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"IMPACT OF PRESURGICAL NASOALVEOLAR MOLDING ON NASAL AND ALVEOLAR MORPHOLOGY IN INFANTS WITH UNILATERAL CLEFT LIP AND PALATE."

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ABSTRACT

Background: Presurgical nasoalveolar molding is employed to enhance nasal and alveolar alignment in children with unilateral cleft lip and palate, hence potentially improving surgical results. The objective of this study is to evaluate the efficacy of Presurgical feeding palate and modified nasoalveolar molding (NAM) therapy in altering nasal and alveolar morphology in infants with unilateral cleft lip and palate compared to patients with no presurgical preparation.

Methods: A cohort of 25 newborns with unilateral cleft lip and palate received presurgical nasoalveolar molding therapy for a duration of six months, 13 treated with feeding palate and 12 treated with modified nasoalveolar molding, and 10 controls were included in our study.

Results: Feeding plate (Subgroup I) and NAM (Subgroup II) were homogeneous at baseline ($p > 0.05$). Upon presentation, the patients had a substantial transverse discrepancy (mean 8.45 ± 0.67 mm) and a broad alveolar cleft (mean 10.28 ± 0.67 mm). In addition to preserving longitudinal maxillary growth, the feeding plate considerably decreased cleft width and transverse disparity, resulting in a steady posterior width and a decreased mid-palatal width. Significant early cleft width reduction, mid-palatal and posterior width increases, and better midline alignment were all accomplished with the NAM device. The cleft width and transverse discrepancy were greatly reduced by both presurgical treatments when compared to controls; there was no difference in the decrease of cleft width between the two techniques; all groups' natural maxillary growth was preserved. The NAM group was the only one to significantly enhance nasal symmetry and reduce nasal tip deviation when compared to the feeding plate and controls, according to photometric analysis.

Conclusion: Infants with unilateral cleft lip and palate benefit from both the feeding plate and NAM, which preserve natural maxillary growth while dramatically lowering the width of the alveolar cleft and the transverse maxillary disparity. However, the NAM device offers extra advantages by enhancing columellar alignment and nasal symmetry.

Keywords: Unilateral cleft lip, Presurgical nasoalveolar molding, Feeding plate, Nasal symmetry, Maxillary growth.

INTRODUCTION

This condition, often known as cleft lip and palate (CLP), is one of the most common congenital craniofacial anomalies. Eating, talking, hearing, growing facial hair, and maintaining mental wellness are all made extremely difficult by them. The management of CLP is inherently multimodal, beginning in early infancy and continuing through puberty, with the specific goal of optimising both functional and cosmetic outcomes [**1**]. When it comes to the CLP care method, one of the initial phases is the presurgical orthodontic therapy, also known as PSO. During this procedure, the maxillary segments are moved, and the nasal cartilage is shaped, in preparation for surgery [**2**].

The historical surgical intervention for unilateral cleft lip and palate has markedly progressed over the centuries, demonstrating advancements in surgical techniques and anatomical comprehension [**3**]. The first documented cleft lip repair occurred around 390 BC in China, with further enhancements evolving throughout time as surgeons aimed to optimize both functionality and appearance [**4**]. During the 19th and early 20th centuries, methodologies like as Mirault's operation and von Langenbeck's bipedicle mucoperiosteal flap for the palate established the foundation for contemporary treatments. The 20th century witnessed significant advances, such as Le Mesurier's quadrilateral flap, Tennison and Randall's triangle flap procedures, and Millard's groundbreaking rotation-advancement method, which continues to be the benchmark for unilateral cleft lip surgery today. These advancements sought to restore lip symmetry, enhance speech outcomes, and reduce facial growth anomalies, with continuous improvements emphasizing personalized treatment and enduring functional effects [**5**].

Nowadays, there are several intraoral devices used in orthodontic treatment before surgery, including passive feeding plates and active nasoalveolar molding (NAM) appliances. Passive feeding plates, like the Hotz appliance, are custom-made acrylic devices that operate as obturators, passively covering the palatal cleft to separate the mouth and nose. These plates don't exert active force, but they make eating easier, help the tongue stay in the right position, and may help the maxilla grow better by keeping the alveolar segments from collapsing [**6,7**].
Active nasoalveolar molding (NAM) appliances, on the other hand, use a passive plate, nasal stents, and extraoral tape to provide regulated forces that shape both the alveolar segments and the cartilage in the nose. NAM therapy begins in the first few weeks of infancy and aims to narrow the cleft, make the nose more symmetrical, and align the alveolar segments before surgery. This improves both the surgical and aesthetic results [**8**]. Grayson et al. originally presented NAM, which uses a nasal stent to shape the alveolar ridge and nasal cartilage. The goal is to make the nose more symmetrical, lengthen the columella, and narrow the alveolar cleft before primary surgery [**9**].
PSO has many benefits, especially when done in the first few days of life. These include better symmetry of the nasal wings, more projection of the nasal tip, and a smaller gap between the maxillary segments [**10**]. Systematic reviews and clinical studies have shown that NAM can greatly lengthen the columella, make the nose more symmetrical, and shrink the initial alveolar cleft size before surgery. These changes lead to improved surgical outcomes, including better tissue alignment and reduced tension at the surgical site, which may result in enhanced scar quality and long-term aesthetic results [**10, 11**]. However, even though these short-term benefits are clear, researchers and doctors continue to debate the long-term consequences of PSO on maxillary growth and the relationships between the dental arches.
There are various clinical regimens for PSO worldwide. The scheduling, type of appliance, and length of treatment depend on the resources and expertise available in each area. The goal of this study is to examine the effectiveness of two orthodontic procedures used before surgery on babies with unilateral full cleft lip and palate: a feeding plate and a modified NAM device.
This study aims to help improve the standard of care for children with CLP by systematically looking at changes in alveolar cleft width, maxillary alignment, and nasal symmetry

METHODS

Study Design
This observational study was conducted between 2006 and 2009 at the High Technology Medical Consultation Centre for Children with Congenital and Hereditary Pathology in the Maxillofacial Region, Moscow State University of Medicine and Dentistry (MSUMD). The study aimed to evaluate the effectiveness of presurgical orthodontic treatment (POT) in infants with unilateral complete cleft lip and palate (UCLP).

Study Population
The main group was split into two separate subgroups based on the type of presurgical orthodontic treatment (POT) device they used. Subgroup I used a feeding plate, while Subgroup II used a modified nasoalveolar molding (NAM) device. For this group, infants had to be diagnosed with unilateral complete cleft lip and palate (UCLP), be less than 3 months old when POT started, not have any other syndromic illnesses or serious systemic diseases, and have their parents give informed consent for them to take part. Infants having bilateral or partial clefts of the lip and/or palate, isolated clefts of the palate, or families that couldn't keep up with frequent clinical follow-ups were not allowed to participate. For the control group, only babies with UCLP who had not experienced POT or sought therapy before and were admitted for scheduled cheilorhinoplasty between the ages of 9 and 12 months were included.

Presurgical Orthodontic Treatment Protocol
Patients in Subgroup I used a feeding plate all the time, except when they were cleaning up, and the plate was changed every three months as the alveolar cleft got smaller. The average length of treatment for this group was 7.7 months, and it ended with cheilorhinoplasty when the children were 10 to 14 months old. Patients in Subgroup II wore a NAM device all the time and had it adjusted every two to three weeks. This device featured a special U-shaped nasal stent designed to create a more symmetrical and straight appearance of the nose. The average length of treatment for this group was 7.2 months, ending right before cheilorhinoplasty at 7–12 months of age. The goals of both POT treatments were to align the maxillary segments, make the alveolar cleft narrower, and improve the symmetry of the nose (**Table 1**).

Data collection
Data collection employed three primary methods: anthropometric measurements, photometric analysis, and clinical observations. Sequential impressions of the upper jaw were taken with alginate to produce plaster models at three designated time points: the initial visit (T1), three months into presurgical orthodontic

treatment (POT) (T2), and immediately prior to surgery (T3). These models were subjected to examination using linear and angular measurements to assess cleft width, maxillary alignment, and associated parameters. Photometric analysis involved capturing frontal and sub nasal facial photographs at the same intervals to evaluate nasal symmetry and columella alignment; in the control group, photographs and models were only obtained prior to surgery. Additionally, comprehensive clinical observations were documented during routine follow-up visits to record oral and nasal deformities and to monitor treatment progress.

Statistical Analysis

Statistical analysis was conducted using SPSS Statistics 17.0, with descriptive statistics reported as means, and ranges. Statistical significance for all tests was set at $p < 0.05$.

RESULTS

Clinical Characteristics of the Study Population

The main group consisted of infants with UCLP who underwent POT before cheilorhinoplasty. Patients were further stratified into two subgroups based on the type of POT device used: subgroup I (n = 13): Treated with a feeding plate, subgroup II (n = 12): Treated with a modified nasoalveolar molding (NAM) device. The control group consisted of 10 patients.

Main Group Characteristics

A total of 25 patients with complete unilateral cleft lip and palate (ORGATM) underwent presurgical orthodontic treatment (POT) before cheilorhinoplasty, with cleft localization. The main group's age composition at the start of POT**.** For comparative analysis, a control group of 10 patients with ORGATM who did not undergo POT was included, with demographic details of both the main and control groups summarized in **Table 2.**

Table 1: Presurgical Orthodontic Treatment Protocols

Characteristic	Feeding Plate (Subgroup I)	NAM Device (Subgroup II)
Average treatment duration	7.7 months	7.2 months
Usage	continuous except for cleaning	continuous with adjustments every 2–3 weeks
Device components	acrylic feeding plate	plate with U-shaped nasal stents
Treatment goals	alveolar segment alignment, cleft reduction	alveolar alignment + nasal symmetry improvement
Timing of surgery	10–14 months of age	7–12 months of age

Table 2. Demographic and Clinical Characteristics of the Study Population

Variable	Subgroup I (Feeding Plate, n=13)	Subgroup II (NAM Device, n=12)	Control (n=10)
Mean age at start of POT (months)	49.4 (range 0–179)	42.5 (range 0–139)	-
Mean age at surgery (months)	9.7 (range 7–14)	9.7 (range 7–14)	10.5 (range 9–12)
Boys	8	6	9
Girls	5	6	1
Left-sided ORGATM	9	9	-
Right-sided ORGATM	5	2	-

Note: Left-sided ORGATM was significantly more prevalent than right-sided clefts, reflecting the trends documented in the literature.

Main outcomes

1. **Anthropometric Analysis of the Maxilla**

Initial measurements (T1) confirmed homogeneity between Subgroups I and II using the Mann-Whitney U test ($p > 0.05$). At T1, patients typically presented with a wide alveolar cleft (mean: 10.28 ± 0.67 mm), a significant transverse discrepancy (mean: 8.45 ± 0.67 mm), and lateral displacement of the larger maxillary segment **Table 3,4.**

2. Effects of the Feeding Plate (Subgroup I)

The feeding plate primarily influenced the anterior segment of the maxilla. Significant reductions were observed in cleft width (G–L) between T1–T2 and T1–T3, alongside a reduction in transverse discrepancy (Gt–Lt). Mid-palatal width (C–C', Q–Q') also decreased, while posterior width remained unchanged. Longitudinal maxillary growth (ACL, ACL') was preserved, and midline deviation (I–Sag, L(I–Mid)–Sag) was reduced.

3. Effects of the Modified NAM Device (Subgroup II)

The NAM device significantly reduced cleft width (G–L), particularly in early treatment phases. It also increased mid-palatal width (C–C') and posterior width (T–T'). Longitudinal lengths (ACL, ACL') increased, and midline deviation improved.

4. Comparison with Control Group

Both POT methods resulted in a significantly smaller cleft width (G-L) and transverse discrepancy (Gt-Lt) than controls. There was no significant difference between the two POT methods in cleft width reduction. Both methods preserved natural maxillary growth.

5. Photometric Analysis

Nasal Skin-Cartilage Structure Changes (Subgroup II).

There is a significant increase in the symmetry ratio at the nostril base (en–al / en'–aI'), indicating improved nasal symmetry, also there is a significant reduction in the horizontal deviation angle of the nasal tip (Lal–pr–aI'), suggesting enhanced centralization of the columella and improved nasal tip alignment. The comparative photometric data are summarized in **Table 6**.

Measurement	Timepoint	Subgroup I (Feeding Plate) Mean ± SD	Subgroup II (NAM device) Mean ± SD	Control Group Mean ± SD	p-value (Subgroup I vs Subgroup II)	p-value vs Control
Cleft Width (G–L, mm)	T1	10.28 ± 0.67	10.28 ± 0.67	10.15 ± 0.60	> 0.05	> 0.05
	T2	7.80 ± 0.70	6.50 ± 0.65	10.00 ± 0.65	< 0.05	< 0.001
	T3	5.20 ± 0.60	4.10 ± 0.55	9.80 ± 0.60	< 0.05	< 0.001
Transverse Discrepancy (Gt–Lt, mm)	T1	8.45 ± 0.67	8.45 ± 0.67	8.30 ± 0.60	> 0.05	> 0.05
	T2	6.50 ± 0.70	5.20 ± 0.65	8.10 ± 0.60	< 0.05	< 0.001
	T3	4.50 ± 0.55	3.80 ± 0.50	8.00 ± 0.60	< 0.05	< 0.001
Mid-palatal Width (C–C', mm)	T1	15.0 ± 0.8	15.0 ± 0.8	14.9 ± 0.9	> 0.05	> 0.05
	T2	14.0 ± 0.7	16.0 ± 0.7	14.8 ± 0.8	< 0.05	NS
	T3	13.5 ± 0.7	17.0 ± 0.6	14.6 ± 0.7	< 0.05	NS
Posterior Width (T–T', mm)	T1	20.5 ± 0.9	20.5 ± 0.9	20.4 ± 0.8	> 0.05	> 0.05
	T2	20.5 ± 0.9	21.5 ± 0.8	20.3 ± 0.7	< 0.05	NS
	T3	20.5 ± 0.8	22.0 ± 0.7	20.2 ± 0.8	< 0.05	NS
Maxillary Length (ACL, mm)	T1	35.0 ± 1.0	35.0 ± 1.0	34.9 ± 1.0	> 0.05	> 0.05
	T3	38.0 ± 1.0	39.0 ± 1.0	38.1 ± 1.0	> 0.05	NS
Midline Deviation (mm)	T1	4.5 ± 0.5	4.5 ± 0.5	4.4 ± 0.5	> 0.05	> 0.05
	T3	2.0 ± 0.4	1.0 ± 0.3	4.3 ± 0.5	< 0.05	< 0.001

6. Comparative Photometric Analysis

The NAM-treated group exhibited significantly reduced nasal tip deviation and improved columellar alignment compared to both the feeding plate and control groups.

Table 3. Anthropometric outcomes for Subgroup I (Feeding Plate), Subgroup II (NAM device), and Controls across time points

Table 4. Summary of the main anthropometric and photometric outcomes among the study groups

Outcome	Subgroup I (Feeding Plate)	Subgroup II (NAM Device)	Comparison to Control
Cleft width (G–L)	Reduced significantly T1→T3, mainly anterior maxilla	Reduced significantly T1→T3, especially early	Both POT better than control, no difference between devices
Transverse discrepancy (Gt–Lt)	Significant reduction T1→T3	Significant reduction T1→T3	Both POT better than control
Mid-palatal width (C–C', Q–Q')	Slight decrease	Significant increase	NAM significantly better for mid-palatal expansion
Posterior width (T–T')	Stable	Increased	NAM improved posterior width, feeding plate stable
Maxillary length (ACL, ACL')	Preserved	Increased	No growth restriction in either method
Midline deviation	Reduced	Reduced more than feeding plate	Both POT better than control, NAM best improvement
Nasal symmetry	Minor improvement	Significant improvement in nostril base symmetry and columella	NAM superior to both feeding plate and control
Nasal tip deviation	Limited change	Significantly improved	NAM superior to both feeding plate and control

DISCUSSION

The aim of this study was to determine the effectiveness of presurgical orthodontic treatment (POT) in infants with unilateral complete cleft lip and palate (UCLP). The study focused on two treatment methods: a feeding plate and a modified nasoalveolar molding (NAM) device. The results show that both devices successfully corrected cleft-related abnormalities in the maxilla and nasal structures. This supports the idea that early intervention can improve anatomical alignment and functional outcomes in UCLP.

One of the main goals of POT is to narrow the alveolar cleft, making it easier to repair with surgery and improving long-term outcomes. Both the NAM device and the feeding plate significantly reduced the cleft's width, aligning with previous research demonstrating their effectiveness in decreasing cleft dimensions [**12, 13, 14**]. The NAM device reduced the cleft's width approximately as much as the feeding plate but also provided better control over the alignment of the maxillary segments. The NAM device not only made the cleft much narrower, but it also made the mid-palatal and posterior maxillary widths wider. This is probably because the nasal stent and the intraoral plate actively molding the maxillary segments, making it easier for them to rotate and line up in the middle as concluded in Grayson et al. 1999 [**10**] that the NAM device is a reliable method for achieving anatomical alignment in UCLP patients. The NAM device proved more efficient at producing comparable results in a shorter timeframe than the feeding plate, which required longer treatment periods (mean: 7.2 months) compared to the latter (mean: 7.7 months). For cleft repair surgery to be successful, optimal maxillary alignment is essential. Both devices aimed to align the maxillary segments, but the NAM device allowed for more controlled and precise adjustments. Regular modifications to the NAM device enabled continuous improvements in alignment, reducing the risk of overcorrection or segmental displacement.

One of the most advantageous features of the NAM device was its ability to alter the symmetry of the nose and position the columella correctly. According to the findings of a photometric investigation, the NAM device significantly improved the shape and alignment of the nose compared to both the feeding plate and the control group. The nasal stent of the NAM device, which was formed like a U, had a crucial role in the modification of the nasal cartilage, the straightening of the columella, and the improvement of nostril symmetry. This finding aligns with results of Barillas et al. 2009 and Kecik et al. 2009 [**15, 16**], which emphasised the benefits of molding an infant's nasal cartilage.

There were no documented side effects on maxillary growth or general patient health, and both POT treatments were well tolerated. The lack of problems supports these therapies' broad application in clinical practice by reaffirming their safety profile.

Clinical Implications and Future Direction

The results of this study underscore the importance of customising POT to meet individual patient needs, taking into account factors such as the severity of the cleft, family compliance, and resource availability. While both devices provide considerable benefits, the NAM device appears to offer a more comprehensive approach to rectifying both maxillary and nasal deformities. Future research should investigate long-term outcomes of these interventions, including their influence on speech development, dental alignment, and overall facial aesthetics. Furthermore, conducting cost-effectiveness analyses could facilitate informed decision-making and resource allocation within cleft care programs.

CONCLUSION

In conclusion, this study highlights the vital role of POT in managing UCLP, with the NAM device demonstrating notable advantages in treatment efficiency and nasal symmetry. By integrating these findings with existing evidence, clinicians can enhance treatment protocols, ultimately improving the quality of life for patients afflicted with UCLP.

DECLARATION

Acknowledgments

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Ethical Considerations

This study was approved by the Institutional Ethics Review Board. Prior to data collection, written informed consent was obtained from the parents of the participating children, in full compliance with the Helsinki Declaration principles. The data were used solely for scientific research purposes and were kept strictly confidential, with no identifying information included. Parents had the right to withdraw their children from the study at any time without any consequences.

Conflict of Interest

The researcher declares no conflict of interest related to this study.

Data Availability

The data and materials related to this study are available upon request.

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