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An Intercenter Comparison of Nasolabial Appearance Including a Center Using Nasoalveolar Molding

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Abstract

Objective: To compare nasolabial appearance outcomes of patients with complete unilateral cleft lip and palate (CUCLP) in preadolescence from 4 cleft centers including a center using nasoalveolar molding (NAM) and primary nasal reconstruction.

Design: Retrospective cohort study.

Setting: Four cleft centers in North America.

Patients: 135 subjects with repaired CUCLP.

Methods: Frontal and profile facial pictures were assessed using the Asher-McDade rating scale. Intra- and interrater reliability were tested using weighted Kappa statistics. Median scores by center were compared with Kruskal-Wallis statistics.

Results: Intrarater reliability scores were moderate to good. Interrater reliability scores were moderate. Significant differences ($P < .05$) among centers were found. For nasal form, center G (median = 2.83) had better scores than centers C and D (C median = 3.33, D median = 3.17). For nose symmetry, center G had better scores (median = 2.33) than all other centers (B median = 2.67, C median = 2.83, D median = 2.83). For vermillion border, center G had better scores (median = 2.58) than centers B and C (B median = 3.17, C median = 3.17). For nasolabial profile, center G (median score = 2.67) had better scores than center C (median = 3.00). For total nasolabial score, center G (median = 2.67) had better scores than all other centers (B median = 2.83, C median = 3, D median = 2.83).

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Conclusion: The protocol followed by center G, the only center that performed NAM and primary nasal reconstruction, produced better results in all categories when compared to center C, the only center that did not perform presurgical orthopedics or lip/nose revisions. When compared to centers that performed traditional presurgical orthopedics and surgical revisions (B and D), center G was not consistently better in all categories. As with other uncontrolled, retrospective intercenter studies, it is not possible to attribute the outcomes to a specific protocol component.

Keywords
nasoalveolar molding, Americleft, nasolabial aesthetics, Asher-McDade scale, intercenter study

Introduction

It has been demonstrated that retrospective comparisons of outcomes in samples with adequate size composed of cohorts treated at different Cleft Centers using different treatment protocols may lead to a better understanding of treatment effects in patients with oral clefts (Asher-McDade et al., 1992; Mars et al., 1992; Mølsted et al., 1992; Daskalogiannakis et al., 2011; Hathaway et al., 2011; Mercado et al., 2011). In these studies, dental arch relationships and craniofacial morphologic differences were found to be associated with different aspects of infant management protocols. The Eurocleft studies were the first to comprehensively analyze important outcome parameters, including nasolabial aesthetics (Asher-McDade et al., 1992), dental arch relationships (Mars et al., 1992), and craniofacial morphology (Mølsted et al., 1992). Although it is impossible to establish a cause-and-effect relationship between a certain protocol feature and its outcomes because of numerous confounding variables inherent in the retrospective noncontrolled study design, the comparison of outcomes in these studies provides a basis to understand certain protocol features that might be associated with favorable or unfavorable outcomes. The experience from the Eurocleft studies prompted 5 cleft centers in North America to conduct similar studies, collectively known as the Americleft Project (Long et al., 2011). Retrospective analysis of outcome parameters in the original Americleft study also included dental arch relationships, craniofacial morphology, and nasolabial appearance. The conclusions of the Americleft studies were quite similar to those of the Eurocleft studies (Mars et al., 1987; Daskalogiannakis et al., 2011; Hathaway et al., 2011; Mercado et al., 2011; Russell et al., 2011).

According to an international survey on treatment of cleft lip and palate published in 2012, 37% of the US cleft teams provided nasoalveolar molding (NAM) treatment in their centers (Sischo et al., 2012). As the popularity of NAM continues to increase in the last 2 decades, it is important to elucidate how the outcomes obtained from protocols using NAM compare to those resulting from protocols that do not include NAM. NAM is an orthopedic technique performed in infants with complete unilateral or bilateral cleft lip and palate prior to primary lip repair. It was first reported by Grayson and coworkers in 1993. Among the principal treatment goals of NAM for patients with oral clefts is reduction of the initial cleft width so as to allow well-approximated lip and alveolar segments prior to surgical lip repair and gingivoperiosteoplasty. The technique is also advocated to improve nasal symmetry, nasal tip projection, and columellar lengthening. Primary surgical repair include both the lip and the nose, which reportedly heal under minimal tension leading to reduced scar formation as a result of the NAM (Grayson et al., 1999). Many studies reported a significant reduction in cleft size and positive changes in nasal features including nasal asymmetry (Bennun et al., 1999; Maull et al., 1999; Pai et al., 2005; Kecik and Enacar, 2009). However, most studies regarding NAM have been either case reports or single-center retrospective comparisons of before-and-after clinical features on small samples with no control non-NAM cases and no long-term follow-up measures. To date, there is no report of a blinded intercenter comparison study on nasolabial appearance outcomes that included a center using NAM.

Recently, the Americleft project reported an intercenter comparison study on dental arch relationships and craniofacial morphology that included a center using NAM as part of its treatment protocol. Results from the study demonstrated that use of NAM did not improve or worsen the dental arch relationships or craniofacial morphology of patient with complete UCLP during preadolescence (Peanchitlertkajorn et al., 2016).

The purpose of the present retrospective cohort study was to evaluate and compare nasolabial appearance outcomes of children with repaired complete unilateral cleft lip and palate (CUCLP) treated at a center using NAM as part of its primary infant protocol to the outcomes of children from 3 of the original Americleft centers, none of which employed NAM. The null hypothesis is that the nasolabial appearance outcomes of the center using NAM are not significantly different from those of the centers not using NAM.

Methods

Subjects

Ethics approval was obtained from each center's ethics review board. One hundred thirty-five patients from 4 centers participated in this nasolabial appearance study. With regard to race/ethnicity, 72% of patients from centers G are Hispanics whereas the rest are Caucasians. All patients from other centers are of Caucasian descent. Three of these centers (B, C, and D) were part of the original Americleft study. These centers were

Table 1. Treatment Protocols and Samples Characteristics for Each Participating Center in This Study.

Treatment	Center B	Center C	Center D	Center G
Presurgical orthopedics	Yes, molding plate	No	Yes, taping only	Yes, NAM (3-5 mo)
Lip repair	2-3 mo Millard	3 mo Tennison	3 mo Millard	3-5 mo Modified Millard
Primary alveolar repair	Primary ABG at 6-9 mo	No	No	No, but 5 cases had GPP
Secondary alveolar repair	No	No	No	No
Hard palate repair	11-15 mo Wardill-Kilner	12 mo Vomer flap	12 mo Vomer flap	2-stage repair, 18 mo Von Langenbeck 1-stage repair 12 mo Bardach
Soft palate repair	11-15 mo Furlow or IVP	18 mo Median suture with IVP	12 mo Von Langenbeck with IVP	2-stage repair 3-5 mo IVP 1-stage repair 12 mo IVP
Primary rhinoplasty	No	No	No	Yes, at the time of lip repair
Use of postoperative nasal stents	No	No	No	Yes, 2 wk postoperatively
Nose/lip revision	Yes, performed at 4-5 y	Yes, performed at 14-20 y	Yes, performed at 4-5 y	None performed in this sample
Surgeons	4	1	1	2
Sample size (male: female)	37 (25:12)	39 (23:16)	27 (19:8)	32 (24:8)
Age range (y:mo)	6:8 to 10:5	8:0 to 10:0	6:7 to 12:6	6:5 to 9:8
Mean age/median age (y:mo)	8:4/8:4	8:7/9:0	8:10/8:5	8:0/8:0
Racial distribution	100% Caucasian	100% Caucasian	100% Caucasian	28% Caucasian 72% Hispanic

Abbreviations: ABG, alveolar bone graft; NAM, nasoalveolar molding; IVP, intravelar veloplasty.

chosen because they represented a range of infant and secondary nasolabial aesthetic management approaches, ranging from no presurgical manipulation or secondary surgical revisions (center C), to presurgical taping and secondary revision surgery (center D), to presurgical infant molding plate and primary bone grafting with secondary revision surgery (center B). Center G's primary infant protocol included NAM, which was typically started within the first 2 weeks after birth. The NAM appliance consisted of an intraoral plate for alveolar molding and a nasal stent for alar cartilage and nostril molding. Both nasal and alveolar moldings were commenced at the same time. The infants were seen weekly for appliance adjustments. A new NAM appliance was fabricated every 6 to 8 weeks to ensure continuing fit of the appliance. An average of 2 appliances were used for each patient during the course of treatment. The parents were also instructed to approximate the lip segments and tape them together with nonsterile 3M Blend Tone (Maplewood, MN). The lip taping was performed not only to approximate the lip segments but also to secure the NAM appliance in place. The NAM treatment usually lasted for 3 to 4 months until the primary cleft lip repair. At the time of primary lip repair, primary nasal reconstruction was done. Postoperative nasal stent was also used for approximately 2 weeks. The treatment protocols and sample characteristics of the centers' samples are described in Table 1.

The criteria for inclusion in the study required treatment histories to confirm that patients in all samples had nonsyndromic CUCLP and were consecutively treated, with all primary procedures performed at the participating center. All patients were between the ages of 6 and 12 years. The mean and median age for each center ranged from 8 to 9 years. Further details on mean ages of the samples are presented in Table 1. No patient had undergone any type of active orthodontic tooth movement, maxillary expansion, protraction orthopedics, or secondary alveolar bone grafting by the time the records were taken.

Nasolabial Appearance Analysis

Frontal and profile facial photographs were obtained from the centers and scanned. The resulting images, as well as any digital images provided, were compressed into JPEG format. Frontal images were leveled on the interpupillary plane using Adobe Photoshop 6.0 software (San Jose, CA). Images were cropped to show only the nasolabial area including the inner canthus, nasal bridge, nostrils, philtrum, and upper lip to reduce influences from other facial features (Figure 1). In the profile images, all backgrounds were standardized to a blue shade (Adobe Photoshop 6.0 color code 88b7f6) for blinding of center identity. Frontal and profile images were loaded into a Microsoft PowerPoint presentation. Each slide contained both profile and frontal view of a single patient (Figure 1). The slides were coded and their order was randomized eliminating patient or center identifiers. The complete PowerPoint file had 135 slides consecutively numbered.

All 6 raters in the study were professionals experienced in cleft care: 4 orthodontists, 1 oral-maxillofacial surgeon, and 1

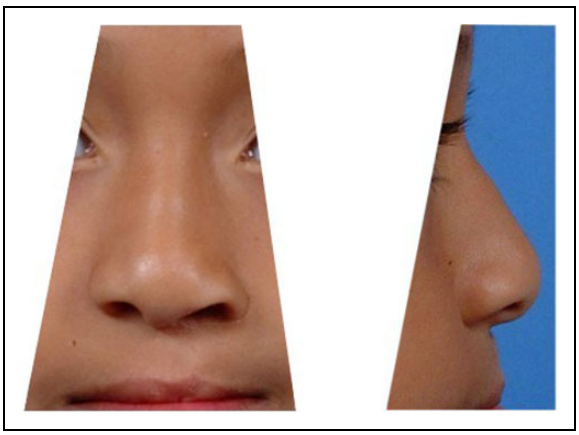

Figure 1. Example of a PowerPoint slide used for the nasolabial appearance rating.

speech-language pathologist. Only 1 rater is from center G whereas the rest are from centers without NAM and primary nasal reconstruction in their protocols. The raters were shown the slide presentation in a group session, but they were asked to rate independently without any conferring with one another. The raters were familiarized and calibrated in the use of the Asher-McDade scale prior to the nasolabial appearance assessment. Four nasolabial features were rated: nasal form, nasal symmetry, vermillion border, and nasolabial profile (Asher-McDade et al., 1991). Each feature was rated on a 5-point scale as follows: 1 = very good, 2 = good, 3 = fair, 4 = poor, and 5 = very poor. The raters received previously published color reference pictures representative of the range of nasolabial appearances in the 1-to-5 scale (Kuijpers-Jagtman et al., 2009). The raters were asked to re-rate 40 randomly selected slides from the study, presented in a different order, to assess the intrarater reliability.

Statistical Methods

Intra- and interrater reliability testing was done with weighted kappa statistics (Fleiss and Cohen, 1973). Six individual ratings for each of the Asher-McDade features were obtained for all patients. The mean of these 6 scores for each feature of each individual patient were calculated and averaged for descriptive purposes to represent a mean score for each center. Although individual scores were recorded on a 5-point categorical scale, the mean of the 6 raters' scores was considered a summary score to estimate values on an underlying continuum (Mercado et al., 2011). For each patient, a combined nasolabial score was also calculated by averaging the means of all features.

Because of the nonparametric nature of the Asher-McDade categorical/ordinal scale, and the fact that the distribution of scores for centers B and C were found not to be normal, the Kruskal-Wallis test with pairwise comparisons between center medians was used with the Bonferroni correction for multiple comparisons (family alpha = 0.20; individual alpha $P = .033$) to examine all pairwise differences between centers (Minitab, State College, PA).

Table 2. Mean Weighed Kappa (K) for Intra- and Interrater Reliability Tests for Each Nasolabial Components of Asher-McDade Rating.

Mean Weighed Kappa Statistics (K)	Nasal Form	Nasal Symmetry	Vermillion Border	Nasolabial Profile
Intrarater reliability	0.62	0.6	0.66	0.71
Interrater reliability	0.58	0.47	0.43	0.46

Results

The mean inter- and intrarater reliabilities are shown in Table 2. These results indicate moderate to good intrarater reliability for all raters (Altman, 1991), and moderate agreement between the raters. The mean scores for each center for each feature as well as the total nasolabial score pooling all features, and the 95% confidence intervals for those mean scores are shown in Table 3. In general, center G had the most favorable scores in all categories, including the total nasolabial score, compared to the other centers. In contrast, center C had the least favorable scores in all but one category compared to the other centers.

Because of the nonparametric nature of the categorical Asher-McDade scale, differences between the median scores from each center for each feature and the total nasolabial score were compared for statistical significance with the Kruskal-Wallis test and pairwise comparisons with the Bonferroni correction for multiple comparisons. The medians from all raters, for each feature and center, and the significant differences found are shown in Table 4. The Kruskal-Wallis pairwise analysis identified that center G's median scores for all the Asher-McDade features were significantly more favorable than those of center C. This consistently significant difference was not observed for the other centers. For Nasal Form, center G also had significantly better median scores compared to centers C and D. For Nasal Symmetry, center G's median scores were significantly better than all other centers. For Vermillion Border, both center D and G median scores were significantly better than centers B and C. For Nasolabial Profile, center G's median scores were significantly superior to those of center C, but not statistically different from centers B and D. For Total Nasolabial score, center G had significantly better median scores than all other centers. In addition, center D's scores were statistically significantly more favorable to those of center C.

The distributions of Asher-McDade scores for each feature and center are shown in Figure 2. For Nasal Form, Nasal Symmetry, and Vermillion Border, center G had a higher frequency of scores 1 and 2 (very good and good) than all the other centers. For Nasolabial Profile, center D had the highest frequency of score 1 compared to all other centers, whereas its combined scores of 1 and 2 were only slightly lower than center G's. Center C had the lowest frequency of combined scores 1 and 2 in all 4 categories examined. Center C also had the highest frequency of combined scores 4 and 5 (poor and very poor) in most features except for Vermillion Border where center B had the highest frequency. Center G had the lowest frequency of combined scores 4 and 5 in all features.

Table 3. Mean Scores and (95% CIs) for Each Component of Asher-McDade Scale and the Total Score Combining All Features, for All Participating Centers.

	Nasal Form	Nasal Symmetry	Vermillion Border	Nasolabial Profile	Total Nasolabial Score
Center B	3.09 (2.87-3.31)	2.68 (2.50-2.85)	3.11 (2.93-3.30)	2.90 (2.71-3.10)	2.95 (2.85-3.04)
Center C	3.32 (3.14-3.50)	2.88 (2.70-3.05)	3.06 (2.88-3.25)	3.01 (2.85-3.17)	3.07 (2.98-3.16)
Center D	3.27 (2.99-3.67)	2.80 (2.56-3.05)	2.73 (2.58-2.89)	2.71 (2.46-2.96)	2.88 (2.76-3.00)
Center G	2.86 (2.63-3.09)	2.33 (2.18-2.50)	2.61 (2.41-2.81)	2.62 (2.42-2.82)	2.61 (2.51-2.70)

Table 4. Median Scores for Each Component of Asher-McDade Scale and the Total Score Combining All Features, for All Participating Centers.

	Nasal Form	Nasal Symmetry	Vermillion Border	Nasolabial Profile	Total Nasolabial Aesthetics
Center B	3	2.67* vs G	3.17* vs D, G	2.83	2.83* vs G
Center C	3.33* vs G	2.83* vs G	3.17* vs D, G	3* vs G	3.00* vs D, G
Center D	3.17* vs G	2.83* vs G	2.83* vs B, C	2.67	2.83* vs C, G
Center G	2.83* vs C, D	2.33* vs B, C, D	2.58* vs B, C	2.67* vs C	2.67* vs B, C, D

*Denotes statistically significant differences when compared to the centers with corresponding letters.

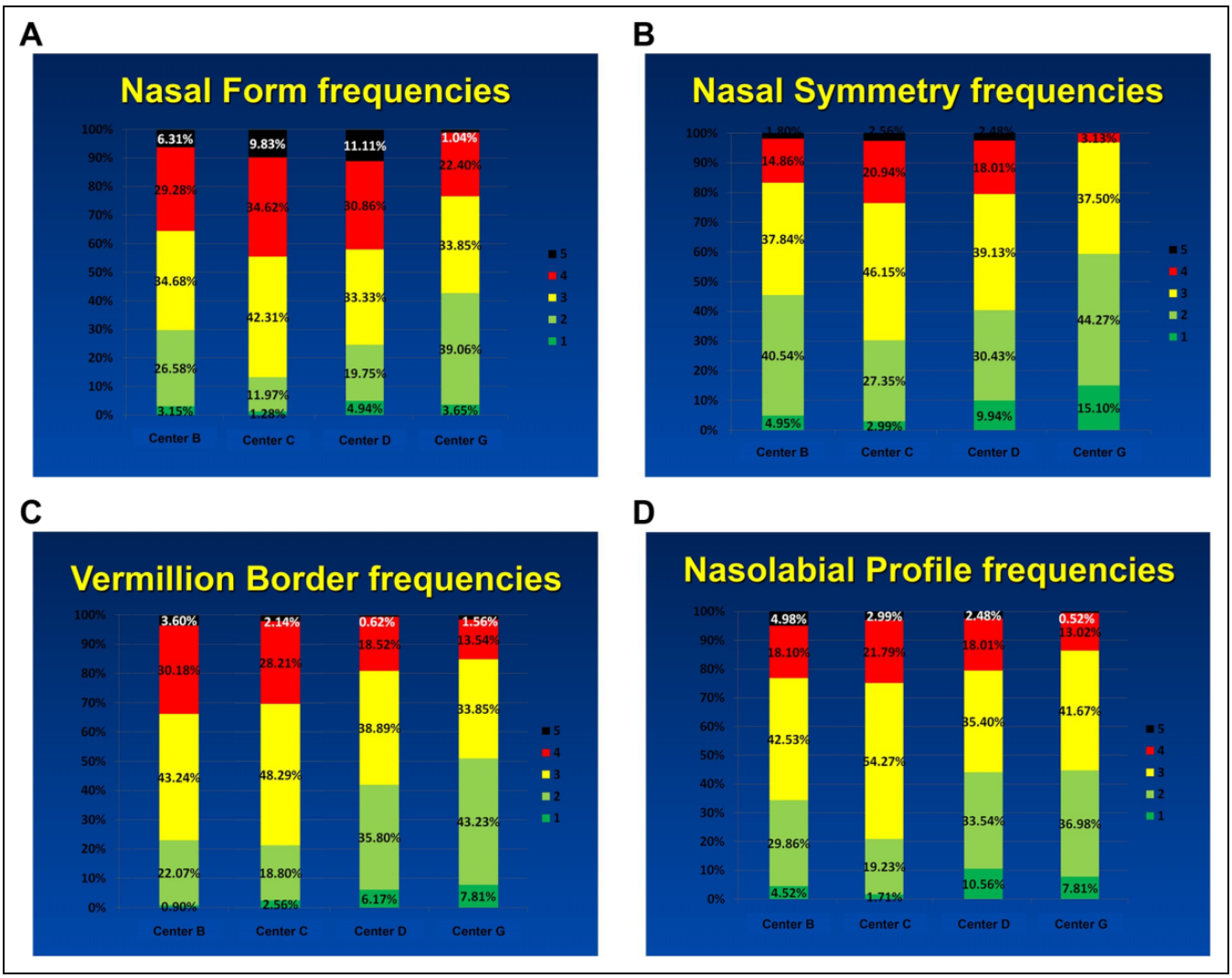

Figure 2. Distributions of Asher-McDade scores from 1 to 5 (most favorable to least favorable) for all participating center are shown. Distribution of Asher-McDade for (A) Nasal Form; (B) Nasal Symmetry; (C) Vermillion Border; and (D) Nasolabial Profile.

Discussion

Nasolabial aesthetic outcome assessment is associated with a high degree of subjectivity.

However, previous studies found the Asher-McDade rating to be an efficient and reliable tool for evaluating nasolabial aesthetics as well as differentiating outcomes from different treatment protocols (Asher-McDade et al., 1991; Asher-McDade et al., 1992; Mercado et al., 2011). Using 2-dimensional photographic images for nasolabial aesthetic evaluation also has its limitations (Asher-McDade et al., 1991; Johnson and Sandy, 2003). Even though rating nasolabial appearance on 3-dimensional images in patients with cleft lip and palate produced a higher reliability, it yielded the same aesthetic scores as 2-dimensional images (Stebel et al. 2016). Other features associated with repaired cleft lip, such as the presence of a scar and the appearance of the philtrum, require the use of higher-resolution photographs taken under standardized lighting and patient positioning or direct patient assessment. Because this is a retrospective study, it was impossible to obtain such photographs or perform direct patient assessment. The lack of a standardized protocol for patient photography in cleft centers, and the consequent range in quality of the images, undoubtedly contributes to the moderate reliability between raters in assessments of nasolabial appearance. It should be noted that the interrater reliabilities reported in this current investigation are slightly lower compared to those from our previous study (Mercado et al. 2011). This could be due to a more diverse group of raters (orthodontists, speech pathologist, and oral surgeon) assessing nasolabial outcomes in this study.

Nonetheless, the nasolabial appearance of patients from center G was more favorable when compared to other centers in this study. Center G's sample had significantly better aesthetics rating for Nasal Form (vs centers C and D), Nasal Symmetry (vs centers B, C and D), Vermillion Border (vs centers B and C), and Nasolabial Profile (vs center C). Center G also had the lowest frequency of cases with poor or very poor aesthetic outcomes. For all features rated, consistent and significant differences were detected between the median aesthetic scores of center G that performed NAM and center C that performed no infant orthopedics or nasolabial surgical revisions prior to the time that the photographs were taken. When compared to centers that perform traditional presurgical orthopedics and surgical revisions, center G was not consistently better in all features. Thus, the most compelling finding of this study was that nasolabial appearance outcomes resulting from primary surgical repair only should not be expected to produce the same level of correction as is possible with the inclusion of augmentative procedures such as NAM or secondary revisions. A comparison of these options involves more than assessment of mixed dentition nasolabial appearance alone, but also must include evaluation of the burden and costs of the various modes of care available. Patel et al. (2015) compared 2 groups of patients with and without presurgical NAM and primary nasal reconstruction had a significantly lower risk of early secondary nasal revision surgery compared with the group treated without NAM and primary nasal reconstruction. They also estimated that presurgical NAM and primary nasal reconstruction could lead to a saving of $491 to $4893 depending on the type of cleft when all associated costs were taken into consideration. It is worth nothing that the aforementioned study is a single-center retrospective nonblinded study design looking at the proportion of patients with surgical revisions of the nose only, whereas the present blinded study include various centers performing surgical revisions of the lip and/or the nose.

A recent study by the Americleft Project with patients from centers B, C, D, and G compared lateral cephalograms taken in the mixed dentition period (Peanchitlertkajorn et al., 2016). The study demonstrated that patients from both centers G and C had significantly more acute nasoform angle (soft tissue Nasion-Pronasale-Subnasale) than patients from centers D and B. A more acute nasoform angle may reflect better nasal tip projection, which is a key component of the nasal profile assessment. The study also demonstrated that the nasolabial angle (Columella tangent-Subnasale-Labrale superius) in centers C, D, and G was significantly more obtuse than center B, a finding that may indicate a more favorable nasal contour. However, in the present study with the Asher-McDade scale, the median scores for Nasolabial Profile in center G were significantly more favorable only than center C and not centers B and D. Thus, the objective measurements of nasoform angle and nasolabial angle from lateral cephalograms cannot be directly extrapolated to the Asher-McDade's subjective ratings of Nasolabial Profile from profile photographs.

Variables including the use of Infant Orthopedics (IO), surgeon's experience and skill, and surgical techniques, could be contributing factors in achieving favorable aesthetic outcomes. Centers B, D, and G employed some form of PSOT while center C did not use any such treatment (Table 1). The effects of IO for infants with oral clefts have been well investigated. In what is the only randomized clinical trial on the topic to date, infants were treated with Hotz plates (for feeding and for molding of the maxillary segments) from birth to 12 months of age, whereas a control group did not receive any form of IO before the surgical repair. Facial photographs of patients at 4 and 6 years of age were evaluated and suggested that IO, at best, had positive effects on facial appearance at age 4 but the positive effect disappeared by the age of 6 (Prahl et al., 2006; Bongaarts et al., 2008).

The effects of NAM on nasolabial aesthetics have been extensively reported (Bennun et al., 1999; Maull et al., 1999; Pai et al., 2005; Kecik and Enacar, 2009). However, most of these studies are short-term, unblinded single-center studies. The present study is the first to report effects of a primary CUCLP infant management protocol that included NAM and primary nasal reconstruction on nasolabial aesthetics as evaluated in a blinded intercenter comparison of patients in the mixed dentition period.

All craniofacial surgeons from centers participating in this study have several years of experience in a high-volume regional cleft center. Therefore surgeon's experience may not play a vital role in the differences of nasolabial outcomes

observed in this study. However, the likely impact of varying degrees of surgical skill on nasolabial esthetic outcomes cannot be underestimated, though it remains impossible to quantify with retrospective comparisons such as these.

Centers B, D, and G employed a variation of the Millard technique while center C utilized the Tennison technique for cheiloplasty. Previous studies did not find any advantage of a particular technique in achieving better nasolabial aesthetics. Zaleckus and coworkers (2011) reported similar nasal aesthetic outcomes between the Millard and Tennison techniques. Therefore, surgical techniques used may not explain the nasal outcome difference. Center G was the only center that included primary rhinoplasty as a part of its treatment protocol (at the time of lip repair). Other centers in this study, except for center C, did not employ the procedure but performed surgical revision of the lip and/or nose on some patients at an older age. A more favorable nasolabial aesthetics outcome observed in patients from center G could be linked to primary rhinoplasty, which was not done in the other centers. However, nasal outcomes from NAM alone have been reported to be more favorable in the long term when compared with primary nasal reconstruction without nasoalveolar molding (Bennun et al., 1999; Chang et al., 2010). Lazarus and colleagues (1998) suggested that the Millard technique may be associated with shorter upper lip. Lip taping, intended to create a tissue expander-like effect on the lip to compensate for the deficiency in height and length as reported by Boorer and coworkers (2011), was carried out by 2 of the 4 centers in this study, and may have contributed to the more favorable vermillion outcome for centers D and G. Only in center G, 5 patients received gingivoperiosteoplasty (GPP) as part of their primary surgical protocol. Because of the small sample size, these 5 patients were grouped together with the patients from the same center that were treated without GPP during the statistical analysis of the data.

It should be noted that the patient populations of the centers assessed in this study were more diverse compared to those in earlier publications from Europe. This is likely due to the multicultural nature of North American populations. In center G, 28% of the subjects were Caucasian, with the remainder being Hispanic, whereas all subjects from the other centers were of Caucasian descent. Therefore, having populations from different ethnic backgrounds in this multicenter study should be considered a confounding variable as it introduces variations in the nasolabial features that are not related to the treatment protocols. In addition, the applicability of the Asher-McDade scale herein can be questioned, because this rating method was developed and validated for use in Caucasian children (Asher-McDade 1991).

This study was performed with preadolescent patients. The Eurocleft studies have demonstrated that the treatment outcomes at the completion of facial growth generally followed the pattern observed in preadolescence (Mølsted et al., 1992; Brattström et al., 2005). Although our findings suggest that the preadolescent sample from the center with NAM as part of its treatment protocol demonstrated a more favorable nasolabial appearance, the authors believe that comparison of treatment outcomes at the completion of facial growth will increase our understanding of the effect of these treatment protocols on final nasolabial outcomes.

It is noteworthy that our previous report of the same samples (Peanchitlertkajorn et al., 2016) revealed significant differences in dentofacial development between centers. Center G (NAM/GPP) achieved poorer maxillary growth than center C (primary repair only), though not as severely as in center B (primary bonegrafting). This may imply the existence of a trade-off associated with NAM/GPP: improved nasolabial form but a higher need for subsequent orthognathic surgery.

It should be emphasized that with retrospective studies of this nature, it is impossible to establish a cause-and-effect relationship between nasolabial aesthetic outcomes and varied cleft management protocols. In addition, there are possible selection biases in the samples. These biases are minimized by using consecutively treated cases and large sample sizes of identical cleft types and comparable ages. Because all patients at their respective centers received the treatment protocols used at those centers, selection bias related to treatment group would be related to center selection rather than treatment group assignment. For future studies of this nature, prospective planning of data recording of all relevant variables and possible confounders, and use of propensity scoring and analysis may be valuable methods to control for selection bias in such nonrandomized comparisons. Nonetheless, even with this limitation to the current study what can be shown is that different protocols may be associated with more or less favorable results. The protocols can then be reviewed in greater detail to identify features of interest that could possibly be contributing to the outcome differences and thereby warrant further study.

Conclusions

This intercenter comparison study employed the Asher-McDade scale to differentiate and categorize treatment outcomes from most to least favorable, and then identified predominant and/or common aspects of treatment protocols for the various outcomes. In this study, the use of NAM as part of an infant management protocol produced significantly more favorable nasolabial appearance scores when compared with the outcomes resulting from primary surgery only. When secondary revision surgery is included in the protocol, as well as other presurgical management approaches, the significant differences are lessened and more variables likely involve the effects of other aspects of a particular protocol (surgical techniques, surgical skill, etc). It should be noted that is impossible to establish a cause-and-effect relationship between nasolabial aesthetic outcomes and varied cleft management protocols with a retrospective study. Ultimately, achieving the best aesthetic outcomes may be possible through a number of different protocol options and combinations of procedures.

Authors' Note

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Declaration of Conflicting Interests

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