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Clinical Paper
Cleft Lip and Palate

An assessment and comparison of nasolabial aesthetics in bilateral clefts using the anatomical subunit-based scale: a nasoalveolar moulding versus non-nasoalveolar moulding study

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Abstract. Nasoalveolar moulding is a presurgical orthopaedic technique used to improve the outcomes of bilateral clefts. However, the lack of a validated scale tailored to bilateral clefts makes it difficult to quantify the merits of nasoalveolar moulding and compare it to other techniques. In this study, a recently published anatomical subunit scale was used to evaluate and compare the early effects of nasoalveolar moulding. Two groups of similarly treated bilateral cleft patients were included: one in which patients underwent presurgical nasoalveolar moulding and one in which they did not. The nasolabial aesthetics were evaluated on two-dimensional photographs at 6 months post cheiloplasty. Cupid's bow, vermilion symmetry, vermilion notching, premaxillary show at rest, scar aesthetics, columella height, columella height, and bialar width were all significantly better in the nasoalveolar moulding group. Using the new scale, it was found that nasolabial aesthetics at 6 months post cheiloplasty were significantly better in patients who had undergone nasoalveolar moulding in infancy.

Key words: bilateral cleft lip and palate; nasoalveolar moulding; outcome assessment; photograph; anatomical subunit scale.

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Bilateral cleft lip (BCL) repairs are some of the most challenging surgeries in the spectrum of cleft deformity correction[1]. With no normal side to make comparisons to, the correction is primarily at the surgeon's discretion. As these patients are more likely to require multiple revision surgeries[2], nasolabial aesthetic evaluation is imperative to select the best set of techniques for an optimal outcome.

Many presurgical and surgical techniques to improve results in BCL have been described[3–14], including presurgical nasoalveolar moulding (NAM). Although the technique has been associated with improved outcomes for bilateral cleft, the lack of a validated aesthetic scale makes it difficult to quantify the efficacy of NAM. In this study, the recently published anatomical subunit-based scale[15], developed by the authors' research group, was used to evaluate and compare the early effect of NAM on nasolabial aesthetics in two similarly treated groups of complete bilateral cleft lip and palate (BCLP) patients: one in which the patients underwent presurgical NAM (NAM group) and one in which they did not (non-NAM group).

Materials and methods

This research was conducted in accordance with the Declaration of Helsinki.

A retrospective study of consecutive BCLP patients who were treated between 2007 and 2014 was performed. The patients were divided into the NAM and non-NAM groups based on their age at presentation to the centre. Infants who arrived prior to 8 weeks of age were treated with the NAM technique of Chen et al.[16] and included in the NAM group. NAM was done for 4–5 months and the device was adjusted every 2 weeks. During the same period, patients who arrived at more than 8 weeks of age were treated surgically without NAM; these patients formed the non-NAM group. The patients in the non-NAM group did not have any prior history of taping or any other manoeuvre to approximate the cleft segments. The cut-off of 8 weeks was used, as the nasal cartilage pliability reduces a few weeks after birth[17]. Furthermore, in the authors' experience, the infant adapts to the NAM appliance and accepts it if it has been introduced before this period.

Table 1. Distribution of patients in the study groups.

Group	Total number	Male	Female
NAM	59	42	17
Non-NAM	62	47	15

NAM, nasoalveolar moulding.

This study included only those patients who underwent a modified Millard's cheiloplasty before 1 year of age. The cheiloplasty was done by the same two surgeons without primary rhinoplasty or gingivoperiosteoplasty. The total sample consisted of 121 patients, with 59 patients in the NAM group and 62 in the non-NAM group (Table 1).

Patients with incomplete clefts and those with craniofacial anomalies were excluded. The nasolabial aesthetic evaluation was done using the anatomical subunit-based scale[15], on standardized two-dimensional photographs taken 6 months post cheiloplasty. Aesthetics of the lip, scar, and nose areas were studied. A total of 12 subunits were grouped under the three areas (Table 2). The scores of the subunits were added to define a score for the individual area. A final

Table 2. Description of the areas and subunits used for the assessment, the mean scores for each subunit in the two groups, and the intergroup comparison.

Evaluation area and subunits	Scores awarded		NAM group Mean ± SD score	Non-NAM group Mean ± SD score	*P*-value[a]
Lip	Score 0	Score 1	Lip subunit score	Lip subunit score	
Prolabium width (Prolabium width should be normal (3–4 mm from the midline; total width 6–8 mm) when compared to lip dimension)	Increased	Normal	0.89 ± 0.30	0.88 ± 0.31	0.854
Cupid's bow (Cupid's bow peaks should be on the same horizontal plane)	Absent	Present	0.62 ± 0.48	0.45 ± 0.5	0.04*
Vermilion symmetry (Equal width of wet and dry vermilion on both sides, with smooth continuity)	Absent	Present	0.71 ± 0.45	0.43 ± 0.49	<0.001*
Vermilion notching (The vermilion should be a continuous smooth curved line without notching)	Present	Absent	0.86 ± 0.34	0.67 ± 0.47	0.003*
Premaxillary show (Absence of premaxillary show at rest)	Present	Absent	0.96 ± 0.18	0.62 ± 0.48	<0.001*
Scar	Score 0	Score 1	Scar subunit score	Scar subunit score	
Discolouration	Present	Absent	0.62 ± 0.48	0.33 ± 0.4	<0.001*
Suture marks/spreading of the scar	Present	Absent	0.64 ± 0.4	0.43 ± 0.4	0.004*
Hypertrophy	Present	Absent	0.71 ± 0.4	0.61 ± 0.4	0.172
Nose	Score 0	Score 1	Nose subunit score	Nose subunit score	
Columella height (Columella height should be adequate (4–5 mm, but not reduced or absent)	Reduced	Normal	0.79 ± 0.4	0.43 ± 0.4	<0.001*
Nostril symmetry (Nostrils should be symmetrical on either side)	Absent	Present	0.86 ± 0.3	0.79 ± 0.4	0.280
Bialar width (Bialar width should be within the medial canthus of the eyes)	Increased	Normal	0.33 ± 0.4	0.17 ± 0.3	0.013*
Nasal tip (Nasal tip should be well defined)	Broad	Well defined	0.83 ± 0.3	0.77 ± 0.4	0.1

NAM, nasoalveolar moulding; SD, standard deviation.

[a] Intergroup comparison, level of significance.

* $P < 0.05$.

combined score was then derived by adding the scores of the three areas.

Standardized two-dimensional full-face frontal view and worm's eye photographs were shot by the same experienced photographer. Equal-sized images were printed on high-quality photographic paper and distributed to three professionally trained cleft surgeons who were not involved in the treatment of the patients. The frontal view was used to evaluate the subunits of the lip and scar area and the basal view was used for the subunits of the nose area.

Intergroup comparisons between the NAM and non-NAM groups were done for each of the 12 subunits, as well as the areas (lip + scar, nose) using the independent samples *t*-test. The level of significance was set at $P < 0.05$. Ten cases from each group were checked for inter-examiner reliability. The intra-class correlation coefficient (ICC) values showed almost perfect agreement for the lip scores (ICC 0.89) and nose scores (ICC 0.83) and strong agreement for the scar scores (ICC 0.73) (ICC values: 0–0.2 = poor agreement; 0.3–0.4 = fair agreement; 0.5–0.6 = moderate agreement; 0.7–0.8 = strong agreement; >0.8 = almost perfect agreement).

Results

The following intergroup comparisons are described: subunit scores (mean ± standard deviation; Table 2), scores for the areas (mean ± standard deviation; Table 3, and the distribution of patients across the various grades (Table 4).

Subunit scores

Among the three subunits of the scar area, discolouration ($P < 0.001$) and suture marks ($P = 0.004$) were significantly improved in the NAM group in comparison to the non-NAM group. There was no statistically significant difference between the groups with regard to the scar hypertrophy.

Table 3. Intergroup comparison of the area scores and mean final combined scores.

Area	NAM group score Mean ± SD	Non-NAM group scor Mean ± SD	*P*-value[a]
Lip + scar outcomes	6.08 ± 1.00	4.9 ± 1.76	0.001*
Nose outcome	2.7 ± 0.69	1.7 ± 1.03	0.001*
Final combined score	8.7 ± 1.2	6.6 ± 2.4	0.001*

NAM, nasoalveolar moulding; SD, standard deviation.
[a] Level of significance.
* $P < 0.05$.

Among the four subunits evaluated in the nose area, columella height ($P < 0.001$) and bialar width ($P = 0.013$) showed statistically significant improvements in the NAM group in comparison to the non-NAM group. The comparisons of nostril symmetry and nasal tip, however, revealed no statistically significant differences between the groups.

Area scores

Intergroup comparison showed that the NAM group had significantly better lip + scar outcomes than the non-NAM group ($P < 0.001$). The mean lip and scar area score in the NAM group was 6.08 ± 1.00, indicating an overall good result, and in the non-NAM group was 4.9 ± 1.76, indicating an overall fair result. The distribution of the patients across the grades also reflected the same findings.

Although the intergroup comparison of the mean nose area scores showed that the results in the NAM group were significantly better than those in the non-NAM group ($P < 0.001$), the overall result was fair in both groups. The distribution of the patients across the grades also reflected these findings: the highest percentages of NAM group patients were in the good and fair grades; in contrast, the highest percentages of non-NAM group patients were in the fair and poor grades.

The mean final combined score in the NAM group indicated a good outcome, with a mean score of 8.7 ± 1.2. In contrast, the overall outcome in the non-NAM group was fair, with a mean final combined score of 6.6 ± 2.4. The difference between the two groups was statistically significant ($P < 0.001$). The final distribution of all patients across the grades reflected the same findings.

Discussion

This study was conducted to evaluate and compare the nasolabial aesthetics in two groups of similarly treated BCLP patients: one in which the patients underwent NAM before surgery and one in which the patients were treated only with surgery. The study used two-dimensional photographs and trained professionals to evaluate the postoperative findings. In this study, the NAM group fared better than the non-NAM group across all three areas studied at the 6 month postoperative evaluation.

NAM is a presurgical orthopaedic technique that moulds the cartilage, elongates the columella, retracts the premaxilla, and aligns the maxillary fragments, reducing the surgical difficulty[9]. Although this technique reduces the severity of the cleft as a whole, the lack of a validated BCLP scale has impaired the accurate identification of areas that need improvement and has also made comparisons between centres difficult. In studies that have assessed aesthetics in BCLP, the Asher–McDade scale and its modifications have been most popular[18]. However, the scale is cumbersome and has been validated only for unilateral cleft. Other scales that have been used include visual analogue scales

Table 4. Patient distribution across the various grades in the NAM and non-NAM groups.

Grading for lip and scar outcomes		Combined score of the subunits for the lip and scar area[a]		Grading for nose outcome		Combined score of the subunits for the nose area[a]		Grading for total lip, scar, and nose outcome		Final combined score of the three areas[a]	
Grade	Score	NAM group	Non-NAM group	Grade	Score	NAM group	Non-NAM group	Grade	Score	NAM group	Non-NAM group
Excellent	7–8	37%	19%	Excellent	4	12%	6%	Excellent	10–12	42%	15%
Good	5–6	56%	44%	Good	3	58%	13%	Good	8–9	51%	27%
Fair	3–4	7%	29%	Fair	2	27%	44%	Fair	6–7	5%	21%
Poor	≤2	0	8%	Poor	1	3%	37%	Poor	<6	2%	37%

NAM, nasoalveolar moulding.
[a] Results are presented as the percentage of patients in the group.

(VAS) and other numerical scales, none of which accurately and simply allow the operator to grade the bilateral cleft results. In this study, a recent anatomical subunit-based scale – a 12-point binary scale[15] – was used, as it is simple and convenient. It was well accepted by the examiners, as the grading was quick and the scoring was straightforward and specific to BCLP.

The intergroup comparisons of the mean score of the lip and scar areas as well as the individual subunits showed statistically significant improvement in the results of the NAM group. With regard to the nose scores, although the mean scores in both groups, NAM and non-NAM, indicated a fair outcome, a statistically significant improvement was found in the NAM group, with better columella height and bialar width. The authors believe that the presurgical anatomical repositioning of the premaxilla and subsequent ease of surgical closure reduced the postoperative tension across the surgical scar and improved the lip and scar scores in the NAM group. Similarly, the early moulding of the nasal cartilage in infancy improved the nose results.

Although all area results in the NAM group were better than those in the non-NAM group, it is believed that the lack of a primary rhinoplasty led to the suboptimal scores in the overall nose results. Chang et al.[19] compared the aesthetic results of NAM only, NAM with rhinoplasty, and NAM with rhinoplasty and overcorrection and showed that NAM with primary rhinoplasty and overcorrection had the best results. Among the other studies that have used primary rhinoplasty along with NAM, Liou et al.[20] found a relative relapse in columella length at the 3-year follow-up in their patients, in contrast to Lee et al.[14], who used the classic Grayson's technique and found a higher degree of stability and a normal columella length at 3 years of age. Although the absence of primary rhinoplasty was a limitation of our technique, it provided an opportunity to study the exclusive effect of NAM on long-term nasal aesthetics.

In this study, nasolabial aesthetics were assessed after primary bilateral cleft lip repair. It was found that at 6 months post cheiloplasty, the NAM group of patients had better nasolabial aesthetics than those who underwent primary lip repair without NAM. Unfortunately, this was not a randomized study and there was no power calculation to determine the sample size. While the study does document benefits of the NAM procedure prior to primary bilateral cleft lip repair in the short term, the longer term aesthetic benefits have yet to be determined.

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Competing interests

None.

Ethical approval

This research was conducted in accordance with the Declaration of Helsinki; reference number BIDS/2012-13/3607.

Patient consent

Not required.

References

1. Cutting CB. Chapter 94: bilateral cleft lip repair.. In: Mathes SJ, Hentz VR, editors. *Pediatric plastic surgery*, Second edition, vol. 2. Philadelphia, PA: Elsevier Inc.; 2006 p. 1217.
2. Noordhoff MS. Bilateral cleft lip reconstruction. *Plast Reconstr Surg* 1986;**78**:45–54.
3. Millard Jr DR. Closure of bilateral cleft lip and elongation of columella by two operations in infancy. *Plast Reconstr Surg* 1971;**47**:324–31.
4. Cronin TD, Upton J. Lengthening of the short columella associated with bilateral cleft lip. *Ann Plast Surg* 1978;**1**:75–95.
5. Mulliken JB. Principles and techniques of bilateral complete cleft lip repair. *Plast Reconstr Surg* 1985;**75**:477–87.
6. McComb H. Primary repair of the bilateral cleft lip nose: a 15-year review and a new treatment plan. *Plast Reconstr Surg* 1990;**86**:882–93.
7. Van der Meulen JC. Columellar elongation in bilateral cleft lip repair: early results. *Plast Reconstr Surg* 1992;**89**:1060–7.
8. Trott JA, Mohan NA. Preliminary report on open tip rhinoplasty at the time of lip repair in unilateral cleft lip and palate: the Alor Setar experience. *Br J Plast Surg* 1993;**46**:363–70.
9. Cutting C, Grayson B, Brecht L, Santiago P, Wood R, Kwon S. Presurgical columellar elongation and primary retrograde nasal reconstruction in one-stage bilateral cleft lip and nose repair. *Plast Reconstr Surg* 1998;**101**:630–9.
10. Mulliken JB. Repair of bilateral complete cleft lip and nasal deformity: state of the art. *Cleft Palate Craniofac J* 2000;**37**:342–7.
11. 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**:193–8.
12. Koh KS, Ock JJ. Columellar lengthening using the interdigitation of triangular flaps. *Aesthetic Plast Surg* 2002;**26**:78–80.
13. Talmant JC, Lumineau JP, Rousteau G. Cleft lip, maxilla and palate treatment by Dr. Talmant's team in Nantes (in French). *Ann Chir Plast Esthet* 2002;**47**:116–25.
14. Lee CT, Garfinkle JS, Warren SM, Brecht LE, Grayson BH. Nasoalveolar molding improves appearance of children with bilateral cleft lip–cleft palate. *Plast Reconstr Surg* 2008;**122**:1131–7. http://dx.doi.org/10.1097/PRS.0b013e318184590c.
15. Bonanthaya K, Shetty PN, Fudalej PS, Rao DD, Bitra S, Pabari M, Rachwalski M. An anatomical subunit-based outcome assessment scale for bilateral cleft lip and palate. *Int J Oral Maxillofac Surg* 2017;**46**:988–92. http://dx.doi.org/10.1016/j.ijom.2017.03.021.
16. Chen PKT, Noordhoff MS, Liou EJW. Treatment of complete bilateral cleft lip-nasal deformity. *Semin Plast Surg* 2005;**19**:329–42. http://dx.doi.org/10.1055/s-2005-925905.
17. Matsuo K, Hirose T. Nonsurgical correction of cleft lip nasal deformity in the early neonate. *Ann Acad Med Singapore* 1988;**17**:358–65.
18. Mosmuller DG, Mennes LM, Prahl C, Kramer GJ, Disse MA, van Couwelaar GM, Niessen FB, Griot JPWD. The development of the cleft aesthetic rating scale: a new rating scale for the assessment of nasolabial appearance in complete unilateral cleft lip and palate patients. *Cleft Palate Craniofac J* 2017;**54**:555–61.
19. Chang CS, Liao YF, Wallace CG, Chan FC, Liou EJ, Chen PK, Noordhoff MS. Long-term comparison of the results of four techniques used for bilateral cleft nose repair: a single surgeon's experience. *Plast Reconstr Surg* 2014;**34**:926–36. http://dx.doi.org/10.1097/PRS.0000000000000715.
20. Liou EJ, Subramanian M, Chen PK. Progressive changes of columella length and nasal growth after nasoalveolar molding in bilateral cleft patients: a 3-year follow-up study. *Plast Reconstr Surg* 2007;**119**:642–8.

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