BULLETIN OF STOMATOLOGY AND MAXILLOFACIAL SURGERY
Volume 22, Issue 1

DOI: 10.58240/1829006X-2026.22.1-3

ORIGINAL RESEARCH

PRESURGICAL NASOALVEOLAR MOLDING IN UNILATERAL CLEFT LIP AND PALATE: EVALUATING ALVEOLAR APPROXIMATION AND MAXILLARY ARCH CHANGES WITH GS-NAM VERSUS CONVENTIONAL NAM TECHNIQUE

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Received: Nov 23. 2025; **Accepted:** Dec 24, 2025; **Published:**Jan13, 2026

Abstract

Background: Presurgical nasoalveolar molding (NAM) is widely used to improve nasal and alveolar morphology in infants with unilateral cleft lip and palate (UCLP) prior to surgical repair. While conventional NAM has established efficacy, the Grayson–Santiago NAM (GS-NAM) technique proposes enhanced practicality and simplified activation. Comparative evidence of its intraoral effectiveness remains limited.

Objective: To compare the effects of GS-NAM and conventional NAM on alveolar alignment and early maxillary growth in infants with complete UCLP over a 3-month presurgical period.

Study Design: A prospective, assessor-blinded, randomized controlled trial with 1:1 allocation.

Setting: Faculty of Dental Medicine, Al-Azhar University, Cairo, Egypt, and Operation Smile Egypt comprehensive cleft care centers. **Participants:** Thirty infants with non-syndromic complete UCLP (aged 1–8 weeks) were randomized into two groups: GS-NAM (n=15) and conventional NAM (n=15). An additional 15 healthy non-cleft infants served as a normative control group. **Interventions:** Both groups received NAM appliances fabricated using digital workflow and 3D printing. The conventional NAM group underwent weekly adjustments with selective grinding and soft-liner addition. The GS-NAM group received adhesive-based stabilization and asymmetric extraoral elastic traction with weekly hard acrylic reduction.

Main Outcome Measures: Intraoral parameters were assessed via 3D digital models at baseline (T0) and 3 months (T3), including: posterior alveolar width (PG-PL), middle alveolar width (BG-BL), cleft gap width (ACG-ACL), midline deviation length (Inc-Sagittal), and midline deviation angle ((Mid-Inc)-Sagittal).

Results: Both NAM techniques produced significant and comparable reductions in cleft gap width (GS-NAM: 13.34±1.26 mm to 6.28±1.33 mm; conventional NAM: 12.16±1.94 mm to 7.17±2.45 mm; $p<0.001$) and midline deviation. No significant differences were found between GS-NAM and conventional NAM groups for any intraoral parameter at T3 ($p>0.05$). Both treatment groups showed growth patterns distinct from healthy controls, with reduced transverse expansion in the canine region.

Conclusions: GS-NAM and conventional NAM demonstrate equivalent efficacy in improving alveolar alignment and reducing cleft gap width over a 3-month presurgical period. While both techniques effectively reshape the alveolar arch, they do not replicate the physiological transverse growth observed in non-cleft infants. Clinical selection may therefore prioritize practicality, comfort, and caregiver adherence, as both methods yield comparable orthopedic outcomes.

Keywords: Nasoalveolar molding, Grayson–Santiago NAM, unilateral cleft lip and palate, presurgical orthopedics, alveolar alignment, randomized controlled trial.

Ahmed Farghaly Abdelnaeem Ahmed , Adel Fathy , Pedro Edgardo Santiago Alicea, Ahmed Taha, Ahmed Bestway. Presurgical Nasoalveolar Molding in Unilateral Cleft Lip and Palate: Evaluating Alveolar Approximation and Maxillary Arch Changes with GS-NAM Versus Conventional NAM Technique Bulletin of Stomatology and Maxillofacial Surgery. 2026;22(1)3-11 doi:10.58240/1829006X-2026.22.1-3

INTRODUCTION

Cleft lip and palate arise from incomplete fusion of the embryonic facial processes during intrauterine development, resulting in discontinuities involving the lip, alveolar ridge, and/or palate. The etiology of CLP is multifactorial, encompassing both genetic susceptibility and environmental factors such as maternal smoking, alcohol intake, folic acid deficiency, and exposure to teratogenic medications. Beyond its impact on the craniofacial structures, this congenital condition compromises vital functions, including feeding, respiration, speech, and psychosocial development, thereby requiring a coordinated multidisciplinary approach to achieve comprehensive rehabilitation.(1)

Early dental involvement is recommended when the cleft affects the alveolar region or primary dentition. Specialist consultation helps determine the need for interim oral prostheses to support feeding or to assist in guiding maxillary arch form before surgical intervention. Presurgical orthopaedic approaches, including Nasoalveolar molding, can favorably alter nasal and alveolar morphology, thereby optimize surgical conditions and potentially minimizing the number or complexity of subsequent procedures. Decisions related to prosthetic use and molding strategies should be individualized, taking into account surgical scheduling, nutritional requirements, and parental preferences. (2)

During the 1990s, Grayson and Cutting highlighted the clinical value of presurgical correction of nasal cartilage and soft-tissue deformities in patients with cleft lip and palate, achieved through a combination of nasal and alveolar orthopedic molding.(3) Drawing on earlier findings regarding the plasticity of neonatal auricular cartilage, they suggested that active molding and repositioning of the nasal cartilages in newborns with CLP could exploit a transient period of increased cartilage malleability. This temporary plasticity is believed to be related to elevated circulating estrogen levels in the early postnatal period. (4)

Both the nasal stent and intraoral components are progressively adjusted, typically on a weekly basis over a three- to four-month period, with the aim of achieving nasal and alveolar symmetry, improved nasal tip projection, and approximation of the cleft alveolar segments prior to primary surgical repair. Grayson further proposed that presurgical reduction of soft-tissue and cartilaginous deformities permits surgical repair under minimal tension, thereby enhancing scar quality and contributing to improved long-term nasal symmetry.(3, 5-7)

Conventional NAM typically continues for 3–5 months until primary lip repair and requires weekly adjustments. Each adjustment is performed manually, so the rate of progress is constrained by both biological adaptation and clinical logistics, including appointment availability. Delays or missed visits may reduce treatment efficiency and prolong the overall treatment duration. (8)

Nasoalveolar molding therapy requires close clinical supervision to allow early identification and management of potential complications. One reported complication is the development of “locked” alveolar segments, which occurs when the greater alveolar segment responds more rapidly to the molding forces than the lesser segment, leading to entrapment of the latter beneath the former. A more frequently encountered adverse effect is soft-tissue and mucosal ulceration. Intraorally, inadequate relief of areas subjected to excessive pressure during adjustment visits may cause the acrylic molding plate to exert friction on the palatal mucosa, resulting in discomfort and the formation of mucosal ulcerations.(9, 10)

In 1996, Dr. Pedro E. Santiago, one of the pioneers behind the NAM technique, pioneered the incorporation of wire-and-acrylic nasal stents, retention buttons, denture adhesive, and limited acrylic trimming. These innovations enhanced clinical efficiency, decreased the need for frequent adjustments, and reduced total treatment duration. This refined method, called the Grayson–Santiago NAM technique (GS-NAM), is considered an advantageous advancement over the original design and protocol, and it remains the version that Santiago and Grayson now teach globally.(11)

For instance, NAM involves custom appliances to mold the alveolus and nasal structures, while lip taping offers a less invasive alternative for segment approximation. However, evidence on their comparative efficacy remains mixed, with some studies indicating no long-term benefits on maxillary arch dimensions, while others report short-term improvements in cleft gap reduction.(12) This study aimed to evaluate and compare the intraoral effects of GS-NAM (Group I) versus conventional NAM (Group II) in UCLP infants over 3 months, using healthy controls (Group III) for reference, to contribute to the ongoing discourse on optimal presurgical strategies.

This approach hypothesizes a simpler application process and potentially greater patient comfort. However, comparative evidence of its clinical effectiveness versus the well-established conventional NAM remains limited.

Therefore, this randomized clinical trial aims to directly compare the effectiveness of the adhesive-based GS-NAM technique with conventional NAM in infants with complete UCLP, specifically evaluating outcomes in alveolar ridge approximation, nasal symmetry, and labial alignment prior to primary surgical repair.

Subjects and Methods

Study design and setting

This was a prospective, assessor-blinded, two-arm, parallel-group randomized controlled trial with 1:1

allocation that was conducted from March 2023 to August 2025. The study was conducted at the Faculty of Dental Medicine (Boys), Al-Azhar University, Cairo, Egypt, and Operation Smile Egypt comprehensive cleft care centers. A non-randomized normative cohort of healthy infants was included for comparison. The trial was prospectively registered at ClinicalTrials.gov (Identifier: NCT06451276) and approved by the Research Ethics Committee of the Faculty of Dental Medicine, Al-Azhar University (approval code 953/5385). The study adhered to the principles of the Declaration of Helsinki, and its reporting follows the Consolidated Standards of Reporting Trials (CONSORT) guidelines.

Participants

This study recruited infants aged 1–8 weeks with non-syndromic, complete unilateral cleft lip and palate (UCLP). Exclusion criteria comprised syndromic clefts, incomplete or bilateral clefts, previous presurgical intervention, and the inability of guardians to comply with the follow-up schedule. Fifteen age-matched healthy non-cleft infants served as normative controls. Before enrollment, written informed consent was obtained from parents or legal guardians of all participants.[13] a clinically relevant difference of 3.1 mm (standard deviation 2.85 mm) was specified. To detect this difference with a two-tailed alpha (α) of 0.05 and 80% statistical power, a minimum of 13 participants per treatment group was required. Accounting for an anticipated attrition rate of 25%, the sample size was inflated to 15 infants per group. Therefore, a total of 30 infants with non-syndromic UCLP were enrolled and randomized to ensure a final analyzable sample of 15 per intervention group (15 GS-NAM, 15 conventional NAM). An additional 15 healthy, non-cleft infants were enrolled as a separate normative control cohort.

Randomization and blinding

Computer-generated block randomization (block size 4) was performed by an independent statistician. Allocation concealment was ensured using sequentially numbered opaque sealed envelopes. Blinding of clinicians and parents was not feasible due to visibly different appliances; however, outcome assessors and the statistician remained blinded throughout the study. All 3D digital models and standardized photographs were coded to conceal treatment identity.

Interventions

Impressions and digital workflow

Impressions were taken using addition-silicone polyvinyl siloxane (Express™ XT; 3M ESPE) in prefabricated infant trays, poured in Type IV dental stone, digitized with a laboratory scanner (3Shape R700), and processed using 3Shape Dental System®, Meshmixer®, and Exocad®. All appliances were digitally designed and three-dimensionally printed in biocompatible denture resin (Printodent® GR-14.2 denture HI; Pro3dure, Germany), then post-cured (SprintRay ProCure), finished, and polished.[7]

Conventional NAM group

With concept "Passive Nasoalveolar molding using selective pressure and relief" A passive acrylic alveolar molding plate covering the alveolar ridges and palate was fabricated. Weekly chairside adjustments were performed by selective grinding and by adding soft liner (Soft-Liner; GC Corp., Japan) to guide the alveolar segments. Retention was achieved using surgical adhesive tape and orthodontic elastics (3/16-inch, 2 oz) secured to the child's cheeks.[14]

Grayson-Santiago NAM (GS-NAM) group

With concept "Active differential extra-oral traction with selective stabilization" For the GS-NAM group, the acrylic alveolar molding plate was extended into the maxillary vestibular fold, relieving all labial and buccal frenum. The greater (non-cleft side) alveolar segment was stabilized with a small amount of denture adhesive cream (Fixodent®; Procter & Gamble). Asymmetric extraoral elastic traction using orthodontic elastics (3/16-inch, 2 oz) was applied at 30–40° to the occlusal plane, with 20-30% greater activation directed toward the cleft side. Weekly activation consisted solely of selective reduction of the hard acrylic, without addition of soft acrylic. Extraoral retention was reinforced using adhesive tape (Steri-Strips™ or surgical tape; 3M) secured to the child's cheeks, with optional liquid adhesive (Mastisol®; Eloquest Healthcare) and skin barrier (PediDerm®; Coloplast) to minimize skin irritation.[11]

Activation and follow-up:

Following appliance delivery, a one-week adaptation period was observed in both groups to allow infants to acclimate without active molding forces. During this period, parental compliance with full-time wear (22–24 hours/day) was monitored, and any pressure points or areas of mucosal blanching were adjusted chairside to maintain a passive, well-fitting appliance. Weekly follow-up visits were then initiated for appliance activation and assessment of treatment progress.[15]

In the conventional NAM group, activation consisted of selective intra-plate hard acrylic reduction in the region of desired segment movement (primarily the lesser segment), combined with the addition of soft tissue conditioner (Soft-Liner; GC Corp., Japan) to the fitting surface adjacent to the cleft to generate controlled molding pressure. [14]

In the GS-NAM group, activation began with selective intra-plate hard acrylic reduction to direct rotation of the greater alveolar segment while allowing growth of the lesser segment. The greater segment was then stabilized with denture adhesive (Fixodent®; Procter & Gamble), after which asymmetric extraoral elastic traction (3/16-inch, 2-oz elastics; Ormco Corp.) was applied at a 30–40° vector with 20–30% greater activation toward the cleft side to achieve the desired rotational movement. [11]

In both groups, a nasal stent (0.032-inch stainless-steel wire coated with hard and soft acrylic; Orthoplast, Vertex-Dental) was incorporated once the alveolar gap had been reduced to ≤5 mm and was activated weekly to apply gentle forward and downward pressure, reshaping the nasal cartilages and promoting columellar elongation.[16]

Measurement Tools and Timing:

measurements: width between posterior ends (PG-PL), middle parts (BG-BL), cleft gap (ACG-ACL), midline deviation length (Inc-Sagittal), and angle (Mid- Inc)-Sagittal). Measurements were performed blinded by two calibrated examiners (intraclass correlation >0.9).as shown in figure (1).

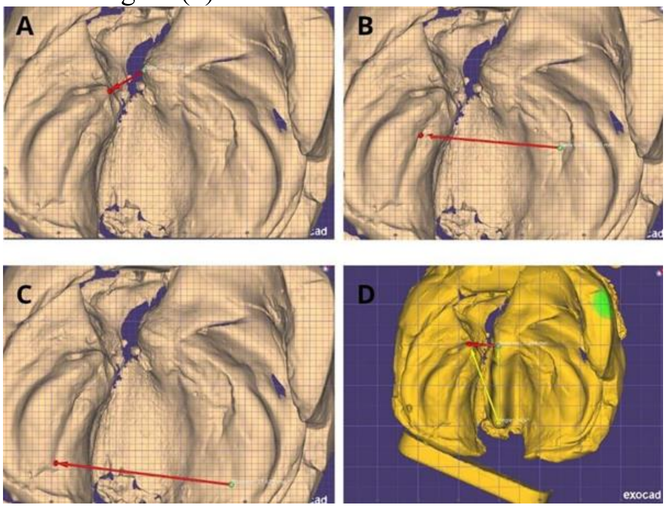

Figure (2): (A) cleft gap (ACG-ACL), (B) middle parts (BG-BL), (C) width between posterior ends (PG-PL), and (D) midline deviation length (Inc-Sagittal), and angle (Mid-Inc-Sagittal).

Statistical Analysis

The variations in intraoral clinical parameters between the three groups at baseline and three months later were evaluated and compared using statistical analysis. The computer program Statistical Package for Social Science SPSS (IBM-SPSS version 29.0) was used to do statistical analysis. Microsoft Excel 2016 was used to gather, verify, and arrange data in tables and figures.

Using the Shapiro-Wilk test at a 0.05 significance level, normality testing was used to determine whether the data were parametric or nonparametric.

Categorical data were conveyed as frequencies and percentages. While numerical data were conveyed as mean ± standard deviation if normally distributed, or median and interquartile range if not.

Intergroup comparisons at each time point were performed using one-way ANOVA followed by Post Hoc Test (adjusted Bonferroni) for pairwise comparisons for normally distributed data and Kruskal–Wallis test for non-normally distributed data. Moreover, intergroup comparisons regarding categorical data were performed using Kruskal–Wallis test followed by Post Hoc Test (adjusted Bonferroni) for pairwise comparisons.

Meanwhile, intragroup comparisons were performed using paired t-tests for normally distributed data and Wilcoxon signed-rank test for non-normally distributed data. Significance of the results obtained was judged at the 0.05 level.

Results

Demographic Data

This study included thirty infants (17 boys and 13 girls) with a diagnosis of unilateral cleft lip and palate. In addition to a different healthy control group of 15 infants without clefts (8 males and 7 females), they were randomly split into two equal groups (Group I: 15 patients, and Group II: 15 patients).

Ten males and five females made up group I, with a mean age of 13.60 ± 6.98 days. The patients' ages ranged from 7 to 35 days. Group II consisted of eight females and seven males, with a mean age of 14.80 ± 7.30 days. Group III consisted of eight males and seven females, with a mean age of 14.53 ± 6.06 days. Age (p=0.880) and gender (p=0.533) did not significantly differ between the groups.

Intraoral Evaluation

1. Width between the Most Posterior Ends (PG-PL)

The mean and standard deviation values of (PG-PL) in group I showed a statistically significant increase from 28.19 ± 2.18 at T0 to 29.40 ± 2.07 at T3 (p<0.001*). For group II, (PG-PL) increased from 27.85 ± 2.90 at T0 to 28.96 ± 2.79 at T3, this change recorded a significant difference (p<0.001*). Also, the recorded mean values of (PG-PL) of group III were 31.90 ± 1.20 and 35.39 ± 2.10 at T0 and T3, respectively. On comparing these values, the difference was highly statistically significant (p<0.001*).

For T0 and T3, there was no significant difference between group I and group II's mean values and standard deviation of (PG-PL) (p=0.304 and p=0.195, respectively). Group III was significantly different from both groups (p=0.003*) and (p=0.001*), respectively.

2. Width between the Middle Parts (BG-BL)

The (BG-BL) group I's mean and standard deviation values changed from 25.34 ± 2.41 at T0 to 23.46 ± 2.31 at T3. These values' intragroup comparison revealed a significant difference (p<0.001*).Similarly, (BG-BL) values of group II decreased significantly from 25.22±3.37 at T0 to 23.61 ± 3.53 at T3 (p<0.001*).In contrast, (BG-BL) values of group III recorded a significant increase from 23.88 ± 1.19 at T0 to 29.22 ± 1.72 at T3 (p<0.001*).

At baseline, there was no discernible change in the mean values and standard deviation of (BG-BL) between the tested groups (p=0.139). Interestingly, at T0 and T3, group III showed a statistically significant difference between group I and group II (p<0.001*). At T3, however, there was no discernible change between groups I and II (p=0.361).

3. Width of the Cleft Gap (ACG-ACL)

Remarkably, from 13.34 ± 1.26 at T0 to 6.28 ± 1.33 at T3 (p<0.001*), the mean and standard deviation values of (ACG-ACL) in group I severely decreased. Similarly, (ACG-ACL) values of group II decreased significantly from 12.16±1.94 at T0 to 7.17 ± 2.45 at T3 (p<0.001*). Intergroup comparison between group I and group II revealed no significant difference either at T0 or T3 (p=0.922), and (p=0.271) respectively.

At groups I and II, an inverse (negative) association between time of observation and (BG-BL) was found. Group I (R^2=0.8756) was the first to decrease from high to low, followed by group II (R^2=0.5807).

4. Midline Deviation Length (Inc-Sagittal)

At baseline (T0) and three months later (T3), group I's midline deviation length averaged 15.03 ± 1.32 and 8.23 ± 0.87, respectively. There was a significant difference (p<0.001*) between T0 and T3. At T0 and T3, group II's mean midline deviation length was 13.95±1.94 and 8.77±0.83, respectively. A statistically significant difference between T0 and T3 was found by analyzing these values (p<0.001*). There was no statistically significant difference between the two cleft groups at baseline, either at T0 (p=0.177) or at T3 (p=0.458), according to an intergroup comparison of midline deviation length values.

5. Midline Deviation Angle (Mid-Inc)-Sagittal)

Group I's midline deviation angle decreased from 33.18 ± 2.40 at T0 to 27.04 ± 0.64 at T3. These values' analysis revealed a statistically significant difference (p<0.001*). Similarly, group II's mean values dropped from 32.88±2.22 at T0 to 26.26±2.77 at T3 (p<0.001*). At T0 (p=0.373) and T3 (p=0.895), there was no discernible difference in the mean midline deviation angle values between groups I and II.

Group I's midline deviation angle decreased from 33.18 ± 2.40 at T0 to 27.04 ± 0.64 at T3. These values' analysis revealed a statistically significant difference (p<0.001*). Similarly, group II's mean values dropped from 32.88±2.22 at T0 to 26.26±2.77 at T3 (p<0.001*). At T0 (p=0.373) and T3 (p=0.895), there was no discernible difference in the mean midline deviation angle values between groups I and II.

There was no statistically significant difference between the two cleft groups at baseline, either at T0 (p=0.177) or at T3 (p=0.458), according to an intergroup comparison of midline deviation length values.

Key findings are summarized below, with complete data presented in Tables 1 and Figures 2-3.

Table 1. Comparison of Key intraoral Parameters Between Study Groups

		Group (I)	Group [17]	Group (III)	P-value
P_G-P_L (mm)	**Baseline**	28.19 ± 2.18	27.85 ± 2.90	31.90 ± 1.20	p<0.001* p_1 =0.304 p_2 =0.003* p_3 =0.001*
	3 Months	29.40 ± 2.07	28.96 ± 2.79	35.39 ± 2.10	p<0.001* p_1 =0.195 p_2 <0.001* p_3 <0.001*
	P-value	<0.001*	<0.001*	<0.001*	
B_G-B_L (mm)	**Baseline**	25.34 ± 2.41	25.22 ± 3.37	23.88 ± 1.19	P=0.139
	3 Months	23.46 ± 2.31	23.61 ± 3.53	29.22 ± 1.72	p<0.001* p_1 =0.361 p_3 <0.001* p_3 <0.001*
	P-value	<0.001*	<0.001*	<0.001*	
AC_G-AC_L (mm)	**Baseline**	13.34 ± 1.26	12.16 ± 1.94	0 ± 0	p<0.001* p_1 =0.922 p_2 <0.001* p_3 <0.001*
	3 Months	6.28 ± 1.33	7.17 ± 2.45	0 ± 0	p<0.001* p_1 = 0.271 p_3 <0.001* p_3 <0.001*
	P-value	<0.001*	<0.001*	1.000	
Inc-Sagittal (mm)	**Baseline**	15.03 ± 1.32	13.95± 1.94	0 ± 0	p<0.001* p_1 =0.177

Wessam M. Abdelrazek, Hanady M. Samih, Waleed R. El Nagar. Cost and Clinical Impact of Digital vs. Conventional Indirect Bonding in Extraction Orthodontic Treatment of Class I Malocclusion. Bulletin of Stomatology and Maxillofacial Surgery. 2026;22(1)3-11 doi:10.58240/1829006X-2026.22.1-3

					p_2 <0.001* p_3 <0.001*
	3 Months	8.23 ± 0.87	8.77 ± 0.83	0 ± 0	p<0.001* p_1 =0.458 p_2 <0.001* p_3 <0.001*
	P-value	<0.001*	<0.001*	1.000	
(Mid-Inc)-Sagittal (°)	**Baseline**	33.18 ± 2.40	32.88± 2.22	0 ± 0	p<0.001* p_1 =0.373 p_2 <0.001* p_3 <0.001*
	3 Months	27.04 ± 0.64	26.26 ± 2.77	0 ± 0	p<0.001* p_1 =0.895 p_2 <0.001* p_3 <0.001*
	P-value	<0.001*	<0.001*	1.000	

*: Statistically significant at $p \leq 0.05$; P_1: p-value for comparing groups I and II ; p_2: p-value for comparing groups I and III; p_3: p-value for comparing groups II and II

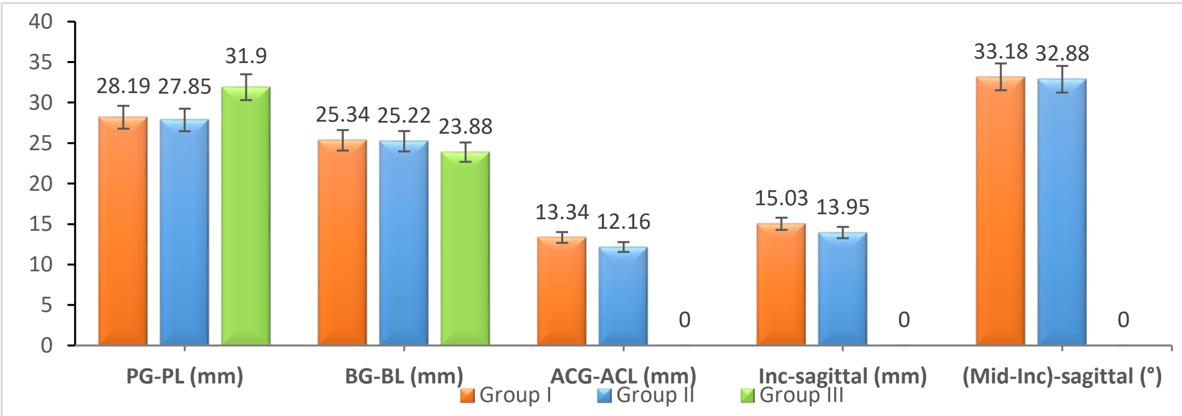

Figure 2. Comparison of intraoral parameters between study groups at baseline

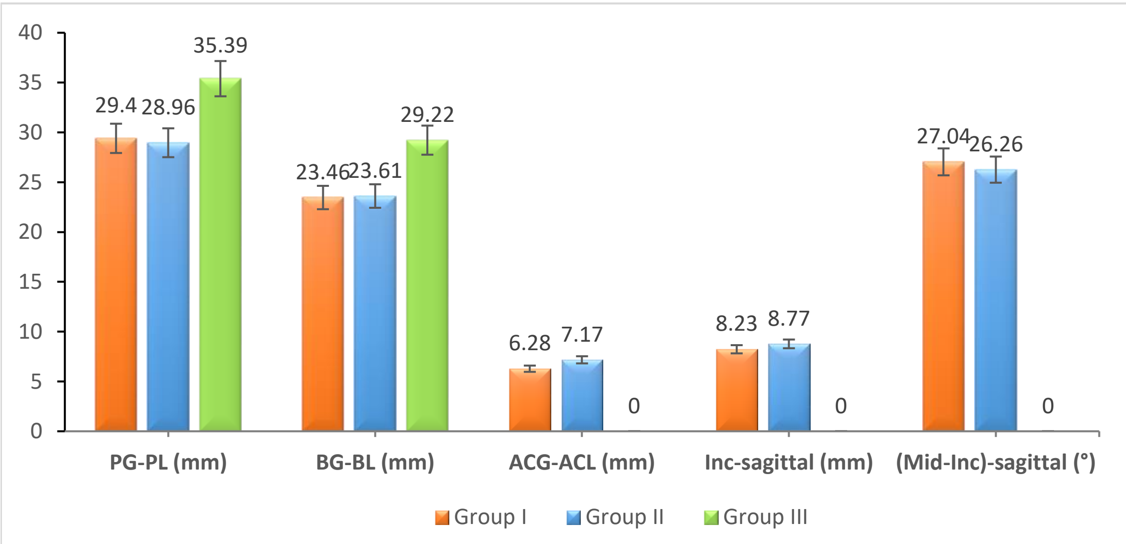

Figure 3. Comparison of intraoral parameters between study groups after 3 months

DISCUSSION

This prospective, assessor-blinded randomized controlled trial provides a three-dimensional comparative analysis of alveolar molding and early maxillary growth in infants with complete unilateral cleft lip and palate (UCLP) treated with two distinct presurgical orthopedic infant (PSIO) protocols. A deliberate methodological choice was the use of a healthy, non-cleft infant cohort as the normative control group, rather than an untreated UCLP group. The rationale for this approach is to establish an objective, physiological growth benchmark. Systematic reviews of PSIO outcomes have emphasized the importance of normative comparisons to accurately assess whether therapeutic interventions achieve development that approximates healthy standards.[12] This approach allows us to evaluate not merely whether PSIO changes arch form, but whether it facilitates growth that parallels the physiological patterns observed in unimpaired development, which is increasingly recognized as a crucial outcome measure in contemporary cleft care research.[15]

However, we acknowledge the rationale against this choice: an untreated UCLP control would more directly isolate the treatment effect of PSIO by controlling for the inherent growth pattern of the cleft condition itself. The absence of such a control group represents a recognized methodological limitation in studies of emerging PSIO techniques, as it prevents definitive attribution of observed morphological changes solely to the intervention rather than to inherent growth variations.[18] Furthermore, without an untreated cleft reference, the study cannot quantify the specific treatment effect size relative to the natural history of UCLP arch development.[9] Nevertheless, the healthy control model provides a clinically meaningful reference point for evaluating whether PSIO-assisted growth trajectories align with physiological norms—a consideration that directly addresses long-term functional and aesthetic outcomes in cleft rehabilitation.

Linear Variables and Alveolar Approximation

The primary finding of this study aligns with the established goal of PSIO. Both the GS-NAM and conventional NAM techniques produced a significant and statistically equivalent reduction in Width between the Most Posterior Ends (PG-PL), achieving approximately 50% closure over three months. This strong, comparable efficacy in segment approximation is consistent with recent comparative trials. For instance, a **recent randomized trial directly comparing PSIO appliances** found that while different mechanisms (e.g., passive vs. active) were employed, their efficacy in reducing intra-alveolar cleft width was comparable within a short pre-surgical period. [13] This suggests that segmental approximation is a common outcome achievable by various contemporary designs.

However, our detailed analysis of arch widths reveals a more nuanced picture. The Width between the Middle Parts (BG-BL) *decreased* significantly in both our treatment groups. This finding **contrasts** with some earlier studies that reported stability or minimal change in this dimension during PSIO. Our results suggest a more active medial convergence mechanism inherent to both tested protocols. This agrees **with** the 3D analysis by Chou **et al. (2021)**, who reported altered pre-surgical growth vectors and emphasized that alveolar approximation does not replicate the posterior width gain of normative growth. [19] The significant postnatal *increase* observed in (BG-BL) in our health control group underscores that the PSIO-induced decrease represents a distinct departure from physiological expansion.

The Width between the Most Posterior Ends (PG-PL) showed a small but significant increase in UCLP infants, though it remained significantly less than the robust growth seen in controls. This partial growth preservation is **supported by** findings from **Lim et al. (2017),** who noted that certain posterior structures remain relatively stable during molding.[20] Yet, the overall failure to match control group expansion rates supports the conclusion of a **systematic review by van der Heijden et al. (2022)**, which found limited evidence that PSIO can "normalize" maxillary arch transverse dimensions.[21] Our data provide direct empirical evidence for this assertion.

Midline Deviation and Arch Form

The significant correction of midline deviation (both Inc-Sagittal and (Mid-Inc)-Sagittal) in our cohort is a consistent and well-documented outcome of PSIO. Our results are in **strong agreement with** recent longitudinal work. **Unno et al. (2025)** demonstrated that PSIO has a measurable positive influence on arch form and symmetry that can be observed up to 5 years of age, with early correction being a key factor. [22] This underscores the importance of early intervention in establishing a more symmetrical arch base prior to surgical repair.

Comparative Efficacy and Mechanistic Insights

The finding of **no significant difference** in any intraoral outcome measure between the GS-NAM and conventional NAM groups is clinically important. It suggests that the proposed clinical efficiency and simplified activation of the GS-NAM protocol do not come at the cost of reduced orthopedic effectiveness in the short term. This **aligns with the principle** discussed by **Grayson (2024)** that evolution in NAM technique aims to improve practicality while maintaining core efficacy. [11] However, it **partially contrasts with** the hypothesis that adhesive-based stabilization and differential traction would lead to *superior* segment control; our data show it to be equally effective, not superior, for the primary intra-alveolar outcomes measured here.

CONCLUSION

Both NAM and lip taping with passive plate yield significant improvements in intraoral parameters for UCLP infants, with equivalent efficacy. These presurgical strategies enhance alveolar alignment, supporting easier surgical interventions and aligning with contemporary PSIO advancements. Clinicians may consider patient-specific factors in selecting approaches to optimize outcomes.

DECLARATIOM

Conflict of interest:

Authors declare that there is no conflict of interest

Source of funding:

There are no funds procured

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