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RESEARCH ARTICLE

A Comparative Evaluation of Presurgical Infant Orthopaedics of Modified Grayson's Technique With Rhinoplasty Appliance System in Patients With Unilateral Cleft Lip and Palate

Martha Mejia[1] | Puneet Batra[2] | Monica Dominguez[3] | Daniela Scarlett Escobar[4] | Mayra Alvarez[4] | Tatiana Castillo[5] | Dhruv Ahuja[2]

[1]Craniofacial Research Associate, Nicklaus Children's Hospital, Coral Terrace, Florida, USA | [2]Department of Orthodontics and Dentofacial Orthopedics, Manav Rachna Dental College, Manav Rachna International Institute of Research and Studies, Faridabad, Haryana, India | [3]Director, Global Oral Health Programs, Smile Train Organization, Mexico | [4]Centro Suma Smile Train, Mexico City, Mexico | [5]Instituto Nacional de Pediatría INP, Mexico City, Mexico

Correspondence: Puneet Batra (drpuneetbatra@gmail.com)

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ABSTRACT

Objective: To evaluate the effects of presurgical infant orthopaedics using the Modified Grayson technique and Rhinoplasty Appliance System on the maxillary alveolus and nasolabial region in infants with unilateral cleft lip and palate (UCLP).

Materials and Methods: This prospective study looked at 26 patients with a mean age of 6.3 ± 1.48 days, having complete UCLP. The study sample was divided into two groups of 13 UCLP infants: Group 1, treated by the modified Grayson technique, and Group 2, treated with the Rhinoplasty Appliance System (RAS). The scanned cast parameters were assessed before and after PSIO treatment, assessing treatment changes in the alveolar arch, which was further supplemented with standardised anteroposterior, Worms-eye view and profile photographs assessing sift tissue facial parameters. Descriptive statistics were applied, and a two-tailed *t*-test for intergroup comparison was used to determine cast and facial parameters across the two techniques.

Results: Intra-group assessment of cast and facial parameters showed a significant difference ($p < 0.005$) across pre and post-treatment assessment using two different treatment modalities. However, intergroup comparison showed no significant difference ($p > 0.005$) between modified Grayson's and RAS techniques.

Conclusion: In infants with UCLP, both techniques significantly impacted the alveolus and nasolabial region while reducing cleft defects. However, an intergroup comparison of both the treatment modalities showed similar effects on intraoral and extraoral parameters. Integrating RAS into PSIO protocols shows promise in treating lip-and-palate cleft deformities. The study emphasises the value of digital technology in enhancing PSIO protocols, with potential benefits for treatment standardisation and improvement in patient experience.

1 | Introduction

Cleft lip and palate (CLP) exhibit substantial variation in severity and form. Wider clefts often result in pronounced nasolabial deformity. In a unilateral cleft lip and palate (UCLP) deformity, the affected side features a broader nostril base and parted lip segments. The displaced lower lateral nasal cartilage leads to a depressed nasal dome, a seemingly larger alar rim, an oblique columella and an overhanging nostril apex. When accompanied by a cleft palate, the nasal septum deviates toward the non-cleft side, shifting the nasal base [1]. The typical septal deviation deformity, often linked to hyperplasia of the inferior turbinates, can cause paradoxical nasal obstruction [2, 3].

Presurgical infant orthopaedics (PSIO) primarily aims to align and approximate the maxillary alveolar segments and reshape the nasal cartilages for better nasal symmetry, creating a more normal anatomy. PSIO of the alveolus and nasal cartilage streamlines soft tissue reconstruction [4]. This early intervention improves nasolabial aesthetics and facilitates more successful and less complex surgical repairs, potentially reducing the need for future corrective nasal surgeries. The evidence from the literature showcases no significant difference comparing PSIO to no PSIO modalities across various domains, including nasolabial aesthetics [5]. In contrast, retrospective studies suggest that PSIO combined with primary rhinoplasty might positively influence nasolabial aesthetics [6, 7]. Dutch cleft and evidence from literature show that the alveolar arch is essential, but the nostril symmetry is equally vital in the long-term outcomes. Despite continuous improvements, PSIO remains a developing field [8].

The presurgical nasoalveolar moulding (PNAM) technique introduced by Grayson et al. [9] in 1999, became a standard method for treating infant clefts due to its effectiveness in reducing the severity in early infancy. Grayson's technique enhances nasal symmetry in UCLP patients by using a single nasal stent for a nostril attached to an intraoral plate. The stent gently lifts and moulds the nasal cartilage on the cleft side, reshaping the nasal structures over time to promote symmetry. Various modifications have been made to the original PNAM technique. Some of the authors have advocated using only nasal elevator with no intra-oral appliance like the Dynacleft nasal elevator system [10]. Newer PSIO appliances have been developed, optimising the use of digital technology like digital nasolaveolar moulding (dNAM) and OrthoAligner NAM with nasal elevators as a key component of modern infant orthopaedics [11].

The Rhinoplastic Appliance System (RAS), introduced by Mejia et al. [12] in 2003 and published the technique on 2023, offers an innovative presurgical approach for infants with UCLP. Proponents of the RAS technique claim it improves the consistency and practicality of nasal procedures for treating CLP in infants. It effectively corrects nasal asymmetry and contributes to the comprehensive care of infants with UCLP conditions. It addresses nasal and intraoral tissue issues by correcting nasal form, nasal tip elevation and nasal septal deviation while improving columellar length and nostril circumference and aligning cleft defect borders. RAS effectively corrects vertical and transverse nasal asymmetries and maintains nasal cartilage positioning post-surgery, unlike traditional NAM appliances, which mainly lift the nasal tip. The RAS includes a lateral component with hooks, an elastic band for precise nasal positioning and a separate intraoral plate for shaping alveolar segments [12, 13].

The current literature lacks evidence regarding the efficacy of RAS. Therefore, this study seeks to rigorously compare the effectiveness of the modified Grayson's technique with the Rhinoplasty Appliance System (RAS) in terms of its effects on nasolabial aesthetic and maxillary arch measures.

2 | Material and Methods

This is a two-centred prospective clinical cohort study conducted on nonsyndromic UCLP infants treated at Suma Center -Mexico City, Nicklaus Children Hospital- Miami and Department of Orthodontics, Manav Rachna Dental College, Faridabad, India and associated peripheral centre at Dr. Shweta's Dental Clinic, Kalkaji, New Delhi, India. The study was conducted after obtaining institutional ethical clearance (Ref No. MRDC/IEC/2023/43), and written informed consent was received from the parents or guardians of all participants. Infants were selected based on specific criteria: age between 1 and 3 weeks with UCLP and without associated syndromes or prior orthopaedic interventions. UCLP infants born at the term were included. Infants with atypical clefts, bilateral cleft lip and palate (BCLP), soft tissue bands, simonart bands and congenital malformations were excluded.

2.1 | Patients

Infants were assigned to each group on a first-come, first-served basis across different centres for the Rhinoplasty Appliance System (RAS) group and modified Grayson's group. The adequate sample size was estimated using G*Power (version 3.1.9.7) based on Cohen's d effect size of 0.5, with a significance level of 5% and 80% power. Following enrolment in the trial, each patient was monitored according to the specific protocol corresponding to their assigned appliance. Twenty-six patients were divided into two groups. Group 1 included 13 patients treated for PSIO using the modified Grayson technique. In comparison, group 2 included 13 patients treated with the Rhinoplasty Appliance System (RAS) technique. Data was obtained for each patient at two-time points: before PSIO (T0) and after PSIO (T1). This included silicone impressions, scanned digital models and extraoral and intraoral photographs [14].

2.2 | Treatment

Modified Grayson's technique: The maxilla plaster cast was made, and modelling wax blocked the cleft. The acrylic appliance was formed using a self-curing resin (DPI, Mumbai, India). A custom-made retention button was positioned anteriorly at a 40° angle, ensuring the vertical arm was aligned at the junction of the upper and lower lips. The edges were smoothed, and surgical tapes secured the plate to the cheeks. Once the alveolus gap narrowed to 5 mm, a nasal stent was placed to mould the nose. In contrast to the original technique, which used an entirely acrylic stent, the modified approach employed a 0.036-in. stainless steel wire with an acrylic bulb. Adjustments to the plate involved selectively removing hard acrylic in areas requiring ridge movement, while a soft liner was added for moulding the alveolar ridge into proper arch form, with adjustments not exceeding more than 1 mm cumulatively at each session. Patients were scheduled for weekly follow-ups for necessary adjustments [9] (Figure 1).

FIGURE 1 | Modified Grayson's appliance with nasal stent (A), initial appliance to reduce the cleft (B) and then with intra-oral plate and RAS (C).

RAS technique with maxillary management consisted of two separate appliances for PSIO treatment, beginning with a maxillary device for the cleft defect wider than 7 mm. This initial device featured a pin, which was used for 3 weeks to rotate the more significant maxillary segment toward the midline. The pin was positioned on the mesial point of this segment, and parents were instructed to feed the baby before the pin to encourage the desired movement. This movement should be maintained every 3 h when the baby feeds to support rotation. Simultaneously, the device applies slight retention on the mesial side to the lesser segment to prevent it from collapsing toward the midline. After 3 weeks, the pin was removed, and the plate was adjusted for comfort, allowing normal maxillary arch development. This device was then secured with a fixed adhesive. At this stage, the RAS was introduced to manage nasal deformity. The RAS system was adjusted every 3–4 weeks to improve septum positioning, with follow-up conducted remotely.

Rhinoplasty Appliance System (RAS) comprises several key components: The nasal prosthesis kit with previous nasal corrections is offered in four sizes. It included nasal stents inserted into the nostrils and connected by columellar support, along with two lateral arms terminating in hooks for secure attachment. The kit included two protective pads between the adhesive tapes and the skin to prevent skin irritation. Additionally, the kit contains one labial adhesive tape and two adhesive tapes to secure the elastic elements for providing orthopaedic force. After applying the labial tape, the appliance is carefully placed in the patient's nostrils. This helped position the protective pads and elastic tapes correctly. Due to the uneven shape of the nostrils, the appliance usually leans toward the side with the cleft. First, the elastic on the unaffected side was attached to the appliance's hook, then the elastic on the cleft side. The RAS kit, which included four appliances, was provided at different stages of the treatment based on how well the nose was shaping. The smallest appliance was used first. As the cleft improved, a more significant appliance was used to adjust the nasal structures before the lip surgery [12] (Figure 1).

2.3 | Assessment of Cast and Facial Photographs

Maxillary arch dimensions and nasolabial parameters were calculated for pre(T0) and post(T1) PSIO using digital models obtained from an intra-oral scanner (Dentsply Sirona) and standard facial photographs. An orthodontic professional assessed the reference points for arch dimensions and facial changes. The reference points incorporated established methods from previous studies [14, 15]. The marked points were then digitised to calculate various linear and angular measurements relevant to cast dimensions (GOM Inspect software v 2.0.12018), and soft tissue facial parameters were measured on NemoStudio (Nemotech 2020) (Figure 2):

I. Cast analysis included reference points and lines based on anatomical structures. Linear, angular and midline variables were identified, and the reference points were marked on the digital models. Linear and angular values were calculated at T0 and T1. The following formula was applied to correct magnification errors in calculated values: measured value/actual value × 100 [15].

II. Facial analysis included standardised anterioposterior, profile and Worm's-eye extra oral photographs were taken pre and post-treatment using a Nikon DSLR camera with Nikon AF-S camera Nikkor 18–70 mm lens. Infants' heads were stabilised with a pillow and caregivers' support. Measurements included nostril width and height, columellar deviation angle, alveolar defect width, soft-tissue cleft distance, nasal bridge length, nasolabial angle and nasal tip projection. These were systematically repeated for randomly selected subjects to ensure consistency and reliability [14].

3 | Statistical Analysis

The data were collected and organised in Microsoft Excel. It was then assessed using SPSS (IBM-version 29 (2023)). The analysis included calculating the average and variability of the data, comparing the results within each group using a paired *t*-test and assessing the reliability of the measurements using Cronbach's alpha. An independent *t*-test was used to measure

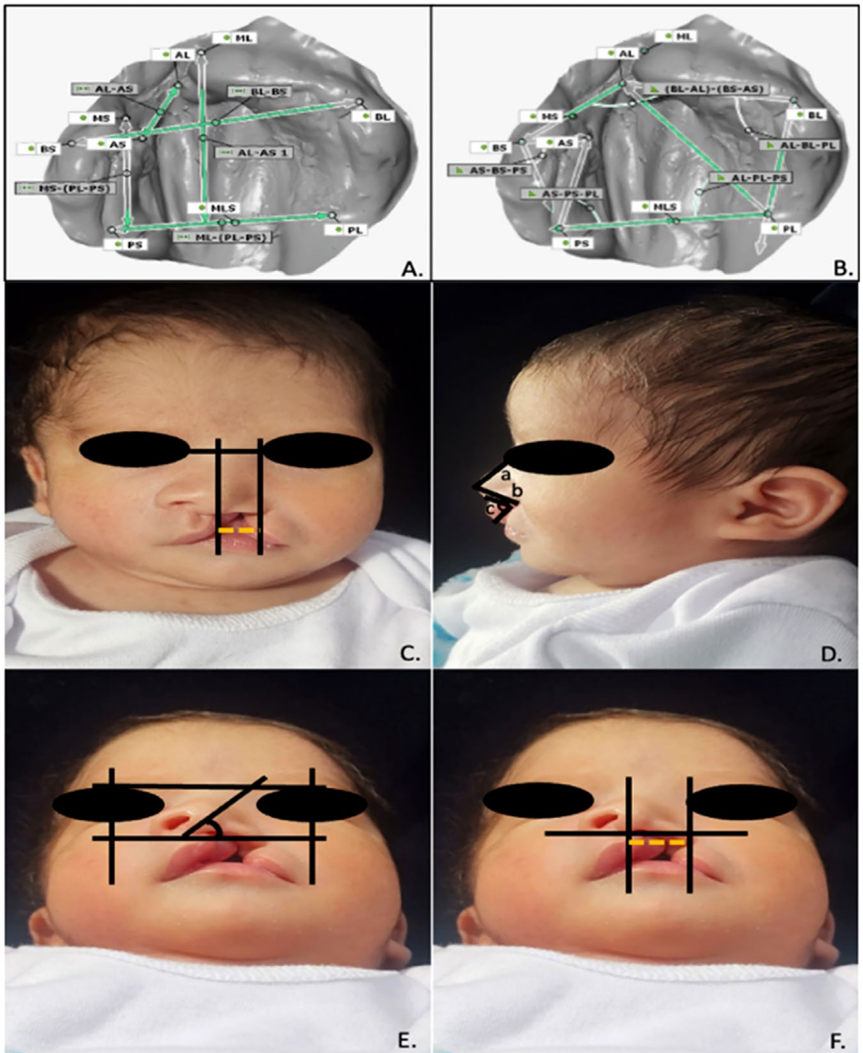

FIGURE 2 | Cast landmarks and planes used for linear and angular measurement in the alveolus (A, B). Reference lines used for measuring soft-tissue cleft defect in the frontal view, perpendicular projections on the interpupillary line for the ipsilateral subalare, columellar insertion and lateral canthus of the eye on the noncleft side. Perpendicular dropped from the interpupillary line to the two cleft margins (C). Points and lines in the profile view are used to measure nasal tip projection, base length, and nasolabial angle in the profile view (D). Measurement in Worm's eye view: Columella deviation angle and Nostril width measurement (E, F).

cast and facial parameters and compare the results between the two groups after treatment.

4 | Results

4.1 | Sample

Twenty-six infants participated in the study. Table 1 provides a sample description, and Figure 3 at T0 and T1 shows a sample representative of each technique. The mean age of the entire study group at the beginning of the treatment was 6.30 ± 1.48 days, with a mean cleft width of 12.53 ± 1.22 mm. The mean age at the post-treatment was 116.36 ± 2.4 days.

4.2 | Reliability of Measurements

In this study, we evaluated reliability using Cronbach's alpha. It was calculated to be 0.75 for cast parameters, demonstrating acceptable internal consistency, and 0.82 for extraoral facial parameters, indicating good internal consistency. Overall, both parameters exhibit satisfactory reliability.

4.3 | Cast Analysis

Table 2 shows the result for cast parameters of the alveolar arch; intragroup comparison using paired *t*-test at T0 and T1 for modified Grayson's techniques showed significant difference for

TABLE 1 | Sample characteristics.

	Group 1 Modified Grayson's	Group 2 RAS
Gender: male/female (*n*)	8/5	8/5
Side of cleft: left/right (*n*)	8/5	7/6
Age at trial entrance (days)	6.23 ± 1.65 days	6.60 ± 3.30 days
Cleft width at birth (mm)	12.87 mm ± 1.80 mm	12.25 mm ± 1.68 mm
Age post PSIO (days)	116 ± 3 days	117 ± 4 days

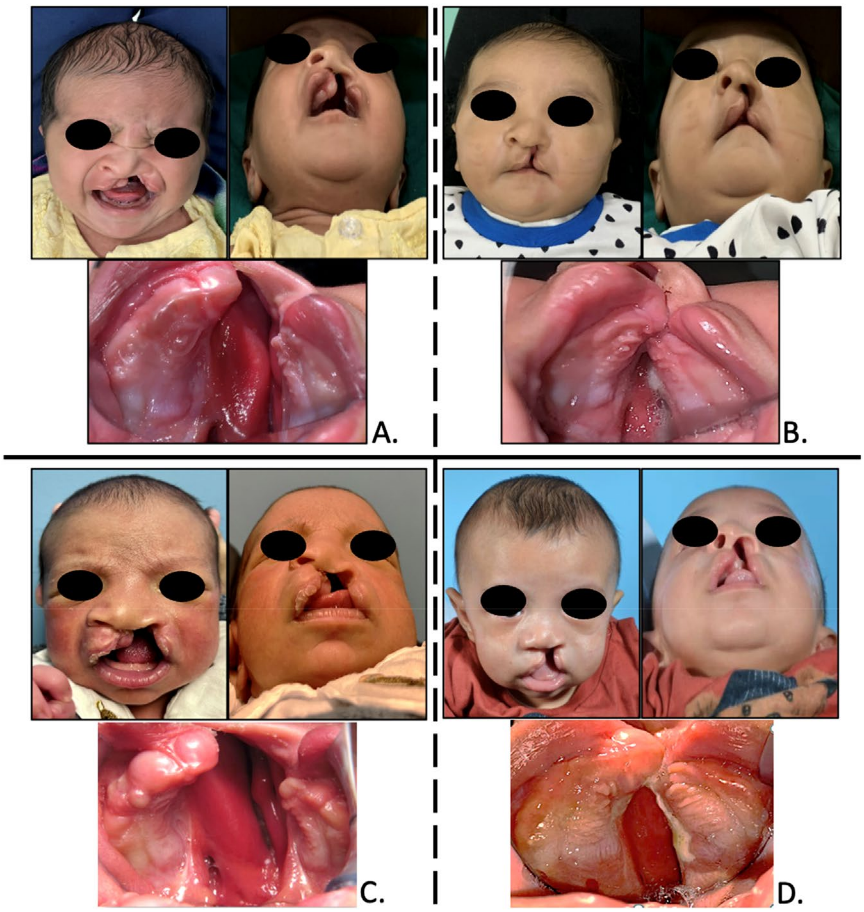

FIGURE 3 | Sample representative of each group: Modified Grayson's (pre-treatment (A) and post-treatment (B)) and RAS group (pre-treatment (C) and post-treatment (D)).

TABLE 2 | Intergroup comparison of cast-based parameters and extraoral facial parameters at T0 and T1 between the modified Grayson and RAS groups.

Cast-based parameters (mm and degrees)		Groups	*N*	Mean	SD	*t*	*p*[*]
PL-PS: Width between the major and minor segments (posterior-most point)	T0	Grayson	13	24.78	2.37	−0.15	0.881
		RAS	13	25.33	2.53		
	T1	Grayson	13	22.7	2.64	−0.41	0.683
		RAS	13	23.01	3		
BL-BS: Width between the major and minor segments at the intersection points between the lateral sulcus line and the gingival groove of the	T0	Grayson	13	28.45	4.25	0.134	0.895
		RAS	13	28.24	3.72		
	T1	Grayson	13	20.85	3.55	−0.987	0.333
		RAS	13	22.49	4.8		
AL-AS: Cleft gap between the major and minor segments (anterior-most points)	T0	Grayson	13	9.26	2.28	0.986	0.334
		RAS	13	8.28	2.76		
	T1	Grayson	13	2.05	1.9	0.043	0.966
		RAS	13	2.02	1.97		
ML-(PL-PS): Major segment length at the anterior-most point measured from the PL-PS line	T0	Grayson	13	24.32	3.78	−0.84	0.409
		RAS	13	25.37	2.53		
	T1	Grayson	13	24.7	3.35	−0.547	0.589
		RAS	13	25.39	3.06		
MS-(PL-PS): Minor segment length at the anterior-most point measured from the PL-PS line	T0	Grayson	13	16.6	3.47	−0.806	0.428
		RAS	13	17.61	2.89		
	T1	Grayson	13	18.27	2.84	−1.367	0.184
		RAS	13	19.76	2.73		
(AL-PL)-(PL-PS): Angle between the anterior and posterior-most point for the major segment	T0	Grayson	13	58.36	4.98	1.045	0.306
		RAS	13	56.46	4.25		
	T1	Grayson	13	58.43	5.73	0.152	0.88
		RAS	13	58.14	3.77		
(AS-PS)-(PL-PS): Angle between the anterior and posterior-most point for the minor segment	T0	Grayson	13	59.77	5.79	−0.567	0.576
		RAS	13	61.15	6.62		
	T1	Grayson	13	62.33	4.96	−0.465	0.646
		RAS	13	63.64	8.88		
AL-BL-PL: Major segment angle between the anterior and posterior-most point at the intersection point of the lateral sulcus and the gingival groove	T0	Grayson	13	97.73	4.17	0.097	0.923
		RAS	13	96.68	3.75		
	T1	Grayson	13	99.55	2.92	1.264	0.218
		RAS	13	98.64	2.78		
AS-BS-PS: Minor segment angle between the anterior and posterior-most point at the intersection point of the lateral sulcus and the gingival groove	T0	Grayson	13	102.95	6.41	1.635	0.115
		RAS	13	99.12	5.49		
	T1	Grayson	13	108.25	6.27	1.753	0.092
		RAS	13	104.18	7.82		

(Continues)

TABLE 2 | (Continued)

Cast-based parameters (mm and degrees)		Groups	N	Mean	SD	t	p*
(BL-AL)-(BS-AS): Major segment and minor segment angle between the anterior and posterior-most point at the intersection point of the lateral sulcus and the gingival groove	T0	Grayson	13	103.72	5.68	−0.179	0.86
		RAS	13	104.14	6.35		
	T1	Grayson	13	110	6.27	−0.19	0.851
		RAS	13	110.44	5.61		

Extra-oral facial parameter (mm and degrees)		Groups	N	Mean	SD	t	p
Nostril width (mm)	T0	Grayson	13	20.53	2.18	−0.32	0.751
		RAS	13	20.83	2.55		
	T1	Grayson	13	11.63	2.46	−0.548	0.588
		RAS	13	12.12	2		
Nostril height (mm)	T0	Grayson	13	2.01	0.32	−1.946	0.063
		RAS	13	2.62	1.09		
	T1	Grayson	13	5.64	0.77	−1.983	0.059
		RAS	13	6.39	1.13		
Soft-tissue cleft gap (mm)	T0	Grayson	13	12.87	1.8	−0.91	0.373
		RAS	13	12.25	1.68		
	T1	Grayson	13	6.21	0.85	−1.571	0.131
		RAS	13	7	1.65		
Columellar deviation angle (°)	T0	Grayson	13	57.99	5.47	0.618	0.542
		RAS	13	56.88	3.52		
	T1	Grayson	13	78.16	6.32	0.326	0.747
		RAS	13	77.42	5.18		
Nasal tip projection (mm)	T0	Grayson	13	1.84	0.39	1.173	0.258
		RAS	13	1.72	0.15		
	T1	Grayson	13	2.24	0.54	0.739	0.467
		RAS	13	2.08	0.55		
Nasal bridge length (mm)	T0	Grayson	13	2.29	0.42	1.171	0.259
		RAS	13	1.9	0.18		
	T1	Grayson	13	2.97	0.15	1.724	0.1
		RAS	13	2.1	0.23		
Nasolabial angle (°)	T0	Grayson	13	61.62	2.42	1.904	0.069
		RAS	13	59.53	3.12		
	T1	Grayson	13	108.96	1.88	−1.557	0.133
		RAS	13	111.01	4.35		

Abbreviations: *N*, Number of samples; SD, Standard deviation.
*Statistical significance set at 0.05.

BL-BS ($p=0.001$), AL-AS ($p=0.001$), AS-BS-PS ($p=0.003$) and (BL-AL)-(BS-AS) ($p=0.003$), while RAS technique showed significant difference for BL-BS ($p=0.001$), AL-AS ($p=0.001$), AS-BS-PS ($p=0.002$) and (BL-AL)-(BS-AS) ($p=0.001$) indicating improvement in cleft defect pre and post-treatment. The intergroup comparison showed no statistically significant difference using an independent *t*-test ($p<0.05$) between the means of both linear and angular assessment techniques.

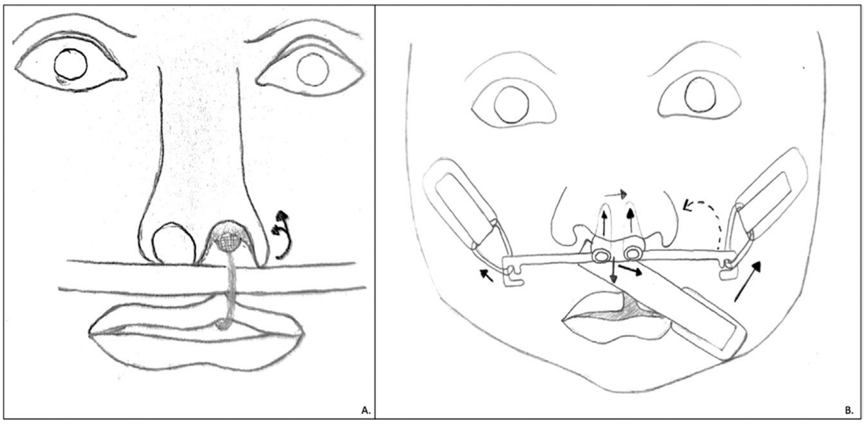

FIGURE 4 | Grayson's appliance: Nasal stent applying an upward and outward force vector for nasal moulding (A) and the RAS appliance applies the upward force from the increasing size of the nasal stents, the downward force from the nasal bridge/columellar support, and the downward pull on the upper lip from the slightly tilted tape (B).

4.4 | Facial Analysis

Pre- and post-treatment facial photographs were analysed for both groups. Within each group, significant improvements in nasolabial aesthetics, including nasal projection and columellar position, were observed when assessed by paired *t*-test ($p < 0.05$). Nonetheless, there were no statistically significant differences between the groups when comparing frontal, Worm's-eye and profile views (independent *t*-test). Detailed results of the group comparisons are presented in Table 2.

5 | Discussion

Various techniques have been developed to mould and approximate alveolar segments in unilateral cleft cases. However, these orthopaedic appliances mainly address the alveolar segments and neglect the surrounding deformed soft tissues like the columella-philtrum region and the nasal dome [16, 17]. PNAM was the first technique to overcome this by moulding bony segments and surrounding soft tissues using a nasal stent, including nasal cartilage moulding. The use of PSIO in CLP treatment has been contentious since its introduction in the 1950s. Prospective studies have highlighted the limited benefits of traditional PSIO in UCLP patients [18, 19]. The concept of PNAM emerged in the past decade, integrating nasal cartilage moulding with conventional alveolar orthopaedics. Nevertheless, critics argue that presurgical treatments are unnecessary, labour-intensive and financially burdensome [20]. This study evaluated and compared the efficacy and efficiency of two PSIO modalities: the widely-used modified Grayson's technique and a novel method using the Rhinoplasty Appliance System (RAS). Both techniques work on different modus operandi.

In the modified Grayson technique, alveolar segment moulding precedes nasal moulding once the alveolar defect reaches 5 mm [5]. Patients require weekly visits for appliance adjustments, including the addition of a soft liner and trimming of the intraoral plate for alveolar arch moulding. This necessitates increased laboratory work and more frequent patient visits. However, a nasal stent is introduced to facilitate soft tissue moulding once the cleft defect is reduced. The modus operandi with Grayson's appliance is the moulding of the alveolar arch by the acrylic intraoral appliance. In contrast, nasal cartilage moulding is done with a nasal stent to push the nasal cartilage upward and outward [9, 21] (Figure 4).

RAS is a preformed appliance that reduces the frequency of patient visits and laboratory work. It features nasal extensions for nasal tissue moulding and an intraoral passive plate that minimises the need for trimming and adjustment. It initially addresses columellar height deficiencies through a multipronged approach: upward pressure from the intranasal extensions, downward support from the columellar component and downward traction on the upper lip via the labial tape, addressing vertical and horizontal nasal imbalances. It also helps maintain post-surgical nasal shape [12, 22]. It exerts a greater force on the cleft side, drawing the RAS toward the cleft and rotating it counterclockwise. This rotation lifts the lower nostril on the cleft side, improving its appearance [13] (Figure 4).

Despite the different modus operandi of both techniques, our findings revealed no significant difference in the maxillary arch and facial parameters among the two treatment modalities. On the RAS system, professionals found that managing maxillary and nasal deformities separately positively impacts feeding physiology. The maxillary plate remains more stable than the NAM (Nasoalveolar Molding) device, which uses a stent connected to the maxillary plate. When these structures are managed separately, the maxillary plate is less likely to shift, leading to better feeding outcomes. In contrast, the NAM device's stent can affect the position of the maxillary plate, potentially disrupting feeding physiology.

Analysis of linear and angular variables and pre- versus post-treatment alveolus measurement indicate a reduction in the width of the cleft gap in both groups and improved nasolabial appearance. Both groups demonstrated similar outcomes in terms of alveolar and nasal cartilage moulding. This suggests that PSIO using RAS is as efficient as the modified Grayson's technique.

5.1 | Limitations

Although the sample size is small, both PSIO modalities appear to be effective treatment options. However, there are limitations due to uncertainties about patient compliance, as irregular clinic visits might impact the consistent use of appliances.

6 | Conclusion

PSIO therapy positively impacts the alveolar segment and facial appearance in UCLP patients using the Grayson technique and the Rhinoplasty Appliance System (RAS). Both groups showed comparable treatment outcomes in moulding the alveolar segment and shaping the nasal structures. No significant difference was observed when comparing the treatment effects of both techniques. While further research is necessary, incorporating the RAS into PSIO protocols appears promising for addressing cleft lip and palate deformities. This study highlights the potential of digital technology to enhance PSIO procedures, offering opportunities for standardising treatment and improving the patient experience.

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Ethics Statement

The board director for the Suma Mexico centre previously approved the study.

Consent

Informed consent was obtained by the centre.

Conflicts of Interest

Invention patent: Mejia, M (2021) Rhinoplasty Appliance and Method (56) of forming the same, Patent No.: US 11166835 B2, U.S. Patent and Trademark Office.

Data Availability Statement

The data that support the findings of this study are available from the corresponding author upon reasonable request.

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Supporting Information

Additional supporting information can be found online in the Supporting Information section.