#### **Original Article**

### Comparative clinical evaluation of modified and conventional Grayson's presurgical nasoalveolar molding technique in infants with complete unilateral cleft lip and palate

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#### ABSTRACT

**Background:** Presurgical nasoalveolar molding (PNAM) was introduced by Grayson et al., in 1993 to presurgically mold the alveolus, lip, and nose in infants with cleft lip and palate (CLP). The aim of this comparative clinical trial was to evaluate the efficacy and efficiency of Modified and Conventional Grayson's PNAM in patients concerning morphological and anatomical changes in maxillary alveolus, nasal symmetry, number of visits, and duration of treatment.

**Materials and Methods:** In this comparative clinical trial study, I 6 infants with unilateral complete CLP were equally divided into two groups: Group I (modified PNAM technique using titanium molybdenum alloy [TMA] wire nasal stent) and Group II (conventional PNAM technique using stainless steel wire nasal stent). Patient photographic evaluation of nasal symmetry and maxillary study model CAD-CAM analysis, pre- and post-operatively in both groups, were compared using a paired *t*-test between the groups using the Chi-square test with P < 0.05 as statistically significant. **Results:** In both groups, on evaluating nasal measurements, statistically significant (P < 0.05) decrease in nasal width and increase in columella deviation angle, a decrease of nostril length, and an increase of columella length in Group I were observed. On maxillary study model evaluation, a statistically significant (P < 0.05) decrease in width of the alveolar cleft was noticed in both groups and lateral deviation of the incisal point in Group I and width of the palatal cleft in Group II was noticed. **Conclusion:** This study showed a morphological improvement in nasal symmetry and maxillary alveolar morphology in complete unilateral CLP patients, treated with both Modified and Conventional PNAM techniques, with the Modified PNAM technique being more efficient for treatment duration and the number of adjustments as there are less number of visits.

Key Words: Cleft lip, cleft palate, nasal, titanium molybdenum alloy, unilateral

#### INTRODUCTION

Nonsyndromic orofacial clefts, including cleft lip, cleft lip and palate (CLP), and cleft palate alone, are among the leading class of birth defects.<sup>[1]</sup> It is the most common structural abnormality in the embryonic period of life, with an incidence of approximately

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Website: www.drj.ir www.drjjournal.net www.ncbi.nlm.nih.gov/pmc/journals/1480 1/500–700.<sup>[2-5]</sup> Its severity and form varies considerably among each patient. The nasolabial deformities also significantly increase with wider, more voluminous clefts. With deficient hard- and

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soft-tissue elements, these clefts pose a compelling surgical challenge for positive functional and cosmetic outcomes.<sup>[6]</sup>

The management of cleft patients should be approached as a multidisciplinary team.<sup>[7]</sup> It has emerged dramatically in recent years because of leading surgical techniques, timing, and integration of methods such as presurgical orthopedics. The basic treatment objective is to bring back the normal anatomy. In the past decade, it has been made known that improvement of nasal abnormality by elongating the nasal mucosal lining, and the fulfillment of nonsurgical columella lengthening, can be united with the shaping of the alveolar process in these patients.<sup>[8,9]</sup> Thus, the presurgical infant orthopedic treatments had a paradigm shift with the addition of presurgical nasoalveolar molding (PNAM) by Grayson in 1993 for CLP patients.<sup>[10]</sup>

PNAM is a nonsurgical procedure performed early after birth in CLP patients to normalize the upper lip, alveolus, and nostrils. Several benefits of PNAM have been reported in the literature, including presurgical reduction of the alveolar cleft gap, correction of the deformity in the nasal cartilages, and reduction of the extent of primary nasal surgery required, thereby minimizing the formation of scar tissue and producing more consistent postoperative results.<sup>[11-14]</sup>

Grayson's technique consists of an intraoral molding plate incorporating a nasal stent attached to the labial flange of the plate, which in conjunction with lip taping, molds the palate, nose, and lip segments before surgery.<sup>[10]</sup> The nasal stent made of titanium molybdenum alloy (TMA) wire with a single loop design, substituting the conventional stainless steel wire as in Grayson's technique, is a recent modification with a few investigations done to check its efficacy.

As every dentist can encounter a case of CLP in his/her clinical practice and also considering an increase in the awareness and desire for PNAM among practitioners, there is an immense need for familiarizing the efficacy and efficiency of the technique and its recent modifications.

Hence, the purpose of the present study was to assess and compare the outcomes of the Modified and Conventional Grayson's PNAM techniques in unilateral complete CLP patients with emphasis on their efficacy and efficiency.

#### **MATERIALS AND METHODS**

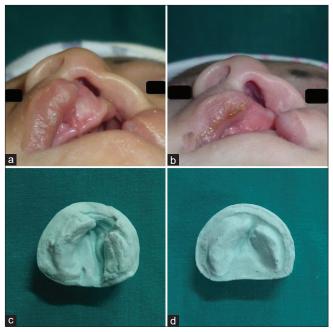
nonsyndromic complete unilateral Sixteen CLP (UCLP) infants were involved in this comparative clinical trial, who were treated in the Department of Pediatric and Preventive Dentistry, H. P Government Dental College and Hospital, Shimla, Himachal Pradesh, India, between 2017 and 2019. From the results of the previous comparative study on PNAM performed in the department, this study required a sample size of minimum 8 (number of pairs) to achieve a power of 80% and a level of significance of 5% (two tailed), for detecting a mean of the differences of 1 between the pairs, assuming the standard deviation of the difference to be 0.7. The PNAM therapy was commenced at an average of 15-20-day-old infants with an average treatment span of 6 months. In Group I, there were 37.5% of male patients, whereas in Group II, there were 87.5% of male patients. Considering the distribution of cleft side, in Group I, 62.5% of patients were having left-sided cleft, whereas in Group II, there were 50% of left-sided cleft patients. The mean age at the start of the treatment in Group I was  $16 \pm 4.6$  days, whereas in Group II, it was  $17.1 \pm 4.2$  days.

The envelope draw method was used for randomization among groups. Sixteen envelops were prepared and randomly picked each time when a new patient reported. The PNAM therapy was accomplished such that Group I (n = 8) infants were treated with the Modified Grayson's PNAM technique [Figure 1], whereas Group II (n = 8)infants were treated using the Conventional Grayson's PNAM technique [Figure 2] as the choice of treatment. The study design had ethical approval from the Institutional Committee for Scientific Ethics of Himachal Pradesh Government Dental College and Hospital, Shimla, and parents/guardian accompanying the participants of the present study were explained in detail about the purpose, the use of photographic records, and the related risks and benefits in the study, and whose parents/guardian gave written consent were enrolled in the present study. PNAM therapy was performed by the same pedodontist and primary cheiloplasty done by the same plastic surgeon.

#### **Inclusion criteria**

All of the following criteria had to be met for inclusion in the study:

- 1. Infants not more than 6 months of age
- 2. Complete UCLP patients



**Figure 1:** Photographs of a patient treated in Group I: (a) Preoperative standard basilar view photograph, (b) postoperative standard basilar view photograph, (c) preoperative maxillary study model photograph, (d) postoperative maxillary study model photograph.



**Figure 2:** Photographs of a patient treated in Group II: (a) Preoperative standard basilar view photograph, (b) postoperative standard basilar view photograph, (c) preoperative maxillary study model photograph, (d) postoperative maxillary study model photograph.

- 3. Infants who have not undergone any surgery in the cleft region
- 4. Infants without any presurgical intervention.

#### **Exclusion criteria**

- 1. All the clefts of lip, alveolus, and palate excluding complete UCLP
- 2. Clefts associated with other craniofacial anomalies or syndromes
- 3. Patients with respiratory difficulty and upper respiratory tract infection
- 4. Patients who suffered from any life-threatening disorder.

#### Methodology

After making an intraoral maxillary impression with heavy-bodied silicon impression material (Affinis, Coltene, Altstatten, Switzerland), a maxillary intraoral plate was made of self-cure acrylic resin (DPI-RR, Mumbai, Maharashtra, India). A retentive button was fabricated and positioned at an angle of 40°-45° down from the horizontal to achieve proper activation and to prevent unseating of the appliance from the palate. The labial flange of the intraoral plate holds a wire with a loop for adjustments and at its end, a nasal stent was wrapped with self-cure acrylic. In the Modified Grayson's PNAM technique, the nasal stent was made of 0.032" TMA wire, whereas in the Conventional Grayson's technique, the PNAM appliance holds a nasal stent made of 0.036" stainless steel wire. After the initial lip taping for the approximation of the lip segments, the appliance was then secured extraorally to the cheeks and bilaterally by surgical tapes that had elastic bands at one end. Modifications of the appliance were done until the pressure of the nasal extension made the cleft nasal cartilage appear rounded and symmetrical as the noncleft side. In the Modified Grayson's PNAM technique, the patient was recalled every 15-20 days, in comparison to 7-10 days in the Conventional Grayson's PNAM technique.

## Assessment of the study models and facial photographs

#### Photographic analysis

At resting posture, the infant's head was tilted back to bring the alar domes to a level below the eyebrows but above the canthi for taking a series of standard basilar view photographs in 1:1 ratio using a digital camera (Lumix DMC-FS4, Panasonic, Kadoma, Japan). Indirect anthropometric unilateral measurements (nostril width, columella deviation) and bilateral measurements (columella length, nostril length, and nostril axis inclination) were performed directly on the digital photograph with the software system (Adobe Photoshop CS5.1, San Jose, CA, USA). Nasal measurements were adapted from Gomez *et al.*<sup>[15]</sup> [Figure 3 and Table 1].

Photographic records of each patient were taken at the initiation of PNAM, and on completion of PNAM before cheiloplasty.

For the assessment of intraobserver and photographic reliability, an intraclass correlation was performed on randomly selected photographs taken before and after PNAM therapy under standardized conditions. The photographs were taken twice and digitized using a computer.

Nasal symmetry was assessed before and after PNAM therapy for unilateral measurements in both the groups, and the quantity of asymmetry (linear difference of each bilateral measurement between cleft and noncleft sides) was also determined. A positive value implies that the cleft side is longer/wider than the noncleft side, whereas a negative value indicates that the cleft side is shorter/narrower than the noncleft side.

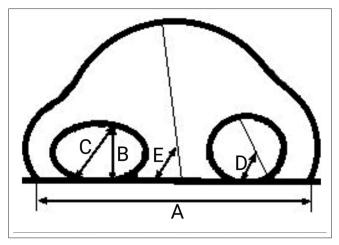
#### Maxillary study model analysis

The maxillary cast data were attained by using a three-dimensional (3D) computer-aided design computer-aided manufacturing (CAD-CAM) laser scanner (Medit T-300, Seongbuk-gu, Korea). The data sets were measured and interpreted by using a computer software package (Exocad Dental CAD, Darmstadt, Germany). The models were scanned at the initiation of PNAM and completion of treatment before cheiloplasty.

Objective and quantified data on the physical characteristics of the cleft maxilla were gathered by the 3D laser scanner. The landmarks and reference lines for maxillary model analysis were adapted from Isogawa *et al.*<sup>[16]</sup> [Figure 4 and Table 2]. To blind the treatment stage of the cast, a random number was enrolled for each model, and measurement was made by the examiner in the next stage. Assessment of facial photographs and maxillary study model analysis were performed by a single-blinded examiner (a pedodontist).

#### **Statistical analysis**

Patient photographic and maxillary study model measurements pre- and post-operatively in both groups and between the modified and conventional PNAM groups were compared using a two-tailed *t*-test or a Chi-square test when indicated. All statistics were performed using statistical computer



**Figure 3:** The linear and angular nasal measurements on the standard basilar view of nose as described in Table 1. Linear measurements: (a) Nasal width, (b) columella length, (c) nostril length. Angular measurements: (d) Nostril axis inclination angle, (e) columella deviation angle.

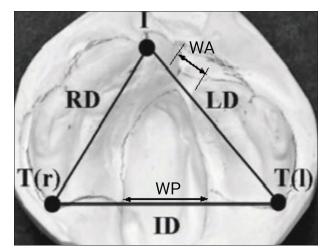


Figure 4: Maxillary study model landmarks and measurements as described in Table 2.

software (SPSS Inc.. South Wacker Drive. Chicago, USA). Intra-observer and inter-observer reliability were also assessed using the intra-class coefficient. Pearson's correlation correlation coefficient (r) of 0.994 for intra-observer correlation and 0.942 for inter-observer correlation shows an excellent correlation between the observations at two different periods by the same observer and also between the two observers. Intra observer and interobserver error were also nonsignificant with P < 0.05 using paired *t*-test.

#### RESULTS

The results are listed in Tables 3-6. Only the significant and clinically germane changes due to

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#### Table 1: Nasal landmarks and measurements (adapted from Gomez et al.)

Abbreviation	Definition
Landmarks	
Prn	Most protruded point of the nose
Highest point of the columella (C')	Most superior point on the columella crest
Sn	Midpoint formed where the lower border of the nasal septum and the surface of the upper lip meet
Sbal	Labial insertion of the alar base
Ac	Facial insertion of the alar base
Linear measurements	
Nasal width (Ac-Ac)	Width between the facial insertion points of the alar base
CL (C-NC)	Distance between the highest point of the columella perpendicular and the subnasale nasal base plane
NL (C-NC)	Distance between the highest point of the columella and subalare
Angular measurements	
NAI (C-NC)	Angular measurement between the nostril length plane and the nasal width plane
CD	Angular measurement between the columella axis and a perpendicular to the nasal width plane based on subnasale

CD: Columella deviation; NAI: Nostril axis inclination; NL: Nostril length; CL: Columella length; AC: Alar curvature; Sn: Subnasale; Sbal: Subalare; Prn: Pronasale

#### Table 2: Maxillary study model landmarks and measurements (adapted from Isogawa et al.)

Serial number	Abbreviation	Definition
	Landmarks	
1	1	The crossing point of alveolar ridge and the line from incisive papilla to frenulum
2	T (r)	The maxillary tuberosity on the right side
3	T (I)	The maxillary tuberosity on the left side
	Measurements	
1	WA	Width of the alveolar cleft
2	WP	Width of the palatal cleft
3	RD	The length between I and T (r)
4	LD	The length between I and T (I)
5	ID	The length between T (r) and T (I)
6	LDI	Lateral deviation of the incisal point

The lateral deviation of the incisal point (LDI) = | RD2-LD2 |/2 ID. LDI: Lateral deviation of the incisal point

## Table 3: Nasal measurements (unilateral) and quantity of asymmetry (linear difference of each bilateral measurement between cleft and noncleft sides) pre- and post-operatively using the Modified and Conventional Grayson's presurgical nasoalveolar molding techniques using paired *t*-test

Variables	Group	I (Modified Gra	ayson's	PNAM) (n	ı=8)	Group II	(Conventional (	Grayso	n's PNAM)	( <i>n</i> =8)
	Preoperatively	Postoperatively	Р	Outcomes	Percentage increase/ decrease	Preoperatively	Postoperatively	Р	Outcomes	Percentage increase/ decrease
Nasal measurements (unilateral)										
Nasal width (pixels)	225.956±35.66	170.827±23.50	0.001*	Decreased	-24.3	172.955±38.55	142.549±43.71	0.014*	Decreased	-17.5
CD angle (°) Nasal asymmetry (Bilateral)	55.780±5.94	64.853±7.35	0.014*	Increased	16.2	47.462±11.11	60.919±5.06	0.019*	Increased	28.3
CL (pixels) NL (pixels)	-27.808±9.73 62.516±20.15	-18.411±5.11 33.084±9.34		Increased Decreased	33.7 -47.0	-18.097±4.66 44.530±18.73	-16.201±4.97 24.713±9.30		Increased Decreased	10.4 -44.5
NAI (°)	-36.883±6.82	-35.047±9.70	0.668	Increased	4.9	-29.202±12.65	-28.282±15.46	0.905	Increased	3.1

Values are expressed as mean±SD, where SD: standard deviation. A decrease in percentage was indicated by a negative sign. \**P*<0.05 significant using paired *t*-test. PNAM: Presurgical nasoalveolar molding; SD: Standard deviation; CD: Columella deviation; NAI: Nostril axis inclination; NL: Nostril length; CL: Columella length

PNAM therapy in both groups will be described. The methodology involved was fruitful in determining the

differences pre- and post-operatively in each group as well as between the groups as follows.

Variables	Group	I (Modified Gra	yson's	PNAM) (n	=8)	Group II	(Conventional C	Grayso	n's PNAM)	( <i>n</i> =8)
	Preoperatively	Postoperatively	Р	Outcomes	Percentage increase/ decrease	Preoperatively	Postoperatively	Р	Outcomes	Percentage increase/ decrease
WA (mm)	12.357±2.35	4.193±1.67	0.000*	Decreased	-66.0	11.226±3.82	4.636±3.65	0.003*	Decreased	-58.7
WP (mm)	14.600±2.16	13.563±2.22	0.246	Decreased	-7.1	13.755±1.94	11.255±2.22	0.031*	Decreased	-18.1
Lateral deviation of the incisal point (mm)	6.352±3.18	2.989±2.07	0.018*	Decreased	-52.9	4.844±2.53	3.375±1.80	0.205	Decreased	-30.3

Table 4: Maxillary study model measurements pre- and post-operatively using the Modified and Conventional Grayson's presurgical nasoalveolar molding techniques using paired *t*-test

Values are expressed as mean±SD. A decrease in percentage was indicated by a negative sign. \**P*<0.05 significant using paired *t*-test. WA: Width of the alveolar cleft; WP: Width of the palatal cleft; SD: Standard deviation; PNAM: Presurgical nasoalveolar molding

# Table 5: Comparison of percentage increase/decrease of nasal asymmetry values betweenGroup I and Group II

Characteristics	Group I (n=8)	Group II (n=8)	Р
Nasal width (%)	-24.3	-17.5	0.746
CD (%)	16.20	28.30	0.573
CL (cleft - noncleft side) (%)	33.70	10.40	0.276
NL (cleft - noncleft side) (%)	-47.00	-44.50	0.922
NAI (cleft - noncleft side) (%)	4.90	3.10	0.858

Values are expressed as percentages. A decrease in percentage is indicated by a negative sign. \*P<0.05 significant using Chi-square test. CD: Columella deviation; CL: Columella length; NAI: Nostril axis inclination; NL: Nostril length

#### Nasal symmetry analysis

The efficacy of the Modified PNAM technique was promising and was comparable to the Conventional PNAM technique. When we compared the pre- and post-treatment unilateral measurements of both the Modified and Conventional Grayson's PNAM technique, it was found that postoperatively, the nasal width (225.956 ± 35.66 to 170.827 ± 23.50 pixels [24.3%] in the Modified PNAM and 172.955 ± 38.55 to 142.549 ± 43.71 pixels [17.5%] in the Conventional PNAM) and the columella deviation angle (55.780° ± 5.94° to 64.853° ± 7.35° [16.2%] in the Modified PNAM and 47.462° ± 11.11° to 60.919° ± 5.06° [28.3%] in the Conventional PNAM) showed an increase after both the PNAM techniques, which was significant.

When the quantity of asymmetry (linear difference of each bilateral measurement [columella length, nostril length, and nostril axis inclination] between cleft and noncleft sides) of pretreatment outcome with posttreatment outcome was assessed in the Modified Grayson's PNAM technique, it was found that columella length (-27.808  $\pm$  9.73 to -8.411  $\pm$  5.11 pixels [33.7%]) increased significantly and nostril length (62.516  $\pm$  20.15 to 33.084  $\pm$  9.34 pixels [47%]) decreased significantly after PNAM therapy, whereas in the Conventional Grayson's PNAM technique, only nostril length  $(44.530 \pm 18.73 \text{ to } 24.713 \pm 9.30 \text{ pixels } [44.5\%])$  showed a significant decrease after the treatment [Table 3].

While comparing the postoperative outcomes, that is percentage increase/decrease in nasal measurements of Group I with that of Group II, both the unilateral measurements and the quantity of asymmetry (linear difference of each bilateral measurement between cleft and noncleft sides) results show no significant difference between the groups [Table 5].

#### Maxillary study model analysis

The efficacy of both the techniques, i.e., Modified Grayson's PNAM and Conventional Grayson's PNAM, on comparing the maxillary cast analysis pre- and post-operatively showed a significant decrease in the width of the alveolar cleft ( $12.357 \pm 2.35$  to  $4.193 \pm 1.67$  mm [66%] in the Modified PNAM and  $11.226 \pm 3.82$  to  $4.636 \pm 3.65$  mm [58.7%] in the Conventional PNAM) in both the groups and there was a significant decrease in lateral deviation of the incisal point ( $6.352 \pm 3.18$  to  $2.989 \pm 2.07$  mm [52.9%]) postoperatively in the Modified Grayson's PNAM group (Group I) [Table 4]. When we compared the percentage increase/decrease in maxillary cast measurements between Group I and Group II, the results were nonsignificant [Table 6].

When the efficiency of Group I and Group II was assessed, the Modified Grayson's PNAM technique showed more efficiency, as it requires less duration of treatment ( $134 \pm 22.1$  days in the Modified PNAM and  $136 \pm 33.8$  days in the Conventional PNAM) and significantly lesser number of adjustments ( $6.5 \pm 1.3$ , visits in the Modified PNAM and  $14.91 \pm 2.3$  visits in the Conventional PNAM) when compared to the Conventional Grayson's PNAM technique [Table 7].

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Variables	Group I ( <i>n</i> =8)	Group II ( <i>n</i> =8)	Р
WA (%)	-66.00	-58.70	0.77
WP (%)	-7.10	-18.10	0.52
Lateral deviation of the incisal point (%)	-52.90	-30.30	0.374

	Table 6: The percentage increase	decrease of the maxillary	v study model measurements i	n Group I and Group II
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Values are expressed as percentages. A decrease in percentage is indicated by a negative sign. \*P<0.05 significant using Chi-square test. WA: Width of the alveolar cleft; WP: Width of the palatal cleft

### Table 7: Comparison of efficiency between Group I and Group II

Variable	Group I	Group II	Р
Duration of treatment (days)	134±22.1	136±33.8	0.116
Number of adjustments	6.50±1.3	14.91±2.3	0.000*

\*P<0.05 significant using Chi-square test. Values are expressed as mean±SD. SD: Standard deviation

#### DISCUSSION

The objective of the present study was to evaluate the anatomic changes occurring in the unilateral cleft lip nose and the maxillary alveolus after the Modified and Conventional Grayson's PNAM techniques in a group of patients with complete UCLP. Digital analysis of standardized photographs and 3D scanned maxillary study models were undertaken to assess the nasal as well as maxillary alveolar changes, to assess the results attained after the use of two PNAM techniques, and to curtail the UCLP deformity.

In this study, both the Modified and Conventional Grayson's PNAM techniques showed improvement in the nasal symmetry and maxillary alveolar morphology. There was a significant reduction of nasal width and columella deviation angle postoperatively using both the techniques when unilateral nasal measurements were considered. When considering nasal asymmetry of bilateral measurements, there was a significant increase of columella length and decrease in nostril length postoperatively using the Modified PNAM technique, whereas there was a significant decrease in nostril length postoperatively using the Conventional PNAM technique. There was no significant difference between Group I and Group II when the percentage increase/decrease in nasal measurements and symmetry were considered.

There was a significant reduction in the width of the alveolar cleft in both groups and a significant decrease in the lateral deviation of the incisal point in Group I postoperatively when digital maxillary cast measurements were considered. However, the number of adjustments of the appliance and thereby the number of visits were lesser in the Modified PNAM technique as compared to the Conventional PNAM technique, making it a more user-friendly technique.

Kecik and Enacar<sup>[17]</sup> conducted a similar study assessing the effects of PNAM in 22 unilateral complete CLP patients using scanned facial casts. They concluded a statistically significant decrease of the cleft width (P < 0.001), increase in the columella deviation angle (P < 0.001), and a decrease in the total alar base width (P < 0.001) on the cleft side. Our results with both the Modified and Conventional PNAM techniques also corroborate these findings. In the present study, similar measurement for cleft width was width of the alveolar cleft, which decreased statistically significantly in both groups (P = 0.000 in the Modified PNAM and P = 0.003 in the Conventional PNAM), columella deviation angle increased statistically significantly in both groups (P = 0.014 in the Modified PNAM and)P = 0.019 in the Conventional PNAM), and similar measurement for total alar base in the present study was nasal width, which also decreased statistically significantly in both groups (P = 0.001 in the Modified PNAM and P = 0.014 in the Conventional PNAM).

Gomez et al.<sup>[15]</sup> conducted a study on thirty UCLP patients (19 males and 11 females) who received PNAM before lip repair. The nasal asymmetry (linear difference of each bilateral measurement between cleft and noncleft sides) of bilateral measurement shows an improvement of columella length by 45.02%, nostril axis inclination by 27.69%, and a nonsignificant increase of nostril length. In the present study, columella length improved significantly in the Modified PNAM group (33.7%) and nonsignificantly in the Conventional PNAM group (10.4%). Nostril axis inclination improved nonsignificantly in both groups (4.9% in the Modified PNAM and 3.1% in the Conventional PNAM) and nostril length also improved significantly in both groups (47% in the Modified PNAM and 44.5% in the Conventional While unilateral PNAM). considering the measurements, columella deviation improved by 10.43% and nasal width increased by 9.07%. In the present study, columella deviation also improved significantly in both groups (16.2% in the Modified PNAM and 28.3% in the Conventional PNAM). All the measurements in our present study show similar results with those of Gomez *et al.* except increasing nasal width, which is in contradiction to our study, where the nasal width decreased significantly in both groups (24.3% in the Modified PNAM and 17.5% in the Conventional PNAM).

Singh et al.[18] compared the efficacy and efficiency of Gravson's technique with Figueroa's modified presurgical nasoalveolar technique in 22 infants with complete UCLP. When they compared nasal asymmetry, it was found that the nostril height increased statistically significantly (P < 0.001) and nostril width decreased statistically significantly (P < 0.001) on the cleft side postoperatively. The similar measurement for nostril height in our study, i.e., the columella length, also increased statistically significantly in the Modified PNAM group (P = 0.034) and increased nonsignificantly in the Conventional **PNAM** group (P = 0.476). The similar measurement for nostril width in our study, i.e., the nostril length, also decreased statistically significantly (P = 0.003 in the Modified PNAM and P = 0.034 in the Conventional PNAM) in both groups.

In our study, patients treated with the Modified Grayson's **PNAM** technique exhibited а significant improvement in the nasal symmetry vertically (columellar length; Р <0.05),horizontally (nasal width, nostril length; P < 0.05), and in angular measurements (nostril axis inclination, columella deviation; P < 0.05). Very few case reports have been done in comparing the pre- and posttreatment outcomes on the Modified Grayson's PNAM technique using TMA wire as a nasal stent. Subramanian et al.[19] reported a case of unilateral complete CLP treated using Grayson's PNAM technique with TMA wire as a nasal stent. They concluded that lesser chairside time, easy adjustments, and a lesser number of recall visits were needed in the Modified PNAM treatment. They also stated that this technique is an effective alternative to a conventional appliance, and it simplifies the appliance modification process during follow-up visits.

The effects on the alveolar cleft were accomplished by the combined effect of redirection of growth of the alveolar segments through the molding plate, active molding by selective addition and removal of acrylic, and prevention of tongue insertion into the cleft, leading to a separation of the cleft margins and using adhesive tape traction applied across the cleft lip as proposed by Grayson et al.[10] Isogawa et al.<sup>[16]</sup> assessed the effect of the palatal molding plate appliance (modified Hotz's plate and modified PNAM appliance) on the alveolar and palatal forms through a quantitative and 3D evaluation. They reported a significant reduction in the width of the alveolar cleft and lateral deviation of the incisal point using a modified PNAM appliance, which was similar to our study, where the reduction in the width of alveolar cleft was 66% in the Modified PNAM technique and 58.7% in the Conventional PNAM technique. In addition, a reduction in the lateral deviation of the incisal point was 52.9% using the Modified PNAM technique and 30.3% in the Conventional PNAM technique.

The results of this study should be viewed in light of its limitations. This study was a preliminary study to evaluate the clinical effectiveness and efficiency of PNAM therapy using the Modified and Conventional PNAM techniques with the need for a larger sample, randomized controlled trial for confirming the current findings. This study is also limited by the photographic analysis of nasal symmetry, which was a two-dimensional depiction of a 3D structure. Although techniques for 3D direct facial images such as 3D stereophotogrammetry have been proposed to overcome this constraint, their higher cost limits routine availability.<sup>[20-23]</sup> Finally, though the results of the study demonstrate the effectiveness and efficiency of the technique, long-term follow-up studies are required to evaluate the prolonged benefits of this approach.

#### CONCLUSION

Within the limitations of this study, both the Modified and Conventional PNAM techniques show morphological improvement in nasal symmetry and maxillary alveolar morphology in the presurgical management of unilateral complete CLP patients. However, the lesser number of adjustments of the appliance and thereby the reduced number of visits in the Modified PNAM technique, make it a more user-friendly technique and ultimately reducing the burden of care in UCLP patients.

#### **Declaration of patient consent**

The authors certify that they have obtained all

appropriate patient consent forms. In the form the patient(s) has/have given his/her/their consent for his/ her/their images and other clinical information to be reported in the journal. The patients understand that their names and initials will not be published and due efforts will be made to conceal their identity, but anonymity cannot be guaranteed.

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#### **Conflicts of interest**

The authors of this manuscript declare that they have no conflicts of interest, real or perceived, financial or non-financial, in this article.

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