

**Comparing Nasolabial Measures Using Casts and Facial Scans
in Infants with Non-Syndromic Clefts**

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Abstract

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Objective: To compare nasolabial measurements on nasal casts and facial scans in infants with non-syndromic clefts.

Data: Two types of clinical records obtained prior to and post- presurgical: (1) digital scans of nasal casts (N = 35); (2) 3dMD facial scans (N = 69); 34 of which had repeated facial scans on the same day.

Main Outcome Measures: (1) columellar angle; (2) columella length on the noncleft or right side; (3) columella length on the cleft or left side; (4) nasal alar base width on the noncleft or right side; (5) nasal alar base width on the cleft or left side; (6) inter-endocanthal width; (7) nostril dome curvature.

Results: There were no significant differences ($p > .05$) between nasolabial measurements obtained from nasal casts and 3dMD facial scans. Both records can be measured with good intra-rater reliabilities except the nasal alar base width and inter-endocanthal width ($p < .005$). However, the discrepancies are not clinically significant. Reliability between two raters based on 20 casts and 20 facial scans is also good.

Conclusions: The nasolabial measurements obtained from casts and 3D facial scans are consistent, both of which show good intra- reliability and inter-rater reliability. These measurements are reproducible across repeated 3D facial scans in infants with clefts.

KEY WORDS: cleft, nose, stereophotogrammetry, cast, infant

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INTRODUCTION

Background and Significance of the Problem

Clefts of lip, alveolus, and/or palate are a group of the most common craniofacial congenital anomalies, which incidence rate ranges from about 1/500 to 1/1000 live births (Hagberg, Larson, & Milerad, 1998). In clefts of lip and/or palate, the nose is rarely spared because its hard and soft tissue bases as well as adjacent structures are disrupted (Latham, 1973; Mulliken, Burvin, & Farkas, 2001). Nasal alar cartilages on the cleft side are often flared and collapsed due to lack of support. The nose tip loses sagittal projection and deviates to the noncleft side. Even in bilateral clefting, symmetry is often violated. The columella is usually shorter, wider, and more deviated in individuals with clefts compared to that in noncleft individuals (Suri, Disthaporn, Atenafu, & Fisher, 2012).

Longitudinal records to document changes in the nose and the lips are essential in evaluation of treatment outcome and growth in patients with cleft lip and/or palate (Simanca, Morris, Zhao, Reisberg, & Viana, 2011). Collection of the records should ideally start at birth and be repeated frequently enough to reflect changes occurring after major surgical or orthodontic interventions as well as with growth. This requires multiple records during infancy and early childhood when presurgical infant orthopedics (PSIO) and primary repairs are carried out. The conventional three-dimensional (3D) record is a cast of the midface that includes at least the endocanthi, the nose and the upper lip. Though casts offer the advantages of three-dimensional replication, the structures studied may deform from the impression pressure or due to facial expression. More importantly, the physical impression introduces the risk of airway obstruction and

needs to be obtained at a hospital where emergency measures are available. The 3dMD system combines techniques of 3D stereophotogrammetry (3D-SPG) and structured light (Chung How Kau, Richmond, Incrapera, English, & Xia, 2007) to produce relatively accurate (0.5 mm) and very fast captures (1.5 ms) of the facial surface (C H Kau et al., 2006; Chung How Kau, Hunter, & Hingston, 2007). This contact-free technique has been used in surgical and orthodontic outcome evaluation in recent years, yet there is no study on its accuracy and reliability in infants with clefts. It is unclear whether 3D-SPG can replace casts and if longitudinal data mixing the two modalities are clinically consistent. This study attempts to assess a new data collection method and establishing whether the new data can be integrated with data collected previously using a different method.

The current common clinical practice of facial image records in infants with clefts includes direct anthropometric measurements on the face (Antoszewski & Kruk-Jeromin, 1997; Farkas, Hajnis, & Posnick, 1993) or facial casts (Krimmel, Kluba, Bacher, Dietz, & Reinert, 2006) obtained with or without general anesthesia. Direct measures are challenging on infants unless they are immobile under general anesthesia. Repeating these measures is not quite practical either, which makes it difficult to test and maintain consistency and accuracy of the measurements. Facial casts have been the primary 3D record in most of published studies on infants with clefts in the past 20 years. This method may require a surgeon or orthodontist holding a swaddled infant upside down while an assistant applies light body vinyl polysiloxane material to the midface. While it provides long-lasting records that can be easily measured and reassessed *ex vivo*, the contact pressure during impression taking may

deform soft tissues, particularly those that are looser and not well supported, such as the nose and the lip. Deformation of soft tissues can also result from the infant's facial grimace and breathing or even crying posture. The extent of deformation has not been measured in infants, while it was measured to be 0.9 to 3.5 mm on average in adults (Holberg, Schwenger, Mahaini, & Rudzki-Janson, 2006) with the greatest deformation seen at the nose tip. The intraobserver reliability was reported to be within 5.3% in infants with cleft at 5-7 months of age (Krimmel et al., 2006). In spite of lacking support for accuracy and reliability in newborns and young infants, low-cost facial casts have been widely used as the primary mode for longitudinal facial records. Other modalities were examined, but discarded due to radiation exposure concerns related to computed tomography (Fisher, Lo, Chen, & Noordhoff, 1999), or motion artifacts under slow scan speed associated with laser scanning (Cutting, McCarthy, & Karron, 1988; Da Silveira, Daw, Kusnoto, Evans, & Cohen, 2003; Harrison, Nixon, Fright, & Snape, 2004). A common limitation for radiographs and laser scans is a lack of color and texture, which does not help with identifying landmarks.

In the past decade, the 3dMD face system (3dMD, Atlanta, GA) has been developed to provide fast and accurate 3D facial image. It combines techniques of 3D-SPG and structured visible light that can acquire facial images in 1.5 ms at its highest resolution with accuracy up to the 0.5 mm level. Because of its extra-high speed in data acquisition, SPG is potentially useful in applications in infants and young children. This technique does not require the subject closing eyes to protect their eyes from the laser, as is necessary during laser scanning. 3D-SPG using the 3dMD system has been reported to be accurate and highly repeatable in imaging faces of mannequin heads

(Weinberg et al., 2006), adults and older children (Heike, Cunningham, Hing, Stuhaug, & Starr, 2009) with or without craniofacial anomalies. It can also be used to digitize the casts to acquire 3D digital data (Krimmel et al., 2006). It is tempting to expect the same for applications in newborns and young infants nevertheless, there are additional challenges such as artifacts from facial grimacing or objects on the face (saliva, tears, food etc.) and difficulty to posture the infants at the ideal angle for scanning the clefts. Nonetheless, quantitative assessment has to be conducted before drawing any conclusion. A number of recent publications (Gomez, Donohue, Figueroa, & Polley, 2012; Simanca et al., 2011) measured nasolabial changes in infants with cleft based on 3D-SPG data. This new modality of data appears to gain popularity in the era of digital records. At present, however, there has been no study comparing anthropometric measurements acquired from casts and 3D-SPG records in newborn and young infants with clefts.

In clinical management and research, the period needing nasolabial assessment often spans from birth to adulthood. Data consistency is critical to interpret the records appropriately. The question arises on how data acquired in two different modalities (cast vs. facial scan) be integrated and remain consistent in longitudinal evaluations of patients.

Purpose of the Study

Treatment in early infancy demands safe, accurate, and reliable longitudinal 3D data on facial morphology changes. The records should be acquired as early as at birth and as frequently as the treatment progresses and the face grows. To establish reliability in the infant population, this study compared nasolabial measures on facial

scans using a popular 3D-SPG system (3dMD) to standard nasal casts in infants with nonsyndromic clefts. It aimed to answer the following questions: (1) Do nasolabial measurements based on 3dMD facial scans differ from those based on nasal casts in infants with clefts? (2) Are nasolabial measurements based on 3dMD facial scans reproducible in infants with clefts? (3) What is the measurement reliability based on 3dMD facial scans and nasal casts in infants with clefts?

Methods

Samples

All available records (nasal casts and 3dMD facial scans) of 39 consecutively treated infants with non-syndromic cleft lip \pm palate who underwent presurgical infant orthopedic (PSIO) treatment between August 2010 and August 2013 were included. The inclusion criteria are (1) non-syndromic cleft lip \pm palate; (2) younger than 120 days at the beginning of PSIO treatment; (3) the lapse of time between taking records of casts and facial scans is less than 2 weeks. Total 35 nasal casts and 69 facial scans from 24 patients (14 males and 10 females) are included. All but one case has two repeated facial scans on the same day of clinical evaluation. 18 patients have pre- and post- PSIO records in at least one format, while the rest have records at one time point only. The demographics of the included data from 24 patients are presented in Table 1. There are 11 patients (4 females and 7 males) with left cleft lip \pm palate, 11 (4 females and 7 males) with bilateral cleft lip \pm palate, and 2 females with right cleft lip \pm palate. The average ages to start and complete PSIO are 27 days (SD = 18.4 days) and 158 days (SD = 44.4 days) respectively. The average duration of PSIO is 131 days (SD = 42.9 days). The nasal casts were digitally scanned using Ortho Insight 3D model

scanner (Motionview software) at the Department of Orthodontics, University of Washington. The resolution of cast scans is 40 μm in each dimension, while the 3dMD facial scans have a resolution of 0.5 mm in each dimension. All 3D cast and facial scans were recoded and randomized before measurements. All measurements were carried out using 3dMD Vultus program (3dMD, Atlanta, GA) at Seattle Children's Hospital.

Measurements

Twelve landmarks, 5 linear measurements, and 1 angular measurement were selected because they represent the typical anomalies associated with clefts (Tables 2-4). Figures 2-5 demonstrate all measurements. To be consistent, in all cases of unilateral cleft, the noncleft side is regarded as the right side, while the cleft side as the left side. In cases of bilateral cleft, the anatomic sides remained unchanged.

The nostril dome curvature was rated with an equal-interval scale (Figure 6) as follows. A reference line was drawn between the columella top point and the ipsilateral subalare. Only the side with lower rating was recorded.

- Severely sigmoid (-2): The superior border of the nostril rim curves downward or inward below the reference line.
- Mildly sigmoid (-1): The superior border of the nostril rim curves downward or inward, but does not extend below the reference line.
- Flat (0): The superior border of the nostril does not show a significant upward/outward or downward/inward curve.
- Convex (1): The superior border of the nostril has an upward or outward curve.

Procedures

An illustration of the study design is in Figure 1.

Intra-rater reliability

The first (primary) rater measured all data twice with the second measure 2-4 weeks after the first measure.

Inter-rater reliability

Inter-rater reliability: The second rater measured randomly selected 40% of all data (20 cast scans and 20 3dMD facial scans) based on the same protocol as what the first rater used. It is impossible to completely “blind” raters in this study because of the use of facial records. However, the rest of personal identifiers were stripped and records were recoded as described before.

Statistical methods

There are repeated measures on the same subjects using different record types, by the same rater, and by different raters. Therefore, comparisons are largely based on matched samples and repeated measures on the same subjects. Three types of statistical analyses are chosen in the present study: mean comparisons, correlations, and descriptive statistics of landmark co-ordinates.

First, results were analyzed using repeated-measure MANOVA in SPSS 19 (SPSS, Chicago, Ill) because of the multiple dependent variables and two independent variables involved. The independent variables are record type (nasal cast, first 3dMD facial scan, second 3dMD facial scan), and measurement order (1st measure, 2nd measure). The inter-rater reliability was analyzed using 40% of data randomly selected. MANCOVA was used with the factor of rater (1st rater, 2nd rater) and a covariate of

record type. The dependent variables in MANOVA and MANCOVA include 5 linear and 1 angular measurements listed in Table 3.

Due to the ordinal scale used and the nature of repeated measures in the present study, similar comparisons of nostril curvature ratings among casts and facial scans were carried out with Wilcoxon Ranked Sign Tests. Intra- and inter-rater reliability of curvature ratings were tested using the same methods.

Pearson correlation tests were conducted on all linear and angular measurements for intra- and inter-rater reliability analyses. In addition, descriptive statistics of coordinates of all landmarks were used to describe the range of variation across record type, measurement order by the first rater, and between two raters. For statistical analyses, significance was set at the level of $\alpha = 0.05$. If there were multiple comparisons in one analysis, Bonferroni correction was utilized.

A priori Effect size estimation of between-method difference is based on a previous study (Germec-Cakan, Canter, Nur, & Arun, 2010) comparing different methods of measurements on the facial soft tissue. The smallest effect size (.58) reported among all between-method differences was chosen. The difference reported in this study was considered not clinically significant, which means that the estimate presented here is quite conservative because an effect size with clinical significance would be much greater. The estimated sample size for two repeated measure MANOVAs at $\alpha = 0.01$ and $\beta = 0.90$ is 12, while that for three Wilcoxon Ranked Sign Tests is 33.

Results

Comparison between record types

The comparison between casts and facial scans does not show any significant difference in MANOVA (Figure 7) and Wilcoxon Ranked Sign Test. Among 35 pairs of records, 29 are matched in curvature ratings, while 6 differ with one level.

Reproducibility across repeated 3dMD facial scans

The two repeated 3dMD facial scans are regarded as two record types in MANOVA and Wilcoxon Ranked Sign Test. The comparison does not show any significant difference with multivariate tests (Figure 7).

Intra-rater reliability

A multivariate test shows significant difference between two measures by the first rater. Further univariate tests with Bonferroni correction, reveals that nasal alar base width on the noncleft or right side and the inter-endocanthal width differ ($\alpha < 0.005$) (Figure 8).

Upon close inspection, the differences in these two measures are 0.26 mm and 0.32 mm respectively. The Pearson correlations between measures by the same rater are between 0.85 and 0.99 (Table 5).

Wilcoxon Ranked Sign Test does not show any significant difference in nostril curvature ratings between two measures by the first raters. 96 out of 104 ratings match between raters, with 8 differ only one level.

Inter-rater reliability

Similar tests were carried out to assess inter-rater reliability. No significant difference was found among the same measures conducted by two raters. This result

was not altered when the record type was considered as a co-variate. The mean differences between paired linear measurements by two raters range from 0 to 0.7 mm with the inter-endocanthal width varies the greatest (Figure 9). The mean difference of columella deviation angle is 2° ($SD = 7^{\circ}$). The Pearson correlations among the same measures by two raters are very strong ($r \geq 0.88$) except for inter-endocanthal width ($r = 0.68$) and columellar length on the cleft or left side ($r = 0.74$) (Table 6). Corresponding coordinates of all landmarks between raters differ less than 0.4 mm by mean, but the range is from 0.4 mm to 4.0 mm. The landmarks with the greatest variations are the top of the columella on the cleft or left side (Max. 3.6 mm) and the endocanthi (Max. 4.0 mm).

Wilcoxon Ranked Sign Test does not show any significant difference in nostril curvature ratings between two raters. Thirty-seven out of 40 ratings match between raters, with 3 differ only one level.

Discussion

Analyses described above do not show any statistically significant difference between measures obtained in nasal casts and 3dMD facial scans at the same time point. The differences between record types are less than 1.5 mm, with most of them less than 0.5 mm. This is inconsistent with previous published findings (Holberg et al., 2006). Holberg et al. reported average anatomical landmark deviations between facial casts and 3D digital scans of adult faces range from 0.95 to 3.55 mm. The contact pressure from impression taking, breathing gesture, and gravity are blamed for the large deviations. Our findings, however, show minimal discrepancies. The distance measurements differ no greater than 1.3 mm and the columellar angle differs less than 3 degree. The measurement differences between casts and 3dMD scans appear to be

similar to those between two repeated 3dMD scans, none of which is clinically significant.

The reasons why our results disagree with previous findings may be the following. First, Vinyl polysiloxane (PVS) is used in impression taking in our study. In contrast to the alginate used in Holberg et al.'s study, PVS has higher dimensional stability and greater accuracy (Bayindir, Yanikoğlu, & Duymuş, 2002; Walker, Rondeau, Petrie, Tasca, & Williams, 2007; White, Fallis, & Vandewalle, 2010). The size of the impression may also play a role in distortion. The present study took impression of the nasolabial area only, whereas Holberg et al. made records of the entire face. The larger the impression, greater deformations would be expected due to the flexibility of the impression materials.

By comparing two repeated 3dMD facial scans, we confirm that nasolabial measurements obtained from 3dMD facial scans are highly reproducible. This is similar to the result of a previous study on older patients at the same institution (Heike et al., 2009). Both studies adopt the same imaging protocol set up for patients with craniofacial anomalies. It is the first time that its reproducibility is proved in infants as young as newborns. Heike et al. discarded data where they had difficulty in identifying landmarks, which makes their reported reliability slightly higher than that of this study. The results of the present study may be a realistic representation of clinical records as no data were excluded because of difficulty with landmark identification. However, the present study includes fewer landmarks for nasolabial measurements associated with cleft lip and alveolus. With a limited number of cases available, we could not have included more measurements (dependent variables), otherwise, the statistical analyses

would not be powerful enough to render meaningful results. Because clinical records were taken during the infants' clinical evaluation, minimizing facial expression was often challenging. One included case demonstrated both crying and calm facial scans on the same day; the differences in measurements ranged from 0.2 to 4 mm in linear measurements and 1.6° in columella angle. This level of linear difference is sufficient to create misinterpretation of clinical significance. We recommend taking multiple facial scans in young infants to minimize the impact of facial expression artifacts.

The results reveal some differences between two measures conducted by the same rater. The differences, however, are only 0.3 mm (mean) for nasal alar base width and inter-endocanthal width, which are not clinically significant. The repeated measures by the same rater remain strongly correlated. All measurements have $r \geq 0.90$, except the columellar length on the cleft or left side ($r = 0.85$). This perhaps is because the columella top point on the cleft side is often the least distinct landmark prior to any surgical or orthopedic treatment. The nasal alar cartilage does not have sufficient support due to clefted alveolus and nasal base. The nostril flares, and the columella on the cleft side usually deviates or is stretched flat. Without an evident dome structure, the "top" point is ambiguous that leads to variability when the rater tries to identify this landmark.

Previous publications (Donatelli & Lee, 2013a, 2013b) on reliability tests suggest that neither paired statistical comparisons (Linnet, 1999) nor Pearson correlation tests (Bland & Altman, 1986) can prove reliability as two sets of data can differ non-significantly by means and correlate well, yet still not clinically "similar." One alternative to solve the problem is to check the landmark coordinate positions (Donatelli & Lee,

2013b). In the present study, the differences between any corresponding coordinates of two repeated measures average 0.2 mm with a range of 0 to 1.5 mm, which agrees with previous studies (Heike et al., 2009; Lübbers, Medinger, Kruse, Grätz, & Matthews, 2010). This further confirms the high intra-rater reliability for the nasolabial measures obtained on 3D scans of both nasal casts and faces.

The inter-rater comparison does not show any significant difference. Further, correlations are strong to moderately strong among measurements by two raters (Table 6). The variation of landmark positions between raters is greater than the intra-rater comparison, which suggests that there is still difference in how the two raters define the landmarks. This highlights the need for establishing operational definitions for landmarks and a more reproducible measurement protocol. Standardized training for raters may also help to reduce the variability across raters.

The landmark identification with greatest variations involves endocanthi and the top of the columella on the cleft or left side. As explained above, the top of the columella is difficult to select on the cleft-affected nose. The endocanthi are not always clear or identifiable on casts and facial scans. They may not show as a clear landmark on the impressions of casts due to facial grimacing or blurred on facial scans due to tear in eyes.

The present study is the first study utilizing measurements obtained from 3D scans of the nasal casts. Direct measures on the casts (Barillas, Dec, Warren, Cutting, & Grayson, 2009; Garfinkle, King, Grayson, Brecht, & Cutting, 2011; Keçik & Enacar, 2009) and measures on 2D photos of nasal casts (Gomez et al., 2012) have been used in previous studies. The advantage of 3D scans of casts is that it allows more accurate

identification of landmarks and measurements that may be difficult to obtain with a ruler or a protractor. Besides, digital scans do not wear over time nor break. It is also easier to transfer digital data among clinicians. As the present study suggests, nasolabial measurements based on casts do not differ from those of facial scans. The digital scans of casts render higher-resolution images, which is more advantageous than facial scans. In some cases of the present study, the casts show more distinct anatomy than the facial scans. If the cleft team has a protocol to take impressions for alveolar segments in order to fabricate PSIO appliances, it does not take an extra appointment to take a nasolabial impression. The discomfort of impression-taking adding to the existing protocol is then limited. Nasal casts are still good low-cost clinical records rendering useful information where 3D facial scans are not accessible.

3dMD facial scans have a resolution of 0.5 mm, which implies that errors no less than ± 0.5 mm are expected in the system. In the present study, changes post-PSIO treatment are not analyzed. However, the range in linear measurements after PSIO is no more than 1.5 mm on average. This creates challenges to whether these small changes can be detected by 3dMD facial scans. Studies on young infants, therefore, require a much more accurate data acquisition system. Systems of high accuracy are yet to be developed. An alternative may be a shape analysis that is less dependent on individual landmark points.

3D facial scans provide rich information of facial and head morphology. Morphometric analysis based on the entire shape instead of landmarks has been adopted in nasolabial evaluation in recent years (Kau & Richmond, 2008; Singh, Levy-Bercowski, Yáñez, & Santiago, 2007). Even though a large number of landmarks must

be identified before the mathematical representation of the shape can be formed, errors on individual landmark identification have less effect on the entire shape. In addition, size variations resulting from growth and differences between individuals have limited impact on morphometric analysis because it extracts the morphological characteristics regardless of the dimensions. Its result produces excellent visualization of detectable differences, but the quantitative report still needs to be improved. This group of methods may be particularly promising in studying complex morphology in the nasolabial region. In theory, 3D scans of the casts can be used for morphometric analysis too, although the field of interest is more restricted. Evaluation of asymmetry is another area that could benefit from 3D facial scans, however, it is not very clear in the published studies how the critical midsagittal plane of the face is determined.

Last, the present study adopted a new measure to evaluate nostril dome curvature. The authors considered nostril esthetics and important clinical outcome, and the dome shape could not be evaluated with traditional linear and angular measurements.

Conclusion

This present study does not find any statistical difference among the specified linear and angular measurements obtained from nasal casts and 3dMD facial scans. Neither is there any significant difference in nostril curvature rating. Given a well-designed and implemented imaging protocol, it is possible to have reproducible facial scans in infants. The analysis protocol adopted by this study is demonstrated to have good intra- and inter- rater reliabilities. However, we should be cautious about the limitations of both nasal casts and current facial scans. We hope that development of

more accurate facial scans and better analyses will improve the current assessment of nasolabial morphology in infants with clefts.

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Figure 1. Study procedures diagram

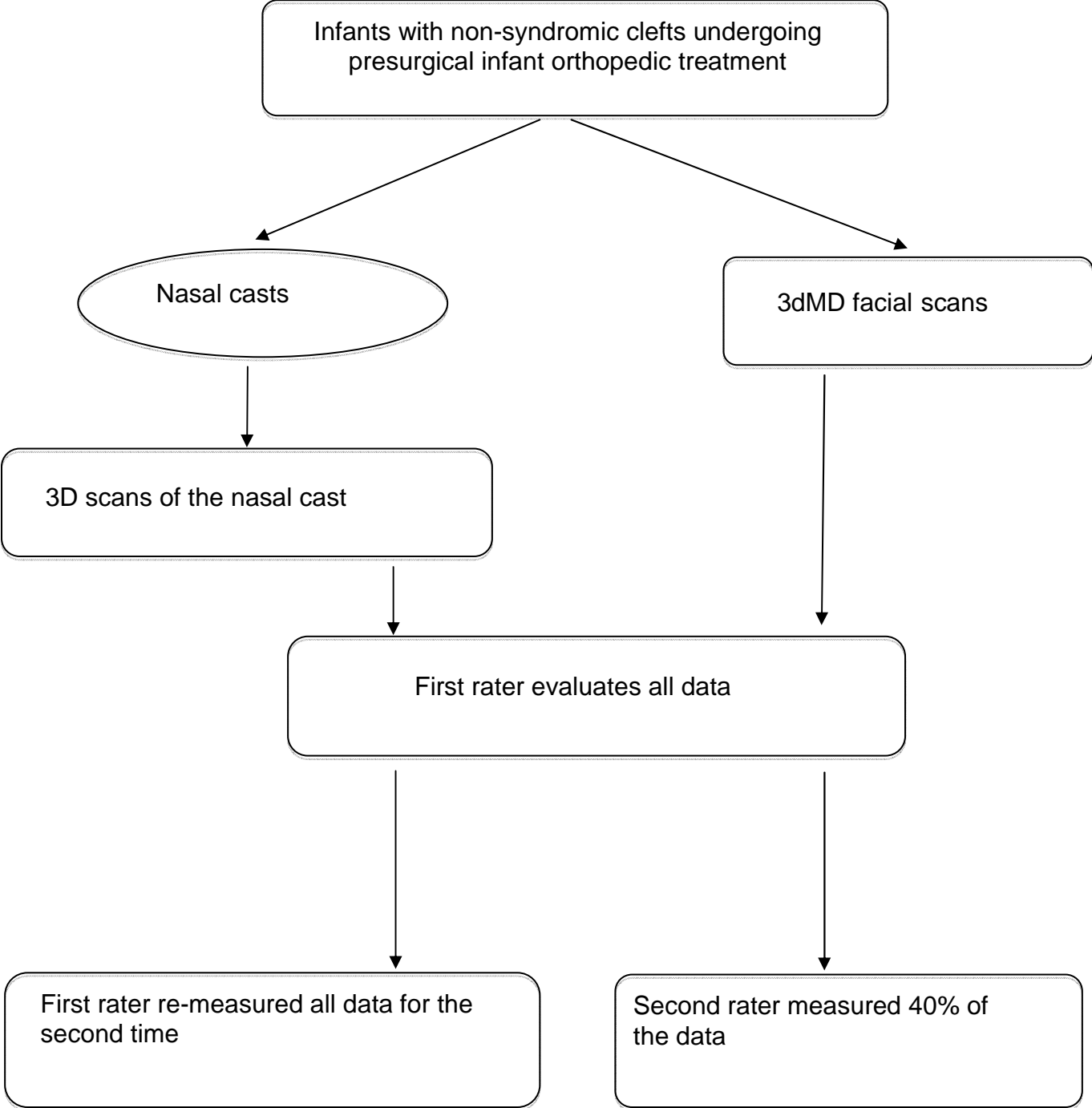
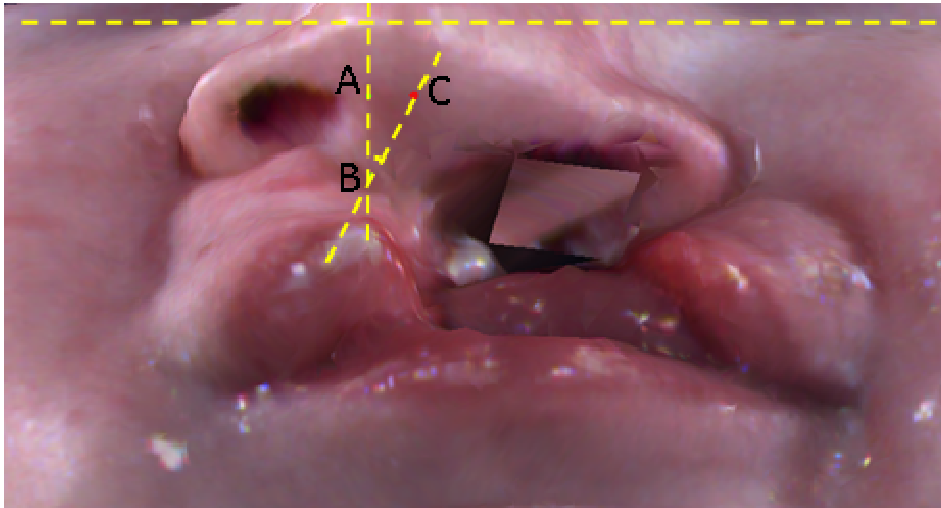
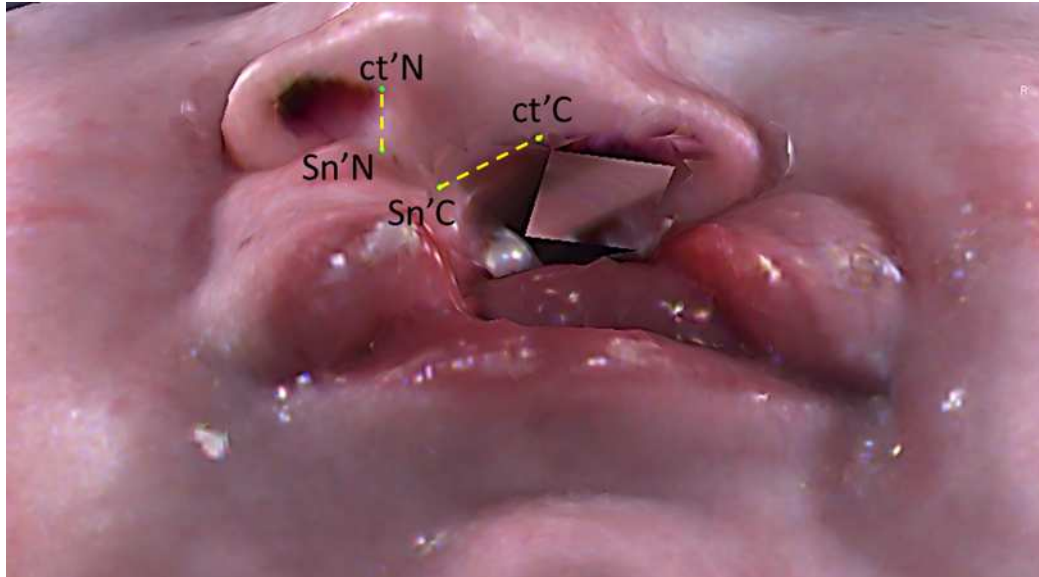


Figure 2. Diagram of the columella deviation angle.



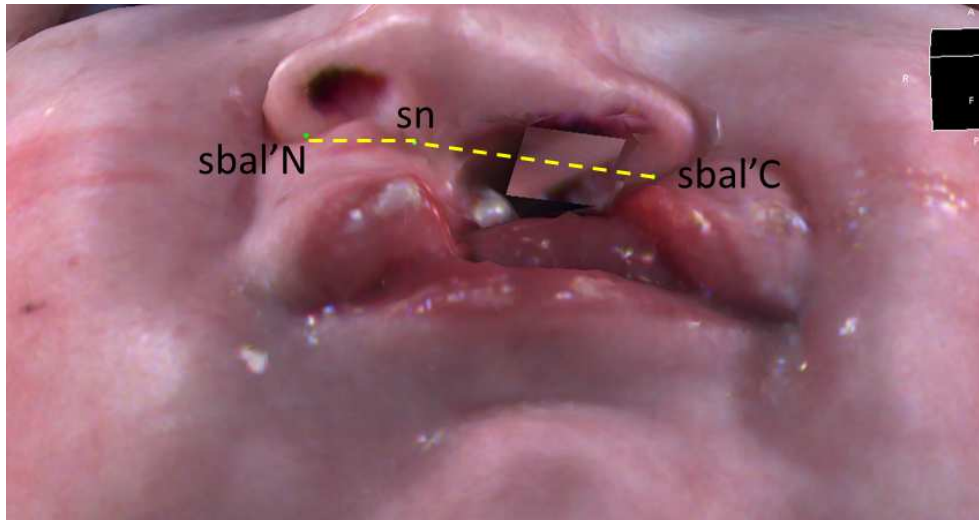
The horizontal line on the top is parallel to the interpupillary line. The line connecting A and B is vertical to the horizontal line. The line across B and C represents the longitudinal axis of the columella. The angle formed by AB and BC lines is the columella deviation angle. The diamond-shaped artifact is due to data loss because of the poor lighting in the nostril.

Figure 3. Columella length measurements.



The columella length is measured as the distance between the top point of the columella and the inferior base point of the columella on the same side. The distance between ct'N and Sn'N is the columella length on the noncleft side in this example of left cleft lip and palate, while that between ct'C and Sn'C is the columella length on the cleft side.

Figure 4. Nasal width measurements.



The distance between sn and sbal'N is the nasal alar base width on the noncleft side in this example of left cleft lip and palate, while that between sn and sbal'C is the nasal alar base width on the cleft side.

Figure 5. Inter-endocanthal width.

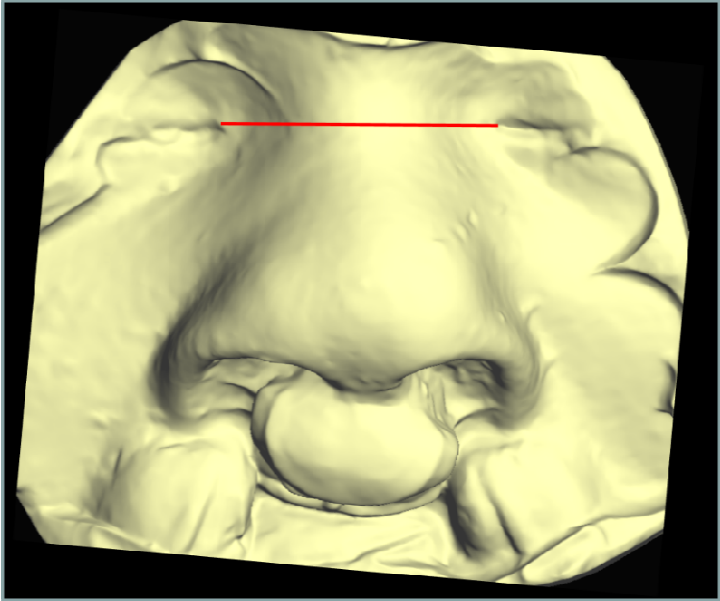


Figure 6. Examples of nostril dome curvature rating.



Severely sigmoid (left nostril)



Mildly sigmoid (left nostril)

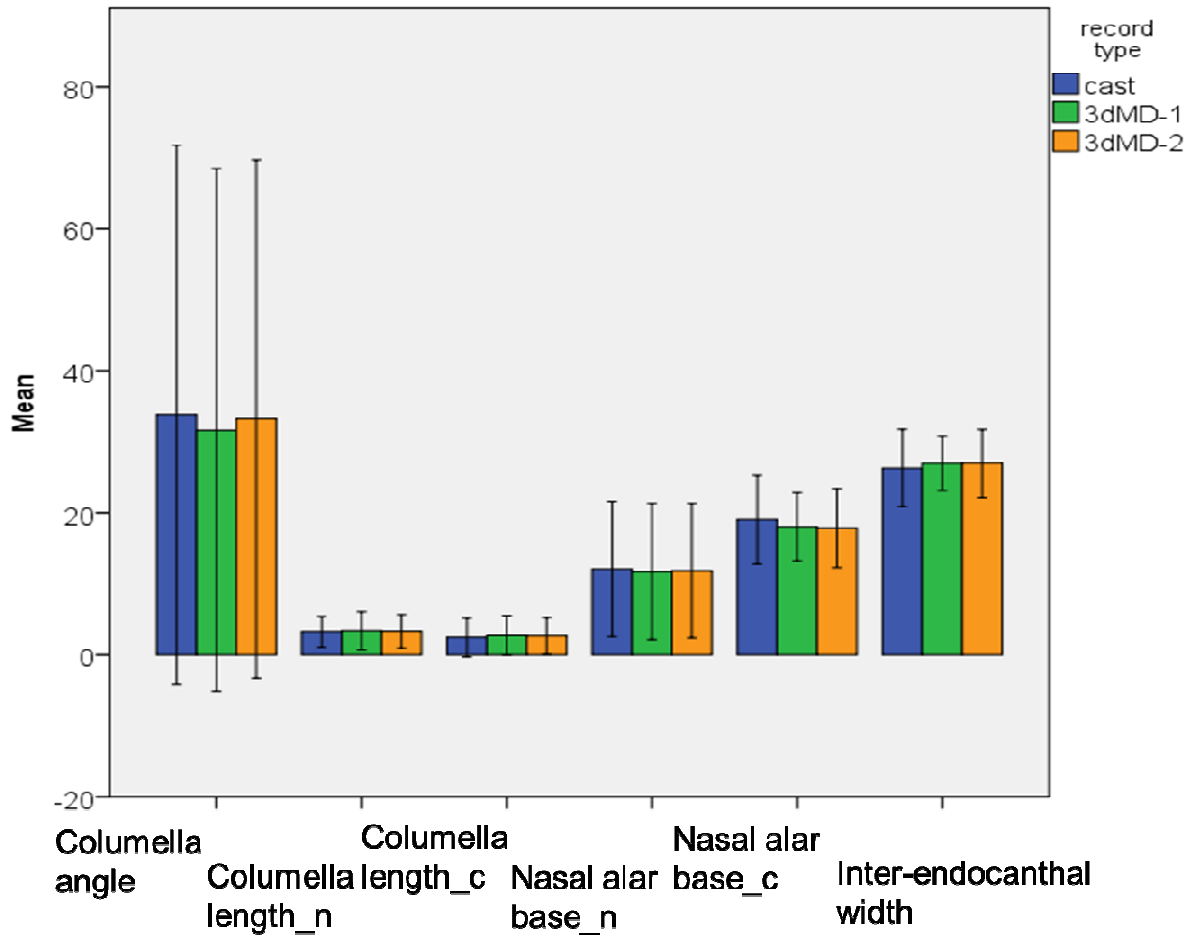


Flat (left nostril)



Convex (both nostrils)

Figure 7. Comparison of nasolabial measurements on nasal casts and repeated 3dMD facial scans.



The color bars represent the mean of measurements, while the vertical black lines indicate their 95% CIs.

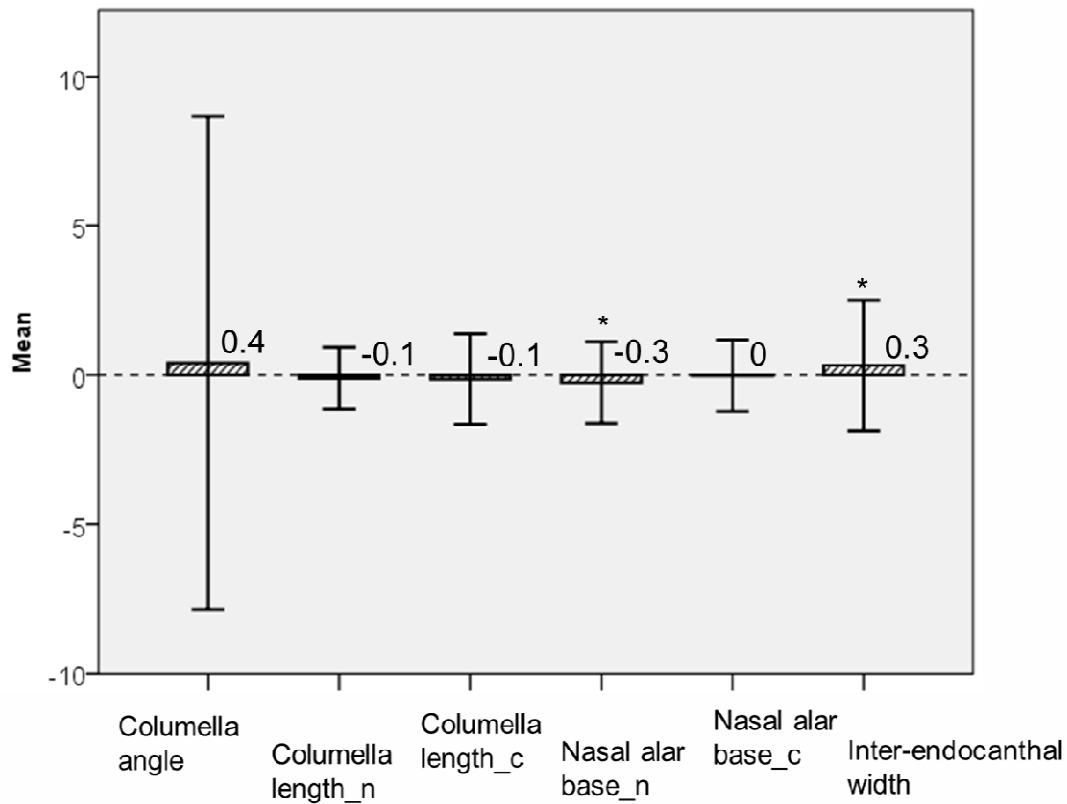
Columella length_n: columella length on the noncleft or right side

Columella length_c: columella length on the cleft or left side

Nasal alar base_n: nasal alar base width on the noncleft or right side

Nasal alar base_c: nasal alar base width on the cleft or left side

Figure 8. Differences between the two repeated measures by the first rater.



The horizontal bars represent the mean of measurements, while the vertical black lines indicate their 95% CIs. Statistical significant differences are indicated with “*”. All linear measurements are in mm, while the columella angle is measured by degree.

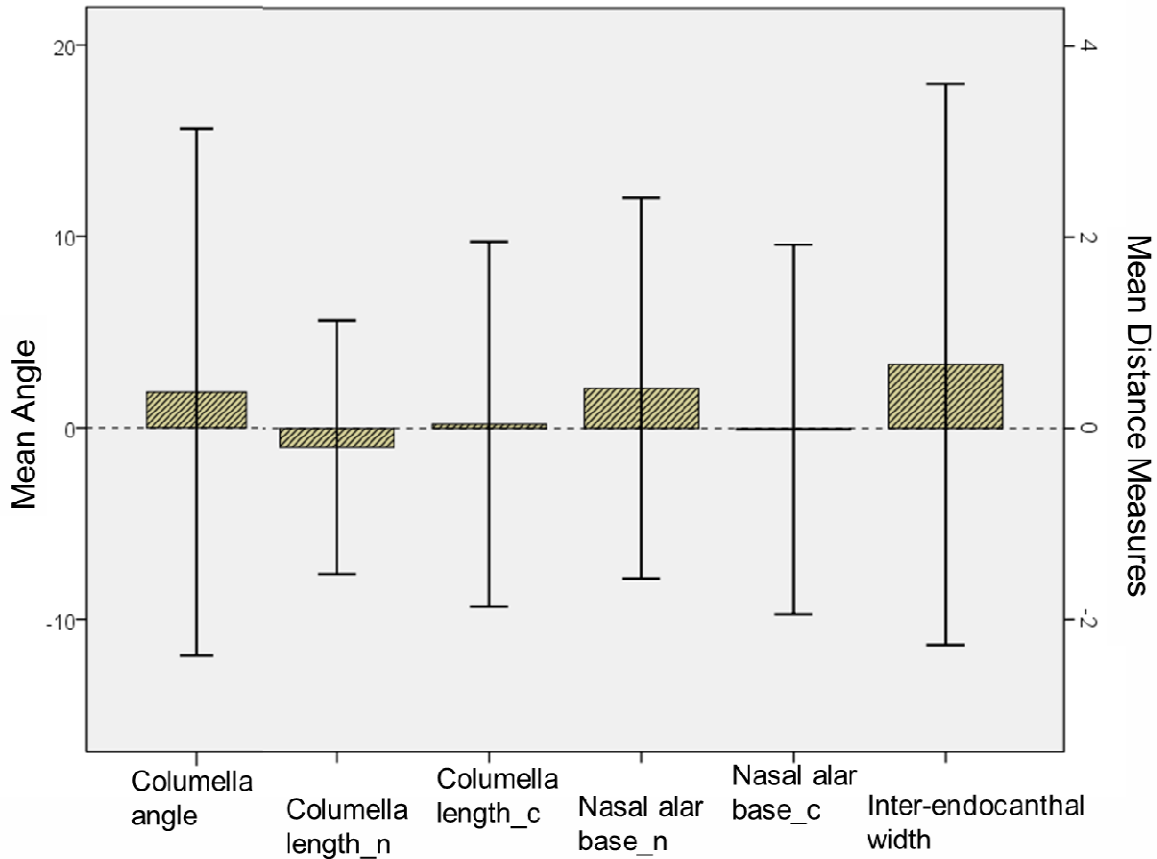
Columella length_n: columella length on the noncleft or right side

Columella length_c: columella length on the cleft or left side

Nasal alar base_n: nasal alar base width on the noncleft or right side

Nasal alar base_c: nasal alar base width on the cleft or left side

Figure 9. Differences of measurements between two raters.



The horizontal bars represent the mean of measurements, while the vertical black lines indicate their 95% CIs. All linear measurements are in mm, while the columella angle is measured by degree.

Columella length_n: columella length on the noncleft or right side

Columella length_c: columella length on the cleft or left side

Nasal alar base_n: nasal alar base width on the noncleft or right side

Nasal alar base_c: nasal alar base width on the cleft or left side

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Table 1. Demographics of patients.

Case #	Gender	Cleft Diagnosis	pre-PSIO age (days)	post-PSIO age (days)	PSIO duration (days)	Records
1	Male	L	19	208	189	both
2	Female	L	23	156	133	both
3	Male	L	52	*	*	pre-PSIO
4	Male	L	30	176	146	both
5	Female	B	17	*	*	pre-PSIO
6	Female	R	7	*	*	pre-PSIO
7	Male	B	7	117	110	both
8	Male	L	20	114	94	post-PSIO
11	Male	B	10	191	181	both
17	Female	B	39	231	192	post-PSIO
19	Female	B	29	*	*	pre-PSIO
20	Male	B	43	149	106	both
23	Female	L	26	*	*	pre-PSIO
24	Female	L	84	197	113	both
25	Female	R	50	163	113	both
26	Male	B	12	132	120	both
29	Male	B	*	140	*	post-PSIO
32	Female	L	13	106	93	both
33	Female	B	13	101	88	post-PSIO
34	Male	L	20	100	80	both
36	Male	L	13	153	140	both
37	Male	B	28	129	101	pre-PSIO
38	Male	B	37	177	140	pre-PSIO
39	Male	L	27	139	112	pre-PSIO

* : missing information.

“L”: left cleft lip ± palate

“B”: bilateral cleft lip ± palate

“R”: right cleft lip ± palate

Records: both nasal casts and 3dMD facial scans at the same time point

pre-PSIO: prior to presurgical infant orthopedic treatment

post-PSIO: after to presurgical infant orthopedic treatment

Table 2. Nasolabial measures and related anomalies associated with cleft.

Typical nasal anomalies found in cleft lip ± palate		Measurements/Landmarks
Columella	Deviated columella	Angle between the longitudinal axis of the columella and the midline
	Shortened columella	Length of the columella on the cleft or left side
	Shortened columella	Length of the columella on the noncleft or right side
Nasal alar base	Flared nasal alar cartilage on the side(s) of the cleft	Width of the nasal alar base on the cleft or left side
		Width of the nasal alar base on the noncleft or right side
Nostril	Slumping of the alar dome	Curvature* of the nostril dome on the more collapsed side
Facial reference	Change with facial growth	Distance between endocanthi

* Curvature of the nostril dome is rated with an equal interval scale: “-2”, severely sigmoid; “-1”, mildly sigmoid; “0”, flat; “1”, convex. Examples are presented in Figure 6.

Table 3. Landmarks and their definitions.

Abbreviation	Landmark	Definition
sn	subnasale	midpoint at the inferior end of the columella
Sn'N	subnasale on the noncleft or right side	inferior end of the columella on the noncleft side (unilateral cleft) or right side (bilateral cleft)
Sn'C	subnasale on the cleft or left side	inferior end of the columella on the cleft side (unilateral cleft) or left side (bilateral cleft)
ct'N	columella top point on the noncleft or right side	top of the columella on the noncleft side (unilateral cleft) or right side (bilateral cleft)
ct'C	columella top point on the cleft or left side	top of the columella on the cleft side (unilateral cleft) or left side (bilateral cleft)
A	columella deviation point	a point on the superior half of the columella along its longitudinal axis
B	angle vertex	a point on the inferior half of the columella along its longitudinal axis
C	sagittal facial plane point	sagittal line across the angle vertex
sbal'N	subalare on the noncleft or right side	lateral alar base on the noncleft side (unilateral cleft) or right side (bilateral cleft)
sbal'C	subalare on the cleft or left side	lateral alar base on the cleft side (unilateral cleft) or left side (bilateral cleft)
en'N	endocanthus on the noncleft or right side	inner corner of the eyes on the noncleft side (unilateral cleft) or right side (bilateral cleft)
en'C	endocanthus on the cleft or left side	inner corner of the eyes on the cleft side (unilateral cleft) or left side (bilateral cleft)

Table 4. Measurements and their definitions.

Measurement	Definition
columella deviation angle	angle formed by A-B-C
columella length on the noncleft or right side	distance between ct'N and sn'N
columella length on the cleft or left side	distance between ct'C and sn'C
nasal width on the noncleft or right side	distance between sn and sbal'N
nasal width on the cleft or left side	distance between sn and sbal'N
inter-endocanthal width	distance between en'N and en'C

Table 5. Pearson correlation among repeated nasolabial measures by the same rater.

Nasolabial Measure	Statistical Parameter	
Columellar angle	Correlation	0.975
	Significance (2-tailed)	0.000*
Columellar length (noncleft/right)	Correlation	0.910
	Significance (2-tailed)	0.000*
Columellar length (cleft/left)	Correlation	0.850
	Significance (2-tailed)	0.000*
Nasal alar base width (noncleft/right)	Correlation	0.991
	Significance (2-tailed)	0.000*
Nasal alar base width (cleft/left)	Correlation	0.980
	Significance (2-tailed)	0.000*
Inter-endocanthal width	Correlation	0.898
	Significance (2-tailed)	0.000*

* Statistically significant after Bonferroni correction

Table 6. Pearson correlation among nasolabial measures by two raters.

Nasolabial Measure	Statistical Parameter	
Columellar angle	Correlation	0.920
	Significance (2-tailed)	0.000*
Columellar length (noncleft/right)	Correlation	0.885
	Significance (2-tailed)	0.000*
Columellar length (cleft/left)	Correlation	0.743
	Significance (2-tailed)	0.000
Nasal alar base width (noncleft/right)	Correlation	0.977
	Significance (2-tailed)	0.000*
Nasal alar base width (cleft/left)	Correlation	0.938
	Significance (2-tailed)	0.000*
Inter-endocanthal width	Correlation	0.677
	Significance (2-tailed)	0.000*

* Statistically significant after Bonferroni correction.