

ASSESSMENT OF PRESURGICAL NASOALVEOLAR MOULDING (PNAM) IN UNILATERAL CLEFT LIP AND PALATE

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Abstract

Background: Midface symmetry is an important indicator of success of complete unilateral cleft lip and palate (CUCLP) treatment. There is little literature on the long-term effects of Presurgical Nasoalveolar Molding (PNAM) on Midface symmetry in children treated for CUCLP.

Material and Methods: This case-control study was carried out in the Department of Burn and Plastic Surgery at Government Medical College and Hospital, Bettiah, Bihar, India from may 2018 to Dec 2019. Complete unilateral CL+P patients had basilar and frontal photographs at two time points: (1) initial (2) postsurgical. 30 nasal molding patients and 20 control patients were included. Presurgical nasal molding was performed prior to primary lip repair in intervention group. No nasal molding was performed in control group.

Results: A statistically significant difference was found for postsurgical nostril height-width ratio ($P < .05$). No other statistically significant differences were found.

Conclusion: Nasal molding and surgery resulted in more symmetrical nostril height-width ratios than surgery alone. Alar groove ratios were not statistically significantly different between groups perhaps because application of nasal molding was not early enough; postsurgical nasal splints were not utilized; overcorrection was not performed for nasal molding

Introduction

Use of presurgical nasoalveolar molding (NAM) and similar orthopedics in the management of cleft deformities has been a subject of occasional controversy.^{1,2} Appliance effectiveness, cost, and treatment time have been previous subjects of debate. Mastuo and Hirose³ recognized the moldability of nasal cartilages in the early months of an infant's life and attributed this to high levels of estrogen and increased hyaluronic acid. They are credited with the first attempt to perform nasal molding on patients with cleft lip and palate by using silicone rubber stents in the nostrils. Within a few years, Grayson et al.,⁴ developed an appliance with a nasal extension attached to the anterior portion of an acrylic alveolar molding plate, which marked the advent of presurgical nasoalveolar molding appliances. A modification of the Grayson-type NAM appliance is utilized by The Craniofacial Center at the University of Illinois Medical Center. An acrylic bulb at the end of a wire is embedded in the plate and can be adjusted in conjunction with alveolar molding. The appliance is intraorally retained by denture adhesive on the palatal surface, and extraoral tapes are not utilized. The University of Illinois cites several advantages in their design including ease of fabrication and adjustment by the operator, less airway obstruction with the smaller acrylic extension, and parental preference for the less noticeable

appearance of the appliance design.⁵ The University of Illinois uses the NAM appliance solely for nasal molding. Assessing outcomes of presurgical appliances may help determine their value. Very recently, the only reported systematic review on presurgical infant orthopedics (PSIO) was released concerning long-term advantages of these appliances. The authors concluded that until the age of 6, there were no positive effects on factors such as facial growth, maxillary arch dimension, or occlusion when treatment included passive infant orthopedic appliances. However, the authors made the distinction between PSIO and NAM appliances, stating that their review yielded the conclusion that nasal symmetry was improved with NAM and that more randomized clinical trials should be conducted to assess long-term nasal symmetry outcomes.⁶ When describing attractive faces, the literature stresses the importance of facial symmetry⁷⁻⁹. Facial symmetry increases attractiveness.¹⁰ The visual impact of symmetry has been shown to be more critical toward the midline¹¹, which is unfortunate for individuals with cleft lip and palate since their greatest deformities are near the midline of the midface; these asymmetries have been shown to produce more negative evaluation of the facial esthetics.¹² Several studies have demonstrated improved nasal symmetry following presurgical NAM.¹³⁻¹⁵ Although the University of Illinois has been performing nasal molding with the NAM appliance since the 1990s, no results were

reported by this institution and the quantitative assessment of outcomes for nasal symmetry in this study is therefore valuable and relevant to what has been previously documented as being esthetically important.

Materials and Methods

This case-control study was carried out in the Department of Burn and Plastic Surgery at Government Medical College and Hospital, Bettiah, Bihar, India from May 2018 to Dec 2019 after taking the approval of the protocol review committee and institutional ethics committee.

Methodology

Subjects must have undergone primary lip repair within the past 60 years. Syndromic patients were excluded. Infant and children patients aged below 4 years old who have complete unilateral cleft lip and palate and have presurgical and postsurgical frontal and basilar photographic records were included. Presurgical records were taken on initial evaluation of each patient, prior to initiation of any molding treatment or procedure. Postsurgical records must have been obtained within two years of the primary lip repair. A total of fifty nonsyndromic patients with complete unilateral cleft lip and palate were included in this study. 30 patients underwent presurgical nasal molding without taping prior to primary lip repair, while 20 patients did not undergo any presurgical orthopedics and only had primary lip repair. Of the 20 control patients. The same surgeon performed lip repair for all patients in the nasal molding group. This same surgeon also performed lip repair for a portion of the control subjects. surgeons performed lip repair according to the Millard procedure. The mean ages for presurgical records were 2.6 weeks for the nasal molding group and 2.4 weeks for the control group, and mean ages for postsurgical records were 7.1 months for the nasal molding group and 6.7 months for the control group. Within the total 50 subjects, there were 18 females and 32 males; 28 were left-sided clefts, while 22 were right-sided clefts. Within the nasal molding subjects, there were 12 females and 18 males; Within the control subjects, there were 6 females and 14 males; Photographs of infants' noses in basilar and frontal views were collected from both pre- and postsurgical time points. All images were digitally scanned, cropped to include only partial facial images, and printed in color on white paper. Removal of the identification of the records according to the Health Insurance Portability and Accountability Act ensured that no patient was identified by the principal investigator. Nasal forms were assessed by means of direct measurement with a digital caliper on each printed photograph for nostril height-width ratios and alar groove height ratios, between cleft and noncleft sides, at each time point based on formulas. All measurements were repeated on a separate day and were all within 0.3 mm of

the first measurements. The methods for measurements of both nostril heightwidth ratios and alar groove height ratios were similar to the study performed by Nakamura et al.¹⁶ Utilizing ratios for each measurement minimized inconsistencies with photographic archives which may have been due to calibration or magnification errors between subjects or within the time points of a particular subject.

Statistical analysis

For statistical analysis, a Shapiro-Wilk test was performed and all ratio measurements at each time point were compared with Students *t*-tests. Significance was accepted at $P < .05$

Results

Table 1: Gender base distribution

Gender	N=50	Percentage
Male	32	64
Female	18	36

Table 2: Distribution of patients on the bases of Primary lip repair

Non-syndromic patients	N=50	Percentage
Without primary lip repair	30	60
With primary lip repair	20	40

TABLE 3: Comparison of ratio means between

Measurement	Group				t-value	p-value
	Nasal Molding		Control			
	Mean	St Dev	Mean	St Dev		
PCNWR*	4.70	3.568	4.10	1.886	-0.627	0.535
OCNWR	1.40	0.466	1.88	0.809	2.350	0.021
PCNAR	1.39	1.88	1.41	0.184	-1.98	0.287
OCNAR	1.20	0.103	1.26	0.145	1.089	0.269

Discussion

In this study, nostril height-width ratios were calculated by the formula $(A/B)/(A/B)$, where "A" measurements were width and "B" measurements are heights. Nakamura et al.¹⁶ used the same formula to calculate ratios, however "A" measurements were height and "B" measurements were width. The nostril height-width ratios can still be compared between studies by simply taking the inverse ratios for either one of the studies. When inverting the OCNWR measurements for the present study, 1.40 becomes 0.62 for the nasal molding group and 1.88 becomes 0.48 for the control group. Nakamura et al.¹⁶ reported postoperative ratios of 0.76 for the nasal molding group and 0.61 for their control group, which was statistically significant at $P < .01$. The results from both studies represent superior

outcomes for nasal molding groups compared to control groups for nostril height-width ratios, however, Nakamura et al.¹⁶ reported ratios closer to 1 : 1.1 than the results of the present study, which could be interpreted to mean that their outcomes were more symmetrical than the present study.

In the alar groove height ratios, mean OCNAR was 1.20 for the nasal molding group and 1.26 for the control group, which was not statistically significant different. Nakamura et al.¹⁶ reported one-year postoperative alar groove height ratios of 1.03 for NAM and 1.13 for controls, but the difference in their results was statistically significant. One must contemplate possible reasons for the lack of statistically significant difference between our nasal molding and control groups for alar groove height ratios. Bennun et al.²⁰ suggested that very early application of NAM by the first two days of life resulted in more symmetrical long-term nasal outcomes than initial NAM application beyond two weeks of age. In our study, the absence of adhesive tape used in conjunction with nasal molding may have resulted in inadequate alar suspension on the cleft side in our population. Use of postsurgical nasal splint appliances for at least six months postoperatively have been advocated by Yeow et al.²¹ and Chang et al.²² to prevent relapse following NAM. These nasal splints help maintain the alar cartilage height and prevent collapse during scar healing and beyond. Wakami et al.²³ proposed the application of a presurgical nostril suspension device consisting of extraoral tape a fixed to the forehead of the infant connected to paper clips which lift the alar cartilage. The infants also wore nasal retainers for six months postoperatively, and the authors reported improved ratings for both nostril symmetry and alar cartilage position in the infants treated with their suspension device. The nasal molding subjects in the present study had a mean age at initial records of 2.6 weeks, which may have been later than ideal to start molding per Bennun et al.²⁰; however, Shetty et al.²⁴ advocate positive effects of presurgical NAM can still be achieved when initiated between one and five months of age. Additionally, without postoperative nasal retention, the subjects may have shown tendency toward relapse. Subjects in this study may have also benefited from a nostril suspension device as described by Wakami et al.²³ Another plausible reason that alar groove ratios were not statistically significantly different in our study was that overcorrection was not performed on nasal molding subjects. Chang et al.²² suggested that overcorrection of 20% maintained nostril height after 5 years, but that NAM alone could not provide nostril symmetry in the long-term.

The college not turn away potential nasal molding subjects based on ability of parents to pay for treatment. Subjects of this study may have perhaps been denied care if they lived in a different region and these results may have gone undocumented. By providing care for such underserved demographic groups, bias and lack of reporting is potentially reduced compared to other centers. Sischo et al.²⁵ suggested that cleft services may be linked to ethnicity in that African American and Latinos from their study demonstrated tendency toward selecting traditional, non-NAM care when offered a choice. The present study as well as future studies from our institution could represent a population with more racial and/or socioeconomic diversity. Additionally, the college of Illinois does not prescribe to primary bone grafting or gingivoperiosteoplasty in its surgical protocol, and the results from this study should be used to compare to other centers that do utilize such surgical procedures. Even without surgical supplement beyond primary lip repair, nostril height-width ratios were superior in the nasal molding group in this study.

There were obvious limitations to this study, most of which stem from the retrospective nature of this study. Since outcomes of different surgeons were assessed, the variations in surgical technique or operator skill contribute possible uneven distribution within groups and results. In the present study, all lip repairs were performed according to the Millard procedure, which the authors feel reduces variation based on surgical type. Ideally, one surgeon would have performed all surgeries for control and NAM subjects, but this factor could not be controlled. Additionally, data was collected from a span of the past 60 years. It would have perhaps been optimal to have all records taken within a more recent time frame, but due to the difficulty in finding adequate quantities of control subjects this was not possible. Also, while it would be valuable to assess nasal changes over a longer period of time following surgical repair, only short-term records were available to the author. Observing changes due to growth and maturation would be important aspects of a future study if follow-up records became available. Only two-dimensional photographs were available in this study and were typical records taken for documentation of patients' progress in the past. More recently, 3D imaging has been utilized at the institution, and future studies may benefit from analysis of these data.²⁶

Conclusion

In this study, nasal molding subjects had superior postsurgical nostril symmetry compared to controls in relation to nostril height: width ratios. Alar groove height symmetry, on the other hand, was not found to be different between nasal molding and control subjects. The

lack of difference for alar groove height symmetry may be due to a delay beyond two weeks of life for initiation of nasal molding activation, lack of nasal splints for retention, or failure to overcorrect alar cartilage molding prior to surgery in order to prevent relapse from occurring. This study investigated only short-term nasal symmetry outcomes after presurgical nasal molding. Long-term assessment of nasal molding is necessary to determine its effects on facial and nasal growth as well as patient self-perception of nasal esthetics. Additionally, long-term studies are needed to analyze whether nasal molding truly reduces the need for future nasal revision or other health care costs with age. As the field of cleft lip and palate care evolves, many NAM opponents may continue to argue its efficacy unless consistently positive results emerge from the literature. This study demonstrated that, for the short-term, nasal molding with a NAM-type appliance was effective in providing symmetrical nostril outcomes. Support for continuation of NAM and for the future improvement of its protocol is therefore warranted

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