Dental Research Journal

Original Article

Changes in nasal symmetry after presurgical nasoalveolar molding in infants treated with complete unilateral cleft lip and palate: A follow-up study

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Received: 27-May-2021
Revised: 22-Jan-2022
Accepted: 03-Jun-2022
Published: 17-Nov-2022

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ABSTRACT

Background: A significant improvement in the nasal symmetry after presurgical nasoalveolar molding (PNAM) is seen in complete unilateral cleft lip and palate (UCLP) infants. However, the follow-up changes in the nasal symmetry before and after PNAM and surgical repair have not been well documented.

Materials and Methods: The purpose of this retrospective study is to assess the progressive changes in the nasal symmetry after PNAM and primary cheiloplasty to 1 year in complete UCLP infants. Out of 28 complete UCLP patients who were given PNAM treatment during the period between January 2014 to March 2019, 19 UCLP infants could be included for the study. Submental oblique photographs at the initial visit (T1), immediately after cheiloplasty (T2), and 1 year (T3) after cheiloplasty were selected, and quantity of nasal asymmetry at each period (T1–T2; T1–T3; and T2–T3) was analyzed by paired *t*-test ($P < 0.05$).

Results: The quantity of asymmetry revealed that there was a highly significant improvement ($P < 0.001$) in nasal asymmetry at T1–T2 and T1–T3. Nonsignificant relapse was observed at T2–T3; however, a significant relapse in nasal dome height was observed during this period.

Conclusion: The improvement in the nasal symmetry after cheiloplasty in PNAM-treated patients is maintained till 1 year postsurgically though there is a nonsignificant relapse.

Key Words: Cleft lip, cleft palate, follow-up studies, nasoalveolar molding

INTRODUCTION

The characteristic features of unilateral cleft deformity are wide nostril base, separated lip segments on the cleft side, the affected lower lateral nasal cartilage displaced laterally and inferiorly, depressed dome of the nasal cartilage on the cleft side, an increased alar rim, an oblique columella, and an overhanging nostril apex with nasal septum deviated to the noncleft side with associated shift of the nasal base. Although considerable variation is seen in severity and form, mostly, wider clefts are associated with more significant nasolabial deformities.

The management of cleft patients should be approached as a multidisciplinary team. It has emerged dramatically in recent years because of leading surgical techniques, timing, and integration

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www.drjjournal.net
www.ncbi.nlm.nih.gov/pmc/journals/1480

How to cite this article: Thakur S, Jishad C, Thakur NS, Deep A. Changes in nasal symmetry after presurgical nasoalveolar molding in infants treated with complete unilateral cleft lip and palate: A follow-up study. Dent Res J 2022;19:95.

of methods such as presurgical orthopedics. The basic treatment objective is to bring back the normal anatomy. In the past decade, it has been made known that improvement of nasal abnormality by elongating the nasal mucosal lining and the fulfillment of nonsurgical columella lengthening can be united with the shaping of the alveolar process in these patients. Thus, the presurgical infant orthopedic treatments had a paradigm shift with the addition of presurgical nasoalveolar molding (PNAM) by Grayson in 1993 for CLP patients.[1]

The PNAM appreciably improves the nasal symmetry, and this is maintained till early childhood.[2-5] The longitudinal progressive changes of the nasal symmetry after the procedures of PNAM and surgical repair have not been well documented, however. This study is, therefore, aimed to assess the progressive changes in the nasal symmetry and the nasal growth/relapse after the PNAM and primary cheiloplasty to 1 year after primary cheiloplasty in the UCLP infants. The records of infants, who are being treated at the Department of Paediatric and Preventive Dentistry, H. P. Government Dental College and Hospital, Shimla, helped us to have quantitative effect of this therapy in long term.

MATERIALS AND METHODS

This retrospective study was funded by the 'Research Grant Program', Department of Health and Family Welfare, Government of Himachal Pradesh, India. Ethical approval was obtained from the Institutional Ethical Committee of Himachal Pradesh Government Dental College and Hospital, Shimla.

The nonsyndromic infants with complete unilateral cleft lip and palate (UCLP) who were treated with PNAM before cheiloplasty in the Department of Paediatric and Preventive Dentistry, H. P. Government Dental College and Hospital, Shimla, Himachal Pradesh, India, during the period between January 2014 to March 2019 were included in the study. Only those patients were included whose clinical and photographic records were available for analysis.

During this period, out of total 34 patients with complete UCLP who were counseled for PNAM before primary cheiloplasty, only 28 gave consent for the treatment. Out of total 34 patients, 21 were male and 13 were female and 15 had cleft on the right side, whereas 19 had cleft on the left side.

Out of these 28 patients, records of 19 patients fulfilled all the inclusion criteria and were enrolled for the study.

Presurgical nasoalveolar molding

After making an intraoral maxillary impression with heavy-bodied silicon impression material, a maxillary intraoral plate was made of self-cure acrylic resin. The average mean age of start of treatment was 16 ± 4.6 days. A nasal stent was attached to the plate for correction of nasal asymmetry. A soft denture liner was used to mold the alveolus and the nasal stent was also lined to prevent the irritation of nasal mucosa and to mold the nostril. Patients were recalled after every 15 days to 1 month depending on the defect, for adjustment of nasal stent and molding of plate with selective grinding and addition of soft liner. Molding of PNAM appliance was done until the alveolar defect is in close approximation, uniform arch form is achieved, and nasal symmetry is observed till the age of 6 months before cheiloplasty.

Records and measurements

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.[6] Submental oblique photographs at the initial visit (T1) Figure 1, after cheiloplasty (T2) Figure 2, and 1 year (T3) after cheiloplasty Figure 3. were selected from the patients' records. For evaluation, only the nasolabial area was shown to the observer, who was blinded to patient information.

Indirect anthropometric five linear measurements[7] were made [Figure 4 and Table 1] on digital photographs with the help of software (ImageJ Software). All the measurements were referenced to the horizontal reference line. The reference line was defined as the line connecting both alar bases.

Nasal symmetry was assessed by the "quantity of asymmetry." To account for different angulations and magnification between photographs, the measurements of nostril height and width were calculated as the ratio of the cleft side to the noncleft side. A ratio of 1 indicates perfect symmetry, and any deviation from 1 is a measure of asymmetry.

Statistical analysis

The quantity of asymmetry at each period (T1-T2; T1-T3; and T2-T3) was analyzed for the significant improvement or relapse of the nasal asymmetry by

Figure 1: Presurgical nasoalveolar molding (T1) photograph

paired *t*-test ($P < 0.05$). If the calculated $P < 0.05$ then it was Statistically significant.

Error of method

To assess intraobserver reliability, the same observer twice measured 20 different randomly selected photographs (10 before treatment and 10 after treatment) 2 weeks apart. The measurements were analyzed by Karl Pearson's correlation coefficient for intraobserver reliability.

RESULTS

The method error showed a highly significant intraobserver correlation ($r = 0.99$, $P < 0.001$) for the repeated measurements.

The quantity of asymmetry revealed that there was a highly significant improvement ($P < 0.001$) in nasal asymmetry at T1–T2 and T1–T3. During the period T1–T2, the percentage increase in nostril height, nasal dome height, and columella length was 102.63%, 36.51%, and 155%, respectively, and nostril width and nasal base width decreased by 49.26% and 44.60%, respectively. During the period T1–T3, the percentage increase in nostril height, nasal dome height, and columella length was 92.11%, 28.57%, and 107.50%, respectively, and a decrease in nostril width and nasal base width was 47.79% and 46.01%, respectively.

Nonsignificant relapse was observed at T2–T3; however, a significant relapse in nasal dome height was observed during this period. The percentage decrease in nostril height, nasal dome height, columella length, and nasal base width was 5.19%, 5.81%, 18.63%, and 2.54%, respectively, with a percentage increase of 2.90% in nostril width [Table 2] [Chart 1].

Table 1: Vertical and horizontal measurements

Serial number	Measurement	Definition
a	Nostril height	The vertical distance between the horizontal reference line and the intersection point of the inner upper border of 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 nostril and the perpendicular bisecting line of the nostril width
c	Columella length	The vertical distance between the most inferior-medial and superior-medial points along the inner medial surface of the nostril apertures
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

DISCUSSION

The overall prevalence of orofacial clefts (OFC) is estimated to be approximately 1 in 700 live births, accounting for nearly one half of all craniofacial anomalies. As reported by the World Health Organization, the prevalence at birth of OFC varies worldwide, ranging 3.4–22.9 per 10,000 births for cleft lip and palate (CLP) and 1.3–25.3 per 10,000 births for cleft palate alone. Syndromic clefts account for about 50% of the total cases in some reports with about 300 syndromes described. Among all the patients who reported to the department of pediatric and preventive dentistry, only nonsyndromic unilateral complete UCLP infants patients were included in the study. During the period mentioned, 34 patients with complete UCLP reported to the department. Out of total 34 patients, 21 were male and 13 were female and 15 had cleft on the right side, whereas 19 had cleft on the left side. Only 28 patients gave consent for the PNAM treatment before primary cheiloplasty and were delivered the treatment. However, the follow-up record of only 19 patients was available for the study.

The average mean age of start of treatment was 16 ± 4.6 days. The duration of treatment is 136.36 ± 38.8 days. In our department, we prefer to make the impression when the patient is between 10 and 14 days old. This is to avoid any possible

Table 2: Intragroup comparisons for nostril height, nasal dome height, nostril width, nasal base width, and columella length

Variables	Mean±SD			T1-T2		T1-T3		T2-T3	
	T1	T2	T3	Mean±SD (*P*)	Percentage change	Mean±SD (*P*)	Percentage change	Mean±SD (*P*)	Percentage change
Nostril height	0.38±0.12	0.77±0.13	0.73±0.15	0.39±0.01 (<0.001*)	102.63	0.35±0.03 (<0.001*)	92.11	0.04±0.02 (0.115)	−5.19
Nasal dome height	0.63±0.15	0.86±0.10	0.81±0.11	0.23±0.05 (<0.001*)	36.51	0.18±0.04 (<0.001*)	28.57	0.05±0.01 (0.047*)	−5.81
Nostril width	2.72±0.69	1.38±0.28	1.42±0.33	1.34±0.41 (<0.001*)	−49.26	1.30±0.36 (<0.001*)	−47.79	0.04±0.05 (0.576)	2.90
Nasal base width	2.13±0.50	1.18±0.16	1.15±0.21	0.95±0.34 (<0.001*)	−44.60	0.98±0.29 (<0.001*)	−46.01	0.03±0.05 (0.476)	−2.54
Columella length	0.40±0.18	1.02±0.37	0.83±0.20	0.62±0.19 (<0.001*)	155.00	0.43±0.02 (<0.001*)	107.50	0.19±0.17 (0.052)	−18.63

*Mean difference is significant at the 0.05 level. Statistical analysis: Paired *t*-test, If the calculated *P*<0.05: Statistically significant. SD: Standard deviation

Figure 2: Postcheiloplasty (T2) photograph

Figure 3: One year postprimary cheiloplasty (T3) photograph

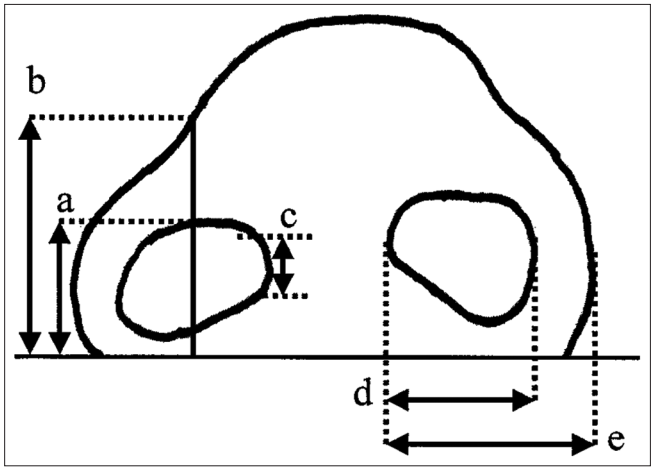

Figure 4: The anthropometric measurements: a: Nostril height; b: Nasal dome height; c: Columella length; d: Nostril width; e: Nasal basal width[7]

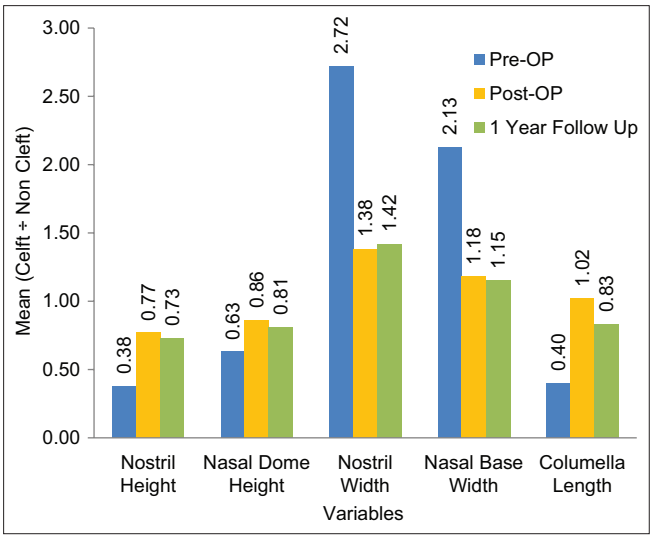

Chart 1: Intragroup comparisons for nostril height, nasal dome height, nostril width, nasal base width, and columella length

complications following any aspiration of the impression material. It is our observation that if the appliance is delivered as early as possible after birth, infants accept it easily without any resistance.

There is substantial proof that PNAM is an effective method for the improvement of nasal symmetry

postprimary surgery in complete UCLP infants;[1-18] this study also verifies this. In the present study, a highly significant improvement in the vertical and horizontal measurements of nasal asymmetry was observed during T1-T2 and T1-T3. However, there is a dearth of information regarding long-time efficacy of this technique with growing age of the patient. Very few follow-up studies have been documented which throw some light on the effect of NAM on nasal symmetry in UCLP cases.

When the nasal asymmetry outcomes postcheiloplasty were compared with the outcomes after 1-year follow-up of PNAM-treated patients, a nonstatistically significant relapse was observed in vertical as well as horizontal dimensions of the nose. However, the relapse in nasal dome height was significant. The relapse in nasal asymmetry can be the result of a significant differential growth between the cleft and noncleft sides in the 1st year postoperatively.

Liou *et al*.[7] also found a significant improvement in nasal symmetry after primary cheiloplasty in UCLP infants treated with PNAM, which relapsed in 1st year postoperatively and then remained stable afterward. To compensate for relapse and differential growth, the authors recommended narrowing down the alveolar cleft as possible as by nasoalveolar molding, overcorrecting the nasal vertical dimension surgically, and maintaining the surgical results using a nasal conformer. In the present study, though there was a relapse in the 1st year postoperatively, it was nonsignificant except the relapse in nasal dome height. The main purpose of our molding technique was to mold the nasal cartilage and narrow down the alveolar cleft to approximate them as was suggested by Liou *et al*.

Pai *et al*.[19] concluded that unilateral complete UCLP infants treated with presurgical nasoalveolar molding showed improved symmetry of the nose in width, height, and columella angle, as compared to their presurgical status. There was some relapse of nostril shape in width (10%), height (20%), and angle of columella (4.7%) at 1 year of age. Mao *et al*.[20] also found an improvement in nasal asymmetry after nasoalveolar molding. However, there was a relapse tendency of nasal asymmetry half a year after the primary cheiloplasty, although the shape of the nasal dome was ideal. Barillas *et al*. (2009[21] demonstrated a greater degree of nasal symmetry in nasoalveolar molding patients compared with the patients treated with surgery alone, which was maintained at 9 years of age. They further concluded that the improved symmetry observed in noses subjected to NAM before the primary surgery is maintained during early childhood. Establishing early nasal symmetry avoids the need for nasal revision surgery before skeletal maturity.

Clark *et al*.[22] evaluated the long-term effectiveness of PNAM in patients with UCLP. Their study suggested a trend toward a long-term clinical improvement in nasal and lip anatomy of unilateral complete UCLP patients treated with PNAM. However, these improved results were not confirmed by three-dimensional stereophotography.

Liang Z *et al*. (2018[23] concluded from their study that PNAM was an early-stage adjunctive therapy for nasal deformity correction, but it was insufficient to maintain long-term nostril symmetry after primary cheiloplasty without nasal cartilage dissection.

The major drawback of this study was a smaller sample size. The sample size for the study is a justified sample for such kind of anomaly that is not routinely found. However, the data obtained in this study can be used for sample size calculations in future studies. Further, the results of the study demonstrate the effectiveness and efficiency of the technique in long term. Yet, studies with larger number of patients are required to evaluate the long-term benefits of this approach.

CONCLUSION

The following conclusion can be drawn from the present study:

- A highly significant improvement is observed in vertical as well as horizontal symmetry of the nose in PNAM-treated patients after cheiloplasty
- This improvement is maintained to 1-year postprimary surgery
- Relapse in nasal symmetry is observed 1 year after cheiloplasty, but it was not significant and relapse in nasal dome height was significant
- PNAM is an effective technique to improve nasal asymmetry in UCLP infants.

Financial support and sponsorship

Nil.

Conflicts of interest

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

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