



# Evaluation of presurgical infant orthopedics by the rhinoplasty appliance system with intraoral alveolar molding appliance in infants with bilateral cleft lip and palate: A preliminary study

Martha Mejia<sup>1</sup>, Puneet Batra<sup>2</sup>, Monica Dominguez<sup>3</sup>, María del Rosario Montoya<sup>4</sup>, Dhruv Ahuja<sup>2</sup>, Silvia Z. Torres Cavallo<sup>5</sup>, Adriana Reyes<sup>6</sup>, Aditya Talwar<sup>2</sup>

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1. Craniofacial Research associate, Nicklaus Children's Hospital, Miami, FL, United States
2. Department of Orthodontics and Dentofacial Orthopedics, Manav Rachna Dental College, Manav Rachna International Institute of Research and Studies, Faridabad, Haryana, India
3. Global Oral Health Programs, Smile Train Organization, Mexico city, Mexico
4. Centro de Especialidades Odontológicas, IMIEM, México City, Mexico
5. Hospital Pediátrico Dr. Humberto Noti, Mendoza, Argentina
6. Fundación Sonrisas desde Corazón, Aguas Calientes, Mexico

## Correspondence:

**Puneet Batra**, Department of Orthodontics and Dentofacial Orthopaedics, Manav Rachna Dental College, Faridabad, Manav Rachna International Institute of Research and Studies (MRIIRS), 121004 Haryana, India.  
[drpuneetbatra@gmail.com](mailto:drpuneetbatra@gmail.com)

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Presurgical infant orthopedics (PSIO)  
Rhinoplasty Appliance System (RAS)  
Bilateral cleft lip and palate (BCLP)  
Burden of care

## Summary

**Objectives** > To evaluate the effectiveness of the Rhinoplasty Appliance System (RAS) in improving alveolar arch morphology and nasolabial morphology in infants with bilateral cleft lip and palate (BCLP) before primary lip repair.

**Material and methods** > A multicentre prospective study was conducted on 20 non-syndromic infants with complete BCLP. Presurgical infant orthopaedics (PSIO) using RAS therapy was initiated within the first three-weeks of life and continued until primary cheiloplasty. Digital maxillary models and standardized extraoral photographs were obtained before and after the PSIO treatment. Study model analyses evaluated three-dimensional maxillary arch morphology, while extraoral photographs evaluated nasolabial parameters, including nostril width, columella height, prolabium height, nasal tip angle, and nasolabial angle. Reliability was tested using repeated measures, and descriptive statistics and paired *t*-tests were applied, with significance set at  $P < 0.05$ .

**Results** > Significant improvements were observed in both arch morphology and nasolabial parameters following RAS therapy. Arch changes included reductions in cleft width and improvements in premaxillary alignment ( $P < 0.001$ ), while nasolabial improvements included reduced

nasal tip angle ( $-7.46^\circ$ ,  $P < 0.001$ ), increased nasolabial angle ( $+23.39^\circ$ ,  $P < 0.001$ ), narrower nostril width ( $-5.84$  mm,  $P < 0.001$ ), and greater columella and prolabium height ( $P < 0.001$ ). **Conclusion** > In infants with BCLP, RAS therapy improved maxillary arch morphology and nasolabial parameters. RAS may offer a controlled and reproducible PSIO approach, enhancing premaxillary positioning, nasal symmetry, and readiness for lip repair while potentially reducing caregiver burden and in-person visits. Adoption of this technique in clinical practice may facilitate standardized early nasal and maxillary correction, improving surgical outcomes. Well-designed, randomized clinical trials with long-term follow-up are warranted to confirm these outcomes.

## Introduction

Bilateral cleft lip and palate (BCLP) present complex challenges in craniofacial treatment, necessitating a multidisciplinary approach to optimize both functional and aesthetic outcomes. A primary surgical difficulty involves managing the prominent, often protruding premaxilla and the diminutive prolabium, which complicate midface alignment and facial symmetry [1]. These structural discrepancies contribute to distortion of the alveolar arches, nasal asymmetry, and columellar shortening; further compromising nasolabial aesthetics and airway patency [2].

To address these challenges, presurgical infant orthopaedics (PSIO) has been widely implemented to enhance surgical predictability by aligning the maxillary alveolar segments and reshaping the nasal cartilages for improved symmetry [3]. This early intervention facilitates soft tissue reconstruction, enhances nasolabial aesthetics, and contributes to more successful and less complex surgical repairs. Among the existing PSIO techniques, Grayson's presurgical nasoalveolar molding (PNAM) technique and its subsequent modifications are well established, which utilizes an intraoral plate with a nasal stent to gently lift and mold the nasal cartilage, improving nasal form and symmetry in early infancy [4]. Several adaptations have since been proposed, including the use of nasal elevators such as the Dynacleft nasal elevator system which apply extraoral traction to remodel nasal cartilage without an intraoral appliance [5]. More recently, the incorporation of digital technologies in infant orthopaedics, such as digital NAM (dNAM) and OrthoAligner NAM systems, has further refined these techniques, with nasal elevators serving as an integral component for achieving balanced nasal morphology in bilateral cases [6,7].

The Rhinoplasty Appliance System (RAS), introduced by Mejia et al. [8], represents a recent advancement in presurgical orthopaedic therapy. RAS appliance integrates structured nasal molding with maxillary alignment to refine nasolabial outcomes in infants with cleft lip and palate. The RAS system is believed to improve the position and orientation of the nasal septum, thereby promoting more symmetrical nasal and midfacial development [9]. Early septal corrections not only support balanced craniofacial development but also play a critical role in optimizing nasal airflow, as nasal obstruction in infancy has been linked to altered maxillary growth and increased vertical facial height

[10,11]. The effectiveness of RAS in BCLP, focusing on premaxillary positioning, lateral segment alignment, prolabium shaping, and nasolabial morphology represents area with limited evidence in existing literature.

Mechanically, the RAS delivers gentle, continuous forces that reshape the nasal septum and columella, promoting improved nasal form and symmetry [12]. These forces elevate the nasal dome and columella upward and medially, centralizing the anterior septum, lengthening the columella, and improving nasal symmetry. While the posterior cartilaginous and bony septum are not directly targeted, their position may improve indirectly through enhanced maxillary alignment, establishing a favourable anatomical foundation for subsequent surgical repair [9,12-14].

Despite encouraging results in unilateral clefts, evidence remains limited regarding the effects of RAS in BCLP patients, particularly concerning premaxillary control and nasal symmetry before primary repair. Addressing this gap, the present study aims to evaluate the preliminary effectiveness of RAS in improving premaxillary positioning in BCLP patients. This approach seeks to optimally align the premaxillary and lateral segments, shape the nasal cartilages, lengthen the deficient columella, and improve nasal aesthetics. The null hypothesis of this study states that RAS therapy does not result in significant improvement in nasolabial aesthetics or maxillary arch morphology in BCLP patients.

## Material and methods

This multicentre prospective clinical study was conducted on non-syndromic infants with complete bilateral cleft lip and palate (BCLP) treated at centres in Mexico, Argentina, USA and India between January 2024 and June 2025. All participating clinicians had prior experience using the same presurgical infant orthopaedic (PSIO) protocol with the Rhinoplasty Appliance System (RAS). The study was conducted after obtaining institutional ethical clearance (Ref No. MRIIRS/MRDC/SDS/IEC/2024/128), and written informed consent was obtained from the parents or legal guardians of all participants.

## Participants, eligibility criteria and settings

A total of 20 non-syndromic infants with complete BCLP were included. Infants were assigned to the study group on a first-

come, first-served basis from four participating centres where the RAS was uniformly used for PSIO treatment. Only infants with complete BCLP, aged within the first month of life at the initiation of PSIO therapy were included. Infants were excluded if they presented with associated craniofacial syndromes, congenital malformations affecting craniofacial growth or nasal anatomy, or Simonart bands that could interfere with appliance therapy, or incomplete records that prevented completion of the PSIO protocol.

The required sample size was estimated using G\*Power software (version 3.1.9.7). Based on a Hedges' g effect size of 0.7, a significance level of 5%, and a statistical power of 80%, the minimum sample size calculated was 20 patients [5]. Each patient was treated following a standardized protocol, with RAS therapy initiated within the first three weeks of life. Data were collected at two time points before and after PSIO including scanned digital models for maxillary arch form analysis and standardized extraoral and intraoral photographs for facial assessment.

## Intervention

The passive presurgical orthopaedic appliance technique utilizes a three-dimensional approach to maxillary alignment, normalizing the occlusal plane while preserving natural maxillary growth [8,9]. This technique facilitates favourable maxillary alignment without anteroposterior collapse, enabling normalization of the occlusal plane throughout natural growth. In cases of a prominently protruded premaxilla, a two-stage presurgical orthopaedic appliance was implemented: initial soft tissue approximation using labial taping (*figure 1a*), after which manually fabricated sequential orthopaedic plates were used to reposition the premaxilla onto the occlusal plane and centralize it through controlled retraction. These plates were constructed using conventional laboratory methods, where guided acrylic extension and wax reconstruction were employed to guide movement and maintain transverse stability, with the final stage introducing appliance fixation (*fixedentR*) to refine tissue alignment and prepare for gingivoperiosteoplasty (GPP) (*figure 1b-d*). Once the alveolar cleft gap was reduced to

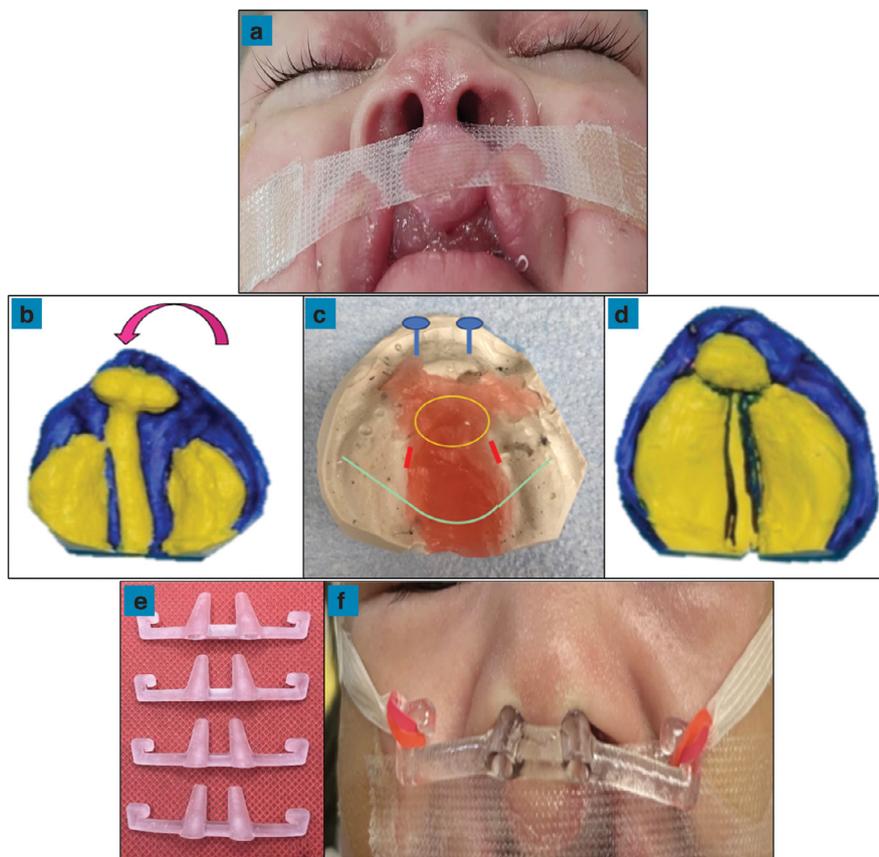


FIGURE 1

### Sequential infant orthopaedic management of a protruded premaxilla

a: labial taping for soft tissue approximation; b-d: guided repositioning with acrylic extensions, wax reconstruction, and alveolus appliance; e and f: digitally designed preformed RAS for staged nasal remodelling.

~7 mm, the RAS was introduced to address nasal deformity. At this stage, maxillary arch modelling and alveolar alignment had already been achieved through the prior use of acrylic molding plates; the RAS was applied for nasolabial soft-tissue reshaping. The RAS used was a prefabricated nasal prosthesis kit supplied in four progressive sizes. Each unit included bilateral nasal stents joined by a columellar post and two lateral arms with elastic hooks, along with protective skin pads and adhesive tapes for secure retention. After applying the labial tape, the appliance was inserted into the nostrils and aligned with the protective pads owing to inherent nasal asymmetry in BCLP to guide progressive nasal remodelling every two weeks, adapted to patient growth [12,13] (figure 1e and f). Treatment began with the smallest stent and progressed to larger sizes as nasal form improved. Adjustments were made every 3–4 weeks, with interim monitoring via parental photographs and remote follow-up. After RAS treatment was completed, a nasal conformer was provided as a passive retainer until the lip repair surgery, to maintain premaxillary and nasal correction achieved during the RAS phase.

## Data acquisition

### Assessment of alveolar arch measurements and facial photographs

Maxillary arch dimensions and nasolabial features were assessed at two stages: before the start of PSIO treatment (T0- prior to labial taping and passive maxillary appliance placement) and after completion of PSIO (T1- after RAS treatment and final appliance removal). Digital impressions were captured using a Dentsply Sirona CEREC Prime scan intraoral scanner. An experienced orthodontist identified reference landmarks for both arch and facial analyses, based on established methodologies [15–17]. The 3D scans were processed with GOM Inspect software (v2.0.1, 2018,) to obtain precise linear (width, length and vertical) measurements of the maxillary arch, while soft tissue facial parameters were measured on standardized facial photographs using NemoStudio software (Nemotech, 2020) (figure 2a–e).

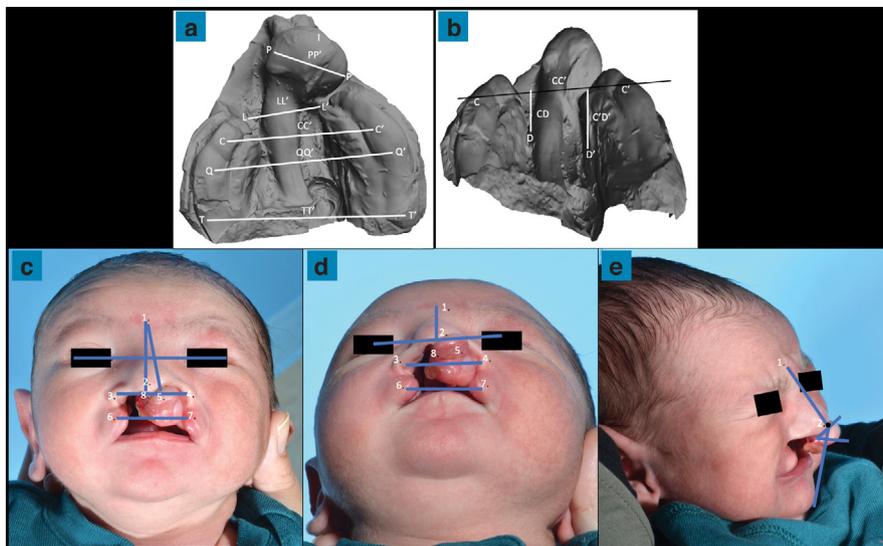


FIGURE 2

### Reference landmarks and planes used for arch measurements and soft-tissue assessment in BCLP patients

Linear and angular measurements were assessed at two stages: before the start of PSIO treatment (T0, prior to labial taping and passive plate placement) and after completion of PSIO treatment (T1, after RAS and final appliance removal): (a–b) linear measurements of the alveolus for width, length, and vertical dimensions. Reference lines for soft-tissue evaluation; perpendicular projections from the interpupillary line to subalare, columellar insertion, and lateral canthus points. (c.) frontal view – intercanthal distance, nasal width, columellar deviation, nostril symmetry; (d.) basal view – nasal tip Projection, Nostril Symmetry; (e.) profile view – Nasolabial Triangle Area, Nasion – Prolabium – Chin (NPC) angle. Anthropometric landmarks: (1) glabella; (2) pronasale (prn), (3) endocanthion left; (4) endocanthion right; (5) highest point of columella; (6) alare left; (7) alare right; (8) subnasale (sn).

### Arch measurements

Arch analysis was performed by marking anatomical reference points and lines on the digital models to evaluate linear variables (width, linear and vertical) at both T0 and T1 time points. Linear measurements, including the intersegmental alveolar gap and arch width, were calculated alongside angular assessments of segment inclination and deviations from the midline [12,15]. To account for potential magnification errors during model acquisition, a correction formula was applied, ensuring the precision and reliability of the measurements. (Calculated values: measured value/actual value  $\times$  100).

### Facial photography and soft tissue analysis

Facial analysis was performed using standardized anteroposterior, profile, and Worm's-eye photographs taken pre- and post-treatment with a Nikon DSLR camera (1/200, f14, ISO800) and 18–70 mm lens. A calibrated operator at each centre captured images, stabilizing infants' heads with caregiver support for consistency. Camera settings and angles were kept identical for pre- and post-treatment photographs. Measurements included nostril dimensions, columellar deviation, soft-tissue cleft distance, nasal bridge length, nasolabial angle, and nasal tip projection, with repeated measures on randomly chosen subjects to ensure reliability [13,17]. Soft tissue changes in the nasolabial region were quantified from standardized frontal photographs using ImageJ software to calculate the soft tissue ratio (cleft width divided by inter-commissural distance, measured in pixels with pixel-to-mm correction). This normalized ratio minimized the effects of facial growth and image scale, providing a reliable indicator of soft tissue improvement and symmetry. All analyses were conducted by a single blinded, calibrated examiner to maintain consistency [12,17].

### Reliability assessment of measurements

To evaluate the inter- and intra-observer reliability of the measurements, a random selection of 30% of the digital models and photographic records was performed after the initial data collection was completed. Specifically, 5 patients' digital scans and corresponding photographs were randomly chosen using a computerized randomization method. The same examiner repeated all measurements on this subset under identical

conditions, with a two-week interval between sessions to minimize recall bias.

### Statistical analysis

Data were compiled and organized using Microsoft Excel and subsequently analysed with IBM SPSS software (version 30, 2024). To ensure blinding, sample coding was implemented so that only the principal investigator had access to the identifying information. Statistical analysis involved calculating means and measures of variability, performing paired *t*-tests for within-group comparisons, and evaluating measurement reliability using Cronbach's alpha. Between-group differences in arch and facial parameters following treatment were assessed using independent *t*-tests.

## Results

A total of 20 infants with BCLP (11 boys, 9 girls) were included in the study. *Table 1* depicts BCLP patients' demographics with the mean age of  $15.23 \pm 1.85$  days at the start of treatment, and the mean bilateral cleft gap at birth measured  $23.63 \pm 1.28$  mm. The RAS was completed at a mean age of  $13.2 \pm 2.1$  weeks, corresponding to a total treatment duration of approximately  $11.67 \pm 2.1$  weeks (*table 1, figure 3*).

TABLE I  
Sample characteristics of BCLP patients undergoing RAS treatment modality

| Characteristics                   | Rhinoplastic Appliance System (RAS) |
|-----------------------------------|-------------------------------------|
| Sex: boy/girl ( <i>n</i> )        | 11/9                                |
| Start of treatment (age in days)  | $15.23 \pm 1.85$                    |
| Bilateral cleft gap at birth (mm) | $23.63 \pm 1.28$                    |
| Age at the end of RAS (weeks)     | $13.2 \pm 2.1$                      |
| Total duration of RAS (weeks)     | $11.67 \pm 2.1$                     |
| Lip repair (age in weeks)         | 18 weeks $\pm$ 2 weeks              |



FIGURE 3  
Sample representative of BCLP infant treated with RAS: pre-treatment (a-d) and post-treatment (e-h)

### Reliability of measurements

In this study, reliability was assessed using Cronbach's alpha, yielding a value of 0.78 for arch parameters, which reflects acceptable internal consistency, and 0.84 for extraoral facial parameters, indicating good internal consistency. Collectively, these findings confirm that both sets of parameters demonstrate satisfactory reliability.

### Descriptive statistics

In BCLP cases, the observed changes in maxillary arch and nasolabial morphology result from the combined effects of intraoral plates, labial taping, and RAS, rather than from RAS alone. In arch dimensions, the PP' increased from 17.46 mm to 19.92 mm, while the transverse width at TT' increased from 24.93 mm to 28.43 mm. Similarly, QQ expanded from 15.80 mm to 24.04 mm, and NLT from 22.29 mm to

26.60 mm. In contrast, anterior maxillary parameters such as the LL' decreased from 19.07 mm to 16.76 mm, and both WPL & NPL reduced from 5.57 mm to 2.78 mm and 6.14 mm to 2.86 mm, respectively, reflecting narrowing of the anterior segments. Soft tissue and nasal parameters showed improvements. The nasal tip angle reduced from 128.33° to 120.88°, and the subnasale angle decreased from 174.49° to 156.83°, while the nasolabial angle increased markedly from 87.58° to 110.98°. Nostril width narrowed from 26.84 mm to 21.00 mm, and lip gap reduced from 23.63 mm to 19.43 mm, demonstrating better nasal and lip approximation. Importantly, columella height increased from 2.65 mm to 5.91 mm, and prolabium height from 5.58 mm to 8.95 mm, improving vertical lip proportions. The descriptive data indicates progressive nasal molding, narrowing of cleft-width, and favourable soft tissue changes (*table II*).

TABLE II

## Landmarks and definitions used for the assessment of arch morphology on digital models and facial morphology on photographs

| Measurement/landmark definition |  |
|---------------------------------|--|
| <b>Arch parameters</b>          |  |
| PP' – premaxillary width        | Distance between the left and right lateral edges of the premaxilla (mm)   |
| LL' – anterior arch width       | Distance between the most anterior point of the alveolar crest of the left and right lateral segments (mm)   |
| CC' – intercanine arch width    | Distance between the cusp tips of the left and right canines (mm)  |
| TT' – posterior arch width      | Distance between the left- and right-most posterior points in the maxillary tuberosity (mm)  |
| QQ' – lateral sulcus width      | Distance between the left and right lateral sulcus at the gingival groove points of intersection (mm)  |
| WPL – wide cleft width          | Distance from the lateral endpoint of the premaxilla to the most anterior point of the lateral segment on the wider cleft side (mm)                  |
| NPL – narrow cleft width        | Distance from the lateral endpoint of the premaxilla to the most anterior point of the lateral segment on the narrower cleft side (mm)               |
| WLT – wide alveolar length      | Distance from the most anterior point of the lateral segment to the most posterior point in the maxillary tuberosity on the wider cleft side (mm)    |
| NLT – narrow alveolar length    | Distance from the most anterior point of the lateral segment to the most posterior point in the maxillary tuberosity on the narrower cleft side (mm) |
| I-LL – premaxilla protrusion    | Distance between the incisal point perpendicular to the anterior arch width (mm)   |
| I-TT – arch depth               | Distance from the incisal point perpendicular to the posterior arch width (mm)   |
| CD – right alveolar height      | Perpendicular distance from the deepest point in the right cleft to the CC' plane (mm)   |
| C'D – left alveolar height      | Perpendicular distance from the deepest point in the left cleft to the CC' plane (mm)  |
| <b>Facial parameters</b>        |  |
| Nasal tip angle (°)             | Angle formed at the nasal tip describing nasal tip projection  |
| Nasolabial angle (°)            | Angle between the columella and the upper lip  |
| Subnasale angle (°)             | Angle formed at the subnasale reflecting columellar and philtral relationships   |
| ANB triangle 1 (°)              | Angle between alar base and nasal tip (right subalare – pronasale – left subalare)   |
| ANB triangle 2 (°)              | Angle between alar base and subnasal point (right subalare – subnasale – left subalare)  |
| ANB triangle 3 (°)              | Angle between outer alar wall and nasal tip (alar curvature – pronasale – alar curvature)  |
| NPC angle (°)                   | Nasion – prolabium – chin angle indicating midfacial projection  |
| Nostril width (mm)              | Transverse width of the nostril aperture   |
| Lip gap (mm)                    | Distance between upper and lower lip at rest   |
| Columella height (mm)           | Vertical height of the columella from the base to the apex   |
| Prolabium height (mm)           | Height of the prolabium measured vertically  |

All linear measurements are reported in millimeters (mm) and angular values in degrees (°).

### Arch dimension

Arch parameters demonstrated significant differences between T0 and T1 (table III). Significant mean reductions were observed in PP' (−2.45 mm,  $P = 0.001$ ), TT' (−3.51 mm,  $P < 0.001$ ), QQ' (−8.23 mm,  $P < 0.001$ ), WLT (−2.55 mm,  $P = 0.003$ ), NLT (−4.30 mm,  $P < 0.001$ ), CD (−3.28 mm,  $P < 0.001$ ), and C'D (−3.44 mm,  $P < 0.001$ ) indicating significant post-

treatment increases in these arch parameters. In contrast, LL' (2.31 mm,  $P = 0.004$ ), WPL (2.79 mm,  $P = 0.008$ ), NPL (3.28 mm,  $P = 0.002$ ), and I-LL (3.56 mm,  $P < 0.001$ ) showed significant decreases from pre- to post-treatment, as positive mean differences in the T0-T1 calculation indicate a reduction following treatment. No statistically significant changes were found in CC' (−0.12 mm,  $P = 0.900$ ) or I-TT (1.97 mm,

TABLE III  
**Intergroup comparison of Arch-based and extraoral facial parameters at pre- (T0) and post- (T1) treatment**

|                             | Pre-treatment mean ± SD | Post-treatment mean ± SD | Std. error mean (pre) | Std. error mean (post) | Mean difference | SD    | SE   | 95% CI (lower-upper) | t-value | df | P-value  |
|-----------------------------|-------------------------|--------------------------|-----------------------|------------------------|-----------------|-------|------|----------------------|---------|----|----------|
| <b>Arch parameters</b>      |                         |                          |                       |                        |                 |       |      |                      |         |    |          |
| PP': premaxillary width     | 17.47 ± 2.59            | 19.92 ± 1.66             | 0.69                  | 0.44                   | -2.45           | 2.20  | 0.59 | -3.72, -1.18         | -4.17   | 19 | 0.001*   |
| LL': anterior arch width    | 19.07 ± 2.36            | 16.76 ± 1.24             | 0.63                  | 0.33                   | 2.31            | 2.50  | 0.67 | 0.87, 3.75           | 3.46    | 19 | 0.004*   |
| CC': intercanine width      | 22.45 ± 3.36            | 22.57 ± 2.25             | 0.90                  | 0.60                   | -0.12           | 3.38  | 0.90 | -2.07, 1.84          | -0.13   | 19 | 0.900    |
| TT': posterior arch width   | 24.93 ± 2.75            | 28.43 ± 2.29             | 0.73                  | 0.61                   | -3.51           | 1.72  | 0.46 | -4.50, -2.51         | -7.61   | 19 | < 0.001* |
| QQ': lateral sulcus width   | 15.80 ± 2.88            | 24.04 ± 2.28             | 0.77                  | 0.61                   | -8.23           | 2.82  | 0.75 | -9.86, -6.60         | -10.91  | 19 | < 0.001* |
| WPL: wide cleft width       | 5.57 ± 4.86             | 2.78 ± 2.11              | 1.30                  | 0.56                   | 2.79            | 3.33  | 0.89 | 0.87, 4.71           | 3.14    | 19 | 0.008*   |
| NPL: narrow cleft width     | 6.14 ± 3.68             | 2.86 ± 1.30              | 0.98                  | 0.35                   | 3.28            | 3.07  | 0.82 | 1.51, 5.06           | 3.99    | 19 | 0.002*   |
| WLT: wide alveolar length   | 22.31 ± 3.45            | 24.85 ± 2.22             | 0.92                  | 0.59                   | -2.55           | 2.56  | 0.68 | -4.03, -1.07         | -3.73   | 19 | 0.003*   |
| NLT: narrow alveolar length | 22.29 ± 2.72            | 26.60 ± 2.73             | 0.73                  | 0.73                   | -4.30           | 3.06  | 0.82 | -6.07, -2.54         | -5.27   | 19 | < 0.001* |
| I-LL: premaxilla protrusion | 15.58 ± 1.63            | 12.02 ± 2.58             | 0.43                  | 0.69                   | 3.56            | 1.92  | 0.51 | 2.45, 4.67           | 6.92    | 19 | < 0.001* |
| I-TT: arch depth            | 37.31 ± 4.15            | 35.34 ± 3.69             | 1.11                  | 0.99                   | 1.97            | 3.82  | 1.02 | -0.23, 4.17          | 1.93    | 19 | 0.075    |
| CD: right alveolar height   | 14.25 ± 1.98            | 17.53 ± 2.17             | 0.53                  | 0.58                   | -3.28           | 2.30  | 0.61 | -4.61, -1.95         | -5.34   | 19 | < 0.001* |
| C'D: left alveolar height   | 13.25 ± 2.06            | 16.69 ± 1.65             | 0.55                  | 0.44                   | -3.44           | 2.01  | 0.54 | -4.59, -2.28         | -6.40   | 19 | < 0.001* |
| <b>Facial parameters</b>    |                         |                          |                       |                        |                 |       |      |                      |         |    |          |
| Nasal tip angle (°)         | 128.33 ± 8.91           | 120.88 ± 7.36            | 2.23                  | 1.84                   | 7.46            | 3.23  | 0.81 | 5.73, 9.18           | 9.22    | 19 | < 0.001* |
| Nasolabial angle (°)        | 87.58 ± 16.32           | 110.98 ± 4.92            | 4.08                  | 1.23                   | -23.39          | 14.78 | 3.70 | -31.27, -15.52       | -6.33   | 19 | < 0.001* |
| Subnasale angle (°)         | 174.49 ± 20.38          | 156.83 ± 20.93           | 5.10                  | 5.23                   | 17.66           | 12.12 | 3.03 | 11.21, 24.12         | 5.83    | 19 | < 0.001* |
| ANB triangle 1 (°)          | 98.78 ± 10.80           | 87.37 ± 7.45             | 2.70                  | 1.86                   | 11.41           | 10.53 | 2.63 | 5.80, 17.03          | 4.33    | 19 | 0.001*   |
| ANB triangle 2 (°)          | 120.37 ± 16.36          | 112.51 ± 15.88           | 4.09                  | 3.97                   | 7.86            | 4.30  | 1.08 | 5.57, 10.16          | 7.31    | 19 | < 0.001* |
| ANB triangle 3 (°)          | 121.49 ± 7.43           | 109.89 ± 9.79            | 1.86                  | 2.45                   | 11.60           | 7.76  | 1.94 | 7.46, 15.74          | 5.98    | 19 | < 0.001* |
| NPC angle (°)               | 239.03 ± 11.86          | 218.19 ± 12.49           | 2.97                  | 3.12                   | 20.84           | 11.41 | 2.85 | 14.76, 26.92         | 7.30    | 19 | < 0.001* |
| Nostril width (mm)          | 26.84 ± 2.03            | 21.00 ± 2.11             | 0.51                  | 0.53                   | 5.84            | 1.11  | 0.28 | 5.25, 6.43           | 21.07   | 19 | < 0.001* |
| Lip gap (mm)                | 23.63 ± 1.28            | 19.43 ± 1.78             | 0.32                  | 0.45                   | 4.20            | 0.90  | 0.22 | 3.72, 4.68           | 18.70   | 19 | < 0.001* |
| Columella height (mm)       | 2.65 ± 1.38             | 5.91 ± 0.97              | 0.35                  | 0.24                   | -3.26           | 1.19  | 0.30 | -3.90, -2.63         | -10.97  | 19 | < 0.001* |
| Prolabium height (mm)       | 5.58 ± 0.79             | 8.95 ± 0.94              | 0.20                  | 0.24                   | -3.37           | 1.32  | 0.33 | -4.08, -2.67         | -10.24  | 19 | < 0.001* |

n: number of samples; SD: standard deviation.  
 \*Statistical significance set at 0.05.

$P = 0.075$ ). The findings highlight arch dimensional changes in both transverse and sagittal arch relationships, with arch expansion and cleft contraction.

**Facial analysis**

With respect to facial parameters, statistically significant changes were observed across nearly all measured domains. The nasal tip angle showed a significant reduction (mean

difference:  $7.46^\circ$ ,  $P < 0.001$ ), indicating improved nasal tip definition, accompanied by a marked increase in the subnasale angle (mean difference:  $17.66^\circ$ ,  $P < 0.001$ ). The nasolabial angle increased markedly from baseline ( $-23.39^\circ$ ,  $P < 0.001$ ). Significant post-treatment increases were also noted in columella height ( $-3.26$  mm,  $P < 0.001$ ) and prolabium height ( $-3.37$  mm,  $P < 0.001$ ), reflecting negative mean differences despite actual clinical gains, whereas nostril width

(5.84 mm,  $P < 0.001$ ) and lip gap (4.20 mm,  $P < 0.001$ ) demonstrated significant decrease. Angular measurements related to the ANB triangles (Anterior Nasal Base) (mean differences ranging from  $7.86^\circ$  to  $11.60^\circ$ ,  $P \leq 0.001$ ) and the Nasion-Prolabium-Chin (NPC) angle ( $20.84^\circ$ ,  $P < 0.001$ ) also showed significant changes. Collectively, these outcomes suggest pronounced remodelling of nasolabial morphology, improved nasolabial harmony, and enhanced soft-tissue proportions following intervention (table III).

## Discussion

BCLP represents a complex craniofacial deformity affecting both alveolar segments and nasolabial structures. Early intervention with PSIO aims to approximate alveolar segments and correct soft tissue deficiencies of the columella, philtrum, and nostrils, ultimately facilitating more predictable and aesthetic surgical outcomes [15,17,18]. While conventional NAM protocols improve nasal and alveolar morphology, they often require frequent adjustments, intensive caregiver participation, and may risk mega nostril [19]. The RAS was developed to streamline PSIO therapy by delivering standardized, independent forces to the nasolabial soft-tissue complex, while alveolar alignment and arch remodelling were achieved through passive acrylic molding appliances used earlier in the treatment sequence [8,12].

PSIO has evolved from passive plates to advanced NAM systems and preformed appliances, utilizing neonatal tissue plasticity for optimal anatomic molding. The goal extends beyond alveolar alignment to achieving functional harmony that supports normal breathing, feeding, and long-term craniofacial growth [20]. Biomechanically, the RAS generates upward pressure through its intranasal component, downward stabilization via the columellar post, and anterior traction from labial taping. These forces act synergistically to correct vertical and horizontal nasal imbalances [8,9]. On the right and left cleft segments in BCLP, differential force vectors induce counterclockwise rotation, elevate the depressed nostril dome, and improve nasal symmetry [9,12]. Cheek-elastic traction applied to the columellar post promotes centralization of the septum and columellar lengthening, while downward lip-tape tension balances soft tissue repositioning. Collectively, these controlled, multidirectional forces guide nasal cartilages into a more centralized and symmetrical configuration, facilitating early correction of nasal deformities and optimizing presurgical morphology [8,9,12] (figure 4). By simultaneously addressing skeletal and soft tissue discrepancies, the RAS promotes more physiologic development of the nasal and maxillary complexes while preserving airway integrity and growth potential. Beyond its biomechanical advantages, the RAS contributes to the global standardization of PSIO. Its preformed design, ease of application, and reduced dependence on specialized laboratory procedures enable its use in a wide

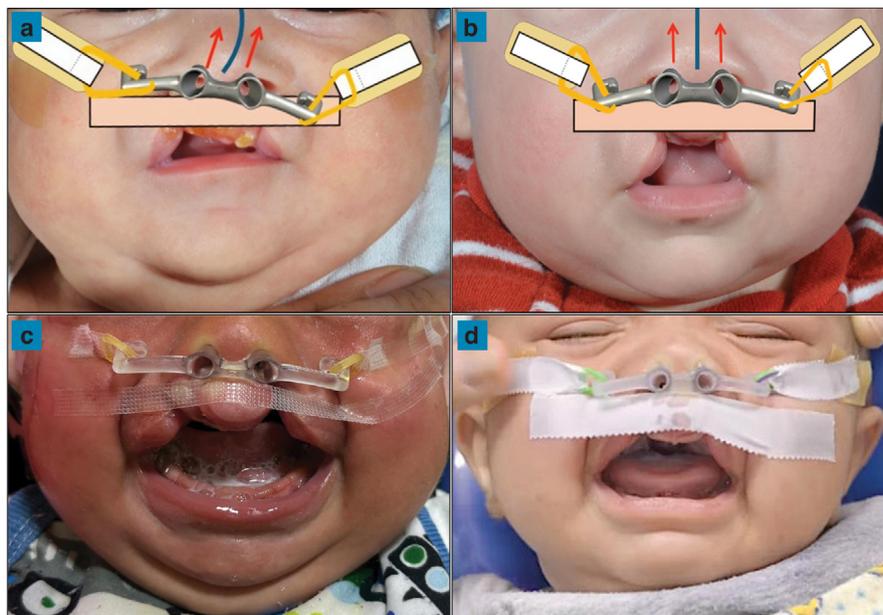


FIGURE 4

### Mechanism of action

(a.) initial insertion with nasal deviation; (b.) after a week the straight septum: RAS appliance delivers an upward force through the progressive enlargement of the nasal stents, a downward force via the nasal bridge/columellar support, and an additional downward traction on the upper lip generated by the slightly inclined tape. RAS appliance in situ with weekly change (c-d).

range of clinical settings, including resource-limited environments [12]. This accessibility encourages consistency across treatment centers and enhances the reliability of multicentre data collection. As PSIO continues to evolve, innovations such as the RAS hold promise for unifying treatment approaches and improving functional and aesthetic outcomes for infants born with cleft lip and palate worldwide. The RAS was introduced only after the alveolar cleft gap was reduced to  $\sim 7$  mm, as effective and safe nasal molding requires adequate stabilization of the premaxilla. In line with established PNAM protocols, nasal stents are incorporated only once the cleft is sufficiently narrowed ( $\leq 5$  mm) to minimize strain on mobile segments and ensure predictable nasal reshaping [4]. RAS integrates nasal stenting and passive orthopaedic appliance, producing coordinated improvements in both arch morphology and cleft gap contraction [12]. Labial taping was used concurrently with both the passive orthopaedic plate and later with the RAS because it provides essential soft-tissue approximation and stabilizes the premaxilla. When combined with the orthopaedic plate, it supports controlled segment alignment, and during the RAS phase it maintains soft-tissue tension needed for predictable nasal molding. Thus, taping complements both appliances rather than functioning as a separate step. This dual effect distinguishes RAS from other PSIO approaches, highlighting its potential as a comprehensive appliance for complex BCLP cases.

In the present cohort, significant alveolar arch improvement and cleft width reduction were achieved during the initial acrylic molding phase, while subsequent RAS therapy contributed primarily to nasolabial soft-tissue refinement; this staged approach resulted in measurable improvements in PP', TT', QQ, NLT, CD, and C'D, with selective expansion of the anterior and sagittal segments (LL', WPL, NPL, I-LL), reflecting favourable maxillary remodelling. Al-Khateeb et al. (2025), who reported significant improvements in maxillary arch form and transverse dimensions following VF-NAM therapy in BCLP patients [21]. Similar reductions in cleft gap and arch remodelling were observed with DynaCleft® therapy [5], while digital NAM (dNAM) and CAD/CAM-based appliances also yielded improvements but required longer adjustment periods and higher caregiver involvement [22–24]. Other PSIO appliance like PLANA (NoseAlign & LipAlign) focus primarily on soft tissue approximation and nasolabial balance, with limited effect on intraoral arch form [25].

Facial analysis revealed significant improvements in nasal and perinasal soft tissue parameters, including reductions in nasal tip and subnasale angles, narrowing of nostril width, decreased lip gap, and increased columella and prolabium heights. These outcomes are consistent with studies using conventional NAM, which report columellar elongation and enhanced nostril symmetry [26–28]. Bahaa et al. (2024) found that modified Grayson NAM appliances resulted in significant improvements in alar length projection, columella angle, and nasal tip projection compared to DynaCleft® therapy [5]. Our results demonstrate

similar findings, with RAS achieving both nasal and alveolar improvements in a reproducible manner. Additionally, nasal elevator-assisted PSIO has been shown to reduce cleft width and improve columellar alignment, supporting the combined effect observed with RAS in our cohort [29].

### Clinical implications

The Rhinoplasty Appliance System (RAS) offers a streamlined alternative to traditional PSIO for both UCLP and BCLP. By anchoring in both nostrils, RAS enhances retention and delivers controlled, independent forces that optimize septal centralization and nasal symmetry. This mechanism improves reproducibility, reduces the risk of mega nostrils, and minimizes caregiver burden. When combined with a passive maxillary plate, alveolar segment alignment is further refined. Compared with nasal elevators and other NAM-based devices, the combined protocol of passive maxillary plates followed by RAS improves both alveolar alignment and nasal morphology, providing consistent, effective outcomes even in complex BCLP cases, and supporting functional and aesthetic development from the earliest stages.

### Limitations and future scope

Despite being a multicentre prospective study, some limitations should be noted. The relatively low prevalence of BCLP limited the sample size, potentially reducing statistical power and generalizability. The study focused primarily on short-term morphological outcomes, without evaluating long-term functional results such as nasal airway patency, speech development, midfacial growth, and psychosocial impact. The absence of a control group limits direct comparison with no PSIO modalities. Although digital models and standardized photographs were used, the absence of three-dimensional stereophotogrammetry may have reduced the precision of nasolabial soft-tissue analysis, as subtle contour changes and volumetric asymmetries could not be fully captured. A potential limitation of the RAS technique is that its biomechanical forces are applied by caregivers rather than clinicians. Variations in caregiver skill, infant compliance, and crying or movement may affect the precision and consistency of nasal molding, despite thorough instruction. This limitation may influence the efficacy of treatment and should be considered when interpreting clinical outcomes. Future studies with larger cohorts, long-term follow-up, and integration of advanced imaging or digital tracking methods are warranted to validate findings, optimize protocols, and assess functional and developmental outcomes comprehensively.

### Conclusion

RAS therapy in infants with BCLP resulted in coordinated improvements in both maxillary arch morphology and nasolabial soft tissue structures. The appliance delivers controlled, reproducible forces that promote favourable alveolar remodelling, enhanced columellar and prolabial development, and

improved nasal symmetry, while reducing caregiver burden and the number of in-person visits. Moreover, the standardized design of the RAS allows for virtual follow-up and remote supervision effectively monitored through tele-consultation/tele-monitoring, enabling clinicians to monitor treatment progress and make timely adjustments regardless of geographic limitations. These findings support RAS as an effective and clinically streamlined presurgical orthopaedic modality, offering a comprehensive approach to optimize both functional and aesthetic outcomes in BCLP management.

**Ethical statement :** The ethical approval for the study was obtained from the Institutional Ethical Committee of Manav Rachna Dental College (Ref No: MRIRS/MRDC/SDS/IEC/2024/128).

**Informed consent :** Informed consent was obtained from all participants by the centres prior to their inclusion in the study.

**Authorship contribution statement :** M.M., P.B., M.D., M.D.R.M., S.T., and A.R.: conception and design of the study, or acquisition of data, or analysis and interpretation of data. D.A., A.T., M.D.R.M., S.T., and A.R.: drafting the article or revising it critically for important intellectual content. M.M. and P.B: final approval of the version to be submitted.

**Data availability :** Data related to this article are available from the corresponding author upon reasonable request.

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