

Presurgical Presentation of Columellar Features, Nostril Anatomy, and Alveolar Alignment in Bilateral Cleft Lip and Palate After Infant Orthopedics With and Without Nasoalveolar Molding

Sunjay Suri, M.D.S., M.Orth.R.C.S. (Edin), F.R.C.D.C., Suteeta Disthaporn, M.S. (Ortho), Eshetu G. Atenafu, M.Sc., David M. Fisher, F.R.C.S.C., F.A.C.S.

Objectives: (1) To evaluate quantitative differences in presurgical presentations of alveolar alignment and nostril anatomy of infants with BCLP treated with nasoalveolar molding (NAM) from those treated with maxillary infant orthopedics only (IO) and (2) to detect interrelationships between presurgical nasoalveolar anatomy, age at lip surgery, age of commencing, and durations of alveolar and nasal molding.

Methods: A retrospective analysis was conducted on nasal-alveolar measurements and presurgical treatment records of infants with BCLP who received lip repair by a single surgeon in a tertiary-care, referral teaching hospital consecutively from 2000 to 2009 after undergoing NAM (n = 29; 51 nostrils) or IO (n = 17; 32 nostrils). Paired *t* tests analyzed nostril and alveolar symmetry in each group. Intergroup comparisons were made by linear mixed-model regression analyses. Pearson's correlation tests were conducted to detect significant interrelationships within groups.

Results: Significant between-group differences were noted in alveolar irregularity (NAM: 3.58 ± 1.02 mm; IO: 7.31 ± 1.28 mm; $p < .01$), columellar length (NAM: 2.88 ± 0.27 mm; IO: 1.48 ± 0.34 mm; $p < .001$), columellar width (NAM: 6.10 ± 0.21 mm; IO: 6.88 ± 0.26 mm; $p < .01$), columellar length/width ratio (NAM: 0.48 ± 0.05 ; IO: 0.20 ± 0.07 ; $p < .05$), and columellar angle (NAM: $0.98 \pm 1.1^\circ$; IO: $3.69 \pm 1.37^\circ$; $p < .05$). Differences in age of commencing presurgical orthopedics, lip surgery, and treatment durations were not significant. Better-aligned alveolar segments in the NAM group did not statistically correlate with nostril dimensions. Alveolar irregularity and nostril height in the IO group strongly correlated.

Conclusions: Infants who received NAM had longer columellae and better-aligned alveolar segments than those who received only IO. Other nostril dimensions were not significantly different.

KEY WORDS: *BCLP, cleft, columella, NAM, presurgical orthopedics*

Columellar deficiency remains one of the hallmark features and persistent stigmata of bilateral cleft lip and palate (BCLP; Latham, 1973; Latham and Workman, 1974; Millard, 1977a;

Dr. Suri is Associate Professor, Discipline of Orthodontics, Faculty of Dentistry, University of Toronto, Canada, and Staff Orthodontist, Division of Orthodontics, Department of Dentistry, The Hospital for Sick Children, Toronto, Canada. Dr. Disthaporn is Former Clinical Fellow, Division of Orthodontics, Department of Dentistry, The Hospital for Sick Children, Toronto, Canada. Mr. Atenafu is Biostatistician, Biostatistics Department, Princess Margaret Hospital Cancer Program, University Health Network, Toronto, Canada. Dr. Fisher is Medical Director, Cleft Lip and Palate Program, The Hospital for Sick Children, Toronto, Canada, and Associate Professor, Department of Surgery, University of Toronto, Toronto, Canada.

Submitted September 2010; Accepted September 2011.

Address correspondence to: Dr. David M. Fisher, Medical Director, Cleft Lip and Palate Program, The Hospital for Sick Children, 555 University Avenue, Toronto, Ontario, Canada M5G 1X8. E-mail david.fisher@utoronto.ca.

DOI: 10.1597/10-204

Fisher and Mann, 1998; Mulliken et al., 2001). A number of surgical techniques have addressed the need to increase the columellar length (Millard, 1971; Millard, 1977b; Cronin and Upton, 1978; McComb, 1990; Mulliken, 1992; Cutting and Grayson, 1993; Trott and Mohan, 1993; Cutting et al., 1998; Grayson and Cutting, 2001; Mulliken, 2001; Garri et al., 2005). Presurgical nasoalveolar molding (NAM) is increasingly becoming popular with cleft teams that include presurgical orthopedics in their treatment protocols. Various methods of employing nasal conformers, stents, and bumpers have been reported that aim to mold the lower lateral nasal cartilages and simultaneously provide nonsurgical preoperative columellar lengthening in unilateral cleft lip and palate and BCLP (Matsuo and Hirose, 1991; Grayson et al., 1993, 1999; Bennun et al., 1999; Grayson and Cutting, 2001; Da Silveira et al., 2003; Grayson and Maull, 2004; Suri and Tompson, 2004; Bennun and Figueroa, 2006; Spengler et al., 2006; Liou et al., 2007; Lee et al., 2008; Bennun and Langsam, 2009).

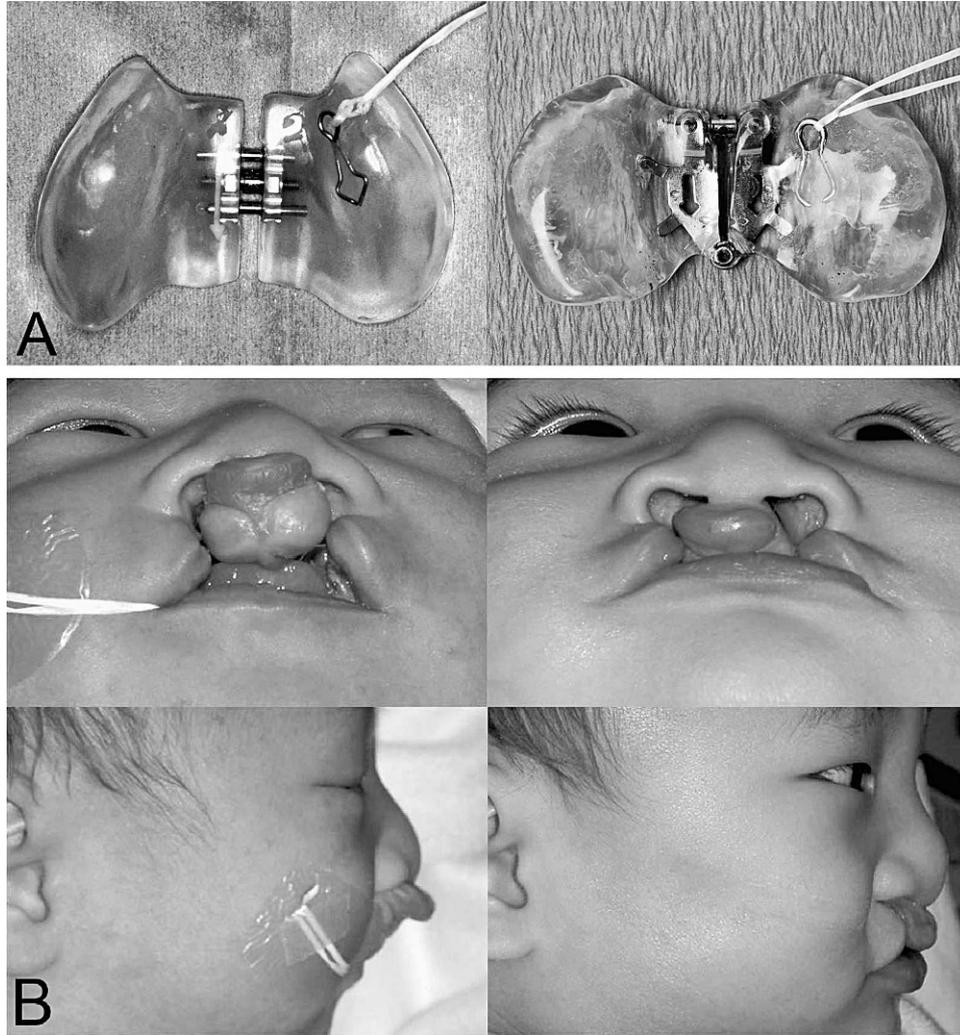


FIGURE 1 A: Two examples of maxillary orthopedic appliances used in the IO group, with expansion screws placed if needed, customized to the individual situation. B: Basilar and profile views of an infant at the start of (left, age 18 days) and after (right, age 8½ months) maxillary infant orthopedics, which did not include nasal molding or columellar lengthening.

In the presurgical orthopedic treatment of BCLP, the premaxilla is retracted and aligned with the lateral maxillary segments. NAM additionally puts a tensile stress on the columella to lengthen it during the presurgical period. However, even without nasal molding, columellar length can develop spontaneously with continued nasal growth during the time the premaxillary retraction is being undertaken. The quantitative differences in columellar length and nostril anatomy when maxillary orthopedic treatment has been conducted with and without nasal molding, however, remain unclear as there is a paucity of published reports that describe direct quantitative data measurements of the presurgical nasal-alveolar anatomy. Furthermore, there are no reports that have explored whether a relationship between the presurgical alveolar approximation and the presurgical columellar and/or nostril dimensions, age of commencing, or duration of infant orthopedic treatment exists. Knowledge of these differences and interrelationships would augment the

understanding of the implications of this treatment on the regional anatomy of the BCLP deformity and be useful in the treatment of infants with BCLP. This retrospective study aimed to evaluate differences in presurgical presentations of alveolar approximation and nostril anatomy of infants with BCLP who had received NAM and those who received orthopedic maxillary alignment but not nasal molding. We also aimed to investigate if any interrelationships exist between the intraoperative presentations of the nasal-alveolar anatomy, age at lip surgery, age at commencing orthopedic treatment, and durations of alveolar molding and nasal molding (when provided) in infants treated with both of these types of presurgical orthopedic treatments.

METHODS

This retrospective study was conducted using prospectively recorded quantitative data of the intraoperative

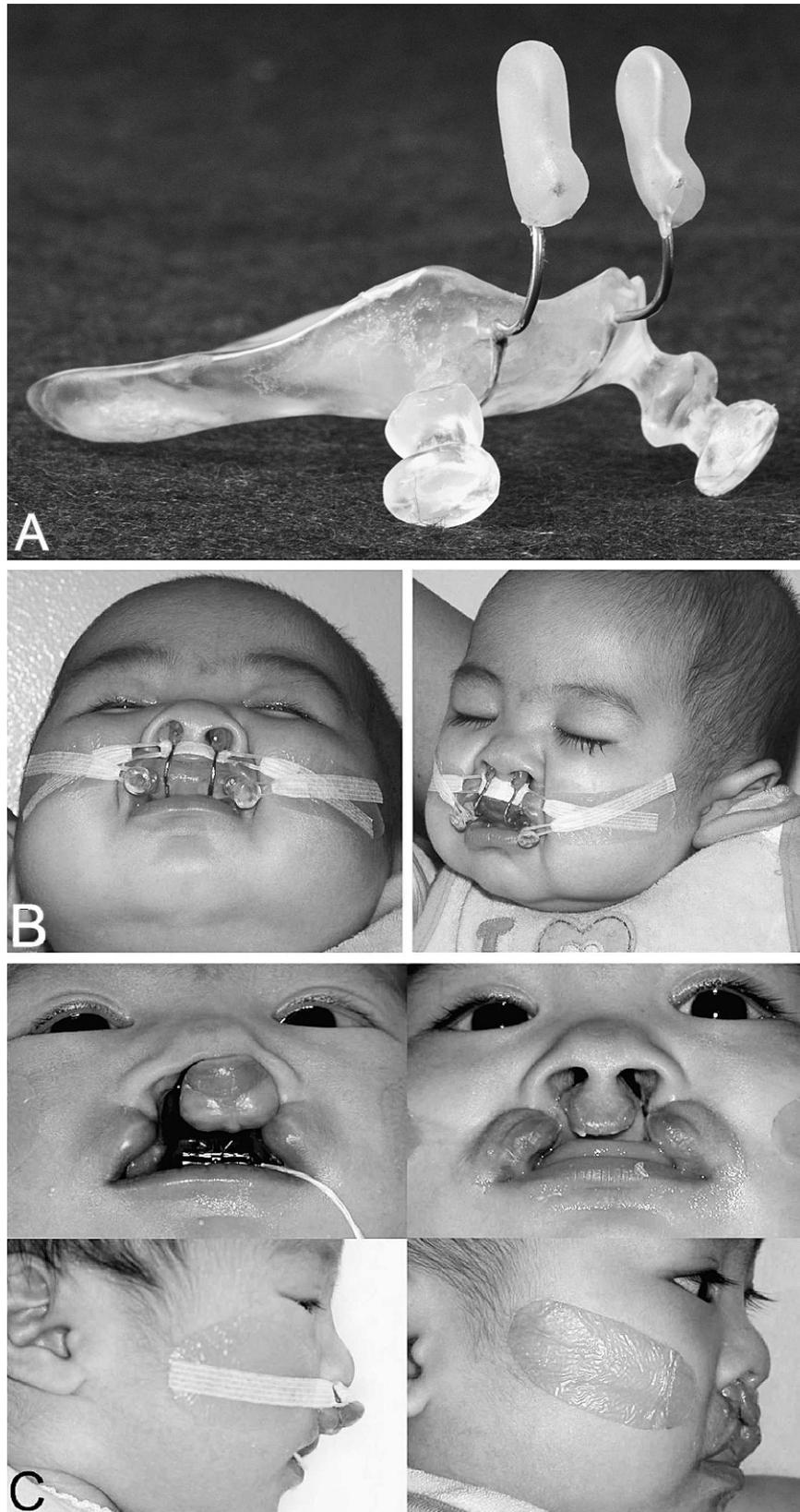


FIGURE 2 A: Example of a maxillary orthopedic appliance used in the NAM group, showing the nasal stents emerging from the labial flange of the alveolar molding plate. B: NAM appliance in position along with simultaneous lip taping. C: Basilar oblique and profile views of an infant at the start of (left, age 15 days) and after (right, age 6½ months) maxillary infant orthopedics. Maxillary orthopedic treatment included initial premaxillary retraction using lip taping and a maxillary expansion plate followed by nasoalveolar molding from age 3½ months to 6½ months. Note: Both infants in Figures 1 and 2 have similar ethnicity and were treated by the same orthodontist (S.S.). Note symmetric alignment of premaxilla in both Figure 1B and Figure 2C but an increase in columellar length evident in Figure 2C.



FIGURE 3 Measurement of the alveolar irregularity was made at the points of alveolar discontinuity where there was departure from ideal and continuous arclike alignment of central axis of alveolar segments.

presentations (at lip repair surgery) of nasal and alveolar features of 50 infants with complete BCLP, each of whom had undergone presurgical infant maxillary orthopedics using either an intraoral plate and nasal molding (nasal-alveolar molding or NAM group) or an intraoral plate alone without nasal molding (infant orthopedics [IO] group). All of these infants had undergone primary lip repair by one surgeon, consecutively, at the Hospital for Sick Children, Toronto, Canada, from June 2000 until September 2009. Four infants had bilateral Simonart's bands, while nine had a Simonart's band on any one side in their otherwise complete BCLP presentations. For the infants who received NAM, both nostrils, irrespective of the existence of a Simonart's band, had been molded individually by using nasal stents shaped and fabricated following the design and methods similar to the descriptions by Grayson et al. (1999) and Suri (2009). The presurgical orthopedics with or without NAM had been provided by multiple orthodontists and for different lengths of time. Either method of orthopedic treatment had been used by the treating orthodontists according to their own clinical judgment and discretion, without any attempt at randomized allocation to the type of orthopedic treatment. Presurgical treatment for infants who received only IO had involved an intraoral maxillary plate (with or without the use of expansion screws as may have been indicated for individual patients; Fig. 1A)

and orthopedic retraction of the premaxilla by lip taping (Fig. 1B), while that for infants who received NAM involved additional nasal molding and columellar lengthening by activating nasal stents added to the intraoral alveolar molding plates (Fig. 2A through 2C). The completion of presurgical orthopedic treatment and timing of lip repair surgery for each infant was based on the treating orthodontist's and surgeon's satisfaction with the outcome of the orthopedic alignment (retraction of the premaxilla to an improved position and alignment with the lateral maxillary segments) and nasal molding (in the infants who received NAM), the infant's overall health and fitness, and available operating room time.

After completion of the presurgical orthopedic treatment, all infants received primary lip surgery by the same surgeon (D.M.F.), who intraoperatively measured the nasal-alveolar features on anesthetized infants just before beginning surgery. All anatomical measurements in this study had therefore been recorded by a single surgeon. Alveolar irregularity was defined as departure from an ideal and continuous arclike alignment of the central axis of the alveolar segments. It was measured as the linear distance between the premaxilla and lateral maxillary segments directly across the alveolar discontinuity at the alveolar ridge crests, where they met the cleft margins (Figs. 3 and 4A). Columellar length, columellar width, nostril height, nostril width, and nasal width measurements were recorded to the nearest 0.5 mm using surgical calipers according to the description in Figure 4A, and columellar angle was recorded with a protractor as shown in Figure 4B, according to the description by Fisher et al. (2008). Data of each infant's age at the time of lip surgery, infant orthopedics experience (age at commencement and duration of use of plate until surgery), nasal molding experience (orthodontist, age at commencement of nasal molding, and duration from commencement of nasal molding until surgery), and ethnicity were retrospectively recorded from the clinic charts.

For data analysis, individual nostrils and cleft widths rather than an average of the right and left sides of a patient were included. To maintain data homogeneity, nostrils with Simonart's bands were excluded from analysis. This excluded four infants who had bilateral Simonart's bands from the study. Data from nine nostrils with unilateral Simonart's bands in an otherwise complete BCLP presentation were also excluded, while data from their contralateral nostrils, which were without Simonart's bands, were included. The analyzed sample, therefore, was divided into two groups: the NAM group, which included all complete cleft side nostrils that had undergone nasal molding ($n = 51$, from 29 infants), and the IO group, which included all complete cleft side nostrils that had undergone presurgical orthopedic treatment using a maxillary plate and lip taping to retract the protruded premaxilla but without nasal molding ($n = 32$, from 17 infants). This study was approved by the hospital's Research Ethics Board.

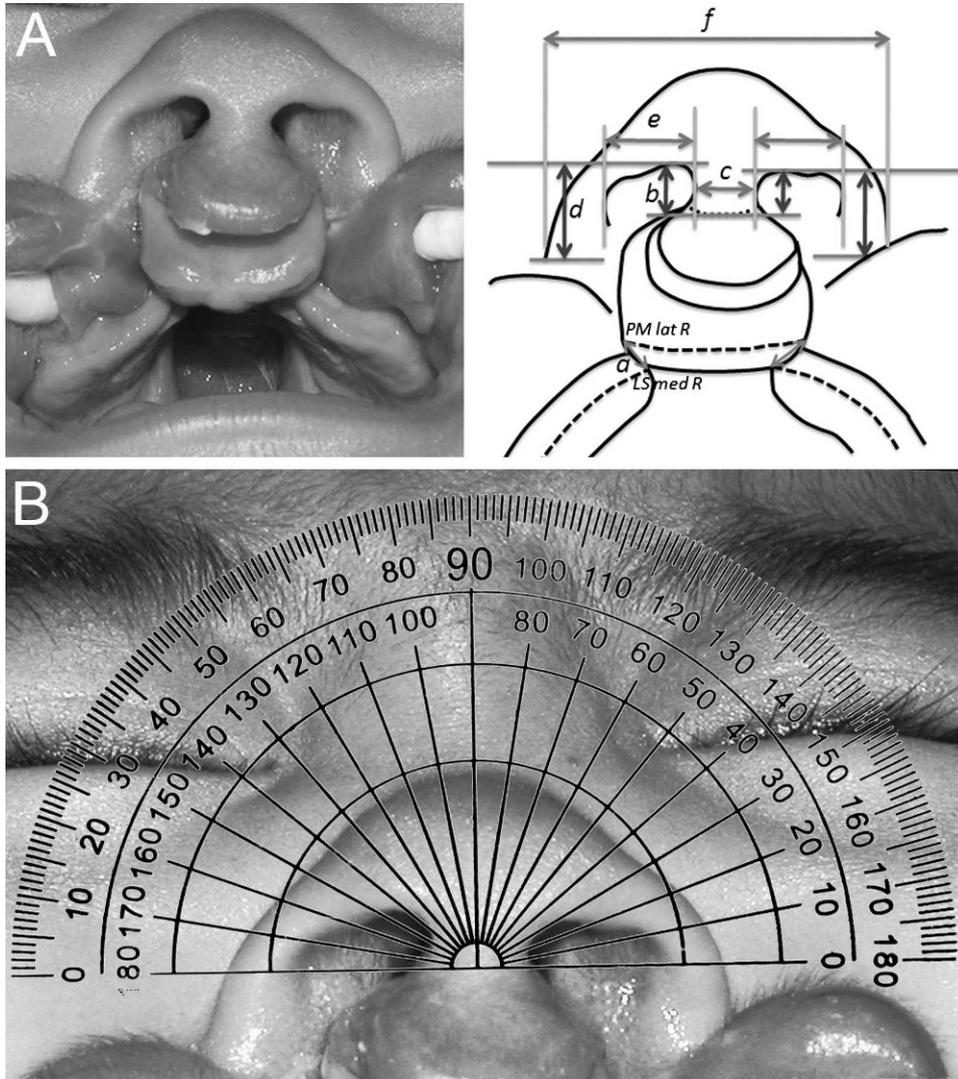


FIGURE 4 A: Measurements made intraoperatively (right-side linear measurements are shown). a: Alveolar irregularity: direct linear measurement between the premaxilla and lateral segments across the alveolar ridge crests where they meet the cleft margins (PMlatR to LSmedR). b: Columellar length: distance between midline base of columella and anterior nostril margin as an anteroposterior measurement. c: Columellar width: narrowest width of the columella as a transverse measurement. d: Nostril height: distance from subalare to the anterior nostril margin as an anteroposterior measurement. e: Nostril width: distance between most medial nostril margin to most lateral nostril margin as a transverse measurement. f: Nasal width: distance between right and left lateral alar margins as a transverse measurement. B: Measurement of columellar angle using a transparent protractor. The plane of the protractor was kept in the same plane as the columella. The base of protractor was then aligned parallel with the intercanthal line, and the angle of deviation of the midline of the columella from the midline vertical was measured.

TABLE 1 Comparison of Age and Duration of Therapy in NAM and IO Patients*

| Measurement | NAM Patients (n = 29) | | IO Patients (n = 17) | | Mann-Whitney (p Value) |
|------------------------------------|-----------------------|------|----------------------|------|------------------------|
| | Mean | SD | Mean | SD | |
| Age at start of plate (days) | 21.9 | 15.4 | 37.9 | 43.8 | 0.530 |
| Age at start of nasal stent (days) | 87.9 | 32.6 | — | — | — |
| Time using plate (days) | 145.8 | 39.7 | 136.4 | 59.9 | 0.079† |
| Time using nasal stent (days) | 80.6 | 25.2 | — | — | — |
| Age at lip surgery (days) | 169.9 | 47.2 | 184.8 | 75.7 | 0.940 |

* IO = infant orthopedics only; NAM = nasopalveolar molding.

† Result of comparison using *t* test after checking assumption of normality following log-transformation of data.

TABLE 2 Comparison of Right- and Left-Side Measurements in the NAM and IO Groups†

| Group | Measurement | Left-Side Mean | SD | Right-Side Mean | SD | Paired <i>t</i> Test (<i>p</i> Value) |
|--------------|----------------------------|----------------|------|-----------------|------|--|
| NAM (n = 22) | Alveolar irregularity(mm) | 3.66 | 2.85 | 3.64 | 3.13 | 0.969 |
| | Columellar length (mm) | 3.23 | 1.02 | 3.09 | 1.01 | 0.030* |
| | Nostril height (mm) | 10.41 | 1.70 | 10.88 | 1.47 | 0.153 |
| | Nostril width (mm) | 11.00 | 1.79 | 11.61 | 1.79 | 0.006* |
| IO (n = 15) | Alveolar irregularity (mm) | 8.67 | 4.59 | 5.90 | 4.18 | 0.009* |
| | Columellar length (mm) | 2.03 | 0.83 | 1.90 | 1.12 | 0.390 |
| | Nostril height (mm) | 10.65 | 2.48 | 10.10 | 2.61 | 0.292 |
| | Nostril width (mm) | 11.43 | 2.31 | 11.03 | 2.26 | 0.364 |

† IO = infant orthopedics only; NAM = nasoskeletal molding.

* *p* < .05, significant.

Statistical Analyses

Descriptive statistics such as means with standard deviation (SD) were used to describe patient recordings. The nonparametric Mann-Whitney test was used for the comparison of age and duration of therapy in NAM and IO patients. For symmetry analysis, the nostrils of infants with Simonart's bands on the contralateral side were excluded. A paired *t* test was conducted on the paired data from the remaining 22 pairs of nostrils in the NAM group and 15 pairs of nostrils in the IO group to study if there were significant differences between right- and left-side nostrils and alveolar irregularity measurements in each group. Differences in the intraoperative presurgical measurements and durations of these two types of presurgical orthopedic therapies between the two groups were analyzed by using linear mixed-model regression analyses (proc mixed) adjusted for the age at the time of lip surgery, age at which the infant orthopedic plate was inserted, and ethnicity, without assuming independence of the nostril pairs in the model. The interrelationships between alveolar irregularity, columellar length, columellar width, nostril width, nasal width, age at the time of lip surgery, and durations of alveolar molding and nasal molding (when provided) were investigated using Pearson's correlation coefficient analysis in each group separately. Statistical analyses were conducted using SAS (version 9.1, SAS Institute Inc., Cary, NC). Results of statistical analyses were considered significant when *p* values were less than .05.

RESULTS

For the infants who underwent nasal molding (NAM group), the maxillary orthopedic plate had been inserted at age 21.9 ± 15.4 days and nasal molding had been subsequently added at age 87.9 ± 32.6 days (Table 1). The difference was due to the fact that as is usually suggested in most infant orthopedic protocols described in the literature, nasal molding had been undertaken after significant retraction of the premaxilla and reduction of the cleft width were achieved. For the infants who underwent only IO, the orthopedic plate had been inserted at age 37.9 ± 43.8 days (Table 1). The differences in ages at which the infant orthopedic treatment plate was inserted in the NAM and IO groups were not significant (*p* = .530). The difference in mean ages at which lip surgery was undertaken in the two groups was also not statistically significant (*p* = .940). The NAM group, on average, underwent maxillary orthopedics for a total period of 4.8 months and wore the maxillary orthopedic appliance (plate) for 9.4 days longer than the IO group, which underwent maxillary orthopedics for 4.5 months. This difference was not statistically significant (*p* = .079). The period of wearing the orthopedic appliance in the NAM group included 2.6 months (approximately 12 weeks) of nasal molding.

Results from the paired *t* test comparison within each group to analyze symmetry (Table 2) revealed that there

TABLE 3 Comparison of NAM and IO Group Measurements by the Linear Mixed Model Regression Analysis Adjusted for Ethnic Group, Age at Lip Surgery, and Age at Insertion of Orthopedic Plate†

| Measurement | NAM Group (n = 51) | | IO Group (n = 32) | | <i>p</i> Value |
|-------------------------------|--------------------|-------------|-------------------|-------------|----------------|
| | Adjusted Mean | Adjusted SD | Adjusted Mean | Adjusted SD | |
| Alveolar irregularity (mm) | 3.58 | 1.02 | 7.31 | 1.28 | .002** |
| Columellar length (mm) | 2.88 | 0.27 | 1.48 | 0.34 | <.001*** |
| Columellar width (mm) | 6.10 | 0.21 | 6.88 | 0.26 | .002** |
| Columellar length/width ratio | 0.48 | 0.05 | 0.20 | 0.07 | <.001*** |
| Columellar angle (°) | 0.98 | 1.10 | 3.69 | 1.37 | .027* |
| Nostril height (mm) | 10.77 | 0.57 | 10.56 | 0.76 | .772 |
| Nostril width (mm) | 11.59 | 0.57 | 11.44 | 0.72 | .812 |
| Nostril height/width ratio | 0.94 | 0.06 | 0.96 | 0.08 | .765 |
| Nasal width (mm) | 34.86 | 0.51 | 33.72 | 0.63 | .042* |

† IO = infant orthopedics only; NAM = nasoskeletal molding.

* *p* < .05, significant.

** *p* < .01, highly significant.

*** *p* < .001, very highly significant.

TABLE 4 Correlations of Variables Measured in the NAM Group†

| Variables <i>r</i> (<i>p</i> Value) | Alveolar Irregularity | Columellar Length | Columellar Width | Nostril Height | Nostril Width | Nasal Width | Age at Lip Surgery | Duration of Plate | Duration of Nasal Molding | Age at Start of Plate |
|---|--------------------------|----------------------|---------------------|-------------------|------------------|----------------|-----------------------|----------------------|------------------------------|--------------------------|
| Columellar length | -.19 (.194) | | | | | | | | | |
| Columellar width | .09 (.543) | | | | | | | | | |
| Nostril height | .14 (.351) | .07 (.649) | .03 (.826) | | | | | | | |
| Nostril width | -.11 (.439) | .28 (.049) | -.33 (.019)* | .15 (.325) | | | | | | |
| Nasal width | .15 (.307) | .12 (.411) | -.23 (.110) | .22 (.133) | .78 (<.001)*** | | | | | |
| Age at lip surgery | .04 (.793) | .01 (.924) | .10 (.471) | -.08 (.567) | -.01 (.936) | .05 (.753) | .92 (<.001)*** | | | |
| Duration of plate | .03 (.835) | -.09 (.537) | .19 (.178) | -.96 (.187) | -.06 (.679) | .01 (.947) | | | | |
| Duration of nasal molding | -.22 (.129) | .25 (.076) | .17 (.237) | -.19 (.208) | .02 (.875) | .07 (.623) | .71 (<.001)*** | .70 (<.001)*** | | |
| Age at start of plate | -.07 (.650) | .22 (.125) | -.15 (.303) | .15 (.304) | -.14 (.328) | .11 (.424) | .65 (<.001)*** | .35 (.012)* | .54 (<.001)*** | |
| Age at start of nasal molding | .18 (.218) | -.19 (.172) | .29 (.041)* | -.01 (.925) | -.03 (.860) | .01 (.924) | .89 (<.0001)*** | .85 (<.0001)*** | .35 (.012)* | .48 (<.0001)*** |

† NAM = nasoalveolar molding.
* *p* < .05, significant.
*** *p* < .001, very highly significant.

was a large and significant difference between the right- and left-side alveolar irregularity measurements in the IO group (2.77 mm; *p* = .009), while there were minor differences in the right- and left-side measurements of columellar length (0.14 mm; *p* = .030) and nostril width (0.61 mm; *p* = .006) in the NAM group. The adjusted between-group comparisons by the linear mixed-model regression analysis (Table 3) showed that the alveolar segments were more closely aligned in the NAM group than in the IO group and that the mean columellar length was longer (2.88 ± 0.27 mm in the NAM group versus 1.48 ± 0.34 mm in the IO group). The mean columellar width in the NAM group was smaller (6.10 ± 0.21 mm versus 6.88 ± 0.26 mm in the IO group), and the columellar length/width ratio was greater (0.48 ± 0.05 versus 0.20 ± 0.07 in the IO group). All of these differences were highly (*p* < .01) or very highly significant (*p* < .001). The columellar angle was smaller in the NAM group (0.98 ± 1.1° versus 3.69 ± 1.37° in the IO group; *p* < .05), and the nasal width was slightly larger (34.86 ± 0.51 mm versus 33.72 ± 0.63 mm in the IO group; *p* < .05). Other differences in the intraoperative measurements were small and not significant. The nostril height/width ratios were almost identical in the two groups.

The results of the correlation analysis using Pearson’s correlation in the NAM group showed that no significant correlations were observed between the alveolar irregularity and any of the variables (Table 4). A strong and highly significant correlation was seen between nostril width and nasal width (*r* = .78; *p* < .001). Statistically significant but relatively weak negative correlations were observed between columellar length and columellar width (*r* = -.31; *p* = .029) and columellar width and nostril width (*r* = -.33; *p* = .019). Columellar width was weakly correlated with the age at which nasal molding had commenced (*r* = .29; *p* = .041). All age and treatment duration variables were significantly correlated with each other.

In contrast, in the IO group, the correlation analysis (Table 5) revealed a strong and highly significant correlation between the alveolar irregularity and nostril height (*r* = .70; *p* < .001) and columellar width and nasal width (*r* = .73; *p* < .001) and medium but significant correlations between nostril height and nostril width (*r* = .53; *p* = .013), nostril width and nasal width (*r* = .46; *p* = .008), and nasal width and age at which the plate was inserted (*r* = .56; *p* < .001). Among the treatment duration variables, a strong and highly significant correlation was observed between the duration of wearing of the maxillary orthopedic plate and age of lip surgery (*r* = .77; *p* < .001).

DISCUSSION

Presurgical maxillary orthopedic treatment in infants with clefts essentially aims to align and approximate the discontinuous maxillary segments and premaxilla into a near-normal form, position, and anatomic relation in the

TABLE 5 Correlations of Variables Measured in the IO Group†

| Variables <i>r</i> (<i>p</i> Value) | Alveolar Irregularity | Columellar Length | Columellar Width | Nostril Height | Nostril Width | Nasal Width | Age at Lip Surgery | Duration of Plate |
|---|--------------------------|----------------------|---------------------|-------------------|------------------|----------------|-----------------------|----------------------|
| Columellar length | -.25 (.171) | | | | | | | |
| Columellar width | .30 (.097) | -.22 (.218) | | | | | | |
| Nostril height | .70 (<.001)*** | .12 (.604) | .31 (.176) | | | | | |
| Nostril width | .27 (.132) | -.14 (.430) | .34 (.054) | .53 (.013)* | | | | |
| Nasal width | .30 (.091) | -.09 (.631) | .73 (<.001)*** | .33 (.139) | .46 (.008)* | | | |
| Age at lip surgery | .16 (.392) | .29 (.109) | .17 (.349) | .28 (.217) | -.00 (.982) | .28 (.117) | | |
| Duration of plate | .23 (.202) | -.05 (.800) | .08 (.673) | .34 (.135) | -.05 (.777) | .05 (.796) | .77 (<.001)*** | |
| Age at start of plate | .07 (.716) | .35 (.047) | .33 (.066) | .01 (.974) | .12 (.507) | .56 (.001)** | .30 (.101) | -.32 (.070) |

† IO = infant orthopedics only.

* $p < .05$, significant.

** $p < .01$, highly significant.

*** $p < .001$, very highly significant.

early infancy period, prior to the reparative lip surgery. When nasal cartilage molding is added to the orthopedic goals, it aims to simultaneously support, upright, and mold the deformed nasal cartilages, correct asymmetry, center the nasal tip, and lengthen the deficient columella. These orthopedic interventions take advantage of the moldability of the alveolar segments and immature cartilages in early infancy. This study analyzed intraoperative, directly recorded measurements to detect differences in the presurgical alveolar and nasal anatomical features following maxillary orthopedics with and without nasal molding. Our method of intraoperative measurement of the alveolar irregularity included discrepancies in alveolar alignment from an ideal arc rather than measuring only the cleft gap (Figs. 3 and 4). The advantage of this measurement method was that it took into account any segment misalignment despite contact of the segments (such as overriding of the lateral segments under the premaxilla).

Within-group symmetry analysis showed that there was a large and significant difference in the approximation and alignment of the premaxilla to the right and left maxillary hemialveolar segments in the IO group. On the other hand, this approximation and alignment were symmetrical in the NAM group. The differences in the left- and right-side measurements of columellar length (0.13 mm) and nostril width (0.61 mm) noted in the NAM group were small and clinically insignificant. Other nostril variables were symmetric in both groups, reflecting the underlying symmetry that is generally recognized in complete BCLP (Millard, 1977a; Fisher and Mann, 1998; Yuzuriha et al., 2008). Because each nostril in the NAM group had undergone nasal molding individually, it was appropriate to include each nostril data individually for statistical tests rather than averaging the data from the right and left sides. The differences noted among the two groups in the alveolar irregularity and columellar length and width measurements support the appropriateness of studying correlations in the two groups separately rather than collectively. Since both right and left nostrils from the same patients had a common columella and experienced the same duration of treatment and age-related growth, therefore, for intergroup analysis, assumption of independence of such data was not possible.

Hence, adjusting for the collinearity of these measurements in the linear mixed regression model was deemed important. The linear mixed regression model with an appropriate covariance structure is a multivariable regression model that assesses a possible predictor's contribution, when some or all of the subjects might have repeated data (in this case, columellar angle, width, and measurements related to age and duration of treatment from paired nostril data), with optimum use of available data, while adjusting for collinearity of the repeated measurements (Fitzmaurice et al., 2004; Littell et al., 2006). Because of the multiethnic data that reflected the ethnic diversity of patients who are treated at the hospital, adjustment for ethnicity was appropriately made in the analysis.

The retrospective chart review showed that the infant orthopedic treatment had been provided by eight orthodontists in the NAM group and nine orthodontists in the IO group. Six orthodontists had used both techniques, while two had used only NAM and three had used only IO. As stated earlier, no attempt at randomized allocation to either type of treatment had been made, and the selection of type of infant orthopedic treatment had been made by these treating orthodontists according to their individual clinical judgment. Reasons for their having selected or preferring one method over the other were not available, as they had not been recorded in the clinic charts, and this limitation in sample selection imposed due to this being a retrospective study should be recognized. For the six orthodontists who had used both types of treatment, NAM had been used, on average, for 68.6% of the infants they treated (ranging from 33.3% to 83.3% among these orthodontists). The potential impact of a possible selection bias does not allow us to determine the superiority of one technique over the other from this retrospective study. This report is based on carefully recorded measurements of a relatively large sample of patients with BCLP, operated consecutively by the same surgeon over a 9-year period. Other than those subjects or nostrils that did not fulfill the inclusion criteria as detailed earlier, there are no omissions in the consecutive data described in this report. Differences in infant ethnicities, ages at appliance insertion and lip surgery, and small numbers of subjects for some orthodontists pre-

cluded conducting a valid analysis of orthodontist-related differences with appropriate adjustment for these relevant effects. It is again clarified that the data reported in this article were appropriately adjusted for ethnicity, age at appliance insertion, and age at lip surgery and therefore should not be used for comparison with individual patients.

The potential implications of the wide variation noted in age at appliance insertion should be discussed. Most orthodontists who provide infant orthopedic treatment would agree that an early start of infant orthopedic treatment is recommended. Various unrecorded factors such as general overall health and fitness of the infants and referral from the community setting to the hospital could have potentially played a role in a later start of treatment (age at start of plate) for some subjects. Whether the relatively late start of orthopedic treatment (especially in the IO group) affected the presurgical presentations is debatable, but it must also be recognized that within-group correlation analysis (Tables 4 and 5) did not detect any significant correlation between age at start of treatment (age at start of plate) and any of the nostril or alveolar measurements in either the NAM or the IO groups.

Our results of the intergroup comparison (adjusted for age at the time of lip surgery and ethnicity) showed that after completion of the maxillary orthopedic treatment, the approximation of the premaxilla with the maxillary hemialveolar segments was much closer to ideal in the NAM group than in the IO group, and the columellar length was much larger while the columellar width was smaller. The columella in the NAM group was also straighter. However, it is clarified that this study was not an investigation aimed at demonstrating the greater effectiveness of one technique over another. Our focus was to detect the nature and magnitude of differences in the presurgical presentations of the nostril and columellar anatomy and alveolar alignment and to evaluate whether the anatomic interrelationships of this region were affected after nasal molding and columellar lengthening. Greater effectiveness of any technique over another is a question that should be addressed by a prospective randomized clinical trial.

The detailed measurements (Figure 4) on which the study is based had been made by one surgeon intraoperatively on anesthetized infants at the start of the lip repair surgery. None of the infants were anesthetized to facilitate making these measurements prior to orthodontics due to ethical reasons. Making such detailed measurements directly in an awake infant who has not been anesthetized is fraught with potential for error and would not be valid. Thus, no preorthopedic measurements were available. Therefore, our comparison included an analysis of the presurgical presentations rather than longitudinal changes with treatment.

From clinical experience and previous reports (Liou et al., 2007; Lee et al., 2008), it can conservatively be assumed that the preorthopedic columellar length in both

groups would have been similar and minimal (Figs. 1B and 2C). Thus, keeping this consideration in mind, it is possible to interpret that NAM was associated with greater presurgical columellar length gain in comparison with maxillary orthopedics alone. Greater columellar length in the NAM group could be expected since it was this group that underwent nasal molding and columellar lengthening in the presurgical orthopedic treatment. At the same time, it is important to note that presurgical columellar length development was also seen in the IO group, even though no direct attempts had been made to lengthen it. However, it was quantitatively about half of the measurement in the NAM group (Table 3). It is also important to recognize that the higher columellar length/width ratio in the NAM group indicated that nasal molding may have led to greater stretching of the columella.

When alveolar molding had been conducted without nasal molding or columellar lengthening (IO group), the strong correlations detected between the alveolar irregularity and nostril height (Table 5) indicated that this dimension was large when the separation or lack of alignment between the premaxilla and the hemialveolar segments was large. This relationship can be understood by recognizing that nostril height was measured as the linear distance from subalare to the anterior nostril margin (Fig. 4a), and therefore, greater separation between these landmarks would manifest as a greater measurement of nostril height in the IO group. The nostril heights, widths, and nostril height/width ratios were similar in both groups, but the alveolar irregularity measurements in the IO group were quantitatively twice as large as in the NAM group. In the absence of nasal molding, examining the other correlation data in the IO group revealed that the columellar width was directly related to the nasal width. Nostril height and width were also correlated, and nostril width was related to nasal width, although less strongly. On the other hand, when nasal molding had been provided in addition to alveolar molding (NAM group), the only strong correlation observed was between nostril width and nasal width. The smaller alveolar irregularity measurement (reflecting better alignment of the premaxilla with the maxillary segments) was not significantly correlated with any nasal anatomical feature (Table 4), indicating that when the segments are closely and more symmetrically approximated, nasal form is independent of alveolar form. The clinical effects of the tensional stresses applied to the columella by the nasal stenting were represented by an inverse relationship between columellar length and columellar width and between columellar width and nostril width. Although these correlations were significant, they were not strong.

These findings collectively indicate that at the conclusion of maxillary orthopedics with NAM in BCLP, although premaxillary alignment may not be a significant determinant of the nostril shape at that stage, columellar tension applied by NAM alters the presurgical dimensions of the

columella. Columellar length in the NAM group was almost twice as much as in the IO group, while columellar width was smaller. The better alveolar alignment seen in the NAM group also supports the concept that nasal molding generates a reciprocal force vector on the alveolus that augments alveolar molding (Suri and Tompson, 2004; Suri, 2010). The greater symmetry noted in the alignment of the premaxilla with the lateral maxillary segments in the NAM group, as seen from the alveolar irregularity measurements (Tables 2 and 3), can be attributed to the greater control of the premaxillary alignment by the labial flange of the appliance (Fig. 2A and 2B), coupled with the alveolar molding effects of the reciprocal force vector from nasal molding mentioned above.

There was no evidence that undertaking NAM affected or delayed the age of lip surgery. However, it should be taken into consideration that in our large teaching hospital, the infant's overall fitness and health for receiving surgery and the availability of surgical operating room time would have played a role in determining the timing of lip surgery in addition to the readiness assessed by satisfactory segment position, alignment, and effective nasal molding. This retrospective analysis was based on direct nasolabial measurements made intraoperatively at the time of lip repair, by one surgeon, consecutively over a 9-year period, beginning in 2000. Future studies could consider the possibility of recording anatomic measurements in three dimensions using 3D surface scanners and 3D photography methods that have currently become available. It should be clarified that this report does not attempt to claim that more favorable presurgical alignment and measurement differences indicate more superior postoperative outcomes or long-term effects. Future studies should examine how the measured variables are affected following surgical repair and facial growth during childhood and whether the presurgical columellar length/width ratio may be a predictor of long-term stability of the presurgical columellar length gain seen following NAM.

CONCLUSIONS

The potential impact of a possible selection bias on the superiority of one presurgical orthopedic technique over the other cannot be determined in this retrospective study. However, within the limits of a retrospective analysis conducted on 46 consecutively operated infants with BCLP over a 9-year period, we concluded that infants who received NAM had more favorable presurgical alveolar and columellar presentations than those who received IO only. They showed more symmetric and more ideal alveolar segment approximation, a straighter columella, and greater columellar length. Their greater columellar length and smaller columellar width indicated that columellar stretching may have resulted from NAM. Other nostril dimensions were not significantly different among the two

groups. Differences in durations of the two therapies or ages and which lip surgery was conducted were not statistically significant.

Acknowledgments. The authors acknowledge the efforts of the Cleft Palate Team and orthodontists at The Hospital for Sick Children, Toronto, Canada, who provided the infant orthopedic treatment, and the assistance of Taras Masnyi in fabricating and Diogenes Baena in photographing the appliances shown in this report.

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