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Objective 3D Assessment of Lip Form in Patients with Repaired Cleft Lip

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Abstract

Objectives—To measure and compare three-dimensional (3D) lip form in participants with a repaired cleft lip and non-cleft ‘control’ participants.

Design—Retrospective study. 3D facial images of each participant were obtained.

Participants—The sample consisted of two groups: A repaired cleft lip group (n = 57), and a non-cleft ‘normal’ group (n = 28).

Main Outcome Measures—Thirty-four variables that described the features of each participant’s lip form were extracted from the image data. A *t*-test was used for each variable to test for significant differences between the groups and a mathematical technique was used to categorize the lip forms in both groups.

Results—Seventeen variables showed significant between-group differences. The differences were focused on the free edges of the upper and lower lip vermilion borders, upper and lower lip protrusion, and lip symmetry. Lip forms were described by seven categories. Participants with cleft lip were represented in all categories, but fell mainly into two categories at one extreme. Non-cleft participants were represented in five categories, but also exclusively in two categories but at the other extreme. The findings show greater variation in lip form for the participants with a cleft lip.

Conclusion—3D lip form in participants with a repaired cleft lip was found to have greater variation and to be significantly different from that for non-cleft participants. This method can be used to assess surgical outcomes of lip form.

Keywords

repaired cleft lip; lip form; three dimensional assessment; lip revision surgery

INTRODUCTION

A repaired cleft lip is characterized by the presence of scar tissue that generally results in obvious deformities of the nasolabial region. Examples of these deformities include an asymmetric upper lip vermilion, a tightened and flattened upper lip, a central pointing of the upper lip with loss of the shape of the Cupid's bow, and an everted lower lip (Park and Roh, 1999; Ras et al, 1995; Schwenzler-Zimmerer et al., 2008). Some researchers contend that this scarring of the upper lip, if excessive, may play a role in restricting growth of the maxilla (Bardach and Mooney, 1984; Meazzini et al., 2008). All of these scar tissue effects combine to impact the function and esthetics of the nasolabial region such that for some patients, surgery to revise the lip may be recommended. Moreover, the specific surgical technique varies depending on the specific clinical esthetic and functional features that need to be corrected (Park and Roh, 1999; Takeshita et al., 2003, Trotman et al. 2007a).

Thus far, the method used by surgeons to determine whether a patient needs a lip revision has been based mainly on the surgeons' subjective evaluation of the nasolabial appearance at rest. Several methods of subjective or qualitative clinical evaluation have been proposed in the past (Anastassov and Chipkov, 2003; Asherj-McDade et al., 1991; Tobiasen, 1989); however, more recent research has demonstrated poor agreement among surgeons when only subjective evaluations are used suggesting the need more objective measures (Trotman et al. 2007a). In our laboratory, we have developed objective functional or 'movement' measures to assess outcomes of facial soft tissue surgeries (Trotman et al. 2007b). Likewise, a systematic and objective method for the evaluation of the lip form under static conditions would be of considerable value to the surgeon for preoperative surgical planning and the subsequent evaluation of surgical results—this method would supplement the objective functional assessments.

Recently, a two-dimensional (2D) quantitative analysis was reported that measured specific morphological traits of the lips (Tanikawa et al., 2009). In the present study, this analysis is expanded to include three-dimensional (3D) data. The study aims were as follows: 1) To establish objective variables that measure static 3D lip form; 2) To determine variables that distinguish between non-cleft participants and participants with a cleft lip; and 3) Based on the variables defined in the second aim, to objectively categorize the morphology of different lip forms; and within each category, to determine the distribution of non-cleft participants and participants with a cleft lip.

MATERIAL AND METHODS

The study was retrospective in design. The sample was obtained from an on-going clinical trial (R01 DE13814) that is designed to evaluate the effects of lip revision surgery on facial soft tissue function in participants with repaired cleft lip and palate (Trotman et al., 2007a). Participants in this trial met specific selection criteria (Table 1) and were screened and recruited from patients who visited clinics at the University of North Carolina at Chapel Hill, School of Dentistry. As part of the data-collection, digital 3D facial images of each participant were recorded. From March 2002 to May 2006, the images were recorded using a Genex camera (Figure 1a; Genex Technologies Inc, Kensington, MD; Lee et al., 2004); and from March 2007 to April 2009, a 3dMD camera (Figure 1b; 3dMD Inc, Atlanta, GA; Aldridge et al., 2005) was used.

For the present study, there were two additional inclusion criteria: 1) Because the number of non-Caucasians recruited in the original clinical trial was small, the sample for this study was limited to Caucasians; and 2) Only participants who had good quality 3D images without

obvious soft tissue distortions (such as, images recorded with the mouth open) were included. Thus, the final study sample consisted of 85 participants of which 28 had a non-cleft 'normal' lip form and 57 had a repaired cleft lip (with or without a cleft palate). The purpose and protocol of the study was explained to the participant(s) and parent(s), and informed consent and assent were obtained. Consent and HIPAA documents were approved by the School of Dentistry Human Subjects Institutional Review Board.

1. Data collection and processing

The facial images were captured using digital cameras (Figure 1). During the image capture process, each participant was seated upright with the face positioned towards, and at the same level as, the camera. The participant was instructed to look directly at the camera with the face 'at rest' in a relaxed pose, and frontal 3D facial images were recorded. Using a similar method, a digital camera was used to capture 2D, facial photographs that included right and left lateral views, and a frontal view. Because the head of each participant was unrestrained, head positions varied both between the captured images for each participant and among the participants. To account for the differences in head position, the 3D images were imported into a new coordinate system for standardization. Because of inaccuracies in and around the ear regions of the 3D images (Lee et al., 2004), to complete the standardization process, the right-sided facial photographs of each participant were utilized as follows. First, an orthodontist (CT) identified and digitized three paired and five single landmarks on the 3D images, and three landmarks on the 2D facial photographs (Table 2; Farkas, 1994). This process was repeated twice for all the images, and the landmark coordinates from both digitizations were averaged to provide the final landmark coordinates. To determine the intra-observer reliability of landmark identification, the 3D facial images of ten participants were randomly selected and the digitization process was repeated one week later. On each set of 3D and 2D images, three reference planes—a sagittal, axial, and coronal—were identified (see inset Figure 2) and a new coordinate system (X, Y, and Z-axis) was established using the reference planes with the origin set at sellion (Table 2). Then, 3D lip surface data, that is the X, Y, and Z coordinate values (voxels) of the lip surface were extracted between the left and right commissures (lcm & rcm) on the X-axis and between the labile superioris and inferioris (ls & li) on the Y-axis. The image resolution estimated by the mean total number of voxels was 3017.8 ± 692.0 (1 voxel = $0.5 \times 0.5 \times 0.5$ mm).

Maps of the lip surface inclination (LSI) and line contours of the free edges of the upper and lower lip vermillion borders (FELVB) were generated. LSI values were generated from the relationships between any two vertically positioned voxels and then stored as an LSI map (Figure 3). FELVB were generated as a curved line that comprised a series of X and Y coordinates with the smallest Z coordinate values in the Y–Z plane and then stored as a line contour. To control for facial size differences, the data were normalized on the distance between the left and right commissures (lcm & rcm). Also, for the purposes of comparison, images of the participants with a right unilateral cleft lip were "mirrored" to left side to simulate a left unilateral cleft lip. Then, from the LSI maps and the FELVB line contours, thirty-four variables were measured (Table 3; Figures 4, 5, and 6).

2. Data analysis

To determine the intra-observer reliability of landmark identification, absolute differences were calculated between the average landmark coordinates of the first and second digitization for the ten randomly selected participants. In order to determine the variables that distinguished between the non-cleft participants and the participants with a cleft lip, two statistical tests were used. The first was a *t*-test to test for significant differences ($p \leq .05$) between the variables from the two participant groups. Significant variables then were combined as feature vector (**V**), and **V** was used as a mathematical descriptor of lip form for each participant. The second

was a mathematical vector quantization method (Linde et al., 1980) that allows large data sets of input vectors to be further categorized based on similarities—similar vectors are closest to their respective centroid in feature vector space. This method was applied to the **V**s from the entire data set to determine the optimal number of categories that described the lip form (Tanikawa et al. 2007). In order to determine whether there were significant differences ($p \leq .05$) among the categories, a one-way ANOVA was performed for each variable of **V**. Tukey-Kramer post-hoc testing was used to control for multiple testing. To determine the distribution of participants with and without a cleft lip in each category, the percentages of these participants were calculated.

RESULTS

Table 4 gives the sample demographics. Table 5 gives the results for the intra-observer reliability. The mean absolute landmark difference was 0.88mm (range = 0.66mm to 1.23mm), and these results were considered to fall within a range of reliable to highly reliable (Aung et al., 1995). Seventeen variables demonstrated significant differences between the two groups of participants (Table 6). These 17 variables were related to five characteristics of lip form or morphology:

1. *The shape of the FELVB line contour*—v3, v4, and v5;
2. *Relative protrusion / retrusion of the upper and lower lip vermilion*—v8, v15, and v32;
3. *Horizontal shape of the upper and lower lips*—v9, v10, v13, v16, v17, v18, v19, and v20;
4. *Orientation of the right side lip fissure at the commissures* —v1 and v31; and
5. *Midline thickness of the upper lip vermilion*: v25.

Lip forms fell into seven morphological categories, the features of which are given in Table 7 and described below. The mean FEL VB line contours, mean profiles, and 3D lip forms that corresponded with each category are shown in Figure 7. Figure 8 gives the results for significant differences ($p \leq .05$) among the categories for each variable of the 17 variables.

Category 1

Participants had a symmetric FELVB line contour (v3, v4) with greater protrusion of the upper versus the lower vermilion (v8, v15, v32). The lower vermilion was even horizontally (v16).

Category 2

Participants had a symmetric FELVB line contour (v3, v4) with greater protrusion of the upper versus the lower vermilion (v8, v15, v32). The upper and lower vermilions were even horizontally (v9, v16); however, the upper vermilion was longer and thicker vertically (v25) with a lip fissure that was slightly inclined superiorly at the commissures (v1, v31).

Category 3

Participants had an asymmetric FELVB line contour with the affected (left side) FELVB line contour located inferiorly when compared with the unaffected (right side) FELVB line contour that was located superiorly (v3, v4). There was greater protrusion of the lower versus the upper vermilion (v15, v32).

Category 4

Participants had a symmetric FELVB line contour (v3, v4) with a flattened FELVB line contour on the unaffected (right) side (v5). There was less protrusion of the lower lip vermilion (v15). The lower lip vermilion was even horizontally (v16) whereas the upper was uneven (v9). At the one-fifth portion of the unaffected (right) side (v10), there was greater partial protrusion of the upper lip vermilion relative to the entire upper lip protrusion. At the two-fifths portion of the affected (left) side (v13), there was less partial protrusion of the upper lip relative to the entire lip protrusion.

Category 5

Participants had a symmetric FELVB line contour (v3, v4) with greater protrusion of the lower versus the upper vermilion (v15, v32). The lower lip vermilion was uneven horizontally (v16), and more retruded at the one-fifth portion of the unaffected (right) side with greater protrusion at the midline when compared with the protrusion of the entire lower lip (v17, v19). The lip fissure was inclined superiorly at the commissures (v1, v31).

Category 6

Participants had a symmetric FELVB line contour (v3, v4) with greater protrusion of the lower versus the upper vermilion (v8, v15, v32). The upper vermilion was shorter and thinner vertically (v25) and uneven horizontally (v9). At the one-fifth portion of the unaffected (right) side (v10), there was greater partial protrusion of the upper lip relative to the entire upper lip protrusion, while at the two-fifths portion of the affected (left) side (v13), there was less partial protrusion of the upper lip relative to the entire upper lip. The lower lip vermilion was uneven horizontally (v16), and less protruded at the one-fifth and two-fifths portions of the unaffected (right) side with greater protrusion at the two-fifths portion of the affected (left) side when compared with the protrusion of the entire lower lip (v17, v18, v20). There was a more asymmetric protrusion of the lower lip vermilion (v18, v20).

Category 7

Participants had an asymmetric FELVB line contour with the unaffected (right side) FELVB line contour located inferiorly and the affected (left side) FELVB line contour located superiorly (v3, v4). The unaffected (right side) FELVB line contour was flattened (v5). There was greater protrusion of the lower versus the upper vermilion (v15, v32). The upper and lower lip vermilions were uneven horizontally (v9, v16). At the one-fifth and two-fifths portions of the unaffected (right) side (v17, v18), there was a less partial protrusion of the lower lip relative to the entire lip protrusion. At the two-fifths portion of the affected (left) side, there was a greater partial protrusion of the lower lip relative to the entire lip protrusion (v20). There was a more asymmetric protrusion of the lower lip vermilion (v18, v20). The lip fissure was inclined superiorly at the commissures (v1, v31).

In each category, the percentages of participants with a non-cleft 'normal' lip and participants with a cleft lip are shown in Figure 9: Category 1, 79% & 21%; Category 2, 72% & 28%; Category 3, 20% & 80%; Category 4, 11% & 89%; Category 5, 9% & 91%; Category 6, 0% & 100%; and Category 7, 0% & 100%; respectively. Thus, the non-cleft participants were represented mainly in Categories 1 and 2, and to a lesser extent in Categories 3, 4, and 5. Participants with cleft lip were exclusively in Categories 6 and 7 and they occupied the vast majority of participants in Categories 3, 4, and 5.

DISCUSSION

The main aim of primary lip repair and any subsequent lip revision surgery is to normalize the morphology of the upper lip (Von Den Hoff et al., 2006; Jones and Tatum, 2008). It may be assumed that for a patient to be selected for a lip revision, the criteria would be based on those features that are most different between participants with and without a cleft lip. In this study, these differences were examined and a holistic, objective assessment of the extent of the clinical problem was provided. Asymmetry of the lip vermillion was one of the main morphological differences for the participants with a cleft lip (Ras et al., 1995; Park and Roh, 1999; Schwenzer-Zimmerer et al., 2008). This characteristic was seen mainly in Categories 3, 6 and 7 that included 36% of participants with a bilateral cleft lip and 40% with a unilateral cleft lip. Thus, even for those participants with a bilateral cleft lip, asymmetry was a typical morphological lip characteristic (Trotman et al., 2007b). Conversely, only 0.4% of non-cleft children were classified into these categories and with this particular problem.

Another characteristic of the participants with a cleft lip was “a flattened upper lip” (Ras et al., 1995; Park and Roh, 1999). Eighty-six percent of participants with a cleft lip demonstrated a flattened upper lip vermillion and / or a somewhat lesser protrusion of the upper lip at the cleft site (Categories 3, 4, 5, 6 and 7). There maybe three possible explanations for this finding. First, a common observation in a child with an unrepaired cleft of the lip is a shortened lip length with tissue deficiency that may be the cause of this flattening (Jones and Tatum, 2008). Second, wound contraction and scarring after the primary lip surgery may result in a partially flattened upper lip (Von Den Hoff et al., 2006). After the lip repair, the tissues show an absence of elastin fibers that provide elasticity to the normal mucosa and skin with the presence of highly oriented collagen fibers that render the tissue rigid and stiff (Von Den Hoff et al., 2006). This scar tissue may explain the horizontal uniformity of the upper lip vermillion shape that was predominant in Categories 4, 6, and 7. Third, the underlying skeletal / dental morphology also influences the formation of a flattened upper lip. A deficient maxilla and / or a congenitally missing tooth in the site of the cleft (Bardach and Mooney, 1984; Meazzini et al., 2008; Shapira et al., 2000) occur frequently in patients with a cleft lip and palate and may lead to this flattening. In fact, a high incidence of missing lateral incisors in these patients has been linked to a low blood supply near the cleft, a finding that would further increase the possibility of scarring (Shapira et al., 2000).

Participants with a cleft lip also tended to have a protruded lower lip as a characteristic feature. This feature probably was more the effect of the flattened upper lip relative to the lower lip and / or, in the case of those participants with a skeletal midface deficiency, a relative mandible protrusion. In particular, a major feature of participants in Categories 5, 6 and 7 was a horizontal uniformity of the lower lip shape with a protrusion at the midline, and those in Categories 5 and 7 had a lip fissure that was oriented downwards at the commissures. It may be that as the lower lip protrudes, lip seal is lost and the free margin of the lower lip expands upwards in the midline resulting in a relative inferior orientation of the lip fissure at the commissures.

The assessment approach presented in this study is a systematic and objective method for the evaluation of the 3D static lip morphology. The participants, the measures obtained, and the Categories that were generated were based on participants who attended one Cleft Palate/ Craniofacial Center, thus, the findings were limited to this one center. Nonetheless, the methodology can be applied to assess outcomes of individual patients at any center and to compare outcomes of patients among different centers. For example, if a clinician is assessing the outcomes of lip revision surgery, then before the surgery a patient may have features in Categories other than 1 and 2, but after lip revision, there should be a shift towards these more non-cleft, ‘normal’ categories. This same approach could be used to compare outcomes among different Cleft Lip and Palate centers that may use different approaches to lip repair.

Specifically, as demonstrated in Figures 9 and 10, the lip morphology of non-cleft participants included features in Categories 1 and 2. The participants with a cleft lip had features that were exclusively in Categories 6 and 7. There was considerable overlap of features in the intervening Categories (3 to 5). For a clinician assessing the outcome of primary lip surgery, the final lip shapes should fall ideally within Categories 1 and 2.

There are, however, several important caveats that must be considered with these findings: 1) Skeletal features such as a midface deficiency were not included in this evaluation and these features may impact the outcomes and must be considered separately in the evaluation process; 2) The specific features and categories identified here might be expected to be different from those of another Center; and 3) Evaluations of the shape of the lip vermillion border, such as the loss of the Cupid's bow, were not included due to inaccuracy of color image data of the Genex camera (Figure 1a); however, preliminary experiments revealed that the data from the 3dMD camera (Figure 1b) can be used, and in future studies measurements of the lip vermillion border will be extracted from the color data.

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Figure 1.
3D camera systems. a. Rainbow 3D camera model 250 system, Genex Technologies Inc, Kensington, MD. b. MU-4 camera system, 3dMD Inc, Atlanta, GA.

Figure 2.

The coordinate system. a. 3D sagittal reference plane. Defined as a plane perpendicular to a line passing through the midpoint of rex & ren and lex & len, and midway between rex & lex. b. 3D axial reference plane. On the 2D photograph, angle rex-sn-tr was defined and transferred to the 3D image by superimposing on rex & sn to produce a virtual line connecting sn & tr on the 3D image. The axial plane was defined as a plane passing through se at a 7.5° upward rotation from se-tr. c. 3D coronal reference plane. Defined as the plane passing through se and perpendicular to both the axial and the sagittal planes.

Lip Surface Inclination: LSI

Angle formed by
the line $b1'-b2'$ and the Y-axis

Figure 3.

Diagram illustrating a lip surface inclination (LSI) map. Two vertically adjacent voxels ($b1$, $b2$) on the 3D lip data were projected on the Y-Z plane ($b1'$, $b2'$), and the angle between the Y-axis and a line connecting the voxels ($b1'$, $b2'$) was calculated. The procedure was repeated for all voxels, and the angular 39 differences (LSI values) were stored in an LSI map (Light gray in a LSI map indicates larger LSI values; black and dark gray, smaller LSI values).

Figure 4.

Diagram illustrating variables $v1, v2, \dots, v7$ (see Table 3 for definitions). The sto was defined as the origin with the x -axis as a line parallel to the X-axis passing through the origin, and the y -axis as a line parallel to the Y-axis passing through the origin. The dotted line is the FELVB line contour (curving line); The solid line: approximated straight lines $rcm-sto$, $sto-lcm$, and $rcm-lcm$ generated by applying a linear square fitting algorithm to the FELVB curving line between rcm and sto , sto and lcm , and rcm and lcm , respectively; $p1, p2$: intersections of the approximated $rcm-lcm$ line and the FELVB line contour.

Figure 5.

Diagram illustrating variables v8, v9, ..., v21 (see Table 3 for definitions). At each point on the FELVB line contour, the LSI values in the middle two-thirds of the distance between ls & sto, and sto & li were averaged to generate a projected LSI value for the upper lip & lower lip, respectively.

Figure 6.

Diagram illustrating variables v_{22} , v_{23} , ..., v_{34} (see Table 3 for definitions).

a, d, e, & f. Origin, rcm that projected on the sagittal plane; x' -axis, a line parallel to the X-axis passing through the origin; and z' -axis, a line parallel to the Z-axis passing through the origin. Gray lines indicate 3D surface data of the lip vermilion on the sagittal plane.

b. Origin, sto that projected on the sagittal plane; u-axis, a line connecting sto and ls that projected on the sagittal plane; and v-axis, a line perpendicular to the u-axis that passes through the origin on the sagittal plane. Gray lines indicate 3D surface data of the upper lip vermilion on the sagittal plane; p3, a point that showed the maximum v value of the upper lip contour at midline; L1, v value of the p3; and L2, u value of the p3.

c. Origin, sto that projected on the sagittal plane; u'-axis, a line that connects sto and li that projected on the sagittal plane; v'-axis, a line perpendicular to the u'-axis that passes through the origin on the sagittal plane. Gray lines indicate 3D surface data of the lower lip vermilion on the sagittal plane; p4, a point that showed the maximum v' value of the lower lip contour at midline; L3, v' value of the p2; and L4, u value of the p4. (Modified from Tanikawa et al., 2009).

Figure 7.
Mean FELVB line contours, mean lip profiles, and mean 3D lip form for each category.

Figure 8. Significant differences between categories (y-axis) for each of the 17 feature variables (y-axis=magnitude of feature variable). The circle points represent the estimated mean values for the variable. Error bars represent Tukey-Kramer comparison intervals: non-overlap between bars for any two categories indicates a significant difference ($p \leq .05$) between the two categories.

Figure 9.

Percentages of participants with and without a cleft lip in each of the seven categories. a. Bar graph with Categories (y-axis) and participants % (x-axis). b. Pie chart of the percentages of the entire sample within each category.

Figure 10.

The example pictures of the lip vermilions within each category.

Table 1

Selection criteria for the clinical trial.

Inclusion Criteria	
1	Interest/parent willingness to participate in the study.
2	Ability to comprehend verbal instructions.
3	Age range of 5 to 21 years.
4	For the participants with repaired cleft lip with or without cleft palate, a previously repaired complete unilateral or bilateral cleft lip with or without a cleft palate.
Exclusion Criteria	
1	Previous orthognathic surgery.
2	Diagnosis of a craniofacial anomaly other than cleft lip and palate.
3	Medical history of diabetes, collagen vascular disease, systemic neurologic impairment, or any medical problem that leads to difficulty with healing.
4	Mental or hearing impairment to the extent that comprehension or ability to perform the tests was hampered.
5	For the participants with repaired cleft lip with or without cleft palate, a previous lip revision surgery or other facial soft tissue surgery within 2 years of enrollment in the study.

Table 2

Definition of soft tissue landmarks on facial 3D images and 2D photographs.

Soft Tissue Landmark	3D	2D	Definition
Right & left exocanthion (rex & lex)	✓	✓	A point at the outer corner of the right and left eye fissures.
Right & left endocanthion (ren & len)	✓		A point at the inner corner of the right and left eye fissures.
Commissure (rcm & lcm)	✓		Mucocutaneous border at the right and left mouth corners.
Sellion (se)	✓		The deepest point on nasofrontal region in a sagittal plane.
Subnasale (sn)	✓	✓	The midpoint of the columella base where the base of the columella and the surface of the upper lip meet.
Labiale superius (ls)	✓		Outermost point on the mucocutaneous border of the upper lip in the midsagittal plane.
Labiale inferius (li)	✓		Outermost point on the mucocutaneous border of the lower lip in the midsagittal plane.
Stomion (sto)	✓		Point between the lowermost point on the vermilion of the upper lip and uppermost point on the vermilion of the lower lip in the midsagittal plane.
Tragion (tr)		✓	The notch on the upper margin of the right ear tragus.

Table 3

Definition of the 34 selected variables.

Variable	Definition	Interpretation
v1 (°)	Angle formed between the approximated straight line rcm-sto and the <i>x</i> -axis.	Inclination of the right side FELVB line contour. Large values indicate an unaffected (right side) FELVB line contour that is inclined more superiorly at the commissure.
v2 (°)	Angle formed between the approximated straight line sto-lcm and the <i>x</i> -axis.	Inclination of the left side FELVB line contour. Large values indicate an affected (left side) FELVB line contour that is inclined superiorly at the commissure.
v3 (°)	v1 minus v2.	Difference between v1 and v2. Large values indicate an unaffected (right) side FELVB line contour inclined more inferiorly when compared to the affected (left) side FELVB line contour.
v4 (°)	Angle formed between the approximated straight line rcm-lcm and the <i>x</i> -axis.	Inclination of the entire FELVB line contour. Large values indicate an elevated FELVB line contour on the affected (left) side of the upper lip.
v5 (%)	Distance between rcm & p1.	Shape of the FELVB line contour. Large values indicate an unaffected (right) side elevation of the FELVB line contour positioned closer to the central portion of the upper lip.
v6 (%)	Distance between p1 & p2.	Shape of the FELVB line contour. Large values indicate a greater distance between the right and left elevations of the FELVB line contour.
v7 (%)	Distance between p2 & lcm.	Shape of the FELVB line contour. Large values indicate the affected (left) side elevation of the FELVB line contour positioned closer to the central portion of the upper lip.
v8 (°)	The mean of the upper projected LSI values.	Upper lip protrusion. Large values indicate greater protrusion of the upper lip.
v9 (°)	The standard deviation of the upper projected LSI values.	Horizontal uniformity of the upper lip shape. Large values indicate more horizontal unevenness of upper lip shape.
v10 (°)	(The mean of the one-fifth right upper projected LSI values) minus v8.	One-fifth of the unaffected (right) side upper lip protrusion relative to the entire upper lip protrusion. Small values indicate less protrusion in this portion.
v11 (°)	(The mean of the two-fifth right upper projected LSI values) minus v8.	Two-fifths of the unaffected (right) side upper lip protrusion relative to the entire upper lip protrusion. Small values indicate less protrusion in this portion.
v12 (°)	(The mean of the three-fifth right upper projected LSI) minus v8.	Three-fifths of the unaffected (right) side upper lip protrusion relative to the entire upper lip protrusion. Small values indicate less protrusion in this portion.
v13 (°)	(The mean of the two-fifth left upper projected LSI values) minus v8.	Two-fifths of the affected (left) side upper lip protrusion relative to the entire upper lip protrusion. Small values indicate less protrusion in this portion.
v14 (°)	(The mean of the one-fifth left upper projected LSI values) minus v8.	One-fifth of the affected (left) side upper lip protrusion relative to the entire upper lip protrusion. Small values indicate less protrusion in this portion.
v15 (°)	The mean of the lower projected LSI values.	Lower lip protrusion. Large values indicate a more protrusive lower lip.

Variable	Definition	Interpretation
v16 (°)	The standard deviation of the lower projected LSI values.	Horizontal uniformity of the lower lip shape. Large values indicate greater horizontal unevenness of the lower lip shape.
v17 (°)	(The mean of the one-fifth right lower projected LSI values) minus v15.	One-fifth of the unaffected (right) side lower lip protrusion relative to the entire lower lip protrusion. Small values indicate less protrusion in this portion.
v18 (°)	(The mean of the two-fifth right lower projected LSI values) minus v15.	Two-fifths of the unaffected (right) side lower lip protrusion relative to the entire lower lip protrusion. Small values indicate less protrusion in this portion.
v19 (°)	(The mean of the three-fifth right lower projected LSI values) minus v15.	Three-fifths of the unaffected (right) side lower lip protrusion relative to the entire lower lip protrusion. Small values indicate less protrusion in this portion.
v20 (°)	(The mean of the two-fifth left lower projected LSI values) minus v15.	Two-fifths of the affected (left) side lower lip protrusion relative to the entire lower lip protrusion. Small values indicate less protrusion in this portion.
v21 (°)	(The mean of the one-fifth left lower projected LSI values) minus v15.	One-fifth of the affected (left) side lower lip protrusion relative to the entire lower lip protrusion. Small values indicate less protrusion in this portion.
v22 (%)	Distance between rcm & ls projected on the sagittal plane.	Length of the upper lip vermillion border in the lateral view.
v23 (%)	Distance between rcm & sto projected on the sagittal plane.	Length of the lip fissure in the lateral view.
v24 (%)	Distance between rcm & li projected on the sagittal plane.	Length of the lower lip vermillion border in the lateral view.
v25 (%)	Distance between sto & ls projected on the sagittal plane.	Thickness of the upper lip vermillion in the lateral view.
v26 (%)	Distance between sto & li projected on the sagittal plane.	Thickness of the lower lip vermillion in the lateral view.
v27 (%)	L1/v25.	Degree of flatness of the upper lip vermillion. Greater values indicate a more 'pointed' shape of the upper lip vermillion.
v28 (%)	L2/v25.	Vertical position of the most protruded point of the upper lip vermillion.
v29 (%)	L3/v26.	Degree of flatness of the lower lip vermillion in the lateral view. Greater values indicate a more 'pointed' shape of the lower lip vermillion.
v30 (%)	L4/v26.	Vertical position of the most protruded point of the lower lip vermillion in the lateral view.
v31 (°)	Angle formed between the line joining rcm & sto and the Z-axis on the sagittal plane.	Inclination of the lip fissure in the lateral view. Greater values indicate a lip fissure that is inclined superiorly at the commissure.
v32 (%)	Difference in the distance between ls & li measured relative to the Z-axis.	Difference between that upper and lower lip vermillion in the lateral view. A positive value indicates that 'li' is more forward than 'ls'.
v33 (%)	Area bounded by the ls-sto line and the ls-sto curve on the sagittal plane.	Size of the anterior portion of the upper lip vermillion in the lateral view.
v34 (%)	Area bounded by the li-sto line and the li-sto curve on the sagittal plane.	Size of the anterior portion of the lower lip vermillion in the lateral view.

Table 4

Sample demographics.

Variable	Non-Cleft 'Control' Participants	Participants with Cleft Lip
Sample size	n = 28	n = 57
Age		
(Mean $\pm$ SD)	13.6 $\pm$ 3.8 years	12.5 $\pm$ 4.1 years
(Range)	6.6 – 21.9 years	5.0 – 21.5 years
Cleft type	..	43 unilateral 14 bilateral
Male	n = 14	n = 37
Female	n = 14	n = 20

Table 5

Intraobserver landmark reliability. Absolute differences between the first and second digitized values.

Landmark	Total Difference (mm)	Difference in X-axis (mm)		Difference in Y-axis (mm)		Difference in Z-axis (mm)	
		Mean	S.D.	Mean	S.D.	Mean	S.D.
sn	0.66	0.40	0.38	0.30	0.48	0.40	0.82
se	0.69	0.43	0.55	0.50	0.90	0.79	0.08
rcm	0.77	0.48	0.73	0.83	0.60	0.65	0.50
li	0.82	0.42	0.70	0.48	0.65	0.49	0.79
ls	0.84	0.50	0.73	0.61	0.98	1.01	0.22
sto	0.85	0.43	1.00	0.70	0.43	0.50	0.56
len	0.89	0.44	1.23	0.67	0.75	0.53	0.32
ren	0.93	0.63	1.45	1.14	0.35	0.29	0.35
rex	0.98	0.39	0.88	0.53	1.03	0.69	0.75
lcm	0.99	0.63	1.40	0.95	0.58	0.50	0.62
lex	1.23	0.81	1.28	0.98	0.55	0.55	1.48

Table 6Mean ($\pm$ SDs) and significant group differences for each variable.

Variable	Non-Cleft Participants (Control)	Participants with Cleft Lip (CL $\pm$ P)	Difference of Means (CL $\pm$ P - Control)
v1 (°)	7.5 $\pm$ 3.9	10.7 $\pm$ 4.6	3.2 *
v2 (°)	7.2 $\pm$ 3.4	8.0 $\pm$ 5.1	0.8
v3 (°)	0.3 $\pm$ 3.0	2.7 $\pm$ 5.2	2.4 *
v4 (°)	-0.3 $\pm$ 1.2	-1.6 $\pm$ 2.7	-1.2 *
v5 (%)	17.8 $\pm$ 4.2	21.7 $\pm$ 6.1	3.9 *
v6 (%)	58.5 $\pm$ 12.3	54.3 $\pm$ 9.7	-4.2
v7 (%)	22.8 $\pm$ 15.0	23.6 $\pm$ 11.4	0.8
v8 (°)	22.2 $\pm$ 4.2	16.5 $\pm$ 4.8	-5.7 *
v9 (°)	3.0 $\pm$ 1.4	4.2 $\pm$ 1.5	1.2 *
v10 (°)	-2.0 $\pm$ 3.6	1.8 $\pm$ 3.9	3.9 *
v11 (°)	-0.5 $\pm$ 2.2	-0.9 $\pm$ 2.3	-0.4
v12 (°)	0.8 $\pm$ 2.6	0.3 $\pm$ 5.1	-0.5
v13 (°)	0.7 $\pm$ 2.0	-2.2 $\pm$ 2.4	-3.0 *
v14 (°)	1.2 $\pm$ 2.5	1.3 $\pm$ 3.8	0.1
v15 (°)	10.7 $\pm$ 2.6	15.5 $\pm$ 6.4	4.8 *
v16 (°)	2.6 $\pm$ 0.9	4.0 $\pm$ 1.5	1.4 *
v17 (°)	-1.9 $\pm$ 2.1	-3.0 $\pm$ 2.7	-1.2 *
v18 (°)	1.1 $\pm$ 1.5	-0.2 $\pm$ 2.2	-1.3 *
v19 (°)	1.3 $\pm$ 1.9	2.7 $\pm$ 3.1	1.4 *
v20 (°)	1.2 $\pm$ 1.9	2.4 $\pm$ 2.8	1.2 *
v21 (°)	-1.6 $\pm$ 1.7	-1.6 $\pm$ 2.6	0.1
v22 (%)	25.6 $\pm$ 4.1	24.3 $\pm$ 5.4	-1.3
v23 (%)	14.1 $\pm$ 3.3	15.1 $\pm$ 4.0	1.0
v24 (%)	17.7 $\pm$ 3.3	17.8 $\pm$ 4.7	0.2
v25 (%)	12.7 $\pm$ 2.7	10.8 $\pm$ 3.3	-1.9 *
v26 (%)	14.2 $\pm$ 2.5	13.6 $\pm$ 2.9	-0.7
v27 (%)	11.1 $\pm$ 4.5	12.0 $\pm$ 6.2	0.9
v28 (%)	67.6 $\pm$ 7.4	65.1 $\pm$ 10.0	-2.4
v29 (%)	20.6 $\pm$ 6.3	21.4 $\pm$ 7.8	0.9
v30 (%)	61.9 $\pm$ 6.6	62.9 $\pm$ 5.9	1.0
v31 (°)	22.5 $\pm$ 10.0	33.3 $\pm$ 14.8	10.8 *
v32 (%)	-4.8 $\pm$ 2.8	0.3 $\pm$ 5.4	5.1 *
v33 (%)	0.1 $\pm$ 0.1	0.1 $\pm$ 0.1	0.0
v34 (%)	0.3 $\pm$ 0.2	0.3 $\pm$ 0.2	0.0

*
 $p \leq .05$

Table 7

Mean values for each of the 17 significant variables within each category.

	v1 (°)	v3 (°)	v4 (°)	v5 (%)	v8 (°)	v9 (°)	v10 (°)	v13 (°)	v15 (°)	v16 (°)	v17 (°)	v18 (°)	v19 (°)	v20 (°)	v25 (%)	v31 (°)	v32 (%)
Category 1	10.5	3.4	-1.7	18.2	22.2	3.7	-4.1	1.7	10.3	2.9	-2.5	1.0	1.5	2.3	11.3	28.5	-4.8
Category 2	3.9	-0.8	0.4	17.2	23.8	2.7	-0.4	-0.2	9.8	2.4	-1.3	1.2	1.5	0.5	14.5	14.3	-6.7
Category 3	7.8	-6.4	2.7	14.5	17.2	4.6	-3.7	-0.6	18.9	3.9	-1.8	2.2	2.8	-0.3	12.2	36.4	0.9
Category 4	11.3	3.7	-2.0	24.1	17.6	4.1	3.5	-3.5	11.0	2.6	-0.7	0.2	1.1	0.6	11.1	29.1	-2.2
Category 5	12.8	2.7	-1.4	21.1	14.8	3.4	-0.2	-1.9	15.4	5.0	-5.6	-0.2	6.6	2.3	11.6	44.1	2.0
Category 6	11.0	1.6	-1.4	20.9	11.5	4.5	4.2	-2.6	22.9	4.7	-4.0	-0.9	1.7	4.4	7.5	34.8	6.7
Category 7	13.5	8.1	-4.3	27.2	18.6	5.2	1.7	-0.6	18.3	6.0	-6.1	-2.8	2.1	7.0	11.2	40.6	0.8