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Long-Term Treatment Outcome of Presurgical Nasoalveolar Molding in Patients With Unilateral Cleft Lip and Palate

Stacey L. Clark, MD^{*}, John F. Teichgraeber, MD, FACS[†], Ruth G. Fleshman, LCSW[†], Joi D. Shaw, DMD[‡], Carmen Chavarria, DDS[‡], Chung-How Kau, PhD, MBA, MOrth, BDS[§], Jaime Gateno, DDS, MD^{||, ¶}, and James J. Xia, MD, PhD, MS^{‡, §, #}

^{*}Department of Otolaryngology-Head and Neck Surgery, the University of Health Science Center at Houston, Houston, Texas

[†]Division of Pediatric Plastic Surgery, Department of Pediatric Surgery, the University of Health Science Center at Houston, Houston, Texas

[‡]Department of Pediatric Dentistry, the University of Health Science Center at Houston, Houston, Texas

[§]Department of Orthodontics, the University of Health Science Center at Houston, Houston, Texas

^{||}Department of Oral and Maxillofacial Surgery, Methodist Hospital Research Institute, Houston, Texas

[¶]Department of Surgery (Oral and Maxillofacial Surgery), Weill Medical College of Cornell University, New York, New York

Abstract

Purpose—The purpose of this study was to evaluate the long-term effectiveness of presurgical nasoalveolar molding (PNAM) in patients with unilateral cleft lip and palate (UCLP).

Methods—Twenty-five patients with UCLP treated by either PNAM or non-PNAM therapy between 1998 and 2003 were recruited in the study. During the clinical examination and data analysis, the evaluators were blinded to which patients received PNAM. The patients were reviewed clinically, and their facial morphology was captured with a three-dimensional scanner. Their dental arch configuration and occlusion were recorded by plaster dental models. After the patient evaluations and measurements were completed, the patient list was unblinded. There were 20 patients in the PNAM group and 5 patients in the non-PNAM group. Fisher exact tests and Wilcoxon rank sum tests were used to compare the outcomes.

Results—Clinically, the improvement in the PNAM group was most evident in nasal and lip anatomy. However, there were no statistically significant differences between the 2 groups on each of the measurements on three-dimensional facial images and dental models.

Address correspondence and reprint requests to James J. Xia, MD, PhD, MS, 6560 Fannin St, Suite 1228, Houston, TX 77030; JXia@tmhs.org.

Dr Clark is now with the Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio.

The authors report no conflicts of interest.

Conclusions—Our study suggests a trend toward a long-term clinical improvement in nasal and lip anatomy of UCLP patients treated with PNAM. However, these improved results were not confirmed by three-dimensional stereophotography. There was no statistically significant difference in the long-term three-dimensional anthropometric measurements and dental model analysis between the PNAM group and the non-PNAM group.

Keywords

Nasoalveolar molding; cleft lip; cleft palate; presurgical orthopedics; three-dimensional facial analysis

Advances in plastic surgery have resulted in improved outcomes for patients with cleft lip and palate (CLP). However, persistent problems with nasal deformities and dental malocclusion have given rise to the use of presurgical nasoalveolar molding (PNAM).^{1–3} Presurgical nasoalveolar molding affects both soft-tissue and bony configuration. The theory of the PNAM treatment is based on research showing that, in neonates, nasal cartilage has temporary plasticity, allowing it to be molded. This plasticity results from increased levels of hyaluronic acid present in infants shortly after birth. The goals of PNAM are to align and approximate the intraoral alveolar segments and to correct the deformed cleft lower lateral cartilage.² There have been a number of reports on the effectiveness of PNAM in patients with unilateral CLP (UCLP).^{1,2,4–9} However, there have been no long-term studies on the effect of PNAM in patients with UCLP. The purpose of this study was to evaluate the long-term effectiveness of PNAM in patients with UCLP.

MATERIALS AND METHODS

A total of 108 UCLP patients treated at the University of Texas-Houston Cleft and Craniofacial Clinic between 1997 and 2003 were initially reviewed. The patient inclusion criterion was the following:

- a nonsyndromic UCLP,
- a completed primary lip and palate repair,
- no dentoalveolar bone grafting surgery,
- no maxillary expansion or orthodontic treatment,
- no nasal surgery or lip revision, and
- a complete medical record.

All the operations were performed by 1 surgeon (J.F.T.). Both sexes and all races were included. The study was approved by the institutional review board of the university.

Forty-eight patients met the inclusion criteria and were invited to participate in the study. The patients who did not respond were followed up with telephone calls until they were either contacted or confirmed lost to follow-up. Fifteen patients were contacted but declined to come back to the clinic. Eight patients were lost to follow-up because they either moved out of state or changed their address and telephone numbers. A total of 25 patients came back to the clinic for evaluation. Informed consent was obtained before enrollment. A coded

table was created to blind the patient's treatment and kept in a password-protected computer that was accessible only to the study coordinator (R.G.F.). Therefore, the examiners were completely blinded to the patient's treatment record during the assessment and analysis.

A comprehensive clinical assessment, including facial and dental examinations, was simultaneously completed by the craniofacial team. In addition, maxillary and mandibular dental impressions and a three-dimensional stereophotography were performed to capture the patient's dental occlusion and facial morphology.

Comprehensive Clinical Assessment

The comprehensive clinical assessment was completed simultaneously by a pediatric plastic surgeon (J.F.T.) and an otolaryngologist (S.L.C.), who were blinded to the treatment methods. The assessment included measurements of the vermillion, philtrum, white roll, and lip scar length; appearance of the nose, alar width, and alar depression; presence and location of palate fistula; and evaluation of the alveolar cleft. If there was a disagreement between the 2 examiners, a consensus was reached before the measurement was recorded.

Quantitative Three-Dimensional Anthropometric Analysis

A three-dimensional surface camera system (3dMD, Atlanta, GA) was used to capture facial morphology (Fig. 1). Each three-dimensional facial image was normalized to the natural head position (Fig. 2). The nasion was positioned in a three-dimensional coordinate system as the origin of the measurements. A set of anthropometric landmarks^{10,11} was simultaneously digitized by 2 examiners (J.J.X. and C.H.K.), who were blinded to the treatment methods. If there was a disagreement between the 2 examiners, a consensus was reached before the landmark was digitized. The three-dimensional coordinates were then recorded. The landmarks, including right and left alar, right and left crista philtri, and right and left cheilion, were measured in (x , y , z) 3 dimensions (Fig. 3, Table 1). Other landmarks, including pronasale, subnasale, and laberale superius, were measured only in the x axis (horizontal dimension) to determine the symmetry between right and left. The discrepancies between the cleft and the noncleft side were also calculated.

Maxillary Dental Arch Analysis

Maxillary dental stone casts were directly fabricated from the patient's dental impressions. The stone models were then digitized using a flatbed scanner (Epson 1680; Seiko Epson Corp, Long Beach, CA).¹² They were simultaneously evaluated on the computer by 2 pediatric dentists (C.C. and J.D.S.). If there was a disagreement between the 2 examiners, a consensus was reached before the landmark was digitized. These examiners were also blinded to the treatment methods. Only 21 dental models were quantitatively analyzed because of patients who were missing both central incisors and canines.

The facial midline and maxillary dental midline deviation were recorded clinically and digitized onto the maxillary casts (Fig. 4). An ideal dental arch midline was created from the recorded facial midline to the midpoint of the intermolar distance ($a = b$ in Fig. 4). The relationship between the lesser and the greater segments was calculated by the perpendicular distances from each canine to the ideal midline (c and d in Fig. 3) and normalized by the

intercanine width. Other measurements included intercanine width, intermolar width, and maxillary arch length.

Statistical Analysis

After the patient evaluations and measurements were completed, the patient list was unblinded. For statistical analysis, the patients were divided into 2 groups: the PNAM group and the non-PNAM group. Three patients in the PNAM group and 1 in the non-PNAM group were excluded from quantitative dental cast analysis because they were missing both central incisors and canines. For comparison purposes, the measurements were normalized to have the cleft on one side (right side) and the noncleft side on the other side (left side). A positive measurement (+) represented deviation toward the cleft side.

The NCSS statistics software package was used (NCSS, Keyville, UT). Fisher exact tests were used to compare the comprehensive clinical assessment. For three-dimensional anthropometric and maxillary arch analyses, Student *t* tests were initially proposed. After the assumptions for Student *t* test were evaluated and found violated, Wilcoxon rank sum tests were used to detect whether there was a statistically significant difference between the PNAM and non-PNAM groups.

RESULTS

A total 20 patients received PNAM therapy (PNAM group), whereas 5 patients did not (non-PNAM group). For the PNAM group, the median age of the patients on commencing treatment was 0.8 months (range, 0.5–1.2 months), the median length of the therapy was 3.6 months (range, 2.3–4.9 months), and the median time for surgery was 5.5 months (range, 2.8–6.2 months). The follow-up time was 5.1 years (range, 2.6–10.0 years). For the non-PNAM group, the median time for the surgery was 5.0 months (range, 2.6–6.4 months). The follow-up time was 6.0 years (range, 4.9–7.6 years).

Comprehensive Clinical Assessment

In evaluating lip anatomy, 95% of patients in the PNAM group and 20% in the non-PNAM group achieved a normal vermilion ($P < 0.01$). The successful reconstruction of the affected philtrum was seen in 55% and 20% of the patients, respectively ($P > 0.05$). A noticeable lip scar was seen in 60% of the patients in the PNAM group and 100% of the patients in the non-PNAM group ($P > 0.05$). Finally, an anterior palatal fistula was found in 10% and 40% of the PNAM and non-PNAM groups ($P < 0.01$), respectively.

In evaluating nasal anatomy, 40% of the patients in the PNAM group achieved normal nasal morphology, whereas this was achieved only in 20% of the non-PNAM group. Normal alar width and nasal projection were seen in 60% and 65% of the PNAM group but only in 20% and 40% of the non-PNAM group. However, there was no statistically significant difference in the nasal anatomy between the 2 groups.

In evaluating dental arch analysis, 28% of the PNAM patients and 60% of the non-PNAM patients had significant midline deviation (> 2 mm). The median of the midline deviation was 0.8 mm (range, -3.2 to 2.7 mm) in the PNAM group, whereas the median of the midline

deviation was 1.2 mm (range, -3.0 to 2.0 mm) in the non-PNAM group. Anterior crossbite was present in 88% of the PNAM patients and 100% in the non-PNAM group. Finally, only 25% in the PNAM group and 40% in the non-PNAM group had lesser segment collapse. There was no statistically significant difference in dental arch analysis between the groups.

Quantitative Three-Dimensional Anthropometric Analysis

In the PNAM and the non-PNAM nasal measurements, the median of the pronasale deviation to the midline was 0.0 mm (range, -2.1 to 2.9 mm) and 0.5 mm (range, 0.2–2.0 mm), respectively, whereas the subnasale deviation was 0.8 mm (range, -1.8 to 3.8 mm) and 1.0 mm (-0.3 to 2.0 mm), respectively. The absolute nasal projection was 8.5 mm (range, 5.8–14.7 mm) and 8.7 mm (range, 6.8–8.8 mm), respectively. In addition, the alar width discrepancies were 0.4 mm (range, -4.8 to 2.8 mm) and 0.3 mm (range, -3.6 to 1.3 mm), respectively. The discrepancies in alar base position in superoinferior direction were -0.7 mm (range, -3.4 to 2.7 mm) and -0.5 mm (range, -1.3 to -0.1 mm). The discrepancies in alar base projection were 0.0 mm (range, -4.6 to 3.8 mm) and 0.6 mm (range, -0.7 to 1.5 mm), respectively. For each of the nasal measurements, there was no statistically significant difference between the 2 groups.

In the PNAM and the non-PNAM lip measurements, there was no difference in the crista philtri projection, whereas the discrepancies in the philtri heights were -0.6 mm (range, -1.7 to 1.3 mm) and 0.2 mm (range, -0.5 to 0.7 mm), respectively. The divergence of the vermillion from the midline was -0.1 mm (range, -0.9 to 1.8 mm) and 0.4 mm (range, -1.4 to 1.1 mm), respectively. Again, for each of the lip measurements, there was no statistically significant difference between the 2 groups.

Maxillary Arch Analysis

Because of missing both central incisors and canines in 4 patients, only 17 patients in the PNAM group and 4 in the non-PNAM group were quantitatively analyzed. The relationship of the lesser and the greater alveolar segments was 14.3% (range, -11.2% to 32.2%) and 11.3% (range, 7.6%–19.9%), respectively. In addition, the intercanine width was 25.5 mm (range, 22.7–36.1 mm) and 27.5 mm (range, 18.1–28.8 mm), respectively, whereas the intermolar width was 41.5 mm (range, 37.1–50.4 mm) and 42.5 mm (range, 37.5–48.9 mm), respectively. Finally, the maxillary arch length was 57.2 mm (range, 49.6–90.5 mm) and 55.7 mm (range, 49.8–88.9 mm), respectively. For each measurement, there was no statistically significant difference between the 2 groups.

DISCUSSION

The treatment of patients with CLP continues to be a challenge.^{13,14} Current advancements in the treatment of CLP have focused on preoperative orthopedic treatment to improve surgical outcomes. The use of nasal stenting, presurgical orthopedics, and PNAM has all attempted to improve facial symmetry before surgery.^{1,4,7,15} The goal of PNAM is to align the alveolar cleft segments and to correct nasal cartilage and soft-tissue asymmetry. In a long-term study, Maull et al¹⁶ compared the effects of PNAM on the nasal shape in patients with UCLP. This study found that patients who had nasal molding in conjunction with

alveolar molding maintained increased long-term nasal symmetry in comparison to those patients who underwent only alveolar molding.

A previous clinical study by the authors demonstrated the shortterm effectiveness of PNAM therapy in the treatment of UCLP patients. In this group, a statistically significant improvement was seen in nasal symmetry and normalization of the dental arch.⁶ That study was limited by the patient sample size and lack of a non-PNAM control group. Ross and MacNamera¹⁷ compared patients with bilateral CLP who had undergone presurgical infant orthopedics with a control group who had not undergone presurgical orthopedics. This study showed no long-term improvement in the aesthetic appearance and no difference in the number of revision operations required. To date, there have been no studies evaluating the long-term results of PNAM on patients with UCLP.

Our study suggests a trend toward a long-term clinical improvement in nasal and lip anatomy after PNAM therapy. However, there was no significant difference in dental arch configuration and occlusion between the PNAM and non-PNAM groups. As an adjunct to our clinical analysis, we also measured three-dimensional images with digitized landmarks. The improved clinical results seen in our patients with PNAM were not confirmed by our three-dimensional measurements. We found it to be a challenge to accurately measure facial landmarks, whether these landmarks were measured clinically or by using the three-dimensional imaging system. It was also difficult to correlate facial measurements with appearance. Therefore, we hypothesize that the disparity between our clinical results and the three-dimensional analysis derives from the fact that the human eye can tolerate mild asymmetry.

There are several inherent problems with our study. The first was that there were only a limited number of patients in the non-PNAM group ($n = 5$), which may have skewed our ability to compare the 2 groups. All of our patients with complete UCLP were offered PNAM. It is possible that the group of patients who refused PNAM therapy may have been less compliant and less likely to follow up. A possible solution to this shortcoming would be to collaborate with a center that does not practice PNAM therapy routinely. The second inherent problem with our study was that the variables measured on the study models were difficult to compare. Two factors contributed to this problem. The first one was that the age ranges between the 2 groups were not identical: 2.6 to 10 years (5.1 years) in the PNAM group and 4.9 to 7.6 years (6.0 years) in the non-PNAM group. As a result, the study models may have included mixed dentition as well as primary dentition. Another factor was that, with palatal nonfusion, the 2 maxillary segments could be differentially rotated in 3 dimensions. In the dental model analysis, the authors may have created additional symmetry that masked the existing discrepancies between the cleft and the noncleft side by creating a midline that bisects the intermolar distance. A possible solution to this problem would be to scan the patient using computed tomography and then incorporate the digital dental models that are generated by scanning the study models using a high-resolution laser scanner or microYcomputed tomography scanner.^{18–22}

CONCLUSIONS

Our study suggests a trend toward a long-term clinical improvement in nasal and lip anatomy of UCLP patients treated with PNAM. However, these improved results were not confirmed by three-dimensional stereophotography. There was no statistically significant difference in the long-term three-dimensional anthropometric measurements between the PNAM group and the non-PNAM group.

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FIGURE 1.
Three-dimensional camera system used to capture facial morphology.

FIGURE 2.
Three-dimensional facial images normalized to the natural head position. A, Frontal view.
B, Right view.

FIGURE 3.
Landmarks for three-dimensional anthropometric analysis.

FIGURE 4.
Dental model analysis.

TABLE 1**Landmark Definitions for Three-Dimensional Anthropometric Analysis¹¹**

Nasion (n)	The midpoint of the nasofrontal suture
Alar (al)	The most lateral point on the nasal ala
Crista philtri (cph)	The point on the crest of the philtrum, the vertical groove in the median portion of the upper lip, just above the vermilion border
Cheilion (ch)	The outer corner of the mouth where the outer edges of the upper and lower vermilions meet
Pronasale (prn)	The most protruded point of the nasal tip
Subnasale (sn)	The junction between the lower border of the nasal septum and the cutaneous portion of the upper lip in the midline
Labrale superius (ls)	The midpoint of the vermilion border of the upper lip