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ORIGINAL ARTICLE

Nasal Changes After Presurgical Nasoalveolar Molding (PNAM) in the Unilateral Cleft Lip Nose

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Purpose: **Nasal reconstruction for patients with unilateral cleft lip and palate (UCLP) is a challenge for the reconstructive surgeon. Presurgical nasoalveolar molding (PNAM) was introduced to reshape the cleft nasal structures prior to lip repair. This study analyzed two-dimensional nasal changes before and after PNAM in patients with complete UCLP.**

Methods: **Thirty UCLP patients (19 males; 11 females) who received PNAM before lip repair were included in this study. PNAM was applied for 100 days. Nasal casts were obtained before and after PNAM. Frontal and 45° standardized digital photographs were taken from all casts, and a photogrammetric analysis (16 linear, six angular, and two area measurements) was performed. Paired Student's *t* tests were used to search for differences by time, and time versus side (cleft versus noncleft).**

Results: **Significant reduction of cleft columella deviation with an increase in columella length, nostril height, and axial inclination on the cleft side were recorded. This resulted in an increase in the projection of the nasal tip. The noncleft measurements remained without significant changes. The cleft nostril area increased significantly more than the noncleft side by 90% with PNAM treatment. Significant normal growth changes were observed in nasal width and nasal height.**

Conclusion: **A favorable reshaping of the nose after 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.**

KEY WORDS: *photogrammetry, presurgical nasoalveolar molding, unilateral cleft lip and palate facial casts, unilateral cleft nasal deformity*

The unilateral cleft lip (UCL) nose is the most challenging aspect of surgical reconstruction in cleft patients. The UCL nose deformity appears as a distortion, displacement, and tissue deficiency of the nasal and maxillary structures (Berkeley, 1959; Stenstrom and Oberg, 1961; Millard, 1976). Quoting Millard (1976): "When the actual platform of the nose is cleft, the projection and outward rotation of the premaxilla and the retroposition of the lateral maxillary element certainly guarantee that the nose will sit *askew*. Even when there is no bony cleft, the discrepancies in maxillary contour are responsible for some degree of nasal asymmetry. This is an architectural fact, for any structure, with one of its key legs shortened or pulled out from under it, must tilt!" Consequently, the premaxilla on the noncleft side is out, and the lower lateral alar cartilage on the cleft side is abnormally stretched and inferior and medially rotated. This rotation leads toward the development of a nostril aperture more horizontal on the cleft side, a more depressed cleft nasal dome, a lower cleft nostril axis, a distorted and short cleft columella, and a septum deviated toward the noncleft side (Millard, 1976; Friede et al., 1980; Nordin et al., 1983; Enemark et al., 1993) (Fig. 1A and 1B). As a result, the neonatal nose can be severely distorted, and traditional surgical efforts have been only partially successful in the correction of the cleft nasal deformity (Fig. 1C).

Several approaches have been used in order to minimize this asymmetry early in life, using surgery alone (McComb, 1975, 1985; McComb and Coghlan, 1996) or in conjunction with other approaches (Friede et al., 1980; Larson and Nilsson, 1983; Nordin et al., 1983; Matsuo et al., 1989; Matsuo and Hirose, 1991) that take advantage of the malleability of the infant cartilage (Matsuo et al., 1984, 1989). Infant maxillofacial orthopedics has been used before or immediately after surgery with variable degrees

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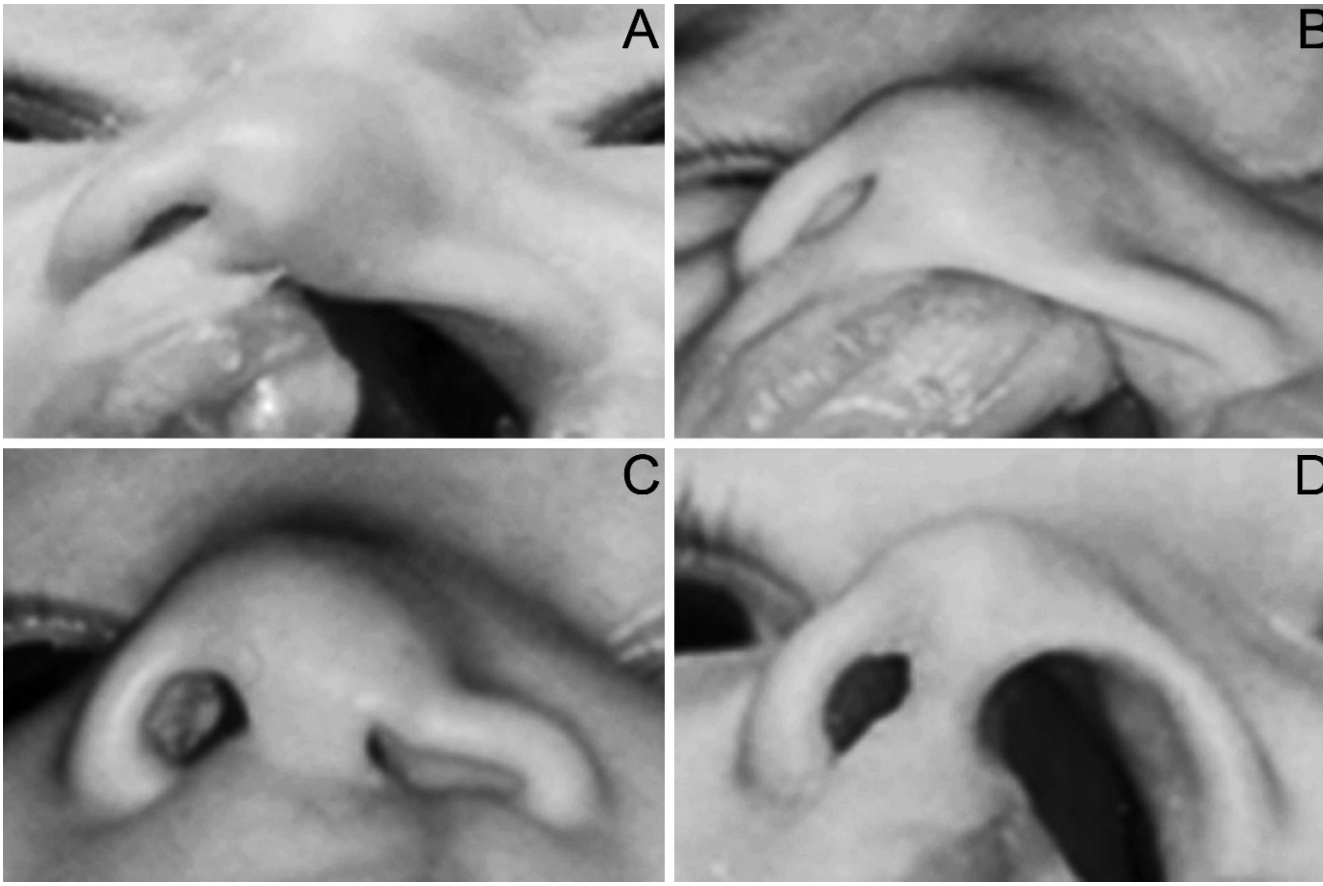

FIGURE 1 A,B: Two cases illustrating the main characteristics of the cleft lip nose: a stretched and rotated cleft lateral nasal cartilage, a horizontal cleft nostril aperture with a decreased nostril axis, a depressed nasal dome, and a short and deviated columella. C: The case shown in (A) after lip repair only. The shape of the nose is not ideal and additional nose revisions will be needed to try improving nasal form and symmetry. D: The case shown in (B) after PNAM. A noticeable improvement in nasal form and symmetry was obtained to facilitate primary surgical nose repair.

of success. The immediate postsurgical nose plug, the presurgical "T-traction" device, or the nasal silicone splints are examples of nonsurgical procedures used to improve or maintain surgical outcome. However, these appliances are used mainly for retention after surgery, and they do not address aspects such as the presurgical alveolar cleft width and nasal deformity (Friede et al., 1980; Larson and Nilsson, 1983; Nordin et al., 1983; Matsuo et al., 1989; Yeow et al., 1999).

When treating infants with a cleft, reshaping the deformed structures and minimizing the cleft deformation before surgery to facilitate repair and improve surgical outcome is desirable. Presurgical neonatal nasal remodeling with a modified intraoral plate was first described by Dogliotti and Bennun (1991). This procedure (Fig. 1B and 1C), popularized in the United States by Grayson and coworkers as presurgical nasoalveolar molding (PNAM), is the next step in the search of improved nasal symmetry in cleft lip patients (Dogliotti et al., 1991; Grayson et al., 1993, 1999; Bennun et al., 1999; Maull et al., 1999; Grayson and Cutting, 2001; Grayson and Maull, 2004; Bennun and Figueroa, 2006). This technique consists of an intraoral plate supporting an acrylic nasal stent, which in conjunction with tape-lip adhesion, molds the nose, lip, and the alveolar segments before surgery. PNAM therapy has been used successfully in bilateral and unilateral cleft lip patients. The UCLP (unilateral cleft lip and palate) PNAM treatment focuses on aligning and approximating the alveolar segments while the nasal stent molds the cleft alar cartilage in elevation and symmetry, thus facilitating surgery (Grayson et al., 1999).

To analyze the effects secondary to PNAM therapy, anthropometric measurements of the face must be taken to objectively evaluate these changes. According to Farkas (1994), two different types of measurements can be used: direct anthropometric measurements taken from the subjects and indirect anthropometric measurements. The indirect measurements can be taken on plaster casts or from standardized two-dimensional (2D), and more recently three-dimensional (3D) photogrammetry of either patients or plaster casts (Larson and Nilsson, 1983; Singh et al., 2005). Therefore, an anthropometric geometric assessment based on plaster casts of the cleft nose modified through PNAM can be undertaken to evaluate changes obtained with this approach. The purpose of the present study was to analyze the anatomic changes occurring in the nose before and after PNAM in a group of UCLP patients.

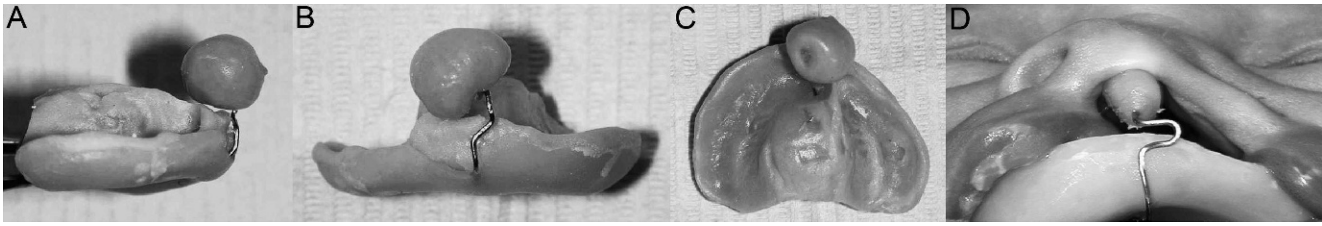

FIGURE 2 Modified intraoral acrylic plate with adjustable wire supported nasal stent. A: Lateral view. B: Frontal view. C: Occlusal view. D: Plate in position. Note the loop in the nasal stent used to adjust its vertical and lateral position. Soft acrylic is added as needed over the nasal stent to further conform the nostril.

Materials and Methods

Thirty patients (19 male; 11 female) with UCLP were included in the study. All patients received a modified unilateral PNAM treatment protocol prior to primary surgical lip repair in use since 1993 (Figueroa and Polley, 2006). A maxillary intraoral plate made of light-cured orthodontic resin was used. The plate supported a wire with a loop for adjustments and at its end, a nasal stent covered with hard acrylic. A soft denture liner was used to cover the inner part of the plate and the acrylic portion of the nasal stent to obtain a close contact with the palatal tissues and to avoid irritation of the nasal mucosa (Fig. 2). A modified tape-lip adhesion procedure was used to apply constant pressure on the maxilla in patients where the cleft was considered to be severe. In patients with milder clefts, tapping was not utilized (Fig. 3). Adjustments to the loop were done weekly to improve vertical and anteroposterior nasal form, and selective grinding and addition of acrylic in specific parts of the plate allowed narrowing of the alveolar cleft before surgery. Adjustments of the PNAM appliance were done until the pressure of the nasal extension made the cleft nasal cartilage appear rounded and until its medial aspect was at the same level as the noncleft nasal cartilage. The appliance was used until the cartilage achieved rounded form without the device. Both PNAM and tape-lip adhesion were done by the same orthodontist. This investigation had institutional review board approval. In order to assess the short-term results of this treatment protocol, nasal impressions were obtained from all children using a custom acrylic tray and alginate dental impression material (Kromopan 100, Lascod, Florence, Italy). The impressions were poured with a type III dental stone (COECAL, GC America Inc., Alsip, IL). The mean age at the initial impression (T1) was 45.24 days, and the post PNAM impression mean age (T2) was 146.21 days. The patients underwent PNAM treatment for an average of 100.97 days (Table 1; Fig. 4).

FIGURE 3 Lip-tape adhesion technique. Observe the increased pressure in the infant cheeks as a result of the application of positive pressure on both sides of the cleft.

Photographic Documentation

Standardized digital photographs of all casts in frontal and 45° views were obtained (Coolpix 4500, Nikon Corp., Melville, NY). Six anthropometric landmarks (two midpoints; two bilateral points) and the surface aspect of the alae were drawn on the cast before the picture was taken to allow accurate reproduction of the measurements (Farkas and Cheung, 1979; Farkas et al., 1983, 1992, 1993; Farkas, 1990, 1994) (Fig. 5). A millimeter scale was used on all photographs to ensure the precision of all measurements. The photographs were downloaded, edited, and converted to TIFF files using digital-imaging computer software (Microsoft Photo Editor 3.0, Microsoft Corp., Redmond, WA).

Measurement of Digital Photographs

The digital measurement of the photographs was performed on a PC using the public domain Scion Image Beta 4.0.2, Scion Corp. (developed in conjunction with the U.S. National Institutes of Health). Six nasal landmarks in the frontal view (two midpoints; two bilateral points) and eight landmarks in the 45° view (two midpoints; three bilateral points) were identified, including the six anthropometric points previously described (Table 2; Fig. 5). Also, three reference planes in the frontal view and four in the 45° view

TABLE 1 Description of the Sample

Male Patients	Female Patients	Total	Age, days T1	Age, days T2	PNAM Treatment, days
19	11	30	45.24	146.21	100.97

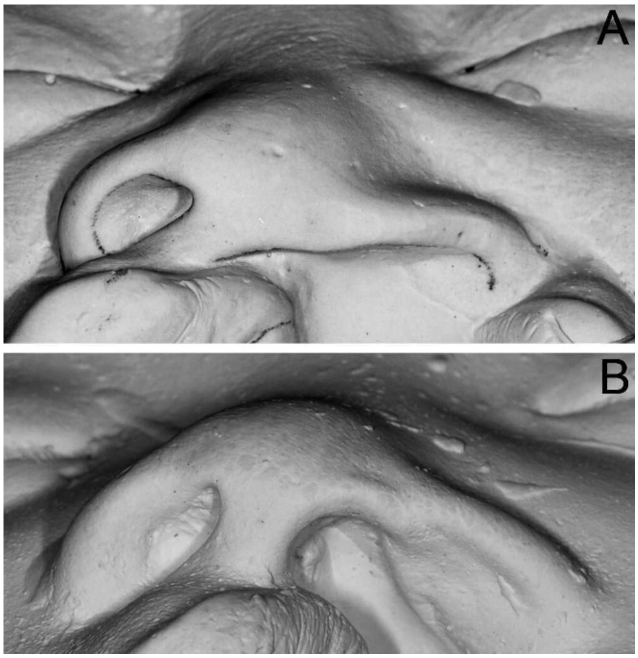

FIGURE 4 **Initial and post PNAM facial cast photographic sequence demonstrating improvement in nasal form after 3 months of PNAM treatment. Note columella elongation and straightening, improved nostril convexity, and better nasal tip definition.**

were digitally traced on the casts (Table 3; Fig. 6). Six measurements in the frontal view (three single linear; one single angular; one bilateral angular), and 18 in the 45° view (three single linear; five bilateral linear; one single angular; one bilateral angular; one bilateral area) were obtained (Table 4; Fig. 6). One measurement (Ac-Ac) was transferred from the frontal to the 45° view to exactly replicate the dimensions present on both casts. All landmarks, planes, and measurements are shown in Tables 2, 3, and 4 and Figures 5 and 6.

Statistical Analysis

The before and after PNAM casts measurements were compared using a paired Student's *t* test (p = .05) to describe changes in single and bilateral measurements as well as the differences between bilateral measurements. All statistics were performed using statistical computer software (SPSS 11.0, SPSS Inc., Chicago, IL).

Error of the Method

To assess intraobserver reliability, double determinations were performed on 10 randomly selected facial casts by the same examiner at an interval of 1 month under standardized conditions. The facial casts were photographed twice and digitized by computer as described previously. The reproducibility of the double determinations of linear, angular, and area measurements was expressed using the Dahlberg method of errors (Dahlberg, 1948). The error values from

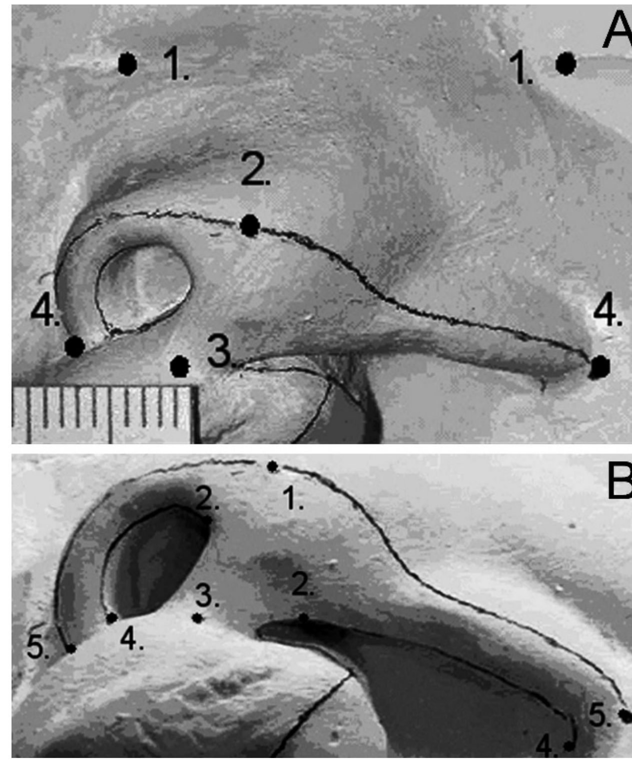

FIGURE 5 **Anthropometric points used in the present study (modified after Farkas, 1994). A: Frontal view: 1. endocanthion (En), 2. pronasale (Prn), 3. subnasale (Sn), and 4. alar curvature (Ac). B: 45° view: 1. pronasale (Prn), 2. highest point of the columella (C′), 3. subnasale (Sn), 4. subalare (Sbal), and 5. alar curvature (Ac).**

the double determinations were less than 1.32 mm for linear measurements, less than 5.39° for angular measurements, and less than 4.28 mm^2 for area measurements. These values were considered clinically acceptable.

Results

The results are listed in Tables 5 and 6. Only the significant and clinically relevant changes due to PNAM therapy will be described. The methodology employed was successful in identifying differences among groups as follows.

Single Measurements

Frontal View

The vertical length of the nose (Na-Sn) increased during the PNAM process (T1: 19.00 mm; T2: 20.99 mm; diff: 1.99 mm; p = .000; a 10.47% increase). An increment in the width of the nose base (Ac-Ac) was observed despite the use of PNAM and lip adhesion procedures (T1: 30.42 mm; T2: 33.18 mm; diff: 2.75 mm; p = .000; a 9.07% increase) (Table 5). A change was noticed in the inclination of the nasal base relative to the intercanthal plane (nasal base inclination [NBI]), with elevation of the cleft side alar base insertion due to the pressure applied by the nasal stent (T1: 2.45°; T2: 3.53°; diff: 1.08°; p = .047; a 44.08% increase). On the other hand,

TABLE 2 Landmark Definitions*

Landmark	*Definition*
1. Endocanthion (En)	Inner eye fissure commissure point
2. Nasion (Na)	Midpoint of the nasofrontal suture
3. Pronasale (Prn)	Most protruded point of the nose
4. Subnasale (Sn)	Midpoint formed where the lower border of the nasal septum and the surface of the upper lip meet
5. Highest point of the columella (C′)	Most superior point on the columella crest
6. Alar curvature (Ac)	Facial insertion of the alar base
7. Subalare (Sbal)	Labial insertion of the alar base

* Modified from Farkas (1994).

the columella displacement from the midline plane (Y axis) (Sn-Y) diminished 0.84 mm (T1: 8.44 mm; T2: 7.59 mm; diff: −0.84 mm; $p = .025$; a 10.07% decrease) (Table 5).

View of 45°

The projection of the nose relative to its base (Prn/Ac-Ac) demonstrated an increase (T1: 11.31 mm; T2: 12.72 mm; diff: 1.41 mm; $p = .000$; a 12.47% increase), while the protrusion of the tip of the nose (Prn-Sn) remained essentially unchanged (T1: 9.49 mm; T2: 9.88 mm; diff: 0.39 mm; $p > .05$; a 4.11% increase). These observations indicate a positional shift of the nasal structures with minimal dimensional change. The deviation of the columella (CD angle) decreased 15°, improving symmetry (T1: 140.74°; T2: 126.06°; diff: −14.68°; $p = .000$; a 10.43% decrease) (Table 5).

Bilateral Measurements

View of 45°

When the position and form of the nasal cartilages that determine nostril shape and size were analyzed, a progressive increase was found in alar displacement (Prn-Ac) on both sides (T1-T2: Prn-Ac: NC [noncleft]: 15.98–17.99 mm; diff.: 2.01 mm; $p = .000$; a 12.58% increase; C [cleft]: 22.44–24.32 mm; diff.: 1.88 mm; $p = .000$; a 8.38% increase). Nostril height (NH) changed minimally on the NC side (T1-T2: 4.24–4.30 mm; diff.: 0.06 mm; $p > .05$; a 1.42% increase) but increased on the C side (T1-T2: 2.86–6.03 mm; diff.: 3.17 mm; $p = .000$; a 110.84% increase). The differences between pre and post PNAM for nostril height comparing cleft and noncleft sides were significant (T1 diff.: −1.38 mm; T2 diff.: 1.72 mm; total diff.: 3.11 mm; $p = .000$; a 225.36% change) (Tables 5 and 6).

The columella length (CL) on the cleft side had an increase after PNAM (T1: 0.60 mm; T2: 2.47 mm; diff.: 1.87 mm; $p = .000$; a 311.66% increase), while minimally changing on the noncleft side (T1: 4.42 mm; T2: 4.56 mm; diff.: 0.14 mm; $p > .05$; a 3.16% increase). However, the cleft columella length remained shorter than the noncleft side after PNAM (T2: NC: 4.56 mm; C: 2.47 mm; diff.: −2.10 mm; a 45.83% decrease). After treatment, a significant, but partial, improvement was found in the CL differences between C and NC sides (T1: −3.82 mm; T2: −2.10 mm; diff.: 1.72 mm; $p = .000$; a 45.02% improvement) (Tables 5 and 6).

The nostril axial inclination (NAI) on the cleft side had a 10° change after PNAM (T1: 17.26°; T2: 27.51°; diff.: 10.25°; $p = .000$; a 59.38% increase), while the noncleft side only increased 4° (T1: 40.37°; T2: 44.22°; diff.: 3.84°; $p = .017$; a 9.51% increase). The difference in this measurement between cleft and noncleft nostrils before and after PNAM improved 6.40° (T1: −23.11°; T2: −16.71°; diff.: 6.40°; $p = .000$; a 27.69% change). However, this change on the cleft side was insufficient to achieve perfect symmetry with the noncleft side (T2: C: 27.51°; NC: 44.22°) (Tables 5 and 6).

The cleft nostril area (NA) increased 35 mm^2 after PNAM (T1: 36.40 mm^2; T2: 71.04 mm^2; diff.: 34.64 mm^2; $p = .000$; a 95.16% increase). The noncleft nostril area increased only 1 mm^2 (T1: 23.24 mm^2; T2: 24.24 mm^2; diff.: 0.99 mm^2; $p > .05$; a 4.25% increase). Analysis of the differences between cleft and noncleft sides before and after PNAM indicated that the cleft nostril area became larger after PNAM compared with the unaffected side (T1: 13.16 mm^2; T2: 46.81 mm^2; diff.: 33.65 mm^2; $p = .000$; a 255.69% change) (Tables 5 and 6).

Discussion

The purpose of this study was to analyze the anatomic changes occurring in the unilateral cleft lip nose after PNAM in a group of patients with complete UCLP. A digital analysis of standardized photographs of facial casts was undertaken to assess nasal changes, with the objective of evaluating the results obtained after the use of our presurgical nasal molding protocol to minimize the unilateral cleft lip nasal deformity.

During the length of the present study (100 days), the nasal length (Na-Sn) of the patients increased an average of

TABLE 3 Plane Definitions†

Plane	*Definition*
1. Intercanthal plane	Endocanthion-endocanthion line
2. Facial vertical midline	Plane perpendicular to the Intercanthal plane going through nasion
3. Nasal base plane	Alar curvature – alar curvature line
4. Subnasale nasal base plane	Projection of nasal base plane going through subnasale
5. Nostril axis plane	C′Point – subalare line
6. Columella plane	Line between subnasale and the midpoint between right and left C′ points

† Modified from Farkas (1994).

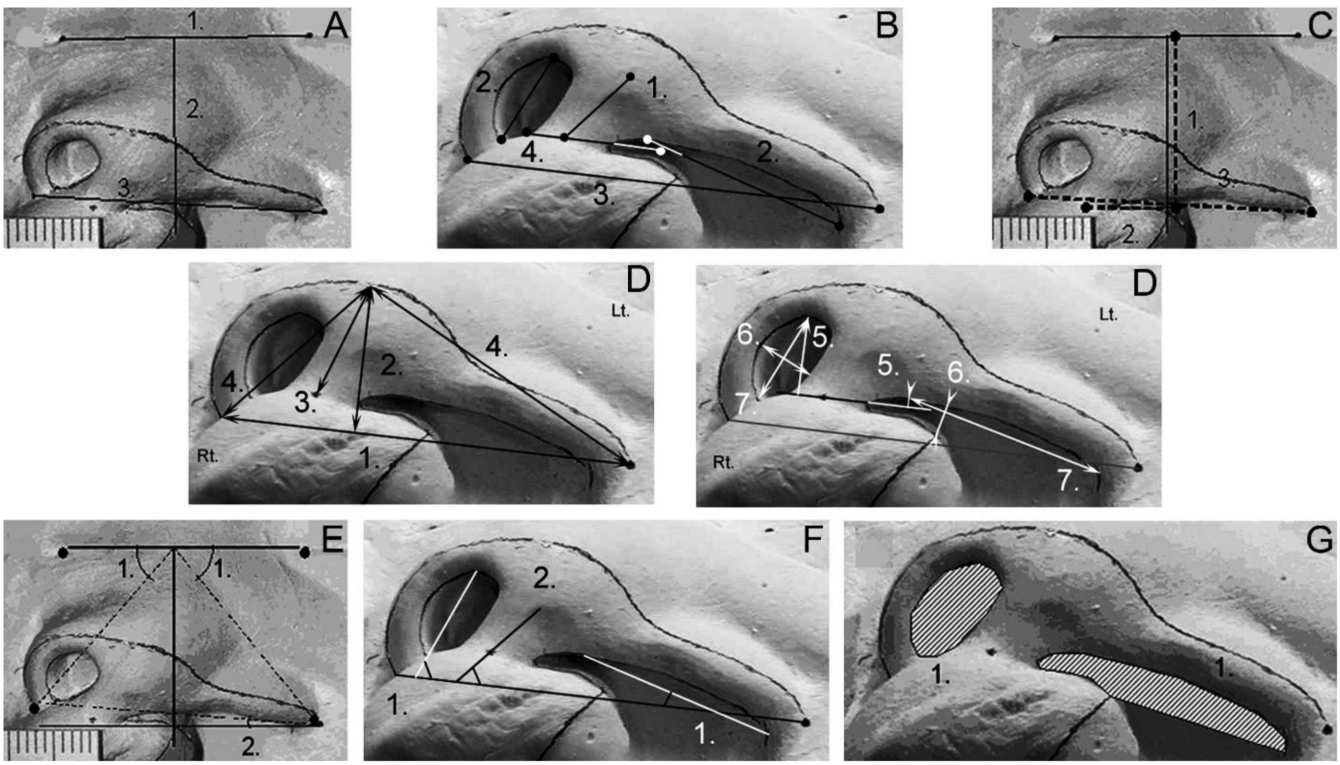

FIGURE 6 **Reference planes and measurements used in the present study (modified after Farkas, 1994). A: Reference planes (frontal): 1. intercanthal plane, 2. facial vertical midline, and 3. nasal base plane. B: Reference planes (45°): 1. columellar plane, 2. nostril axis plane, 3. nasal base plane, and 4. subnasale nasal base plane. C: Linear measurements (frontal): 1. nasal height, 2. columella displacement, and 3. nasal width. D: Linear measurements (45°): 1. nasal width, 2. projection of nasal tip, 3. nasal tip protrusion, 4. alar displacement, 5. columellar length, 6. nostril height, and 7. nostril length. E: Angular measurements (frontal): 1. alar deflection and 2. nasal base inclination. F: Angular measurements (45°): 1. nostril axis inclination and 2. columella deviation. G: Area measurements (45°): nostril area.**

2 mm, a value slightly greater than anthropometric changes in noncleft infants between birth and 12 months (Farkas, 1994). The width of the base of the nose (Ac-Ac) increased slightly more in our sample, and the projection of the nose relative to the nasal base (Prn/Ac-Ac) had changes similar to those reported for noncleft infants, albeit measured slightly differently. Although the cleft and noncleft noses are obviously different, it is interesting to note that no negative growth effects were observed as a result of the PNAM treatment when compared to normal growth increments reported by Farkas for the period of the study (Fig. 7).

The NBI was slightly uneven at the start of treatment and it worsened by 1.08° after PNAM. This is an unfavorable posttreatment change as it magnifies the original vertical asymmetry of the position of the cleft side alar base insertion. This may be the result of the upward and lateral lift exerted in the cleft alar base insertion (Ac point) by the nasal stent. However, the horizontal position of the alar bases as measured by the alar deflection angle (ADE) was relatively stable. The horizontal position of subnasale (Sn-Y) was minimally changed toward the midline and the columella deviation (CD) significantly improved after PNAM by 14.7°. In addition, the cleft nostril axis inclination (NAI) improved by 10.25°. All of these changes were favorable towards decreasing the nasal asymmetry present at the beginning of treatment (Fig. 7).

When the nostrils were evaluated, it was noted that the cleft side columella length (CL-C) increased significantly by 1.9 mm (312%), while the noncleft side changed minimally. This increment was the result of the positive pressure exerted against the alar rim to "elongate" the apparently short columella. Interestingly, the nostril length (NL) in both sides did not significantly change. However, the cleft side nostril height (NH-C) increased by 3.2 mm (111%), while the noncleft side nostril did not change after PNAM. The area of the cleft nostril (NA-C) increased by 35 mm^2 (95%), while the noncleft side did not change. Since the nostril length remained unchanged, the form and size of the cleft nostril was altered by an increase in the height of the cleft nostril, product of the reestablishment of the cleft columella length. As a result, an increased cleft nostril area and alar cartilage convexity were found (Fig. 7). The above changes explain why the nose became more symmetrical after PNAM treatment in this sample of UCLP patients.

Pai et al. (2005) in their photographic study of 57 patients with UCLP reported a correction of the columella deviation by 16.6° after completion of PNAM treatment. In our study, we found the correction of the columella deviation to be 14.6°. Although these numbers are quite

TABLE 4 Nasal Linear, Angular, and Area Measurement Definitions†

Measurement		*Definition*
Linear		
1. Nasal height	Na-Sn	Distance between nasion and subnasale
2. Columella displacement	Sn-Y	Displacement of the base of the columella from the midline of the face
3. Nasal width	Ac-Ac	Width between the facial insertion points of the alar base
4. Projection of nasal tip	Prn/Ac-Ac	Perpendicular distance between pronasale and the nasal width plane
5. Nasal tip protrusion	Prn-Sn	Distance between pronasale and subnasale
6. Alar displacement	Prn-Ac (C-NC)	Distance between the facial insertion of the alar base and pronasale
7. Columella length	CL (C-NC)	Distance between the highest point of the columella perpendicular to the subnasale nasal base plane
8. Nostril length	NL (C-NC)	Distance between the highest point of the columella and subalare
9. Nostril height	NH (C-NC)	Maximum distance between the outer and the inner aspects of the nostril perpendicular to the nostril length plane
Angular		
1. Nasal base inclination	NBI	Angular measurement between the nasal width plane and the intercanthal plane
2. Alar deflection	ADE (C-NC)	Angular measurement between the nasion-alar curvature plane and the intercanthal plane
3. Columella deviation	CD	Angular measurement between the columella axis and a perpendicular to the nasal width plane based on subnasale
4. Nostril axis inclination	NAI (C-NC)	Angular measurement between the nostril length plane and the nasal width plane
Area		
1. Nostril area	NA (C-NC)	Area covering the open space inside the nostril. In the cleft side, it refers to the nostril area above a line drawn between subalare and the intersection of the mucogingival line with the center of the maxillary alveolar process

† C-NC = for cleft and noncleft sides (modified from Farkas, 1994).

similar, it should be noted that the original average deviation was more severe in our sample (140.74° versus 127.74°). The height of the cleft nostril in their sample improved 30%, while in our study it increased 70%. The width of the cleft nostril was decreased by 50% in their study, and in our sample it had a 3% increase. Both studies reveal favorable changes in the nose, with the columella deviation being similar, the achieved cleft side nostril height higher in the present study, and the nostril width significantly narrower in the Pai et al. study. These differences might be explained by different measurement and analysis methodology, different racial groups studied, different degrees of clefting, and a more effective tapping technique used by Pai et al. (2005).

Ezzat et al. (2007) analyzed casts from 12 patients with UCLP with a similar treatment time and protocol to that reported in our study. They used a stereoscope with a charge-coupled device camera to analyze the casts in the frontal view. They found a 16.58° change in columella deviation, similar to the results of Pai et al. and this study. Interestingly, they found other changes similar to those found in our study. The cleft nostril height increased by 1.82 mm, while in our study it increased by 3.16 mm. The base of the nose increased in width by 1.60 mm. In our sample it similarly increased by 2.75 mm. While in their sample the nostril length decreased by 1.66 mm, in our sample it increased only by 0.59 mm. Like the study from Pai et al. (2005), it appears that Ezzat el al. (2007) have a more effective tapping technique than the one used in our sample. However, we were able to achieve higher nostril height with similar midline symmetry as indicated by the columella angle deviation improvement.

Keçik and Enacar (2009) performed a similar study evaluating the effects of PNAM in 22 UCLP patients using scanned facial casts. They found a decrease in the deviation of the columella and the alar base width on the cleft side. In addition, a significant increase of the cleft nostril area was recorded. Our results on a larger sample corroborate these findings, except for the decrease in the alar base width. Mishra et al. (2010) analyzed 23 mixed unilateral and bilateral cleft lip and palate cases treated with PNAM, compared to a diagnosis-based control group treated without PNAM. They found a significant increase in nostril height, without significant changes in nostril width and alar displacement. In our study we found similar findings in a treatment group just with UCLP patients.

PNAM treatment affects both maxillary bone and nasal cartilaginous structures. In the present study, we observed an increase in cleft nostril width, height, and area, which are measurements that describe the change in alar convexity. Nakamura et al. (2009) did a comparative up to 5-year follow-up study between 15 patients with complete UCLP treated with PNAM and 15 patients who received only presurgical maxillary orthopedics. The PNAM group nostril height and width and the columellar length were significantly higher when compared to the just maxillary orthopedics group, decreasing the columella asymmetry present after treatment. In addition, they subjectively observed improved alar curvature of nostril cartilage in the PNAM group.

Singh et al. (2005) performed a study to evaluate 3D changes in nasal morphology in 10 UCLP patients after PNAM using digital 3D stereophotogrammetry. They also reported direct linear and angular measurements, and some of them were similar to the ones utilized in this study. Although direct comparisons cannot be made between the two studies because different measuring methodologies (3D

TABLE 5 Paired Samples *t* Test Before (T1) and After PNAM (T2)†

				Paired Differences (T2-T1)							
				T1		T2		Difference			
		Type of Measurement		Mean	SD	Mean	SD	Mean	SD	Sig. (2-tailed)	% Change
Frontal view	Single	Linear, mm	Na-Sn	19.00	2.02	20.99	1.70	1.99	1.88	.000 **	10.47
			Ac-Ac	30.42	2.45	33.18	2.46	2.75	2.22	.000 **	9.07
			Sn-Y	8.44	1.95	7.59	1.92	−0.84	1.95	.025 *	−10.07
		Angular, degree	NBI	2.45	2.97	3.53	2.51	1.08	2.85	.047 *	44.08
	Bilateral	Angular, degree	ADE (NC)	46.94	5.23	47.66	3.33	0.72	4.63	NS	1.54
			ADE (C)	53.45	4.16	54.58	4.10	1.12	5.00	NS	2.11
45° View	Single	Linear, mm	Prn-Sn	9.49	1.33	9.88	1.25	0.39	1.08	NS	4.11
			Prn/Ac-Ac	11.31	1.51	12.72	1.28	1.41	1.08	.000 **	12.47
		Angular, degree	CD	140.74	11.20	126.06	10.61	−14.68	11.45	.000 **	−10.43
	Bilateral	Linear, mm	Prn-Ac (NC)	15.98	1.28	17.99	1.61	2.01	1.14	.000 **	12.58
			Prn-Ac (C)	22.44	1.51	24.32	1.72	1.88	1.68	.000 **	8.38
			CL (NC)	4.42	0.78	4.56	0.94	0.14	0.75	NS	3.16
			CL (C)	0.60	0.88	2.47	1.36	1.87	1.34	.000 **	311.66
			NL (NC)	7.26	0.99	7.45	1.02	0.19	1.09	NS	2.61
			NL (C)	13.58	1.82	14.17	2.27	0.59	1.67	NS	4.34
			NH (NC)	4.24	0.79	4.30	0.84	0.06	0.77	NS	1.42
			NH (C)	2.86	1.91	6.03	2.51	3.17	2.50	.000 **	110.84
		Angular, degree	NAI (NC)	40.37	9.61	44.22	9.47	3.84	8.30	.017 *	9.54
			NAI (C)	17.26	4.82	27.51	6.28	10.25	6.44	.000 **	59.36
		Area, mm^2	NA (NC)	23.24	5.78	24.24	6.28	0.99	4.78	NS	4.30
			NA (C)	36.40	14.13	71.04	30.10	34.64	27.78	.000 **	95.16

† C = cleft side; NC = noncleft side; NS = not significant; n = 30.
* Significant at 5% level. ** Significant at 1% level.

TABLE 6 Paired Samples *t* Test of the Differences Between Cleft (C) and Noncleft (NC) Sides Before (T1) and After PNAM (T2)†

			Paired Differences (T2-T1)							
			T1		*T2*		*Difference*			
	Type of Measurement		*Mean*	*SD*	*Mean*	*SD*	*Mean*	*SD*	*Sig. (2-tailed)*	*% change*
Frontal view	Angular, degree	ADE (C-NC)	6.51	5.06	6.92	4.45	0.41	5.77	NS	-
45° View	Linear, mm	Prn-Ac (C-NC)	6.46	1.92	6.34	2.44	−0.12	2.14	NS	-
		CL (C-NC)	−3.82	0.93	−2.10	1.01	1.72	1.04	.000**	45.02
		NL (C-NC)	6.32	1.89	6.71	2.58	0.40	1.87	NS	-
		NH (C-NC)	−1.38	1.82	1.73	2.60	3.11	2.55	.000**	225.36
	Angular, degree	NAI (C-NC)	−23.11	10.06	−16.71	10.63	6.40	8.04	.000**	27.69
	Area, mm^2	NA (C-NC)	13.16	13.76	46.81	29.54	33.65	27.06	.000**	255.69

† (C-NC) = Difference between cleft and noncleft values. NS = not significant; n = 30.
* Significant at 5% level; ** Significant at 1% level.

versus direct photogrammetry) and sample sizes were utilized, some interesting observations can be made. These included the width of the nasal base, which slightly decreased in their study but slightly increased in our sample. As indicated above, this might be related to a more effective tapping technique than the one used in our patients. The nasal tip protrusion (Prn-Sn) had similar increases in both studies. The alar length (Prn-Ac) on the noncleft side increased minimally and similarly in both studies, while on the cleft side it slightly increased in our sample and minimally decreased in their study.

Pai et al. (2005) and Ezzat el al. (2007) in 2D evaluations and Singh et al. (2005) in their report on 3D nasal changes after PNAM have demonstrated the additional effects of a more efficient tapping technique than the one used in our sample. Despite the lack of a significant nasal width reduction as shown by Pai et al. and Ezzat et al., we were able to achieve higher nostril height with similar midline symmetry as indicated by the columella angle deviation improvement.

Analyzing 3D nasal changes after PNAM and primary lip and nose repair, Singh et al. (2007) in their 1-month follow-up study compared the 3D facial morphology in 15 UCLP patients surgically corrected after PNAM and 10 noncleft control subjects. They concluded that 3D nasal morphology in the treated UCLP patients was almost indistinguishable from the control group. Our unpublished postsurgical short-term results regarding nasal symmetry (Gomez et al., 2003) are in accordance with the findings of Singh et al. (2007). Maull et al. (1999) performed a study using nasal casts of 20 UCLP patients after lip repair, 10 of which had received PNAM. A significant difference was found in the mean asymmetry index score, indicating that the PNAM group 4.5 years after lip repair remained more symmetrical than the control group. Barillas et al. (2009), in a follow-up study in 15 UCLP patients of the same sample, indicated that PNAM changes remained after late childhood (9 years of age) and their noses were significantly more symmetrical than in their control group. Longer (15+ years) follow-up

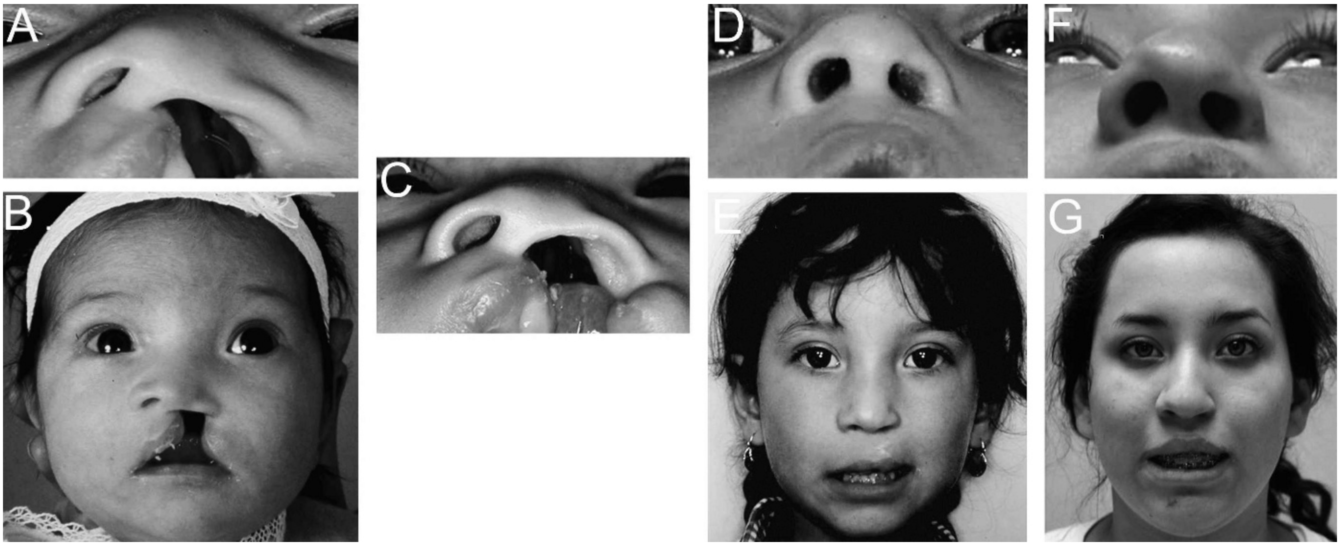

FIGURE 7 PNAM treatment outcome. A,B: Before PNAM. C: After PNAM. D,E: After primary lip and nose reconstruction. F,G: At 16 years of age. This patient has not received additional surgical nasal procedures.

studies should be done to evaluate the maintenance of PNAM effects after the completion of maxillary and total facial growth.

Mao et al. (2006) reported in a group of 10 patients a significant improvement after PNAM and 2 weeks after lip surgery. However, they found a moderate degree of relapse 6 months after lip repair. Pai et al. (2005) found in 57 UCLP patients after PNAM and lip surgery, a reduction of 10% in nostril width, 20% in nostril height, and 4.7% in columella deviation. Liou et al. (2004) found in 25 UCLP infants that there was nasal relapse and indicated that it was the result of a significant differential growth between the cleft and noncleft sides in the first year postoperatively. Postoperative relapse has been attributed in part to elasticity remaining in the deformed alar cartilage, even after PNAM treatment (Lo, 2006; Mao et al., 2006).

The follow-up of patients with clefts should ideally include a 3D quantitative method to evaluate facial form and asymmetries (Wood et al., 1997; Maull et al., 1999; Singh et al., 2005, 2007; Baek and Son, 2006). The ideal method includes obtaining fast and accurate 3D direct facial images as those obtained by 3D stereophotogrammetry (Singh et al., 2005, 2007). Three-dimensional photogrammetry analysis is the state of the art to analyze facial changes on patients with orofacial clefts. This methodology avoids any distortion caused by the application of alginate that could make the deformity appear more severe, thus minimizing treatment results. Also, it prevents the loss of accuracy from sample processing (errors during facial impressions, during photographic conversion, etc.), a flaw in plaster-based photogrammetric studies like ours. However, high costs prevent routine availability (Maull et al., 1999).

Plaster casts and digital 2D photogrammetry is one of the most accessible methods to record the progress of treatment. However, this methodology has disadvantages, such as the difficulties in obtaining facial and maxillary casts while the infant is awake or the secondary distortions that lead to inaccuracies that may occur because of pressure exerted against the structures. Finally, another source of error is introduced when the photographic record is taken. The effect of nasal impression pressure on the nose is to increase nasal width while decreasing nasal height. If it is recognized that the impression might exert pressure on the nasal structures, it can be assumed that the results without the impression pressure could actually be better than the ones reported in this study. The present PNAM technique is part of a long-term, prospective study that started in 1993 (Figueroa and Polley, 2006). This fact explains why 2D photogrammetric analysis of facial casts was chosen instead of the more modern and accurate measuring methods available today. Our PNAM technique has been reliably utilized and has demonstrated favorable nasal changes, helping to reduce the deformation and displacement of cleft nasal cartilages in a simpler way. Our technique does not rely on external tapping for its effectiveness, without compromising the overall objectives of presurgical nasoalveolar molding. The PNAM nasal extension, as used in this sample, allowed rapid adjustments by modifying the loop integrated into the stent. The appliance has been well tolerated by the infants and accepted by the parents.

As shown by this and other studies, the use of PNAM improves nasal symmetry prior to surgery. It appears that these changes are favorable after repair of the lip, as postsurgical follow-up studies in PNAM treated patients report improved symmetry when compared to patients treated without PNAM (Maull et al., 1999; Nakamura et al., 2009). Mishra et al. (2010) also suggested that PNAM can be a cost-effective technique by reducing the number and improving the result of future secondary rhinoplasty procedures. In addition, a presurgical "symmetrical" cleft nose with narrower alveolar cleft is likely to simplify the primary lip-nose repair. This may decrease surgical time, thus reducing cost.

This treatment approach has some critical points, and the following recommendations need to be addressed to improve PNAM protocols:

1. PNAM should attempt to decrease and not increase the presurgical width of the alar base to facilitate future surgery. This is different to what we found in our study (Table 5) in which the alar base increased slightly. This suggests that "tapping" might be required to counteract possible tissue stretching and/or normal width growth changes.
2. PNAM treatment should start as early as possible. This helps to maintain the achieved symmetry. The neonatal hyaluronic acid, increased by a transient increment in estrogen levels, acts as a temporary barrier between the intercellular materials, giving the cartilage a temporary lack of elasticity. If started later, the results would be less rewarding due to a decreased amount of estrogen and hyaluronic acid in the neonatal cartilage (Matsuo et al., 1989; Matsuo and Hirose, 1991). As a result, PNAM treatment in patients under 1 month of age is desirable and has led to higher subjective alar satisfaction than in patients treated later (Deng et al., 2005).
3. Extend the PNAM treatment as much as possible as longer treatment results in better nose symmetry (Ezzat et al., 2007).
4. Overtreatment of patients to compensate for relapse and possible differential growth is a controversial aspect of PNAM treatment. Some authors suggested a slight orthopedic vertical overcorrection of the alar dome on the cleft side (Singh et al., 2005), while another group had preference for vertical surgical nasal overcorrection (Liou et al., 2004). However, the goal of the treatment is to obtain a nose as symmetrical as possible before surgery to improve stability and form. Caution should be exercised during PNAM not to increase the circumference of the nostril ("meganostril") and to not extremely thin the nasal cartilages as a result of the PNAM pressure that could lead to an unstable nasal

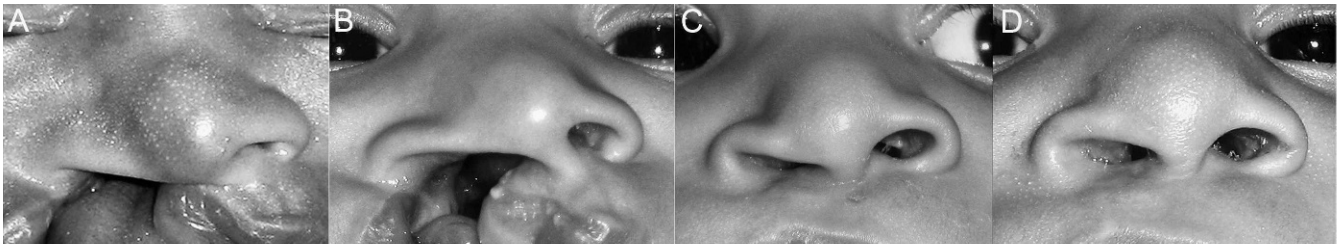

FIGURE 8 Improvement of the cleft lip nose after a combined PNAM-CL Surgery-PNM (postsurgical nasal molding) treatment. A: Before PNAM. B: After PNAM. C: After primary lip and nose repair. It was noticed that additional molding would be useful in this case. D: After PNM a better nasal contour was achieved after 1 month of treatment with the use of a custom-made acrylic nasal conformer.

outcome. In our study, the cleft side nasal cartilage maintained its proportional length relative with the noncleft side throughout the period of observation (Table 5), thus preventing the creation of a "meganostril." With symmetrical nasal structures the surgeon should be able to equalize nostril diameters at the time of surgery.

5. The use of retention postsurgical stents is highly recommended to improve nostril stability and form. Clinicians have advocated the use of postsurgical acrylic or silicone stents to maintain the achieved surgical results since relapse is still a concern (Friede et al., 1980; Matsuo and Hirose, 1991; Liou et al., 2004; Pai et al., 2005). In addition to commercially available stents, we have used a customized external nasal retainer to assist in the maintenance and additional improvement of postsurgical nasal form (Fig. 8).

A presurgical nasoalveolar and postsurgical nasal molding protocol, taking into account all points previously discussed, should be used to improve the long-term outcomes of this treatment approach. This paper demonstrated our short-term nasal results. As most of the patients in our series are entering adolescence, a report of nasal form at the end of midfacial growth and prior to the final rhinoplasty to determine the long-term effects of the technique will be conducted. More studies are still needed to assess long-term nasal outcomes after PNAM treatment and to determine if there is a reduction in the complexity and number of secondary rhinoplasty procedures. If this point is corroborated, the technique will be validated as it may ultimately reduce the burden of care in UCLP patients.

Conclusion

A favorable reshaping of the infant unilateral cleft nasal deformity after PNAM was achieved in the present sample. This was the result of a geometric improvement in nasal form by a straightening and elongation of the columella length on the cleft side, an increase in nostril height and convexity of the cleft alar cartilage, an increase in nasal tip projection without affecting nasal tip protrusion, and an increase in the area of the cleft nostril. These nasal changes, in conjunction with the narrowing of the alveolar segments obtained by the intraoral portion of PNAM, lead to improved and favorable nasal symmetry before primary lip and nasal repair.

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