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The nasoalveolar molding technique versus DynaCleft nasal elevator application in infants with unilateral cleft lip and palate

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Background: The introduction of presurgical nasoalveolar molding represented a significant departure from traditional molding methods. Developed by Grayson and colleagues in 1993, this technique combines an intraoral molding device with a nasal molding stent. This study aimed to compare the Grayson nasoalveolar molding appliance versus DynaCleft appliance as two methods of presurgical nasoalveolar molding.
Methods: A single-blinded, randomized, parallel-arm clinical trial was conducted. Sixteen infants with complete unilateral cleft lip and palate were enrolled and divided into two groups of eight. Group 1 was treated with a modified Grayson nasoalveolar molding appliance that included a nasal stent, while group 2 was treated with DynaCleft elastic adhesive tape and an external nasal elevator. Standardized digital photographs of each infant were taken at baseline and post-treatment using a professional camera. Nine extraoral anthropometric measurements were obtained from each image using image measurement software.
Results: The modified Grayson nasoalveolar appliance demonstrated a more significant improvement compared to DynaCleft in terms of alar length projection (on both sides), columella angle, and nasal tip projection. Symmetry ratios also showed enhancement, with significant improvements observed in nasal width, nasal basal width, and alar length projection ($p<0.05$).
Conclusion: Both the modified Grayson nasoalveolar appliance and DynaCleft appear to be effective presurgical infant orthopedics treatment options, demonstrating improvements in nasolabial aesthetics. The modified Grayson appliance, equipped with a nasal stent, improved nasal symmetry more effectively than DynaCleft, resulting in a straighter columella and a more medially positioned nasal tip.

Abbreviations: CLP, cleft lip and palate; NAM, nasoalveolar molding; PSIO, presurgical infant orthopedics; UCLP, unilateral cleft lip and palate

Keywords: Anthropometry / Cleft lip / Nasoalveolar molding

Original Article

INTRODUCTION

Cleft lip and palate (CLP) is a birth defect characterized by deficiencies and displacements in the soft tissues, bone, and cartilage of the orofacial region [1,2]. Although surgical advancements in lip repair have significantly improved outcomes for CLP, the procedure alone is insufficient to address all aspects of the anomaly. The primary objective in treating cleft lip, alveolus, and palate is to restore the normal anatomy of the affected area. Ideally, expanding deficient tissue and repositioning malpositioned structures should be done before surgical correction, allowing for a less invasive procedure for the patient. In recent years, the multidisciplinary management of patients with CLP has made significant strides due to advanced surgical tech-

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niques, optimal timing, and the integration of methods such as presurgical infant orthopedics (PSIO) [3]. The introduction of presurgical nasoalveolar molding (NAM) represented a departure from traditional molding methods. Developed by Grayson et al. in 1993 [4], this technique combines an intraoral molding device with a nasal molding stent. Presurgical NAM has become the preferred method of molding due to its effectiveness and efficiency in preparing patients for surgical lip repair. However, there is still no ideal technique or appliance that is universally accepted in the literature for providing the necessary presurgical facilitation and aesthetic improvement with long-term stability and satisfaction for both infants and parents [5,6].

The primary mechanism of action of presurgical NAM suggests that the elevated levels of hyaluronic acid in infant cartilage result in a temporary reduction in elasticity, coupled with enhanced flexibility and plasticity of the cartilaginous structure [7]. The underlying principle of alveolar and nasal molding is based on negative sculpting and passive molding. Passive molding employs custom-made plates to guide the growth and orientation of the alveolus. Conversely, negative sculpting involves a sequence of adjustments to the surface of the molding appliances, achieved by adding or removing material in specific areas to sculpt the desired shape of the alveolus and nose [8].

Introduced in 2013, the DynaCleft represents an alternative PSIO that features an elastic adhesive tape and a nasal component, but lacks alveolar plates [9]. It operates on the same principles as presurgical NAM, aiming to reshape and optimize the misshapen deformity before surgery through the use of an elastic adhesive tape and an external nasal elevator. The DynaCleft method offers an advantage over the Grayson technique in that it is easier for parents to manage and apply at home. This system also decreases the necessity for clinical visits and professional adjustments, thereby enhancing parental compliance with the treatment [10,11].

According to recent systematic reviews on PSIO treatment modalities, there are no randomized clinical trials that compare the effectiveness of NAM and DynaCleft in treating unilateral CLP (UCLP) [12,13]. The literature shows considerable variation in assessing the effectiveness of PSIO, lacking a unified consensus on the appropriate measures to use. However, Castillo et al. [14] have proposed a new core outcome set of anthropometric measures, which has been validated through expert consensus and is recommended for use before and after PSIO treatment.

Therefore, the primary objective of this study is to assess the impact of using the modified Grayson NAM appliance with a nasal stent versus the DynaCleft with a nasal elevator on the aesthetic appearance of the nasolabial soft tissue in infants with UCLP immediately before surgical lip repair. This evaluation will utilize a newly proposed core outcome set specifically designed for nasolabial anthropometric measures. The core outcome set comprises 18 anthropometric measures, both intraoral and extraoral, targeting the nostril, columella, alar base, lip, and cleft segment.

METHODS

Trial design

This was a randomized, parallel-arm clinical trial with a 1:1 allocation ratio, conducted within a superiority trial framework. The study protocol was registered in the PACTR (Pan African Clinical Trial Register) under the identification number PACTR202310506519010. Ethical approval and written informed consent were obtained from the patients' guardians.

Participants

The infants enrolled in the current study were selected according to the following criteria: (1) infants between 1 week and 3 months of age; (2) non-syndromic with no other medical conditions; and (3) complete UCLP.

Infants with syndromic CLP, incomplete UCLP, or bilateral CLP were excluded from the study. The research was carried out at a private maxillo-facial center, Innovinity Medical Hub, located in Heliopolis, Cairo, Egypt. This facility served as the sole center for PSIO treatment, follow-ups, and data collection. To exclude any cleft-associated syndromes, all infants underwent evaluation by a genetics specialist. This evaluation included a comprehensive review of family and medical histories along with a detailed clinical examination. During the examination, anomalies in the eyes, ears, skin tags, and both upper and lower limbs were assessed. Sixteen infants with complete UCLP were recruited and subsequently randomized for the study.

Interventions

After the diagnosis and selection of eligible infants, written consent was obtained from the parents or caregivers to approve participation in the study and initiation of the treatment. Infants were then randomized to receive either a modified Grayson NAM appliance with a nasal stent or elastic-taped DynaCleft with an external nasal elevator.

In the NAM group, the infant was securely held upside down in the parent/caregiver's lap to facilitate the impression-taking of the maxillary arch. This was done using a custom-made tray of appropriate size, loaded with heavy-body rubber putty and a light-body rubber as a washout (Zetaplus System, Zhermack). Before taking the impression, a piece of gauze soaked in glycerin was placed in the cleft gap and secured with dental floss.

Care was taken to ensure that all impression material was completely removed from the oral cavity once set, to prevent any blockage of the airways. The impressions were then cast in dental stone to create a master cast, on which the NAM plate was constructed using clear self-cure acrylic. The nasal stent component, included from the outset, was made from stainless steel wire (0.036-inch width) with an acrylic bulb at the end. Alongside the NAM plate and nasal stent, a dental conditioner was applied to the acrylic plate, and adhesive tape was used to approximate the lips and alveolar segments and to secure the plate in place. Patients were scheduled for weekly follow-ups, during which the NAM plate was modified by selectively grinding the acrylic in areas where movement was desired and adding a soft liner in the opposite areas. Adjustments to the position of the nasal stent were made at each visit to maintain the correct positioning and desired pressure.

In the DynaCleft group, the elastic adhesive DynaCleft tape was applied directly over the cleft area to bring the lips and alveolar segments closer together. An external nasal elevator was placed on the nostril of the affected side and secured with adhesive tape on the forehead. The tension from the elastic adhesive tape was maintained by progressively shortening the ends, and the nasal elevator was adjusted regularly to ensure it remained in the correct position. Infants in both groups attended weekly follow-up appointments for adjustments. The study lasted for at least 2 months, culminating in a surgical lip repair at 3 months of age. This procedure was performed by an experienced oral and maxillo-facial surgeon using the Delaire technique, which notably avoids the blind dissection of the alar cartilage [15]. The surgery took place in a specialized maxillo-facial hospital, not at the center.

Outcomes

The newly proposed core outcome set for anthropometric evaluations for PSIO in UCLP [14] served as the primary outcome of this study. Nine anthropometric measures were employed to assess the effectiveness of PSIO using extraoral measures targeting the nasolabial soft tissue esthetics. The measures are as follows: (1) Columella height: the vertical distance between the junction point of the columella to the philtrum and the superior medial point of the nostril apertures; (2) Nasal tip projection: the vertical distance between the nasal apex and the junction point of the columella with the philtrum; (3) Projection alar length: the vertical distance between the nasal apex and the alar grooves; (4) Width of the nostril: the horizontal distance between the inner lateral and medial borders of the nostril aperture; (5) Nasal basal width: the horizontal distance between the junction point of the columella to the philtrum and the point of the labial insertion of the nasal ala; (6) Angle of the columella: the angle formed from the tip of the columella to the junction

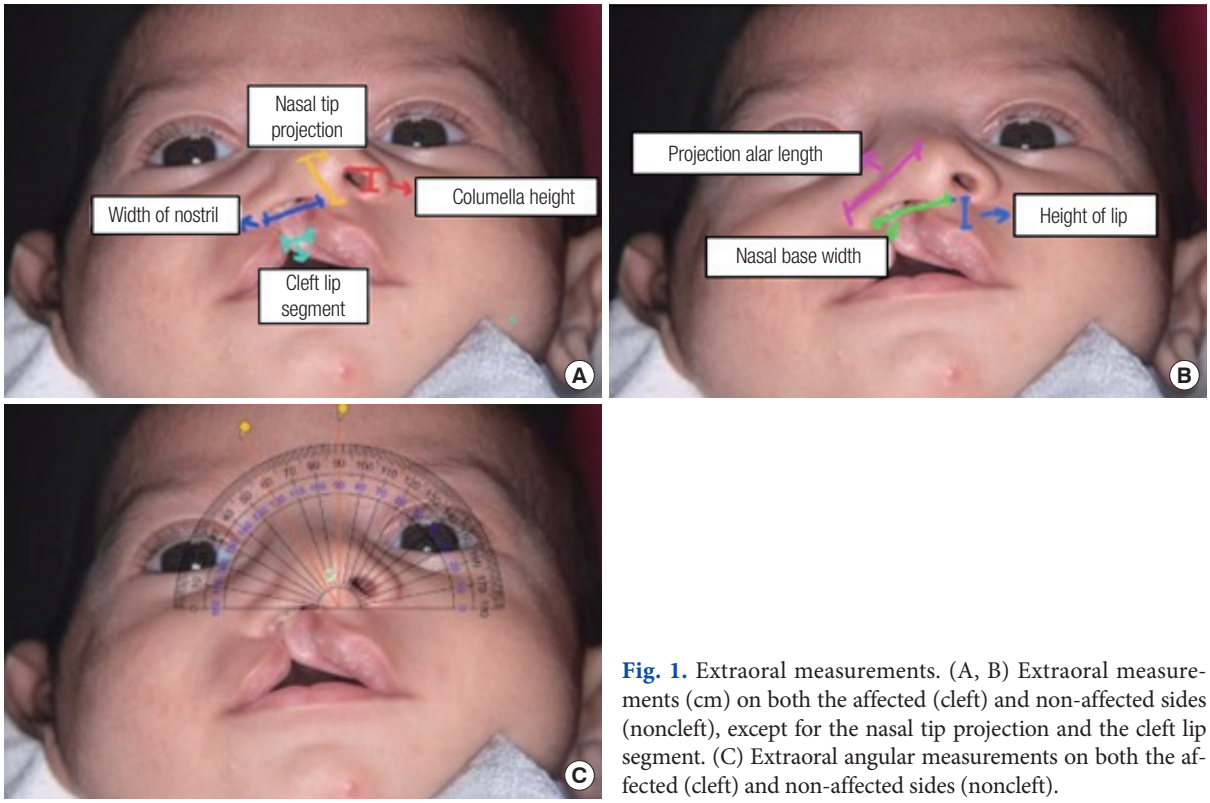

Fig. 1. Extraoral measurements. (A, B) Extraoral measurements (cm) on both the affected (cleft) and non-affected sides (noncleft), except for the nasal tip projection and the cleft lip segment. (C) Extraoral angular measurements on both the affected (cleft) and non-affected sides (noncleft).

point of the columella with the philtrum and the bisector of the reference line. The angle measurement is done on the affected nostril; (7) Cleft lip segment: it represents the cleft gap length presented by the distance between the medial point of the greater lip segment to the more medial point of the lesser lip segment; (8) Height of the noncleft lip: distance between the midpoint of the junction of the columella with the philtrum to the junction of the ridge and external cupid's bow inside the noncleft lip; and (9) Height of the cleft lip: distance between the midpoint of the junction of the columella with the philtrum to the junction of the ridge and external cupid's bow inside the cleft lip.

The extraoral measurements were taken in centimeters on both the affected (cleft) and unaffected (noncleft) sides, with the exception of the nasal tip projection and the cleft lip segment. These measurements are depicted in Fig. 1. Data were collected at baseline (T0) and after PISO treatment (T1) using standardized high-resolution images captured with a Canon EOS 2000D camera. The software tool imagemeasurement.online was utilized for these measurements. Each image included a ruler for photo calibration and standardization purposes. During the sessions, infants were seated on the lap of a parent or caregiver, and both frontal and basal extraoral views were captured at baseline and post-treatment.

In addition to the primary measures, the symmetry ratio was calculated as the ratio of the affected side to the non-affected side before and after PISO treatment. Improved symmetry is indicated by a ratio value approaching one [16]. Two blinded researchers conducted all the measurements. To ensure inter-observer and intra-observer agreement, these measurements were repeated after 1 week by the same researchers.

Sample size

The sample size was calculated based on a previous study [17] that assessed cleft lip height following PSIO treatment. The independent *t*-test was used, assuming a 5% level of statistical significance, 80% power, and an effect size of 1.95. Initially, the total sample size required was 12 infants. To accommodate a potential 25% dropout rate, this number was increased to 16. Consequently, with an allocation ratio of 1:1, each group consisted of eight infants. The sample size calculation was performed using G*Power software version 3.1.9.7 [18].

Randomization

Sequence generation was performed using a computer-generated random number from the random.org website, maintaining a 1:1 allocation ratio [19]. Allocation sequence concealment was achieved through the use of opaque sealed envelopes, sequentially numbered and containing a folded paper with the name of the intervention. Implementation was conducted by a researcher who was blinded to the intervention, enrolling patients irreversibly into each group based on the contents of the envelope.

Blinding

The current study employed a single-blind design. Outcome assessors were blinded, as they evaluated images that did not reveal the PSIO appliance being used. Due to the nature of the intervention, it was not possible to blind the operators or the parents of the patients.

Statistical methods

The level of statistical significance was set at 5%. Statistical analysis was conducted using R and R Studio software [20,21]. Data were organized, manipulated, and summarized with the "tidyverse" R package [22]. Continuous data were presented as mean and standard deviation. The normality of the data distribution was assessed using the Shapiro-Wilk test function from the "rstatix" R package [23]. For intergroup comparisons at T1, the independent *t*-test was utilized. In contrast, the paired *t*-test was employed for intragroup comparisons between T0 and T1, as well as for the symmetry ratio intragroup comparison. These analyses were performed using the *t*-test function from the "rstatix" R package, with the "paired" argument set to true when necessary [23]. Effect sizes and their 95% confidence intervals were calculated using Cohen's d effect size with the Hedge's bias correction for small sample sizes. This was done using the Cohen's d effect size function from the "rstatix" R package, again setting the "paired" argument to "true" for paired samples [23]. Results were tabulated using the "knitr" and "kableExtra" R packages [24,25]. Interclass correlation coefficients, which assess intra-observer and inter-observer reliability, were calculated using the intraclass correlation function from the "psych" R package [26]. Higher values (i.e., closer to 1) indicate greater reliability.

RESULTS

A total of 30 infants were assessed for eligibility, and 16 were enrolled in the study to receive either NAM with a nasal stent

Table 1. Baseline characteristics of the infants in each group

Group	No. of patients	Age in days, mean ± SD	Sex (M/F)	Cleft side (right/left)
DynaCleft	8	40.43 ± 25.75	5/3	4/4
Nasoalveolar molding	8	38.57 ± 30.86	4/4	5/3
Total	16	39.5 ± 27.32	9/7	9/7

SD, standard deviation.

or DynaCleft with an external nasal elevator as in (Figs. 2,3). Each group consisted of eight infants, with one infant from each group lost to follow-up and unreachable upon recall. Baseline characteristics for the infants in each group are presented in Table 1. The CONSORT flowchart, depicted in Fig. 4, illustrates the flow of participants through the study.

Intra-observer and inter-observer agreement

Interclass correlation coefficients were calculated to assess both intra-observer and inter-observer reliability. The reliability values for intra-observer measurements ranged from 0.76 to 0.87, while inter-observer measurements ranged from 0.79 to 0.89, indicating good reliability in all assessments.

Intragroup comparison

Tables 2 and 3 present the measurement values for each group before and after PSIO treatment. Approximately half of the measurements (on both cleft and noncleft sides) demonstrated statistically significant improvement at T1 compared to baseline values, while the remaining measurements showed nonsignificant improvement.

Intergroup comparison

Table 4 presents a comparison between the two groups at T1 (after PSIO treatment). The projection alar length (on both sides), the angle of the columella, and the nasal tip projection were statistically significantly greater in the DynaCleft group

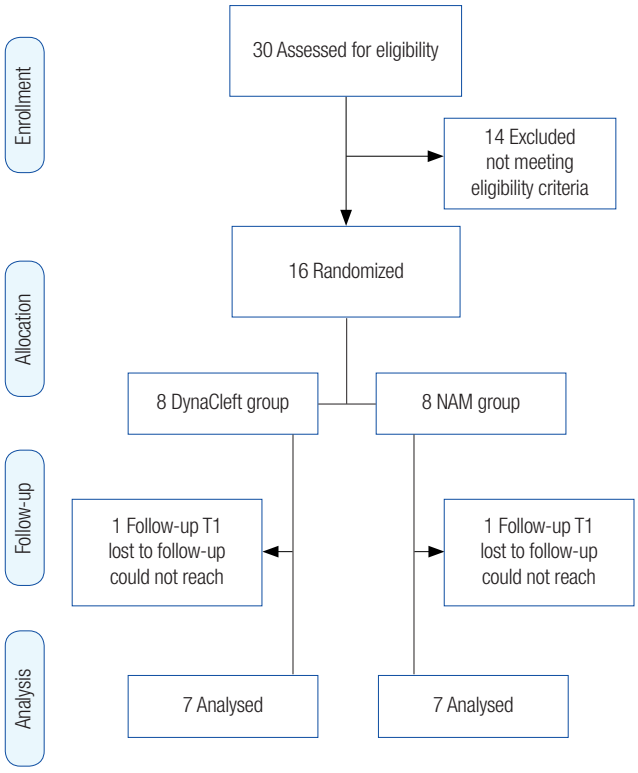

Fig. 4. The CONSORT flowchart. NAM, nasoalveolar molding.

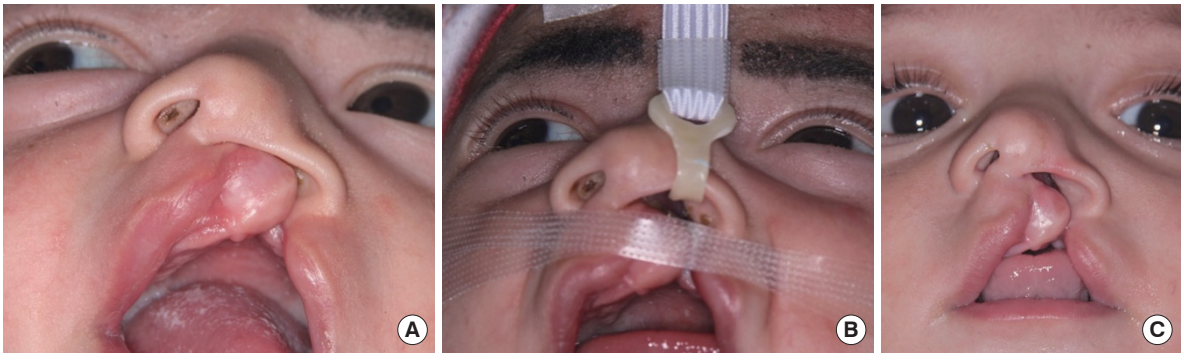

Fig. 2. Clinical photograph of a patient treated with DynaCleft. (A) Before use of the DynaCleft device. (B) During treatment. (C) After DynaCleft application.

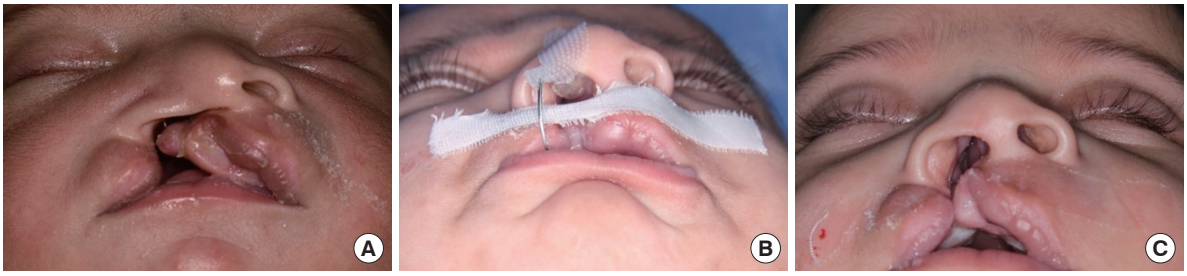

Fig. 3. Clinical photographs of a patient treated with nasoalveolar molding (NAM). (A) Before NAM. (B) During NAM. (C) After NAM.

Table 2. DynaCleft group measurements at baseline and after treatment

Measurement name	Baseline (cm), mean ± SD	After treatment (cm), mean ± SD	Cohen's d (95% CI)	*p*-value
Projection alar length (noncleft side)	2.46 ± 0.29	2.36 ± 0.42	–0.18 (–0.96 to 0.7)	0.596
Projection alar length (cleft side)	3.46 ± 0.28	2.89 ± 0.21	–1.14 (–2.36 to –0.73)	0.013[a]
Cleft lip segment	1.47 ± 0.41	0.77 ± 0.37	–1.29 (–2.63 to –0.94)	0.008[a]
Angle of columella (º)	44.57 ± 15.82	36.86 ± 15.52	–1.37 (–4.07 to –0.73)	0.006[a]
Columella height (noncleft side)	0.90 ± 0.12	0.86 ± 0.18	–0.18 (–0.90 to 0.83)	0.604
Columella height (cleft side)	0.34 ± 0.24	0.43 ± 0.21	0.47 (–0.13 to 2.13)	0.200
Height of the noncleft lip	1.20 ± 0.22	1.06 ± 0.25	–0.56 (–1.97 to –0.12)	0.014[a]
Height of the cleft lip	0.71 ± 0.17	0.77 ± 0.42	0.16 (–0.82 to 0.9)	0.643
Nasal basal width (noncleft side))	1.06 ± 0.31	0.93 ± 0.16	–0.52 (–2.48 to 0.12)	0.163
Nasal basal width (cleft side)	3.10 ± 0.38	2.27 ± 0.36	–1.15 (–3.14 to –0.86)	0.013[a]
Nasal tip projection	1.49 ± 0.25	1.36 ± 0.15	–0.36 (–1.20 to 0.39)	0.321
Nostril width (noncleft side)	0.96 ± 0.10	0.91 ± 0.09	–0.38 (–1.27 to 0.18)	0.289
Nostril width (cleft side)	2.66 ± 0.48	1.87 ± 0.44	–1.01 (–2.81 to –0.63)	0.022[a]

SD, standard deviation; CI, confidence interval.
[a]Significant *p*-value.

Table 3. Nasoalveolar molding group measurements at baseline and after treatment in cm

Measurement name	Baseline (cm), mean ± SD	After treatment (cm), mean ± SD	Cohen's d (95% CI)	*p*-value
Projection alar length (noncleft side)	1.97 ± 0.41	1.71 ± 0.42	–0.35 (–1.25 to 0.37)	0.325
Projection alar length (cleft side)	2.86 ± 0.69	2.44 ± 0.45	–0.55 (–1.61 to 0.07)	0.145
Cleft lip segment	1.36 ± 0.35	0.80 ± 0.42	–1.25 (–7.20 to –0.74)	0.009[a]
Angle of columella (º)	32.86 ± 13.95	22.86 ± 8.53	–0.78 (–3.67 to –0.11)	0.044[a]
Columella height (noncleft side)	0.87 ± 0.49	0.73 ± 0.21	–0.22 (–0.80 to 0.87)	0.535
Columella height (cleft side)	0.41 ± 0.38	0.41 ± 0.17	0 (–0.53 to 1.97)	1.000
Height of the noncleft lip	0.86 ± 0.26	1.00 ± 0.17	0.45 (–0.22 to 1.54)	0.220
Height of the cleft lip	0.51 ± 0.40	0.57 ± 0.26	0.11 (–0.72 to 0.83)	0.752
Nasal basal width (noncleft side)	0.86 ± 0.15	1.07 ± 0.14	1.27 (1.00 to 2.63)	0.008[a]
Nasal basal width (cleft side)	2.44 ± 0.68	1.97 ± 0.52	–0.63 (–1.86 to –0.08)	0.013[a]
Nasal tip projection	1.11 ± 0.46	1.11 ± 0.22	0 (–0.68 to 0.89)	1.000
Nostril width (noncleft side)	0.84 ± 0.15	0.87 ± 0.16	0.26 (–0.38 to 1.97)	0.457
Nostril width (cleft side)	1.94 ± 0.39	1.47 ± 0.36	–0.89 (–2.29 to –0.39)	0.035[a]

SD, standard deviation; CI, confidence interval.
[a]Significant *p*-value.

than in the NAM group.

Intragroup symmetry ratios

Table 5 presents the symmetry ratios for each group by calculating the ratio of the affected side (cleft side) to the non-affected side (noncleft side) before and after treatment. While symmetry improved in both groups, significant enhancement was observed in only three measures.

DISCUSSION

This study aimed to investigate the effects of using a modified Grayson NAM appliance with a nasal stent compared to a DynaCleft with an external nasal elevator on nasolabial esthetics and symmetry. While the Grayson NAM appliance is a common PSIO treatment option, DynaCleft offers advantages such as ease of use and application, and it does not interfere with an infant's feeding [3]. However, no randomized clinical trials have been published that compare the use of NAM with DynaCleft, as indicated by two recent systematic reviews [12,13]. Two cohort studies [9,10] have compared NAM to DynaCleft, and one retrospective study compared DynaCleft to no treatment [27]. These studies were compromised by a significant risk of bias due to confounding factors, participant selection, and measurement issues. Thus, there is a clear need for a well-designed randomized clinical trial to serve as the gold standard for comparative effectiveness.

The NAM appliance utilized in this study is a modified Gray-

Table 4. Intergroup comparison at after treatment

Measurement name	DynaCleft (cm), mean ± SD	NAM (cm), mean ± SD	Cohen's d (95% CI)	*p*-value
Projection alar length (noncleft side)	2.36 ± 0.42	1.71 ± 0.42	1.43 (0.67 to 3.02)	0.014[a]
Projection alar length (cleft side)	2.89 ± 0.21	2.44 ± 0.45	1.17 (0.35 to 2.67)	0.044[a]
Cleft lip segment	0.77 ± 0.37	0.80 ± 0.42	–0.07 (–1.1 to 1.17)	0.895
Angle of columella (°)	36.86 ± 15.52	22.86 ± 8.53	1.05 (0.20 to 2.19)	0.045[a]
Columella height (noncleft side)	0.86 ± 0.18	0.73 ± 0.21	0.61 (–0.45 to 2.39)	0.249
Columella height (cleft side)	0.43 ± 0.21	0.41 ± 0.17	0.07 (–1.06 to 1.52)	0.889
Height of the noncleft lip	1.06 ± 0.25	1.00 ± 0.17	0.25 (–0.80 to 1.46)	0.630
Height of the cleft lip	0.77 ± 0.42	0.57 ± 0.26	0.54 (–0.69 to 1.76)	0.310
Nasal basal width (noncleft side)	0.93 ± 0.16	1.07 ± 0.14	–0.89 (–2.39 to 0.09)	0.100
Nasal basal width (cleft side)	2.27 ± 0.36	1.97 ± 0.52	0.62 (–0.31 to 2.30)	0.241
Nasal tip projection	1.36 ± 0.15	1.11 ± 0.22	1.21 (0.28 to 3.40)	0.035[a]
Nostril width (noncleft side)	0.91 ± 0.09	0.87 ± 0.16	0.31 (–0.88 to 1.65)	0.552
Nostril width (cleft side)	1.87 ± 0.44	1.47 ± 0.36	0.94 (–0.09 to 3.05)	0.086

NAM, nasoalveolar molding; SD, standard deviation; CI, confidence interval.
[a]Significant *p*-value.

Table 5. Symmetry ratios for each group before and after treatment

Measurement name	Baseline (cm), mean ± SD	After treatment (cm), mean ± SD	Cohen's d (95% CI)	*p*-value
DynaCleft group				
Columella height	0.39 ± 0.26	0.50 ± 0.21	0.42 (–0.21 to 1.73)	0.253
Projection alar length	1.42 ± 0.12	1.26 ± 0.24	–0.76 (–1.89 to –0.25)	0.045[a]
Nostril width	2.78 ± 0.42	2.07 ± 0.54	–0.84 (–2.23 to –0.34)	0.043[a]
Nasal basal width	3.16 ± 1.03	2.55 ± 0.72	–0.55 (–1.84 to 0.07)	0.143
Lip height	0.61 ± 0.16	0.76 ± 0.49	0.28 (–0.87 to 0.74)	0.423
NAM group				
Columella height	0.45 ± 0.25	0.56 ± 0.1	0.39 (–0.25 to 1.97)	0.278
Projection alar length	1.53 ± 0.65	1.53 ± 0.62	–0.002 (–0.72 to 0.68)	0.995
Nostril width	2.34 ± 0.46	1.75 ± 0.55	–1.35 (–3.19 to –0.88)	0.006[a]
Nasal basal width	2.94 ± 0.99	1.87 ± 0.56	–0.91 (–2.25 to –0.69)	0.032[a]
Lip height	0.57 ± 0.35	0.55 ± 0.21	–0.05 (–0.91 to 0.74)	0.884

SD, standard deviation; CI, confidence interval; NAM, nasoalveolar molding.
[a]Significant *p*-value.

son NAM, enhanced by the immediate addition of a nasal stent before treatment commencement. This approach demonstrated greater improvement in nasolabial outcomes compared to the outcomes observed when the addition was delayed, as indicated by a previous study [28]. This was particularly evident in cases with wider cleft gaps (more than 5 mm). The DynaCleft tape, equipped with an external nasal elevator, was selected as a simpler alternative to PSIO due to its ease of use and the straightforwardness of follow-ups by parents. However, it requires diligent compliance from the parents to maintain the correct positioning of both the elevator and the tape to achieve the desired outcomes [3]. Standardized digital photographs of infants, taken with a professional camera, were employed for measurements following image calibration. The application of image measurement software is recognized as a quick, noninvasive, and reliable method for two-dimensional indirect assessment [29]. Training for outcome assessors and the repetition of measurements were conducted to ensure robust intra-observer and inter-observer agreement.

The choice of outcome measures for nasolabial aesthetics in the literature on PSIO treatment options varies widely, with no consensus on which measures to use. This variability can hinder comparisons among studies and lead to differing interpretations and results [13]. The newly proposed core outcome set for anthropometric evaluation in PSIO treatment of UCLP infants has been validated through the consensus of subject-matter experts from various geographical settings. It is recommended for use before and after PSIO treatment to produce meaningful and comparable data that will facilitate future study comparisons [14]. This core outcome set includes 18 anthropometric measures, both intraoral and extraoral, of which nine were specifically selected to reflect changes in the nose and lip

before and after PSIO treatment.

This study was conducted as a single-blinded randomized clinical trial, with only the outcome assessors blinded due to the nature of the intervention. Ideally, blinding both parents and operators would be preferred to minimize bias and enhance compliance with the intervention. This represents one of the limitations of the current study, which was addressed by adhering closely to a prespecified protocol. Another limitation is the ongoing need for larger, high-quality randomized clinical trials that explore various PISO options in different cases of UCLPs. The use of two-dimensional indirect anthropometric measurements on digital images is considered reliable; however, it is susceptible to distortion and magnification errors, which could pose limitations.

The current study demonstrated improvements in anthropometric measures related to nasolabial aesthetics following treatment with different PISO approaches. Both the NAM with nasal stent and DynaCleft with external nasal elevator enhanced nasolabial aesthetics, showing significant improvements in cleft lip segment, angle of the columella, nasal basal width, and nostril width. Notably, the projection of alar length on the cleft side in the DynaCleft group showed more significant improvement post-treatment. This enhancement is likely due to the external nasal elevator's pulling force, which increases the height and reduces the width of the nostril. This is further supported by the improved symmetry in the projection of alar length, which improved from 1.42 to 1.26 after treatment with DynaCleft. These findings are consistent with previous studies that reported improvements following PISO treatment for both modalities [9,10].

In the intergroup comparison, NAM with the nasal stent significantly improved the projection and alar length on both the affected and non-affected sides compared to DynaCleft. This resulted in more rounded nostrils and a reduction in nostril width. These findings highlight the potential benefits of using the NAM nasal stent from the outset. Unlike the DynaCleft nasal elevator, which requires frequent adjustments by parents to maintain the correct angle, the NAM nasal stent is fixed in place and only adjusted by the orthodontist to achieve the desired position [3].

Unlike previous studies on NAM versus DynaCleft [9,10], this current study demonstrated a significant improvement in the columella angle on the affected side and in nasal tip projection following NAM treatment. This treatment helped in straightening the columella and positioning the nasal tip projection more vertically. These findings are consistent with a previous study that compared the use of NAM with the immediate or delayed addition of a nasal stent once the cleft width was reduced to less than 5 mm [28].

Regarding the symmetry of the nose before and after treatment, both nostril width and nasal basal width demonstrated values closer to 1, indicating a significant improvement with NAM. This aligns with other studies that have noted enhanced symmetry following NAM therapy [16,28]. Additionally, the projection of alar length showed notable improvement in symmetry with DynaCleft, likely due to the external pull exerted by the nasal elevator. To summarize, our study results indicated greater improvements in columella angle, nasal tip projection, and alar length projection when using NAM with a nasal stent compared to DynaCleft. This enhancement in symmetry after treatment further supports these findings.

In conclusion, both the Grayson NAM and DynaCleft may serve as effective PSIO treatment options, improving nasolabial aesthetics and reducing cleft size before surgical lip repair. The NAM with a nasal stent notably improved nasal symmetry compared to DynaCleft, resulting in a straighter columella and a more medially positioned nasal tip. Therefore, the use of Grayson NAM with a nasal stent is recommended for infants with UCLP to achieve greater improvements in nasolabial aesthetics.

NOTES

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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Ethical approval

This study was approved by the Research Ethics Committee of the Faculty of Dentistry, Al-Azhar University (IRB000141311-15/22) and performed in accordance with the principles of the Declaration of Helsinki.

Patient consent

The informed consent forms were signed by the patients' guardians.

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