Presurgical Nasoalveolar Molding Therapy for the Treatment of Bilateral Cleft Lip and Palate: A Preliminary Study

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Objective: **To evaluate the outcome of presurgical nasoalveolar molding therapy in the treatment of patients with bilateral cleft lip and palate.**

Design: **A prospective study with blinded measurements.**

Setting: **The Cleft and Craniofacial Clinic at the University of Texas at Houston Medical School, Houston, Texas.**

Patients: **Eight patients with bilateral cleft lip and palate, treated between 2002 and 2004.**

Interventions: **The starting age for presurgical nasoalveolar molding therapy was 34.9 days and the average length of the therapy was 212.5 days.**

Main Outcome Measures: **Measurements of intraoral and extraoral casts were performed, and statistical analyses were used to compare the differences between measurements before and after therapy.**

Results: **Intraoral measurements demonstrated that there was a statistically significant reduction of the premaxillary protrusion and deviation. There was also a significant reduction in the width of the larger cleft. Extraoral measurements revealed that there was a significant increase in the bi-alar width and in the columellar length and width. Moreover, there was a significant improvement in columellar deviation. Finally, the nostril heights of both sides were increased.**

Conclusion: **The authors have quantitatively shown that presurgical nasoalveolar molding therapy has significant advantages in the treatment of bilateral cleft lip and palate patients. It improves the nasal asymmetry and deficient nasal tip projection associated with bilateral cleft lip and palate. It also forces the protruded premaxillary segment into alignment with the dental alveolar segments, improving the shape of the maxillary arch. As a result, the changes associated with presurgical nasoalveolar molding therapy help decrease the complexity of subsequent surgeries.**

KEY WORDS: *bilateral cleft lip and palate, presurgical nasoalveolar molding therapy*

The treatment of patients with cleft lip and palate (CLP) remains a subject of considerable controversy. At present, there are two competing philosophies. One involves surgical correction alone, whereas the other philosophy involves surgical correction in conjunction with presurgical molding of the cleft segments. Advances in plastic surgery have corrected many of the deformities associated with CLP. However, persistent problems with associated nasal deformities have given rise to the use of presurgical nasoalveolar molding (PNAM) in cleft-treatment protocols. The theory of PNAM treatment is based on Matsuo's research that the nasal cartilage is still developing and is subject to repositioning within the first 6 weeks of life (Matsuo and Hirose, 1991). Grayson et al. (1999) described the first treatment protocol for PNAM. Although there have been a number of reports regarding the effectiveness of PNAM in patients with unilateral CLP (Bennun et al., 1999; Grayson et al., 1999; Maull et al., 1999; Cho, 2001; Grayson

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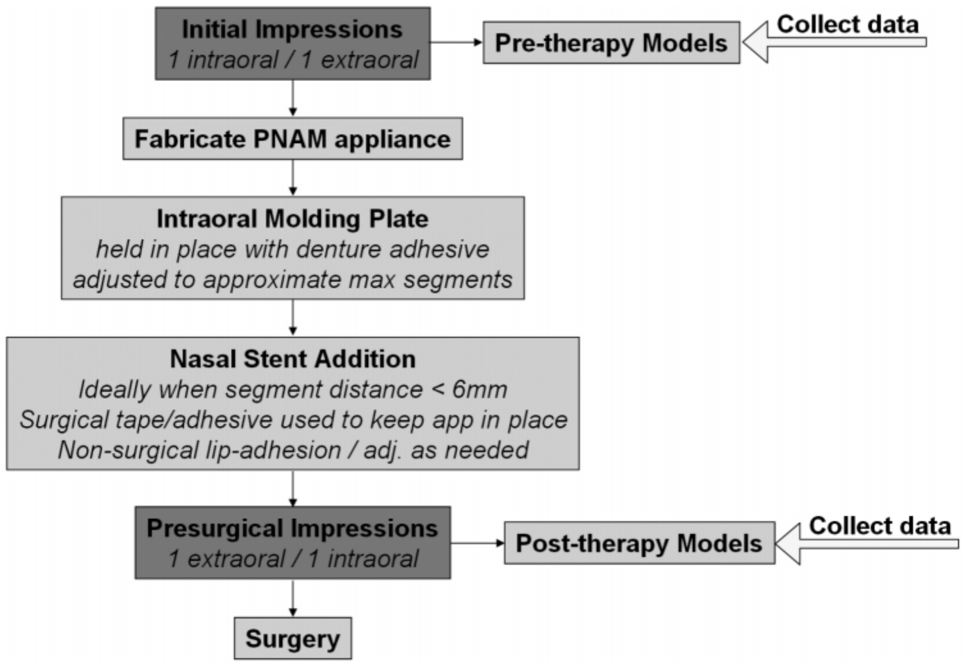

FIGURE 1 **PNAM technique and data collection.**

and Cutting, 2001; Pfeifer et al., 2002; Da Silveira et al., 2003; Yang et al., 2003; Liou et al., 2004), there have been few reports on its efficacy in patients with bilateral CLP (BCLP) (Grayson and Cutting, 2001; Da Silveira et al., 2003). The purpose of this study was to quantitatively evaluate the outcomes of PNAM therapy in patients with BCLP. The particular focus of this study was on the effect that PNAM has on the alignment of alveolar segments and nasal symmetry.

Materials and Methods

PNAM therapy was used on eight patients with BCLP who presented at the Cleft and Craniofacial Clinic at the University of Texas at Houston Medical School between February 2002 and May 2004. The protocol was approved by an Internal Review Board, and informed consent forms were obtained. The average age of the patients on commencing PNAM therapy was 34.9 days (range: 15 to 70 days) and the average length of therapy was 212.5 days (range: 63 to 385 days). The criteria for inclusion in this study were that the patient had a bilateral, nonsyndromic CLP, and that the patient's family agreed that the patient would undergo PNAM therapy.

After the initial evaluation by a multidisciplinary cleft craniofacial team, the patient had impressions taken while the patient was under general anesthesia to fabricate the PNAM appliance (Fig. 1). Oral intubation was used to prevent distortion of the nasal structures. A throat pack was used to prevent alginate material from being extruded into the oropharyngeal airway. Alginate impression material was used for both intraoral and extraoral impressions. The impressions were made using noncustom trays. The reverse side of these maxillary

FIGURE 2 **Taking an impression for an extraoral model.**

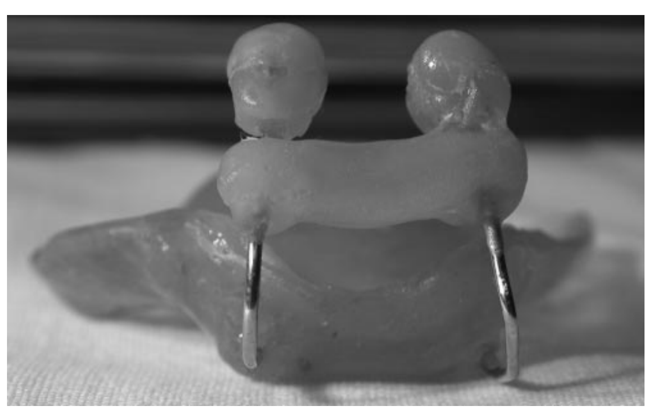

FIGURE 3 **Presurgical orthopedic appliance.**

FIGURE 4 A patient with the PNAM appliance in place.

alginate trays was also used to take the extraoral impressions (Fig. 2). Both intraoral and extraoral casts were fabricated using regular dental stone. Excess dental stone around the buccal and labial alveolar ridges was removed from the intraoral casts to ensure that any excess stone did not interfere with the scanning process. The bases of the extraoral casts were trimmed and adjusted so that the planes of the casts were identical before and after treatment. All casts were marked and stored for measurements.

The PNAM appliance was similar to the appliance described by Grayson et al. (1999). It included an intraoral molding acrylic palatal plate and two nasal stents. The nasal stents were fashioned in two ways. Initially, the stents consisted of acrylic extensions from the palate into both nostrils. More recently, the authors have used two spherical acrylic balls attached to the intraoral palatal plate with two 0.036-inch diameter wires (Fig 3). The stents were added to the molding plate only after

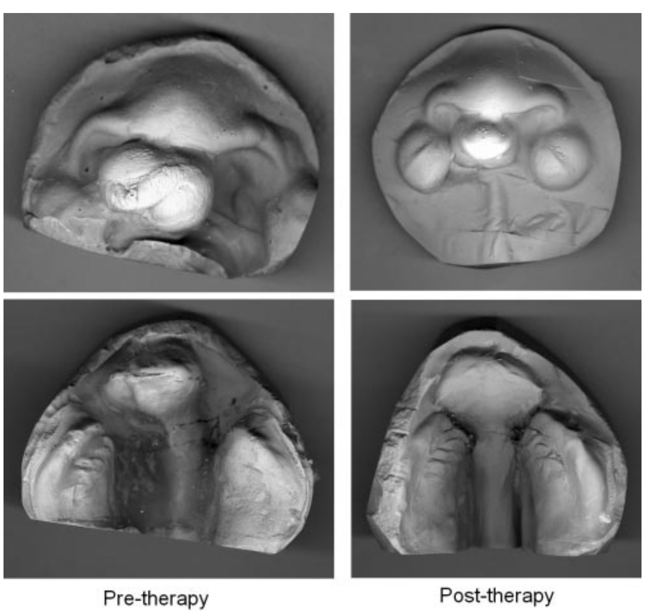

FIGURE 5 Two pairs of casts from one patient for measurements.

FIGURE 6 Placement of the cast on the flatbed scanner.

the alveolar cleft intrasegmental distance was less than 6 mm. A horizontal prolabial band was placed across the base of the columella at the nasolabial fold. Surgical tape was used to reposition the soft tissue elements of the bilateral cleft lip. The PNAM plate was held in place with dental adhesive.

The appliance was adjusted weekly based on the infant's progress. By modifying the PNAM plate and the external forces applied by the taping and elastics, the premaxilla was repositioned between the lateral alveolar segments. The advancement of the alar cartilages into the nasal tip was accomplished by adding acrylic to the nasal stents. Columellar lengthening was achieved by the combined force of the nasal stents and the horizontal prolabial band. All parents were instructed on how to insert and remove the PNAM appliance, which was worn at all times except for routine cleaning (Fig. 4).

The endpoint for the treatment of patients with PNAM was when the columella was sufficiently lengthened, the prolabium was sufficiently increased in width, and the prolabium was brought back into the maxillary arch. In this study, this was at approximately 7 months of age. After completion of the PNAM therapy, another set of intraoral and extraoral casts were made, using the same technique. A computerized random number was assigned to each model to blind the treatment stage of the casts to the examiner who would make measurements in the next stage. All impressions, casts, and PNAM appliances were made by the same author (C.C.) (Fig. 5).

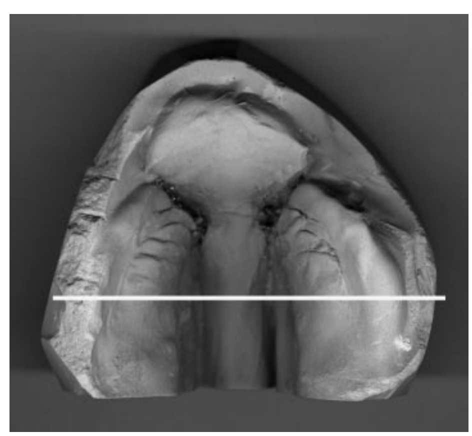

FIGURE 7 Normalization of an intraoral cast.

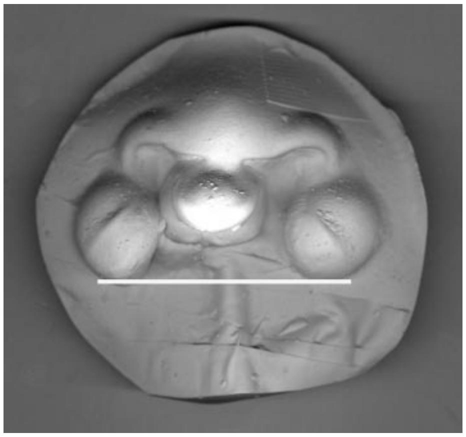

FIGURE 8 **Normalization of an extraoral cast.**

TABLE 1 **Intraoral Cast Measurements**

Measurements	*Descriptions*
Intersegment distance (ISD)	Distance between the most anterior aspects of the alveolar ridges
Intraoral arch width (AW)	Distance between widest curvature of the maxillary alveolar arches
Premaxillary protrusion (PMP)	Distance from the most anterior point of the premaxilla to the intersection with a line connecting the most anterior points of the alveolar ridges
Larger cleft width (LCW)	Distance between the most anterior point of the alveolar ridge at the larger cleft side to the most right lateral point of the premaxilla
Smaller cleft width (SCW)	Distance between the most anterior point of the alveolar ridge at the larger cleft side to the most left lateral point of the premaxilla
Premaxillary deviation (PMD)	Deviation of the premaxillary segment, using the line constructed from the midpoint of the intraoral arch width and the line passing through the most anterior point of the premaxilla, and perpendicular to the intraoral arch width. Positive values represent PMD toward the smaller cleft side; negative valves represent PMD toward the larger cleft side

Measurements were performed on the actual casts, as well as on the digital format of the two-dimensional (2D) projection images of the casts. To create the projection image, the casts were digitized into a computer, using an Epson 1600 Expression scanner (Seiko Epson Corp., Tokyo, Japan). The resolution of each projection image was 600 dots-per-inch. A projection of each intraoral cast was initially created. It was constructed using the three highest points of each cast: one from the premaxillary segment and one from each of the maxillary alveolar segments. Each cast was placed onto the scanner with the three points in contact with the glass of the scanner (Fig. 6). Next, the projection of each extraoral cast was created. The facial side of the model was placed on the glass of the scanner, whereas its base was parallel to the horizontal plane.

It was necessary to normalize the projection images of the casts in the same orientation to measure and compare them before and after PNAM therapy. To this end, Adobe Photoshop 6.0 (Adobe Systems Inc., San Jose, CA) was used. For the images of the intraoral casts, a horizontal line was constructed by connecting the widest points of the left and right maxillary segments (Fig. 7). For the images of the extraoral casts, a tangent line was constructed by connecting the most inferior points of the left and right labial segments (Fig. 8). In addition, for comparison purposes, the images were normalized to have the larger cleft on one side (the right side) and the smaller cleft on the other side (the left side). The tangent lines of both the intraoral and extraoral casts were then oriented to the horizontal plane, serving as the x-axis. After the images were oriented, they were imported into a custom-made measurement program (J.X.).

The following measurements were performed on the 2D projection images of the intraoral casts: intersegmental distance, intraoral arch width, premaxillary protrusion, premaxillary deviation, and cleft width of the larger and the smaller clefts (Table 1; Fig. 9). The following measurements were performed on the 2D projection images of the extraoral casts: bialar width, columellar deviation, nostril height, and width and length of the larger and smaller clefts (Table 2; Fig. 10). Because the prolabium and the columella overlap on the projected image, the columellar height and width (Fig. 11) were measured directly on the casts, using a digital caliper that is accurate up to 0.01 mm. The measurements were completed and repeated three times by the same examiner (A.S.) on three different occasions. The examiner was also blinded to the previous completed measurements.

The measurements were tabulated in a spreadsheet, and

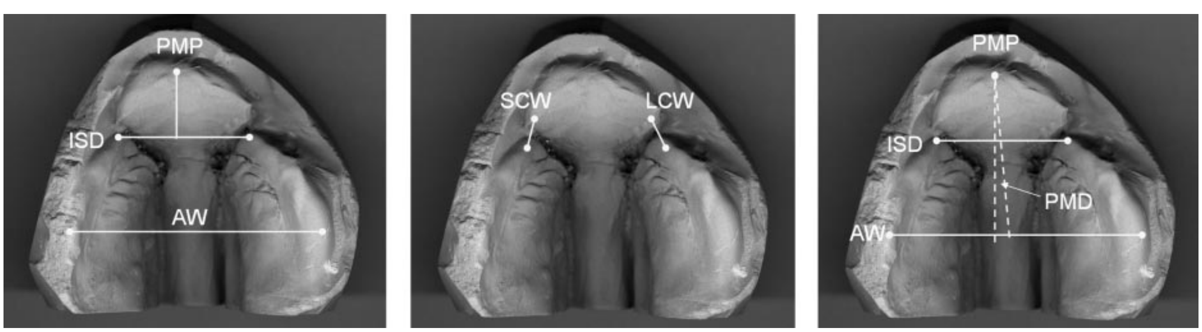

FIGURE 9 **Intraoral 2D projection measurements.**

TABLE 2 Extraoral Cast Measurements

Measurements	*Descriptions*
Bi-alar width (BAW)	Distance between the most lateral aspect of the right and left alar
Columellar width (CW)*	Distance between the most lateral points at the base of the columella
Columellar length (CL)*	The length of the columella
Columellar deviation (CD)	Using a vertical line from the most inferior point on each lip segment as a base, measure the angle of the intersection of a line constructed through the columella with that of the base. Positive values represent CD toward the smaller cleft side; negative values represents CD toward the larger cleft side
Larger Cleft Nostril Height (LCNH)†	Distance from the most cranial aspect of the inner rim of the nostril at the larger cleft side to the base
Smaller Cleft Nostril Height (SCNH)†	Distance from the most cranial aspect of the inner rim of the nostril at the smaller cleft side to the base
Larger Cleft Nostril Width (LCNW)	Distance in the horizontal plane at the widest point of the nostril at the larger cleft side to the inner rim of the ala
Smaller Cleft Nostril Width (SCNW)	Distance in the horizontal plane at the widest point of the nostril at the smaller cleft side to the inner rim of the ala
Larger Cleft Nostril Length (LCNL)	Length of the inside rim of the nostril at the larger side from the most lateral point to the columellar base
Smaller Cleft Nostril Length (SCNL)	Length of the inside rim of the nostril at the smaller side from the most lateral point to the columellar base

* The measurements were taken with a digital caliper.

† The measurements use a line connecting the inside of each lateral ala to the inner aspect of the base of the columella as the base for the measurements. The normal distance function was used to measure the two heights.

SPSS 12.0 software (SPSS Inc., Chicago, IL) was used to perform statistical analyses. An intraclass correlation coefficient was initially calculated. If the coefficient was greater than .75, the three repeated measurements were averaged. Means and standard deviations were then calculated. Paired *t* tests were used to test the differences of the measurements taken before and after therapy. Finally, various correlation coefficients were calculated.

Results

The mean intraclass correlation coefficient was .997, and consistently ranged from .997 to .998. Therefore, the three repeated measurements were averaged. The mean and standard deviation of the changes between before and after PNAM therapy were then calculated for each measurement.

The intraoral measurements (Table 3) revealed a statistically significant reduction of the premaxillary protrusion and deviation. There was no statistically significant reduction in the intersegmental distance, although there was a reduction trend in six patients. In addition, there was a statistically significant reduction of the width of the larger cleft. There was also no statistically significant change in the arch width and cleft width of the smaller cleft. The arch width was increased in five patients and reduced in three patients. The width of the smaller cleft was increased in half of the patients and reduced in the other half.

The extraoral measurements (Table 3) revealed a statistically significant increase in bi-alar width. In addition, there was a statistically significant increase in the columellar length and

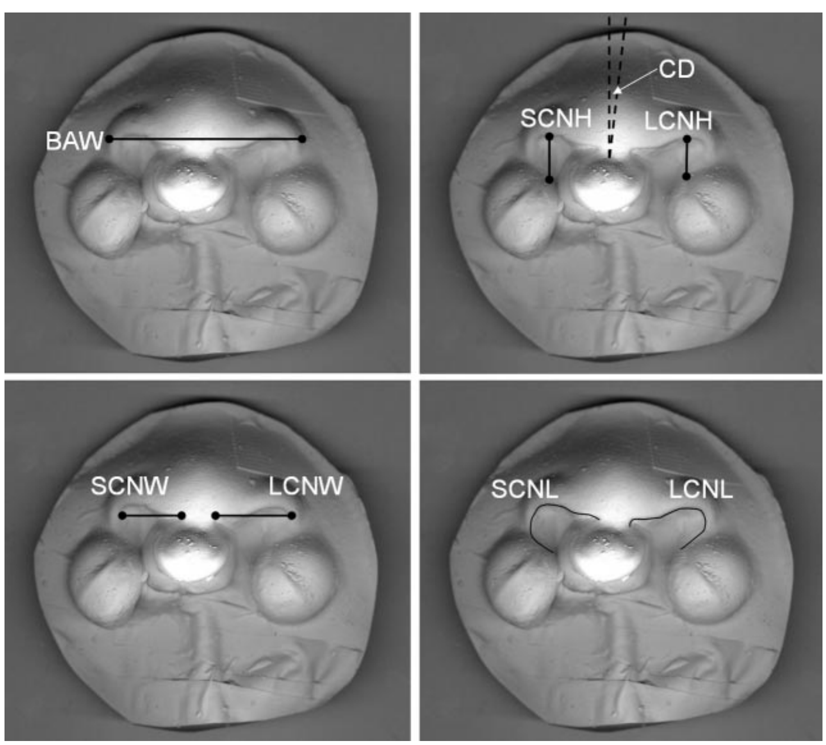

FIGURE 10 Extraoral 2D projection measurements.

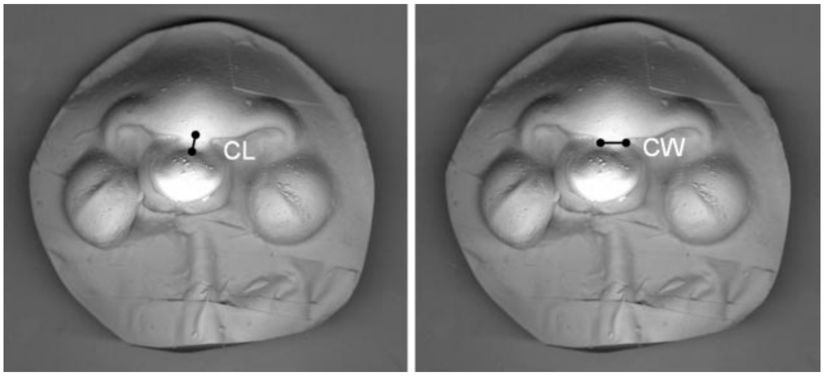

FIGURE 11 **Extraoral direct measurements.**

width. Moreover, there was a statistically significant improvement in columellar deviation. There was a decrease in the nostril width of the larger cleft and an increase in the nostril width of the smaller cleft, although neither of these numbers was statistically significant. An increase in the nostril length of both clefts was also noted. However, the increase in the nostril length of the larger cleft was minimal, whereas the increase in the nostril length of the smaller cleft was statistically significant. Finally, the nostril heights of both sides were statistically increased.

The results of the correlation coefficient tests are shown in Tables 4 and 5. The initial severity of the columellar deviation was found to positively correlate with the initial severity of the nostril width and length of the larger cleft. In addition, the initial severity of columellar deviation was found to be positively correlated with the correction of the columellar deviation. The initial severity of the premaxillary deviation was also found to be positively correlated to the correction of the premaxillary deviation. The correction of the premaxillary deviation was found to be correlated with the reduction of the width of the smaller cleft. Furthermore, the difference between before and after PNAM measurements of columellar deviation and premaxillary protrusion were positively correlated, as were the premaxillary protrusion and the premaxillary deviation. Finally, there was no significant correlation between the starting age of the PNAM therapy and the degree of correction, or between the duration of the PNAM therapy and the degree of correction.

TABLE 3 **Comparison Between Measurements Before and After Treatment**

	Before Treatment	*After Treatment*	*Difference*	*p Value*
Intraoral Measurements				
ISD	22.36	20.70	1.66	0.226
AW	39.23	40.31	−1.08	0.609
PMP	9.72	8.11	1.61	0.038
LCW	12.03	6.20	5.83	0.000
SCW	4.50	3.51	1.00	0.385
PMD	11.56	2.77	8.80	0.045
Extraoral Measurements				
BAW	31.38	35.05	−3.67	0.006
CW	5.12	6.68	−1.56	0.001
CL	2.22	3.69	−1.46	0.000
CD	19.75	6.30	13.45	0.008
LCNH	2.57	4.01	−1.44	0.006
SCNH	4.16	5.64	−1.48	0.003
LCNW	13.15	11.67	1.48	0.172
SCNW	8.37	9.71	−1.35	0.143
LCNL	14.51	16.05	−1.54	0.150
SCNL	12.85	15.89	−3.04	0.035

* $p < .05$.

Discussion

Evaluation of the intraoral casts revealed that PNAM therapy significantly reduced the protrusion and, if present, the deviation of the premaxilla. Simultaneously, PNAM significantly reduced the width of the larger cleft. This realignment helped reposition the premaxilla and align it with the dental alveolar segments. However, the width of the smaller cleft was increased in half of the patients as a result of this repositioning, which also helped reduce the width of the larger cleft.

Evaluation of the extraoral casts revealed that the PNAM therapy significantly improved nasal symmetry. Columellar deviation, length, and width were also significantly improved. In addition, the nostril length of the smaller cleft was significantly increased. However, the nostril length of the larger cleft was found to be minimally increased because it was already larger than the nostril of the smaller cleft. The combination of columellar lengthening and repositioning with nostril lengthening helped improve the nasal symmetry. Finally, both nostril heights were significantly increased, improving tip projection.

The average age at which PNAM was begun was 34.9 days. This is near the end of the ideal cartilage-molding period, which Matsuo and Hirose (1991) determined to be within the first 6 weeks of life. The average length of therapy was 212.5 days, with a range of 63 to 385 days. Although the correction of the bilateral cleft lip was delayed to 8 months of age, the authors still repaired the palate before 12 months of age, which has been their current practice in all but one patient with cleft palate. Finally, there was no significant correlation between the starting age of the PNAM therapy and the degree of correction, or between the duration of the PNAM therapy and the degree

TABLE 4 Correlation Coefficients of Intraoral Measurements

	Intersegment Distance	*Intraoral Arch Width*	*Premaxillary Protrusion*	*Larger Cleft Width*	*Smaller Cleft Width*	*Premaxillary Deviation*
CD (before versus before)*	0.71	0.19	−0.41	0.35	−0.10	0.40
CD (Δ versus Δ)	0.00	−0.05	0.82	−0.39	0.20	0.56
CD (Δ versus before)	0.79	0.04	0.41	0.18	−0.20	0.38
PMD (before versus before)	0.50	−0.11	−0.82	0.39	−0.70	—
PMD (Δ versus Δ)	−0.50	0.00	0.71	0.19	0.66	—
PMD (Δ versus before)	0.73	−0.11	−0.75	−0.11	−0.69	0.79

* Before = before treatment; Δ = difference between before and after treatment.

of correction. This may be because of the small sample size of the study.

There have been a number of studies that have documented the technique of PNAM therapy in the treatment of the patients with BCLP (Mishima et al., 1998; Fang et al., 1999; Grayson and Cutting, 2001; Da Silveira et al., 2003; Delgado et al., 2004). However, only a few studies have documented the actual changes seen in patients treated with PNAM therapy (Mishima et al., 1998; Fang et al., 1999; Delgado et al., 2004). The present study quantifies the effectiveness of implementing PNAM therapy in the treatment of BCLP patients, especially in correcting nasal asymmetry. The authors have found that PNAM therapy improves both nasal symmetry and premaxillary alignment. This study also validates the widely accepted use of PNAM therapy in the treatment of patients with BCLP.

In conclusion, we have quantitatively shown that PNAM therapy has significant advantages in the treatment of BCLP patients. It improves the nasal symmetry and deficient nasal tip projection associated with BCLP. PNAM therapy also forces the protruded premaxillary segment into alignment with the dental alveolar segments, improving the shape of the maxillary arch. As a result, the changes associated with PNAM therapy help decrease the complexity of subsequent surgeries.

This study was a preliminary study to evaluate the clinical effectiveness of PNAM therapy. The small patient sample size (eight patients) may not provide enough power to perform statistical analysis. However, the data obtained in this study could be used for sample-size calculations in future studies. Therefore, additional studies are needed to obtain a sample population large enough to statistically prove the effectiveness of PNAM therapy in treating patients with BCLP. Nonetheless, in this study, PNAM therapy made the subsequent nasal and lip reconstruction easier to perform. The authors think that PNAM therapy is a useful adjunct in the treatment of BCLP patients and that it should be considered a routine procedure in the treatment protocol for BCLP.

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References

Bennun RD, Perandones C, Sepliarsky VA, Chantiri SN, Aguirre MI, Dogliotti PL. Nonsurgical correction of nasal deformity in unilateral complete cleft lip: a 6-year follow-up. *Plast Reconstr Surg.* 1999;104:616–630.

Cho B. Unilateral complete cleft lip and palate repair using lip adhesion and passive alveolar molding appliance. *J Craniofac Surg.* 2001;12:148–156.

Da Silveira AC, Oliveira N, Gonzalez S, Shahani M, Reisberg D, Daw JL Jr, Cohen M. Modified nasal alveolar molding appliance for management of cleft lip defect. *J Craniofac Surg.* 2003;14:700–703.

Delgado MD, Marti E, Romance A, Romero M, Lagaron E, Salvan R, Herrero E. Presurgical orthopedic treatment for cleft lip and palate [in Spanish]. *Cir Pediatr.* 2004;17:17–20.

Fang B, Qiu WL, Yuan WH, Shen GF. Presurgical infant orthopedics in complete bilateral cleft lip and palate reconstruction [in Chinese]. *Shanghai Kou Qiang Yi Xue.* 1999;8:96–98.

Grayson BH, Cutting CB. Presurgical nasoalveolar orthopedic molding in primary correction of the nose, lip, and alveolus of infants born with unilateral and bilateral clefts. *Cleft Palate Craniofac J.* 2001;38:193–198.

Grayson BH, Santiago PE, Brecht LE, Cutting CB. Presurgical nasoalveolar molding in infants with cleft lip and palate. *Cleft Palate Craniofac J.* 1999; 36:486–498.

Liou EJ, Subramanian M, Chen PK, Huang CS. The progressive changes of nasal symmetry and growth after nasoalveolar molding: a three-year follow-up study. *Plast Reconstr Surg.* 2004;114:858–864.

Matsuo K, Hirose T. Preoperative non-surgical over-correction of cleft lip nasal deformity. *Br J Plast Surg.* 1991;44:5–11.

TABLE 5 Correlation Coefficients of Extraoral Measurements

	Bi-Alar Width	*Columellar Width*	*Columellar Length*	*Columellar Deviation From 90°*	*Larger Cleft Nostril Height*	*Smaller Cleft Nostril Height*	*Larger Cleft Nostril Width*	*Smaller Cleft Nostril Width*	*Larger Cleft Nostril Length*	*Smaller Cleft Nostril Length*
CD (before versus before)*	0.58	−0.28	0.34	—	0.55	0.74	0.81	0.39	0.80	0.64
CD (Δ versus Δ)	0.32	0.11	0.00	—	0.29	0.45	−0.71	0.44	−0.12	0.37
CD (Δ versus before)	0.40	−0.45	0.35	0.94	0.53	0.75	0.75	0.25	0.75	0.49
PMD (before versus before)	0.11	−0.52	0.26	0.40	0.12	−0.07	0.00	0.17	0.07	−0.05
PMD (Δ versus Δ)	0.08	−0.42	−0.27	0.56	0.37	0.49	−0.43	0.56	−0.05	0.65
PMD (Δ versus before)	−0.15	−0.75	0.15	0.45	0.41	0.30	0.18	−0.07	0.32	−0.16

* Before = before treatment; Δ = difference between before and after treatment.

Maull DJ, Grayson BH, Cutting CB, Brecht LL, Bookstein FL, Khorrambadi D, Webb JA, Hurwitz DJ. Long-term effects of nasoalveolar molding on three-dimensional nasal shape in unilateral clefts. *Cleft Palate Craniofac J.* 1999;36:391–397.

Mishima K, Sugahara T, Mori Y, Minami K, Sakuda M. Effects of presurgical orthopedic treatment in infants with complete bilateral cleft lip and palate. *Cleft Palate Craniofac J.* 1998;35:227–232.

Pfeifer TM, Grayson BH, Cutting CB. Nasoalveolar molding and gingivoperiosteoplasty versus alveolar bone graft: an outcome analysis of costs in the treatment of unilateral cleft alveolus. *Cleft Palate Craniofac J.* 2002;39:26–29.

Yang S, Stelnicki EJ, Lee MN. Use of nasoalveolar molding appliance to direct growth in newborn patient with complete unilateral cleft lip and palate. *Pediatr Dent.* 2003;25:253–256.