

A Comparative Evaluation of Efficacy and Efficiency of Grayson's Presurgical Nasoalveolar Molding Technique in Patients with Complete Unilateral Cleft Lip and Palate with Those Treated with Figueroa's Modified Technique

Abstract

Background: Presurgical nasoalveolar molding (PNAM) has been used for aligning and not only for approximating the maxillary alveolar segments preoperatively but also for improving the nasal symmetry and therefore facilitates primary surgical repairs in cleft patients. **Aim:** This study was conducted to compare the efficacy and efficiency of Grayson's technique with Figueroa's modified presurgical nasoalveolar technique in complete unilateral cleft lip and palate (UCLP) infants. **Materials and Methods:** Twenty-two infants aged 10–15 days were randomly divided into two equal groups: Group I treated with Grayson's PNAM technique and Group II with Figueroa's PNAM technique. **Results:** When we compared nasal asymmetry values preoperatively and postoperatively of Group I and Group II, it was found that the nostril height increased significantly on the cleft side and nostril width decreased significantly postoperatively on the cleft side. When we compared nasal asymmetry values postoperatively of Group I with Group II, all the values were nonsignificant. When we compared the digital maxillary cast analysis outcomes preoperatively and postoperatively in Group I and Group II, it was found that there was a significant reduction in the alveolar gap and there is a significant increase in the arch width. When we compared the efficiency of Group I with Group II, it was found that Group II was more efficient than Group I. **Conclusion:** This study showed a morphological improvement in nasal symmetry and maxillary alveoli of infants with UCLP treated with both Grayson's PNAM technique and Figueroa's PNAM technique with Grayson's PNAM technique being more efficient.

Keywords: Cleft, molding, nasoalveolar, presurgical

Anjali Singh,
Seema Thakur,
Parul Singhal,
Vijay Kumar
Diwana¹,
Alka Rani²

Department of Pediatric and Preventive Dentistry, H.P. Government Dental College and Hospital, Shimla, Himachal Pradesh, ¹Department of Plastic Surgery, Indira Gandhi Medical College and Hospital, Shimla, Himachal Pradesh, ²Private Practitioner, New Delhi, India

Introduction

In 1993, Grayson *et al.*^[1] were first to describe a technique for the correction of the alveolus, lip, and nose in infants with cleft lip and palate. Matsuo observed that in newborn, the cartilage is soft and lacks elasticity.^[2-5] Hence, the principle of presurgical nasoalveolar molding (PNAM) treatment is based on Matsuo's research that the nasal cartilage is still developing and subject to repositioning within the first 6 weeks of life.^[2]

Grayson's PNAM technique is most commonly followed, and a number of studies have supported its application for correction of cleft lip and nose deformity.^[6-9]

The Figueroa's presurgical nasoalveolar technique is less commonly used with few investigations done to check its efficacy.^[10-13]

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This study is aimed to assess and compare the outcome of Grayson's and Figueroa's nasoalveolar molding technique with emphasis on their efficacy and efficiency.

Materials and Methods

Twenty-two nonsyndromic infants with unilateral cleft lip and palate (UCLP) were included in the study from 2013 to 2017. The commencement of PNAM therapy was between 10 and 15-day-old infant, and the average duration of the therapy was 6 months. In Group I, there were 72.7% of male patients, while in Group II, there were 54.5% of male patients. In Group I, there were 55% of left-sided cleft patients, while in Group II, there were 45% of left-sided cleft patients. The mean age of start of treatment in Group I was 5.4 + 8.3 days, while in Group II, it was 7.18 + 8.5 days.

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Address for correspondence:

Dr. Seema Thakur,
Department of Pedodontics
and Preventive Dentistry, H.P.
Government Dental College,
Shimla - 171 001,
Himachal Pradesh, India.
E-mail: cima2009@hotmail.com

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Twenty-two envelopes were prepared and randomly picked each time any patient reported. The technique of PNAM was rendered such that Group I ($n = 11$) infants were treated using Grayson's PNAM technique [Figure 1], while Group II ($n = 11$), infants were treated using Figueroa's PNAM technique [Figure 2] with the choice of treatment. The study design was ethically approved, and parents' consent was taken before the treatment. PNAM therapy was done by the same pedodontist, and primary cheiloplasty using the method of triangular repair most often described as P. Randall's modification (1959) of C.W. Tennison's original technique (1952) was done by the same plastic surgeon.

Statistical analysis

Measurements were made on patient's photographs and maxillary casts of Grayson's and Figueroa's modified PNAM groups and were compared using a two-tailed two-sample *t*-test or a Chi-square test when indicated. All statistical analyses were performed using SPSS version 17.0 (SPSS Inc. South Wacker Drive, Chicago, United States). The method error showed a significant intraobserver correlation ($r = 0.75$, $P < 0.05$) for repeated measurements and also a significant correlation ($r = 0.86$, $P < 0.05$) between the photographs.

Methodology

The impression was taken using elastomeric impression material. In Grayson's PNAM technique, all the undercuts and the cleft space are blocked with wax, while in Figueroa's PNAM technique, the wax-up was done according to the contour and topography of an intact arch before the fabrication of the molding plate. The molding plate of hard, self-cure clear acrylic was fabricated on the dental stone model obtained from the impression.

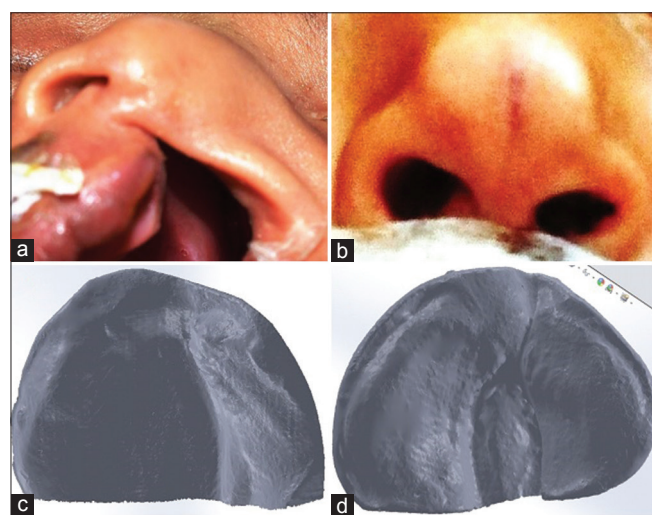


Figure 1: Photograph of a patient treated in Group I: (a) Preoperative standard 1:1 ratio basilar view. (b) Postoperative standard 1:1 ratio basilar view. (c) Preoperative computer-aided design-computer-aided manufacturing scanned maxillary cast photograph. (d) Postoperative computer-aided design-computer-aided manufacturing scanned maxillary cast photograph

In Grayson's technique, a stent was added when the alveolar gap reduced to 5–6 mm and the baby was seen weekly, i.e., 7–10 days to make adjustments to the molding plate to bring the alveolar segments together. While in Figueroa's technique, a stent was added at the time of delivery of the appliance and patients were recalled after 15–20 days.

Assessment of the study models and facial photographs

Photographic analysis

A series of standard basilar view photographs in 1:1 ratio were taken for each patient at resting posture by tilting the infant's head back to bring the alar domes to a level below the eyebrows but above the canthi.^[14] Indirect anthropometric measurements (nostril height, nasal basal height, columellar height, nostril width, and nasal basal width) were made on the digital photographs with the help of a software (SolidWorks software, Dassault Systèmes, Concord, Massachusetts, United States). Nasal measurements were done according to Liou et al.^[9] [Figure 3 and Table 1].

The photographs were taken at the time of initiation of nonaligned movement (NAM), on completion of NAM, i.e., before cheiloplasty and after cheiloplasty.

For the assessment of intraobserver and photograph reliability, the method error was done by doing double determination on 132 randomly selected photographs taken before and after PNAM therapy under standardized conditions. The photographs were taken twice and digitalized using the computer.

Nasal symmetry was quantified by the following linear anthropometric measurements such as nostril width, nasal base width, nostril width, nasal dome width, and columellar length were carried out directly on photographs.

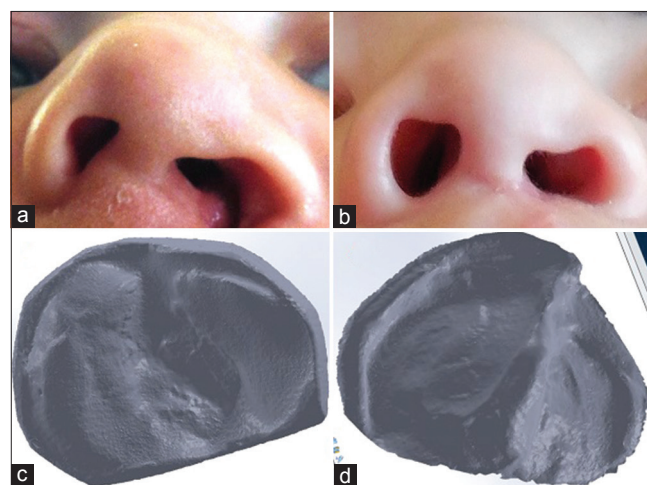


Figure 2: Photograph of a patient treated in Group II: (a) Preoperative standard 1:1 ratio basilar view. (b) Postoperative standard 1:1 ratio basilar view. (c) Preoperative computer-aided design-computer-aided manufacturing scanned maxillary cast photograph. (d) Postoperative computer-aided design-computer-aided manufacturing scanned maxillary cast photograph

Nasal symmetry was assessed by the “quantity of asymmetry.” The quantity of asymmetry (in millimeters) was the linear difference of each measurement between cleft and noncleft (cleft–noncleft).

A positive value indicates that the cleft side is longer/wider than the noncleft side, and a negative value indicates that the cleft side is shorter/narrower than the noncleft side.

Cast analysis

The cast data were acquired by a three-dimensional (3D) laser scanner (3M computer-aided design-computer-aided manufacturing scanner) which used a laser line triangulation scanner that produced the 3D image. The data sets were measured and analyzed with the software package. The digital geometrical 3D model was judged by applying a software system (Dental automation software). The casts were scanned at the time of initiation of PNAM and then on completion of PNAM before cheiloplasty.

A 3D laser scanning device was used to obtain objective and quantified data on the physical characteristics of the cleft maxilla in infants with UCLP. The present study confirmed the landmarks and reference lines using the methods described by Mazaheri *et al.*^[15] [Figure 4 and Table 2].

To blind the treatment stage of the cast, a random number was assigned to each model and measurement was made by the examiner in the next stage.

Results

Nasal symmetry

The efficacy of both the groups, i.e., Grayson's PNAM and Figueroa's PNAM was almost equal as there was a significant increase in nostril height and columellar length ($P < 0.001$) and there was a significant decrease in nostril width and nasal basal width ($P < 0.001$) postoperatively on the cleft

side in both the groups [Table 3]. However, on comparing the postoperative outcomes of Group I with that of Group II, the results were nonsignificant [Table 4].

Maxillary cast analysis

The efficacy of both the techniques, i.e. Grayson's PNAM and Figueroa's PNAM on comparing the maxillary cast analysis preoperatively and postoperatively showed a significant decrease in the distance between major and minor segments and increase in the arch width postoperatively in both Group I and II [Table 5], but on comparing the postoperative outcomes of Group I with Group II, the results were nonsignificant [Table 6].

Table 1: Nasal measurements (adapted from Liou *et al.*)

Measurement	Description
Vertical measurements	
a. Nostril height	The vertical distance between the horizontal reference line and the intersection point of the inner upper border of the nostril and the perpendicular bisecting line of the nostril width
b. Nasal dome height	The vertical distance between the horizontal reference line and the intersection point of the outer upper border of the nostril and the perpendicular bisecting line of the nostril width
c. Columellar length	The vertical distance between the most inferior-medial and superior-medial points along the inner medial surface of the nostril apertures
Horizontal measurements	
d. Nostril basal width	The horizontal distance between the outer lateral border and the inner medial border of the nostril
e. Nostril width	The horizontal widest distance between the inner lateral and medial borders of the nostril aperture

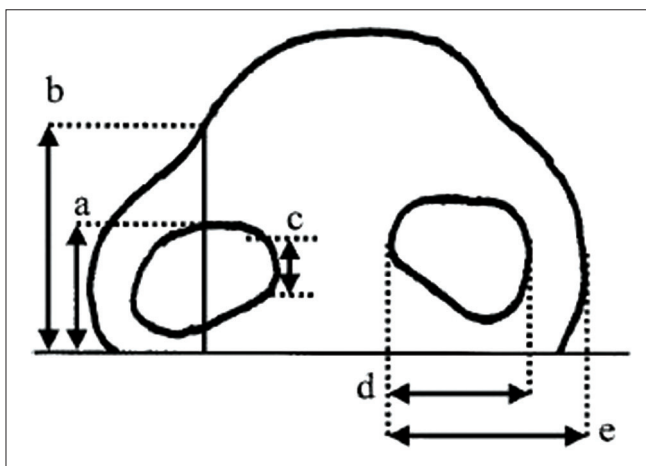


Figure 3: The anthropometric measurements: a, nostril height; b, nasal dome height; c, columellar length; d, nostril width; e, and nasal basal width as described in Table 1

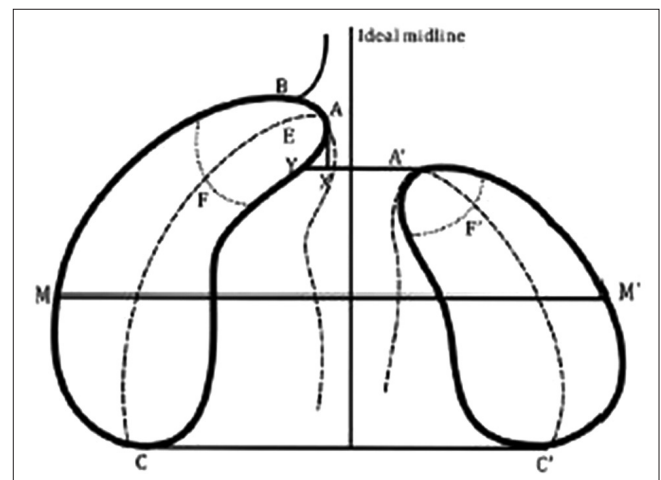


Figure 4: The landmarks and reference lines of the maxillary alveolar measurement are described in Table 2

Table 2: Definition of landmarks and measurements done on the maxillary cast

Abbreviation	Definition
Landmarks	
A/A' (margin of the cleft)	A point is the anterior end point of the noncleft segment. A' point is the anterior end point of the cleft segment
C/C' (tuberosity points)	The tuberosity and the crest of the ridge were outlined on the model, and the junction of these lines was called C and C'
X	Intersection of the transverse line from A' (parallel to the to the baseline C-C') with the perpendicular from the baseline to point A
M/M'	A perpendicular will be erected from the baseline C-C' to the point E; at the level of the bisection of this distance, a line parallel to the baseline was drawn, reaching the crest of the alveolar ridges of both segments. The intersections of this transverse line with the outlines of the alveolar crest on both sides were labeled points M and M', respectively
Measurements	
A'-X	Transverse and oblique width of the anterior cleft, which is the transverse relation of the cleft to noncleft segment. When segments are separated at the alveolar cleft and A' is farther from Y than X, the reading is positive. In situations where the noncleft segment overlaps the cleft segment, that is, X is farther from Y than A', the reading is negative
A-A' (cleft gap)	Distance between point A and A'
A-X	Anteroposterior relation of cleft to noncleft segment. If the alveolar border of the cleft segment is positioned anterior to the noncleft segment, this measurement is negative; otherwise, a positive measurement should be anticipated
M-M'	Middle arch width
M-X	The maxilla arch width of the noncleft side
M'-X	The maxilla arch width of the cleft side

When the efficiency of Group I and II was assessed, it was found that Group II was more efficient than Group I as it required less number of adjustments and hence less number of visits to achieve the desired goal of the treatment [Table 7].

Discussion

The main aim for the treatment of cleft lip, alveolus, and palate is to enhance the esthetic appearance of the face and thus helps in social acceptability of the patient in the society.

Descriptive studies on Grayson's PNAM technique by Keçik *et al.*, Liou *et al.*, and Suri *et al.* enlightened that the maxillary alveolar segment molding simultaneously supports and hold the deformed nasal cartilage which sequentially corrects the central nasal tip projection and causes lengthening of the deficient columella.^[9,16,17] These findings were in accordance with our study which also showed a significant improvement in the nasal symmetry in patients treated with Grayson's PNAM technique in terms of both vertical (nostril height and columellar length; $P < 0.001^*$) and horizontal symmetry (nostril width and nostril basal width; $P < 0.001^*$).

In our study, patients treated with Figueroa's modified PNAM technique exhibited a significant improvement in the nasal symmetry both vertically (nostril height and columellar length; $P < 0.001^*$) and horizontally (nostril width and nostril basal width; $P < 0.001^*$). Very few studies have been done for comparing the pre- and posttreatment outcomes on Figueroa's PNAM technique.^[10] A study done by Bennun and Figueroa^[12] and Gomez *et al.*^[13] concluded that favorable reshaping of the nose after Figueroa's PNAM was achieved, resulting in an improvement in form before lip surgery. These changes lead to improved nasal symmetry before primary lip and nasal reconstruction in UCLP patients.

A study was done by Liao *et al.*^[18] who concluded that the two nasoalveolar molding techniques differed in efficacy, efficiency, and incidence of complications in patients with complete unilateral cleft lip – cleft and palate. Understanding these differences may help surgeons, and orthodontists improve outcome expectations and

Table 3: Nasal asymmetry values pre- and postoperatively using Group I (Grayson's presurgical nasoalveolar molding technique) and Group II (Figueroa's presurgical nasoalveolar molding technique) using Chi-square test

Variables	Group I (Grayson's PNAM) (n=11)			Group II (Figueroa's PNAM) (n=11)			Outcome
	Preoperatively	Postoperatively	P	Preoperatively	Postoperatively	P	
Nostril height (mm)	-1.0±0.7	0.9±0.8	<0.001*	-1.7±1.1	1.3±0.5	<0.001*	Increased
Nasal dome height (mm)	-1.2±1.6	1.2±0.7	<0.001*	-1.2±0.9	1.7±1.1	<0.001*	Increased
Columellar length (mm)	-0.7±0.6	0.8±0.4	<0.001*	-1.0±0.5	0.8±0.5	<0.001*	Increased
Nostril width (mm)	3.7±2.1	0.7±2.4	<0.001*	5.1±2.8	2.0±3.1	<0.001*	Decreased
Nostril basal width (mm)	4.2±1.8	0.5±2.2	<0.001*	5.6±2.9	2.3±3.1	<0.001*	Decreased

* $P < 0.05$ significant using paired *t*-test, Values are expressed as mean±SD. SD: Standard deviation; PNAM: Presurgical nasoalveolar molding

consultations with patients' families. Our findings were also in agreement with aforementioned study, i.e., when we compared postoperative outcomes of both the techniques, results were nonsignificant. Figueroa's modified PNAM technique was more efficient than Grayson's PNAM technique as it requires less number of activation ($P = 0.00^*$) and hence less number of visits for achieving the desired goals.

Effects on the alveolar cleft were accomplished using adhesive tape tractions applied across the cleft lip as proposed by Grayson *et al.*^[6] Deng *et al.*^[19] reported cleft narrowing by 0.5 mm after a month's treatment, while Pai *et al.*^[10] observed a reduction of 5.8 mm after 3–4 months of treatment. The reduction in cleft width is most likely to result from the combined effect of redirection of growth of the alveolar segments through the molding plate and 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. The study conducted by Ezzat *et al.* has shown a statistically significant reduction

in the intersegmental distance, i.e., in the cleft gap. At the same time, it was found that the arch was not collapsed as there was an increase in maxillary arch width.^[20] Bongaarts *et al.*^[21] reported that infant orthopedics does not have any influence on the maxillary arch dimensions. 3D analysis of the effect of alveolar molding was done by Baek *et al.* The results of the study suggested that the cleft gap was significantly reduced. It was also found that alveolar molding took place mainly in the anterior alveolar segment and growth occurred mainly in the posterior alveolar segment.^[22] No studies have been conducted for assessment of alveolar changes using Figueroa's PNAM technique. In our study, there was a significant reduction in the alveolar gap (A'-X and A-A') and there was a significant increase in the arch width (C-C') in both Group I and Group II. However, on comparing the posttreatment outcomes of both the groups, i.e. Group I and II, there was no significant difference observed.

Conclusion

This study demonstrated that both the techniques, i.e. Grayson's and Figueroa's PNAM are equally effective in improving the nasal symmetry. There is a significant reduction postoperatively of horizontal symmetry (nostril width and nostril basal width) and a significant increase in vertical symmetry (nostril height, nostril dome height, and columellar height) on the cleft side using both the techniques when nasal asymmetry was measured. There is a significant reduction of the alveolar gap and there was a significant increase in the arch width postoperatively when digital maxillary cast analysis was done using both the techniques. However, the number of adjustments of appliance and thereby the number of visits are lesser in number in Figueroa's modified PNAM technique as compared to the Grayson's PNAM technique, making it more user-friendly technique. Nevertheless, we still emphasize the need for randomized trials to confirm our findings.

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Nil.

Table 4: Comparison of nasal asymmetry postoperative outcomes between Group I and Group II using Chi-square test

Variables	Posttreatment outcomes		P
	Group I (Grayson's PNAM) (n=11)	Group II (Figueroa's PNAM) (n=11)	
Nostril height (mm)	0.9±0.83	1.27±0.47	0.22
Nasal dome height (mm)	1.19±0.75	1.72±1.1	0.19
Columellar length (mm)	0.81±0.40	0.86±0.55	0.83
Nostril width (mm)	0.72±2.45	2±3	0.295
Nostril basal width (mm)	0.54±2.3	2.32±3.15	0.145

* $P < 0.05$ significant using paired *t*-test, Values are expressed as mean±SD. SD: Standard deviation; PNAM: Presurgical nasoalveolar molding

Table 5: The descriptive statistical analyses of the digital model measurements in Group I (Grayson's presurgical nasoalveolar molding technique) and Group II (Figueroa's modified presurgical nasoalveolar molding technique)

Parameters	Group I (Grayson's PNAM) (n=11)			Group II (Figueroa's PNAM) (n=11)			Outcome
	Pretreatment	Posttreatment	P	Pretreatment	Posttreatment	P	
A'-X	5.69±3.15	5.00±3.07	0.007*	6.5±1.1	4.5±0.8	0.000**	Decreased
A-X	3.9±4.32	-0.8±4.7	0.186	4.3±6.6	0.9±4	0.039*	Decreased
A-A'	7.89±5.19	3.7±3.2	0.061	5.2±2.6	4.6±3.4	0.000**	Decreased
M-M'	34.17±2.78	37.43±2.63	0.001*	33.9±2.7	37.2±2.3	0.000**	Increased
M-X	16.55±3.13	17.73±1.9	0.454	16.7±2.7	18.1±1.6	0.022*	Increased
M'-X	16.7±3.13	19.6±2.24	0.638	17.2±3	19±2.4	0.042*	Increased
C-C'	35.15±5.83	39.07±2.7	0.008*	35.13±4.6	38.5±3	0.001**	Increased

**Highly significant, *Significant. All the linear measurements are in (mm). PNAM: Presurgical nasoalveolar molding

Table 6: The independent-samples *t*-test of the variables' posttreatment measurements in Group I and Group II

Parameters	Posttreatment		<i>P</i>
	Group I	Group II	
	(Grayson's PNAM) (<i>n</i> =11)	(Figueroa's PNAM) (<i>n</i> =11)	
A'-X (mm)	5±3	5.4±2.3	0.69
A-X (mm)	-0.8±4.7	2.7±2.3	0.040
A-A' (mm)	3.7±3.2	5.6±3.6	0.208
M-M' (mm)	37.4±2.6	37.07±2.2	0.733
M-X (mm)	17.7±1.9	18.4±1.2	0.278
M'-X (mm)	19.6±2.2	18.4±2.5	0.26
C-C' (mm)	39.07±2.7	37.63±3.3	0.282

**Highly significant, *Significant, All the linear measurements are in (mm). PNAM: Presurgical nasoalveolar molding

Table 7: Comparison of efficiency between Group I and Group II using Chi-square test

Variable	Posttreatment		<i>P</i>
	Group I	Group II	
	(Grayson's PNAM) (<i>n</i> =11)	(Figueroa's PNAM) (<i>n</i> =11)	
Duration of treatment (days)	136.36±33.84	136.36±38.8	1.0
Number of adjustments	14.91±2.3	7.91±1.4	0.000**

**P*<0.05 significant using paired *t*-test, Values are expressed as mean±SD. SD: Standard deviation; PNAM: Presurgical nasoalveolar molding

Conflicts of interest

There are no conflicts of interest.

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