INTRODUCTION

Efforts to ease the surgical challenges of cleft lip and palate have a long history, with records from the 16th century detailing attempts to improve outcomes for patients with bilateral cleft lip and palate (BCLP). The original research on neonatal moulding of the nasal cartilage was performed by Matsuo using silicone tubes to mould the nostrils.

The core principle of reducing deformities prior to surgery has persisted over time and extends into orthodontics. The modern school of presurgical orthopaedic treatment in cleft lip and palate was started by McNeil in 1950.[1] Hotz in 1987 described the use of a passive orthopaedic plate to slowly align the cleft segments.[2] **Matsuo** following the successful application of moulding therapy to correct deformed auricular cartilage applied the same method to correct unilateral cleft lip nasal structures.[3]

Presurgical infant orthopaedics is an umbrella term that covers any treatment of an infant's cleft deformity before the definitive primary lip surgery.[4] Presurgical infant orthopaedics (PSIO) emerged, with techniques such as maxillary plates, lip taping, and the introduction of nasoalveolar moulding (NAM) by Grayson for patients with unilateral and bilateral clefts. Nasoalveolar Moulding (NAM) is a technique to pre-surgically mould the alveolus, lip and nose in infants born with cleft lip and palate.[5]

Objectives of Nasoalveolar Moulding for bilateral cleft lip and palate are retraction of the premaxilla with extraoral traction by lip taping, Maintenance of the arch form using passive appliance, create a clinically appreciable columellar tissue and harmonize the nasal tip projection.[6]

NAM is widely practiced in various regions, including the U.S. and parts of Europe, its use remains controversial. Surveys indicate that around 30-50% of cleft teams adopt NAM, yet the evidence supporting this technique is mixed. American Cleft Palate–Craniofacial Association

and Canadian Society of plastic surgeons revealed nasoalveolar moulding is used at least occasionally by 38 percent and greater than half the time by 24 percent of surgeons.[7]

Proponents claim it improves nasal symmetry, reduces the severity of clefts, and minimizes the need for additional surgeries, while opponents argue that its long-term benefits are inconsistent, and the burden it places on families can outweigh its advantages[8].

Thus, while NAM remains one of the most practiced infant orthopaedic techniques, the medical community has yet to reach a consensus on its effectiveness, leaving the scientific debate unresolved. This ongoing discourse underscores the need for standardized treatment protocols and more robust long-term studies to determine NAM's true impact on patients with cleft lip and palate

AIMS AND OBJECTIVES

To access effectiveness of Naso-alveolar moulding on alveolus and nose in infants with bilateral cleft lip and palate.

MATERIAL AND METHOD

This study was designed as a prospective cohort study and received approval from the Institutional Ethics Committee of IGIMS, Patna. This prospective study comprised 10 infants with bilateral cleft lip and palate (BCLP), undergoing nasoalveolar moulding (NAM). The mean age of the infants at the start of the study was <6 weeks days, with the treatment duration extending to 25 to 29 weeks. Inclusion Criteria was infants diagnosed with non-syndromic bilateral cleft lip and palate reported within five weeks of birth. Infants whose families provided informed consent for treatment were included in the study.

Initial Patient Evaluation and Impression Procedure

Each participant underwent a comprehensive initial evaluation by the multidisciplinary cleft craniofacial team. Upon receiving clearance, impressions of both the intraoral and extraoral structures were obtained. This procedure was performed under the supervision of an anaesthetist and a paediatric surgeon to ensure the safety and comfort of the infant. The impressions were taken using a custom-made tray with putty impression material. After impression, the materials were meticulously disinfected and poured using Orthocal, a Class III dental stone, to ensure the precision of the model. Pre- NAM cast is shown in figure 1.

Fig 1. Pre Nasoalveolar-Moulding Maxillary and Nasal cast

Fabrication and Adjustment of the NAM Appliance

The NAM appliance fabricated in this study followed the protocol established by Grayson et al. (1999).[10] The appliance consisted of an acrylic plate, with two retention buttons (figure 2). The buttons were placed at a **30- to 40-degree** angle to the occlusal surface of the alveolar ridges to achieve proper retention and avoid unseating of the appliance from the palate.

Fig 2 . Nasoalveolar Moulding plate with two retention button

The two nasal stents incorporated once the cleft width had been reduced to 6mm .The stents were made up of 0.36 inch, round stainless-steel wire and takes the shape of a 'Swan Neck'.[11] (figure 3)

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Fig 3 . Stent added in Nasoalveolar Moulding plate

The appliance was subjected to weekly adjustments based on the infant's progress, as assessed by the clinical team. The premaxilla was repositioned by modifying the PNAM plate, in conjunction with external taping and elastic forces. The alar cartilage was gradually advanced towards the nasal tip through the incremental addition of acrylic material to the nasal stent. When 2 to 3 mm of columella have been produced, the two nasal stents are connected by a band of soft acrylic resin. Total timing for Naso-alveolar moulding was 4-5 month. Post NAM plaster model is shown in figure 4.

Fig 4. Post Nasoalveolar Moulding Maxillary and Nasal cast measurement

Description of parameters measured on maxillary cast (Fig-5)

1) Alveolar cleft width in right side in BCLP -RCW
2) Alveolar cleft width in left side in BCLP - LCW
3) Mid-palatal arch width - PP'

Fig.5- Parameter for Maxillary cast measurement

Description of parameters measured on nasal cast (Fig-6)

1. Columellar length - CL
2. Nasal width (right) - RNW
3. Nasal width (left) - LNW
4. Nasal height (right) -RNH
5. Nasal height (left) - LNH
6. Bialar width -BAW

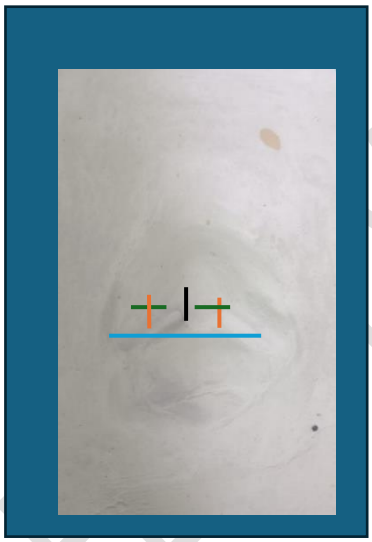


Fig.6 - Parameter for Nasal measurement

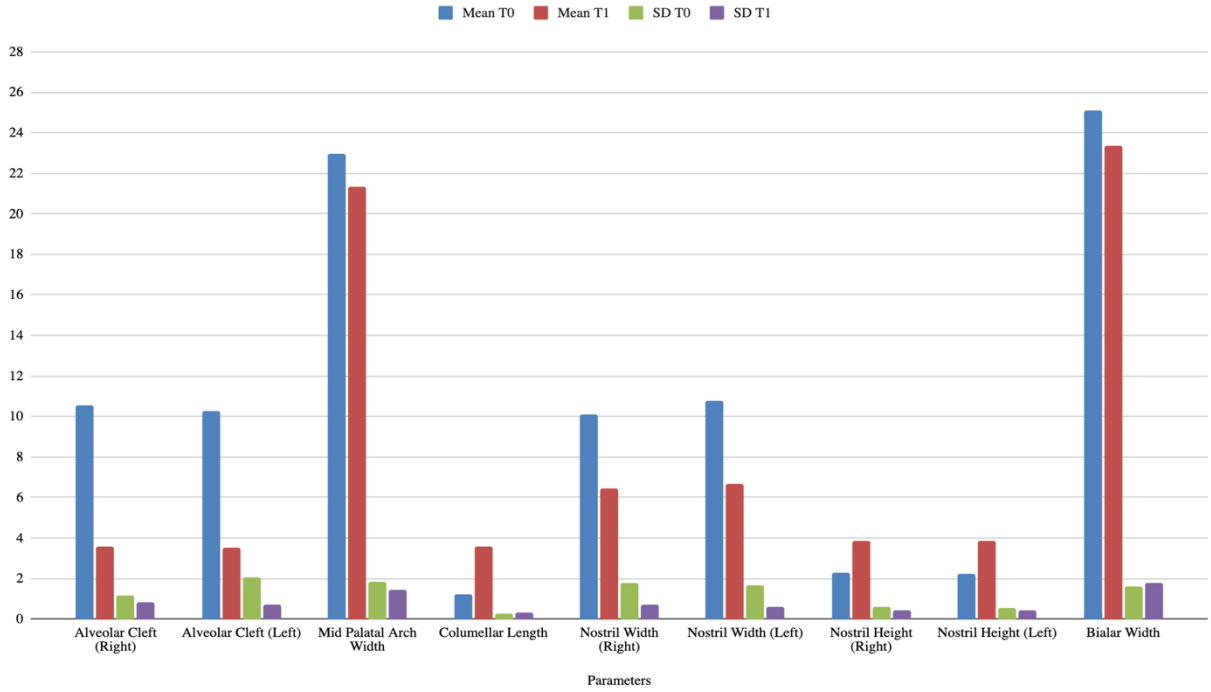
RESULT

Table 1 and graph 1 show the mean values for parameters in the study at two time points, T0 and T1. **Alveolar Cleft (Right and Left)** shows a decrease from T0 to T1. The right side shows a more significant reduction (from 10.56mm to 3.60mm) compared to the left side (from 10.27mm to 3.50mm). This suggests that there was a substantial change in these parameters over time. **Mid Palatal Arch Width** shows a slight reduction from T0 (22.95) to T1 (21.34), indicating a minor decrease over time. **Columellar Length** demonstrates a noticeable increase from T0 1.23mm to T1 3.59mm, suggesting growth or elongation of the columella. **Nostril Width (Right and Left)** both sides show a decrease over time. The right nostril width decreases from 10.12mm to 6.46mm, while the left decreases from 10.79mm to 6.67mm, indicating a significant reduction in width. **Nostril Height (Right and Left) b**oth sides show an increase in height. The right nostril height increases from 2.29mm to 3.85mm, and the

left from 2.21mm to 3.86mm, suggesting a rise in nostril height over time. **Bialar Width** shows a slight decrease from T0 25.10mm to T1 23.36mm, indicating a marginal narrowing over time.

Parameters	Mean T0	Mean T1	SD T0	SD T1
Alveolar Cleft (Right)	10.56	3.60	1.17	0.85
Alveolar Cleft (Left)	10.27	3.50	2.06	0.74
Mid Palatal Arch Width	22.95	21.34	1.83	1.46
Columellar Length	1.23	3.59	0.29	0.34
Nostril Width (Right)	10.12	6.46	1.79	0.74
Nostril Width (Left)	10.79	6.67	1.66	0.59
Nostril Height (Right)	2.29	3.85	0.62	0.42
Nostril Height (Left)	2.21	3.86	0.52	0.41
Bialar Width	25.10	23.36	1.63	1.76

Table 1: Illustrates the mean (T0 and T1) and standard deviations (SD T0 and SD T1)



Graph 1 : Depicts the mean and standard deviation values for the given parameters before (T0) and after Nasoalveolar Moulding (T1).

DISCUSSION

The main purpose of our moulding technique was to mould the nasal cartilage and narrow down the alveolar cleft so that primary cheiloplasty would be easier. Evaluation of the intraoral casts revealed that PNAM therapy significantly reduced the protrusion and, if present, the deviation of the premaxilla. Simultaneously, PNAM significantly reduced the width of the cleft.

This realignment helped reposition the premaxilla and align it with the dental alveolar segments. **Spengler et al** also found similar result in his study. In this study significant reduction in right and left alveolar cleft width was observed after the intervention, with a mean decrease of 6.96 mm and 6.77 mm respectively**.** [12]

Evaluation of the extraoral casts revealed that the PNAM therapy significantly improved nasal symmetry. Columellar length were also significantly improved to 2.36 mm and standard deviation 0.39 mm ($P = 0.001$). This indicates that NAM therapy significantly lengthens the columella. **Mobin et al** also found in his study that nasoalveolar moulding more effectively increases columellar height.[13]

Right and left nostril height was significantly increased. Mean increase by 1.57mm with standard deviation 0.51mm and increase of 1.65 mm and standard deviation 0.48 mm respectively found. Right and Left Nostril width significantly reduces to mean decrease of 3.90 mm and standard deviation 1.83 and 4.27 mm and standard deviation of 1.50 mm respectively. **Grill et al** also found similar result in hid study**.**[14]

A significant reduction in bialar width was observed after NAM therapy, with a mean decrease of 1.93 mm and standard deviation 1.61mm (P = 0.001). NAM therapy indicates that the change in the nasal shape is stable with less scar tissue and better lip and nasal form.[15] This improvement reduces the number of surgical revisions for excessive scar tissue, oronasal fistulas, and nasal and labial deformities.[16]

CONCLUSION

In conclusion, NAM therapy serves as a critical adjunct to cleft lip and palate surgery, offering substantial preoperative benefits by modifying soft and hard tissues to create a more favourable environment for surgical repair. The therapy's ability to reduce the cleft width, optimize arch shapes, and improve nasal and columellar dimensions enhances the effectiveness of subsequent surgical interventions, leading to superior outcomes. Thus, NAM therapy should be considered an integral part of the multidisciplinary approach to managing cleft lip and palate, improving not only the surgical outcomes but also the overall quality of life for affected infants.

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