

## Section 7: Multi-disciplinary Outcomes of Primary Infant Protocols

### Nasolabial Esthetic Ratings

#### 1) *Example of Request Application for IRB approval*

Refer to the information described in the Cephalometric Outcomes section. Additionally, it is important to state in the IRB proposal that patient names will be removed from all images and replaced with codes. Also, it should be stated that the eyes will be masked from all images to protect patients' identities not only during transit of records but also for the duration of the study.

#### 2) *Sample considerations*

##### **Inclusion criteria:**

- Caucasian patients with non-syndromic complete unilateral or bilateral cleft lip and palate,
- Patients who had complete orthodontic records taken in the mixed dentition, prior to any orthodontic movement of teeth (including maxillary expansion or incisor alignment). Patient may or may not have received primary and/or secondary alveolar bone grafting.
- Each subject has received all primary surgery and previous care at the Institution concerned.
- Cases must be consecutively treated patients.
- Patients who had a complete set of extra and intraoral photos: full face at rest, left and right profile pictures at rest.

##### **Exclusion criteria:**

- Non Caucasian patients, patients with associated syndromes, patients with incomplete clefts, cleft lip only, or cleft of secondary palate only.
- Patients who did not have complete orthodontic records (radiographs, study models, and photos) taken in the mixed dentition.
- Patients who had orthodontic treatment such as maxillary expansion or incisor alignment or orthopedic maxillary treatment (face mask, head gear, chin cup or functional appliances).
- Patient who did not have a complete set of extra and intraoral photos: full face at rest, left and right profile pictures at rest. A patient with an incomplete set of quality photos should be excluded.
- Patients whose photos or images are blurred, excessively dark or bright, or grainy (poor quality image).

#### 3) *Photographic protocol*

- Images that can be used include Polaroids, slides, photos, and digital images.
- Photos should be taken at the same appointment but before alginate impressions are taken.
- Use a single color, well-lit, non-textured background to take the photos. Remove eye-glasses, hats, nose jewelry, and tuck patient's hair behind ears.

- Full face frontal photo should be taken at repose (not smiling), without strain on the lip musculature. Attempt to line interpupillary plane parallel to the floor. Patient's head should be oriented at natural head position. If the camera has a single point flash, it should be oriented at either the right or left side of pt's head.
- Profile photos must be taken from **both** the right and left side of the patient's full face. Lips should be at rest. Head should be oriented at natural head position. Single point flash should be located on the same side as the patient's nose to prevent shadowing on facial outline.
- Each patient must have a complete set of quality photos. If a patient has one image in the set that is not of adequate quality, the patient must be excluded from the study.

**4) *Coding of patients and descriptive data***

Each center should collect the descriptive data for each patient as described in the Cephalometric Outcomes section (please refer to previous pages), including the date at which the facial images were taken. Each center should disclose the surgical treatment protocol followed at that Institution. All patient names must be removed from photos and replaced by code numbers. Only codes for each patient (no names) should be used in the images and descriptive data sheets

**5) *Scanning of Polaroids, photos and slides***

Scanning of Polaroids, photographic prints, and slides must be done at the centers of origin. Those should be scanned and saved as JPEG images with at least a 1400dpi resolution.

**5) *Orienting the images and blocking the eyes***

- This applies both to scanned images and to digital photos.
- Frontal images – use a Photo-software like Adobe Photoshop to tilt the image so that an interpupillary plane is horizontally to the floor. This corrects for canting on the face due to posturing. Following this step, use a small white circle to block or cut out individually both irises of the eyes, while preserving the inner canthi of the eyes visible in the image. The Nasion area (between the eyes) should not be blocked.
- Profile images – use a small white triangle to block out the eye on each image. There is no need to tilt the profile images.
- Remember to save each image with the patient's code followed by the suffix “.jpeg”.

**6) *Storing of images for shipping***

- Burn all images (coded) into a compact disc and also include the data sheet listing each patient's descriptive data.
- A summary print out of all images in 1-2 pages is useful, but not mandatory.
- Ship the compact disc and any hard paper copies to:  
 Dr. Ana M. Mercado  
 Ohio State University College of Dentistry, Section of Orthodontics  
 305 W. 12<sup>th</sup> Ave.  
 Columbus, OH 43218

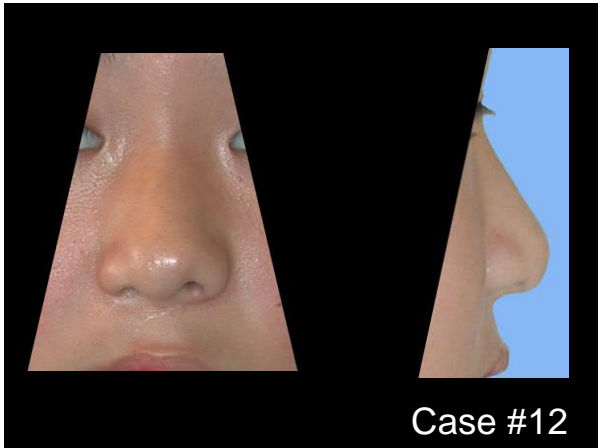
**7) *Image cropping, subtraction of background, and re-sizing***

- This is done by Dr Mercado and staff at Ohio State University.
- Adobe Photoshop software is used to crop all images. The only areas to show will be the nasolabial area, innercanthus, nose bridge, nostrils, philtrum and upper lip.
- Any background shown on the profile images will be standardized to the same color.

- All images will be re-sized to scale into the same dimensions.

**8) Preparation of PowerPoint slides for rating**

- Each PowerPoint slide will contain a patient's frontal and profile image.
- A number will be assigned to each slide (patient) that is different from the original code (see figure below).
- All slides will be grouped into a single PowerPoint file, stored into CD's, and distributed to raters for their evaluation.
- If using the Q-sort method (Stoutland et al., *J of Craniofac Surg*, 28:1911-1917, 2017), each slide will be printed as a 3"x5" card and laminated, with the case code.



Example of a coded slide for rating. It has frontal and profile images for Case #12.

**9) Panel of raters and their responsibilities**

- Raters can include but is not limited to orthodontists, plastic surgeons, oral surgeons, speech pathologists, lay persons, and parents of affected children.
- Raters should agree to participate in a training and calibration session (about one hour long) with the principal investigator, to be described below.
- Raters will receive one CD with all study subjects' slides and a second "reliability" CD with a smaller selection of subjects' slides randomly ordered and coded differently than those in the first CD.
- Raters should agree to rate all study subjects' slides and also to re-rate a number of random "reliability" slides to determine intra-rater reliability testing.
- If using the Q-sort method (Stoutland et al., *J of Craniofac Surg*, 28:1911-1917, 2017), raters will receive a stack of "cards" to rate.

**10) Rating scale of nasolabial outcomes**

- Refer to the methodology described by Asher-McDade C. *et al.*, *Cleft Palate J* 28: 385-90, 1991 with modifications described in Mercado, et al., *Cleft Palate-Craniofac J*, 53:30-37, 2016.
- Three or four features are rated: nasolabial frontal (a merge of the original nasal form and nasal symmetry), vermilion border, and nasolabial profile.
- Features are rated on a 1-5 scale:
  - 1 – Very good (for a patient with a cleft)
  - 2 – Good
  - 3 – Fair
  - 4 – Poor
  - 5 – Very poor

### 11) *Training and Calibration*

- Raters will receive a brief training on the purpose of the study and the types of images that they will be evaluating. A series of PowerPoint slides of patients that are not actual study subjects will be presented to the raters to familiarize them with the facial cropping and the layout of the images on the slides.
- A calibration session will be done with each rater or with a group of raters by showing them 20 slides and asking them to rate all slides. Ratings for each slide will be reviewed with the principal investigator.
- For the Q-sort method, see Mercado et al., *Cleft Palate-Craniofac J*, 53:30-37, 2016, and Stoutland et al., *J of Craniofac Surg*, 28:1911-1917, 2017.

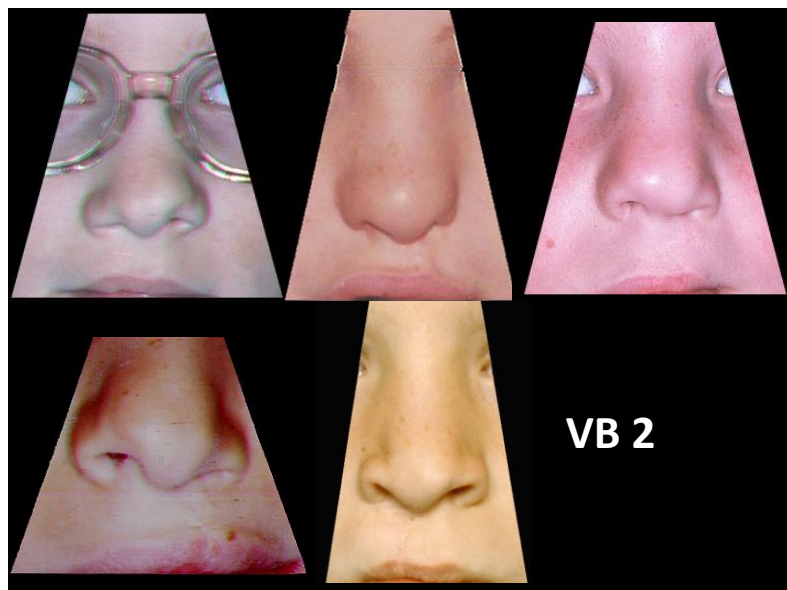
### 12) *Reference images*

- Raters will receive a printed color copy of images of different severities on the scale of 1-5, one page for each one of the facial features.
- These printed color copies are meant to be used by the raters as reference images or as a “yardstick” of the scale of severity for each nasolabial feature.
- For 7-9 year old patients in the mixed dentition, this includes the original 4 features of the Asher-McDade method and was illustrated in the “yardstick” developed by Kuijpers-Jagtman et al., *J of Craniofac Surg*, 20:1683-1686, 2009. The Americleft modification of the original Asher-McDade method, and the use of the of Q-sort method resulted in merging nasal symmetry and nasal form into one category, Nasal Frontal). The following are the unpublished reference images developed for use in the Americleft studies:

Vermilion Border Rating: 1



Vermilion Border: Rating 2



Vermilion Border: Rating 3



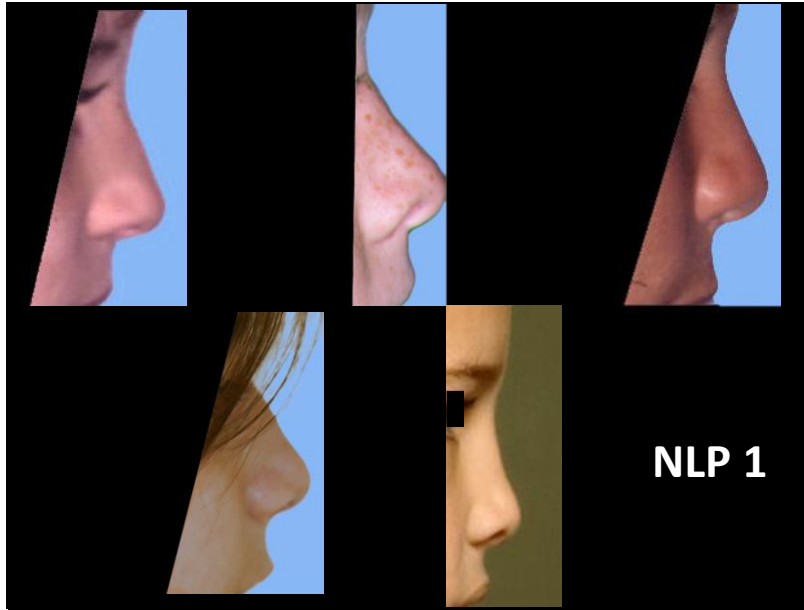
Vermilion Border: Rating 4



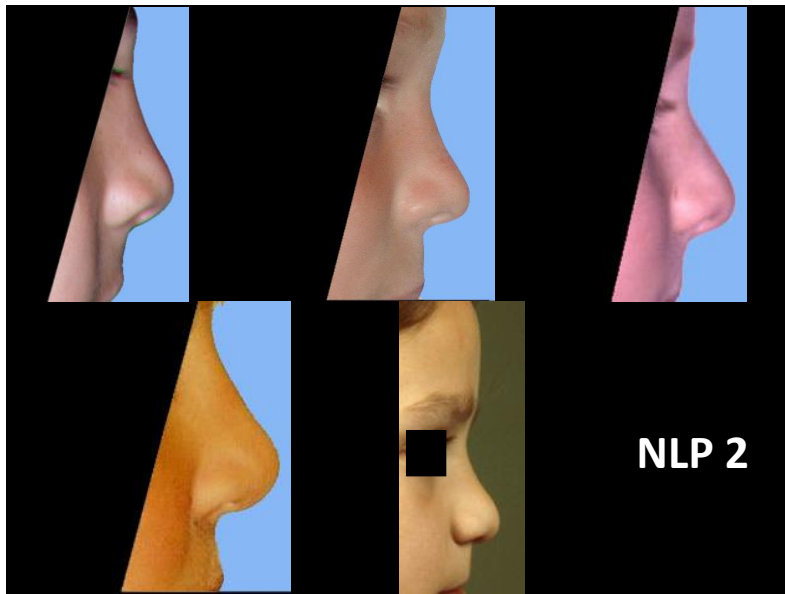
Vermilion Border: Rating 5



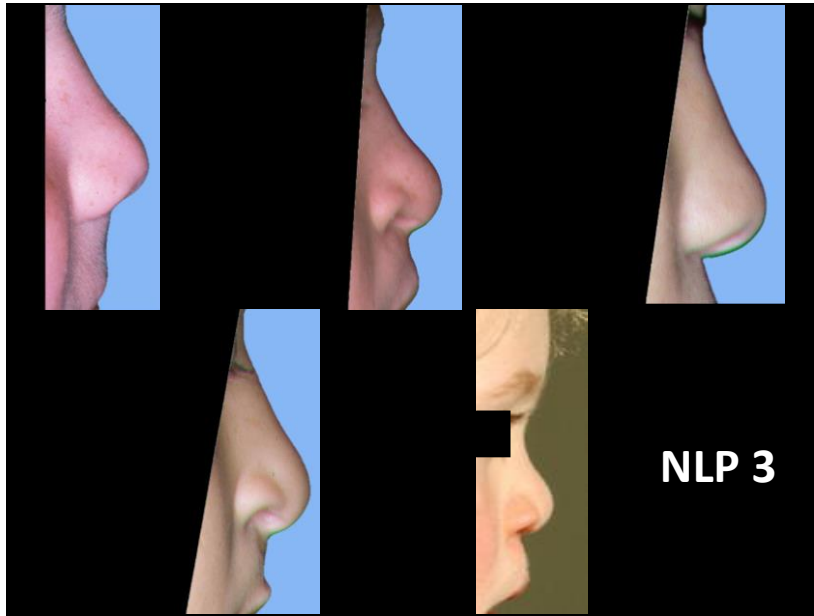
Nasolabial Profile: Rating 1



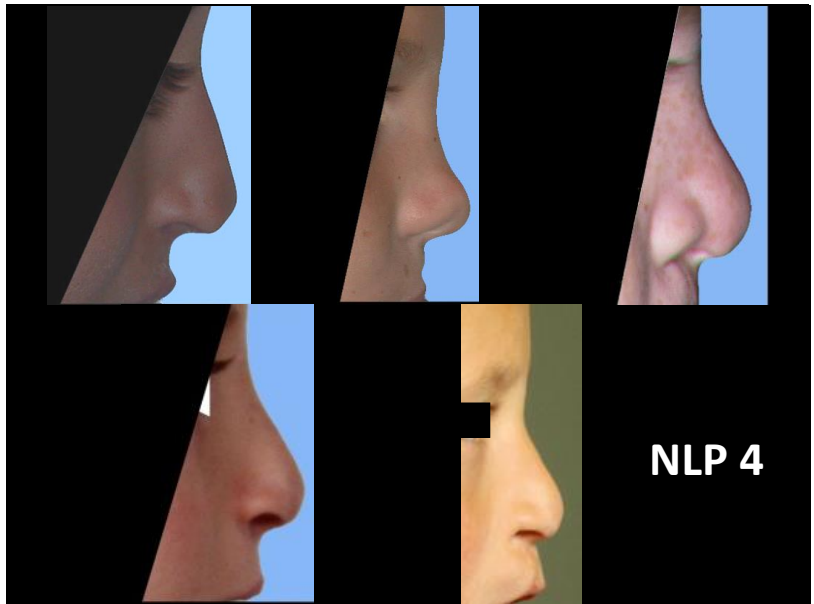
Nasolabial Profile: Rating 2



Nasolabial Profile: Rating 3

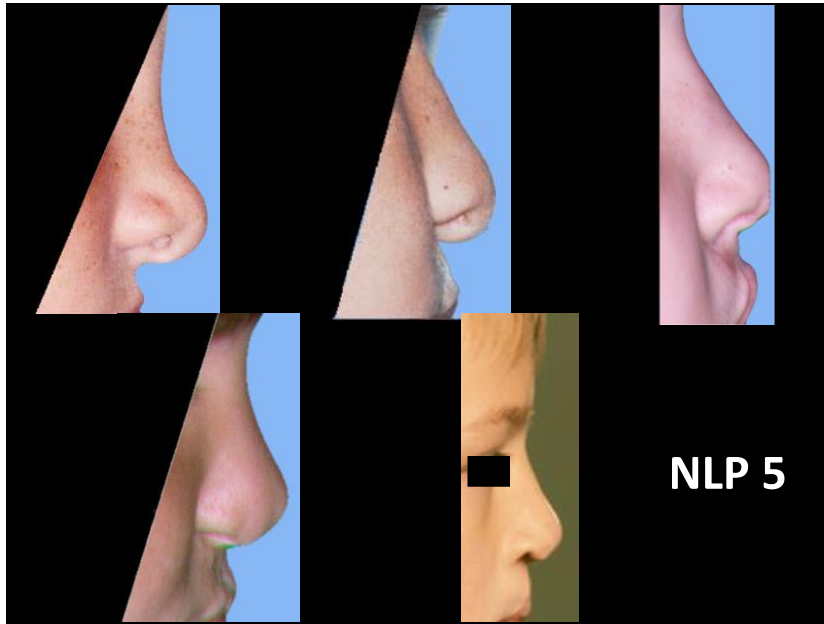


Nasolabial Profile: Rating 4

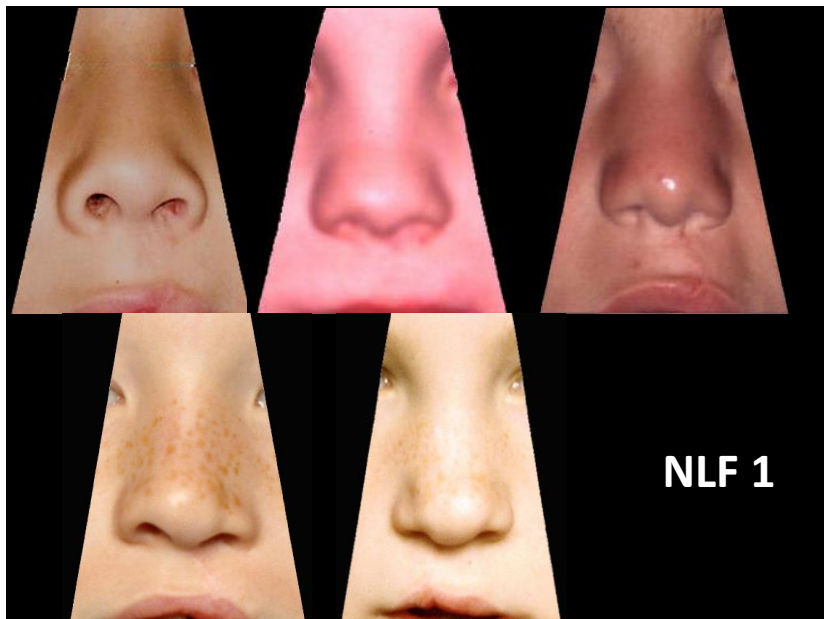




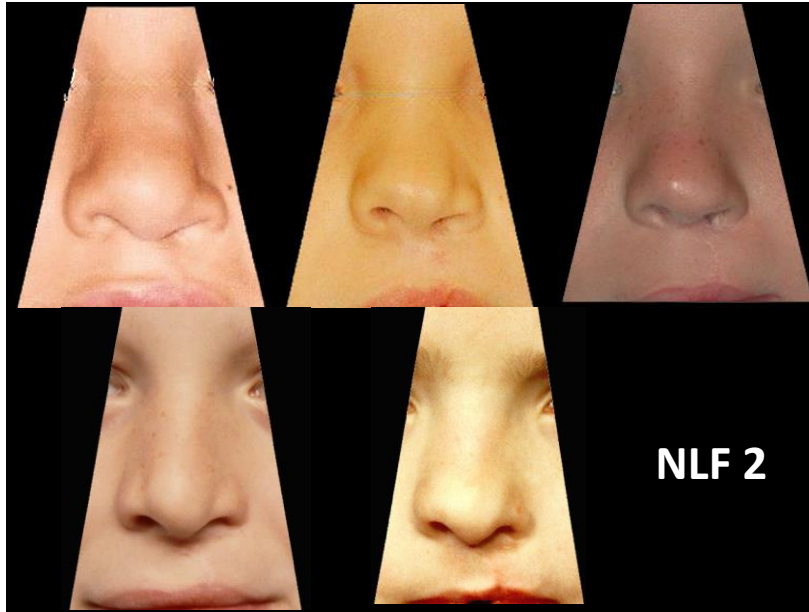
Nasolabial Profile: Rating 5



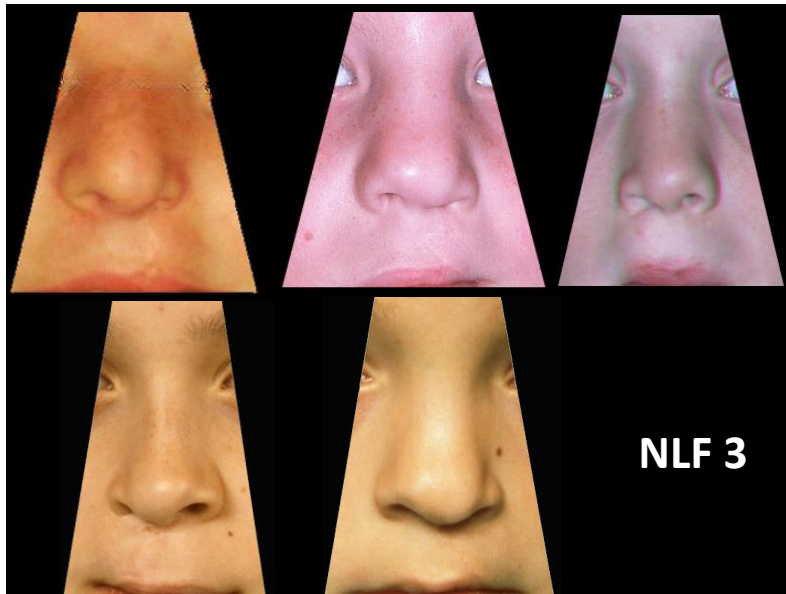
Nasal Frontal: Rating 1



Nasal Frontal: Rating 2



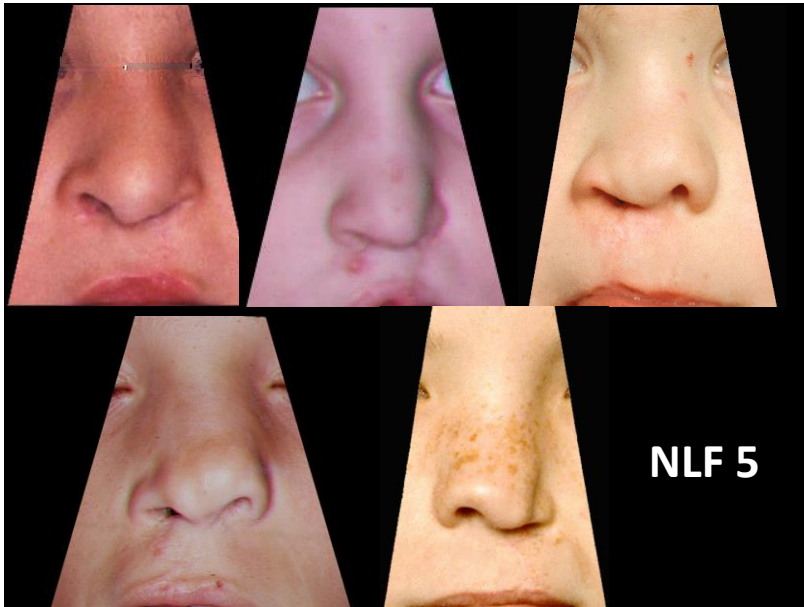
Nasal Frontal: Rating 3



Nasal Frontal: Rating 4



Nasal Frontal: Rating 5



- For 5-7 year old patients in the late primary/early mixed dentition, this includes the three features of Q-sort method (merging nasal symmetry and nasal form into one category, nasolabial frontal) using the “yardstick” developed by Mercado et al., *Cleft Palate-Craniofac J*, 53:30-37, 2016.
- Reference images for each feature are shown below:

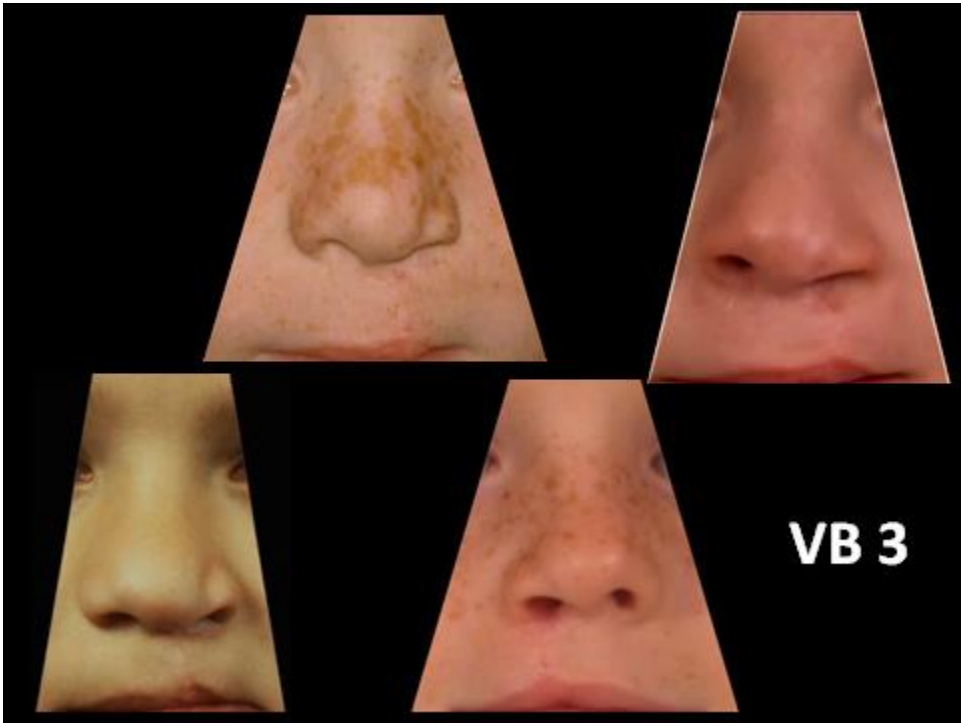
Vermilion Border: Rating 1



Vermilion Border: Rating 2



Vermilion Border: Rating 3



Vermilion Border: Rating 4

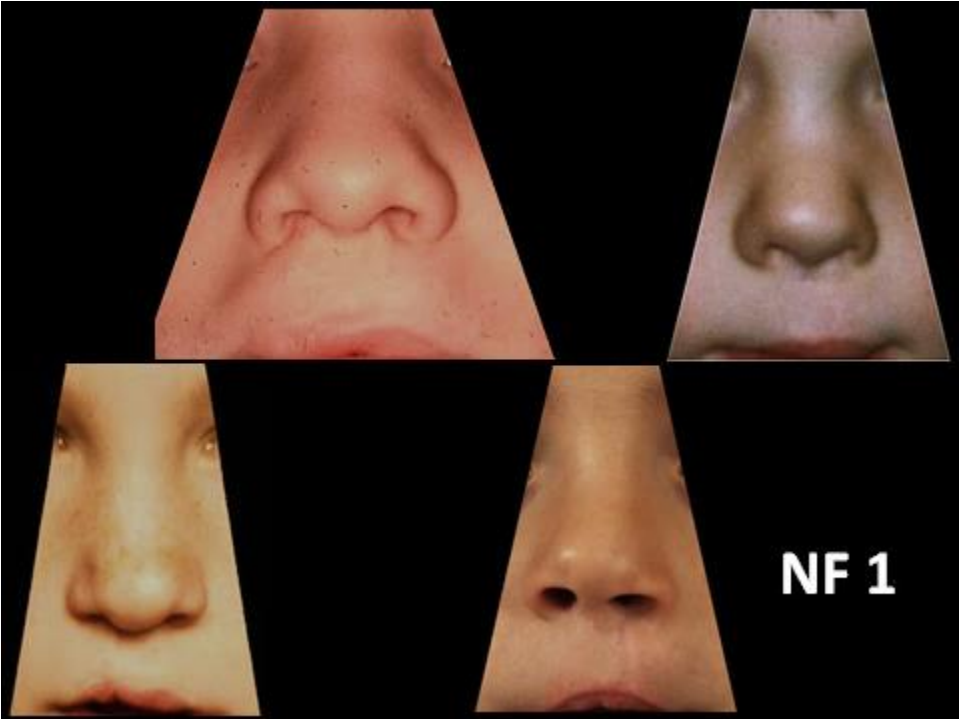


Vermilion Border: Rating 5





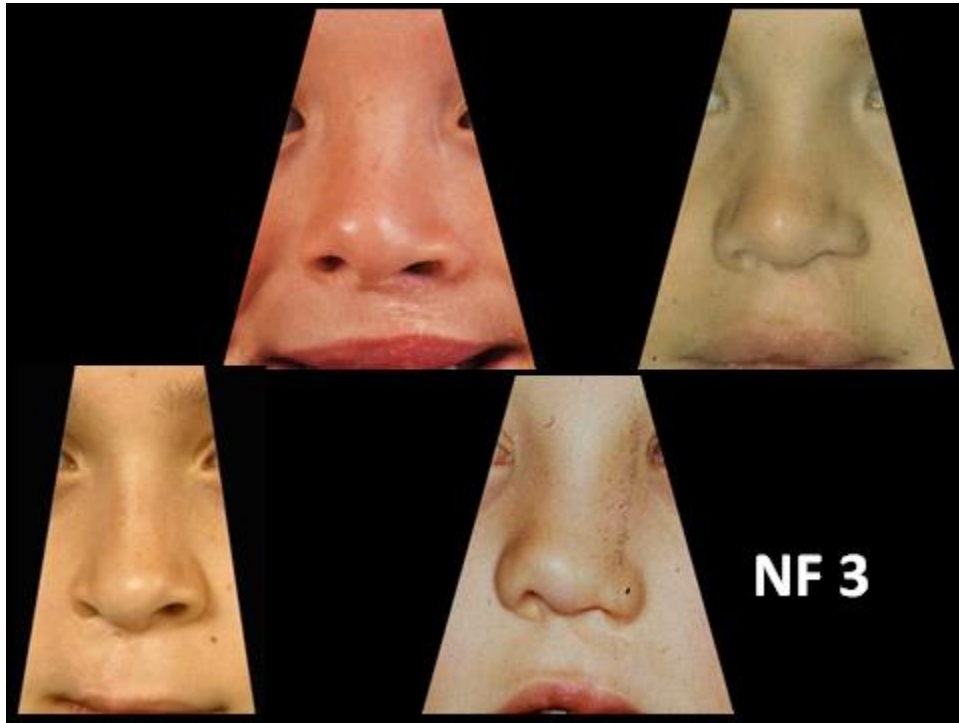
Nasal Frontal: Rating 1



Nasal Frontal: Rating 2



Nasal Frontal Rating 3

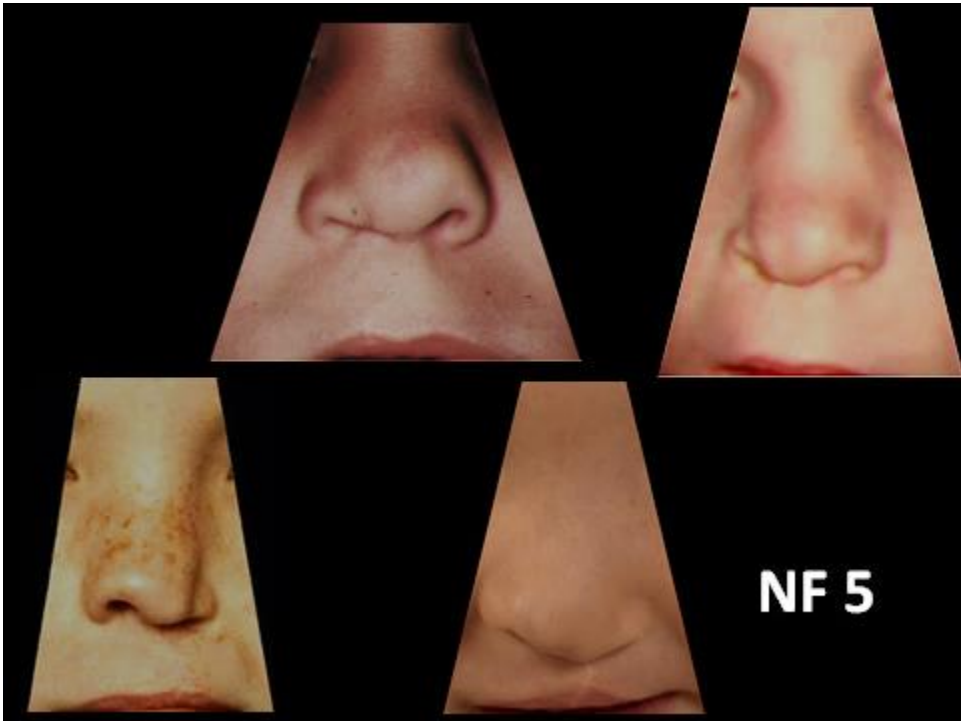


Nasal Frontal Rating 4

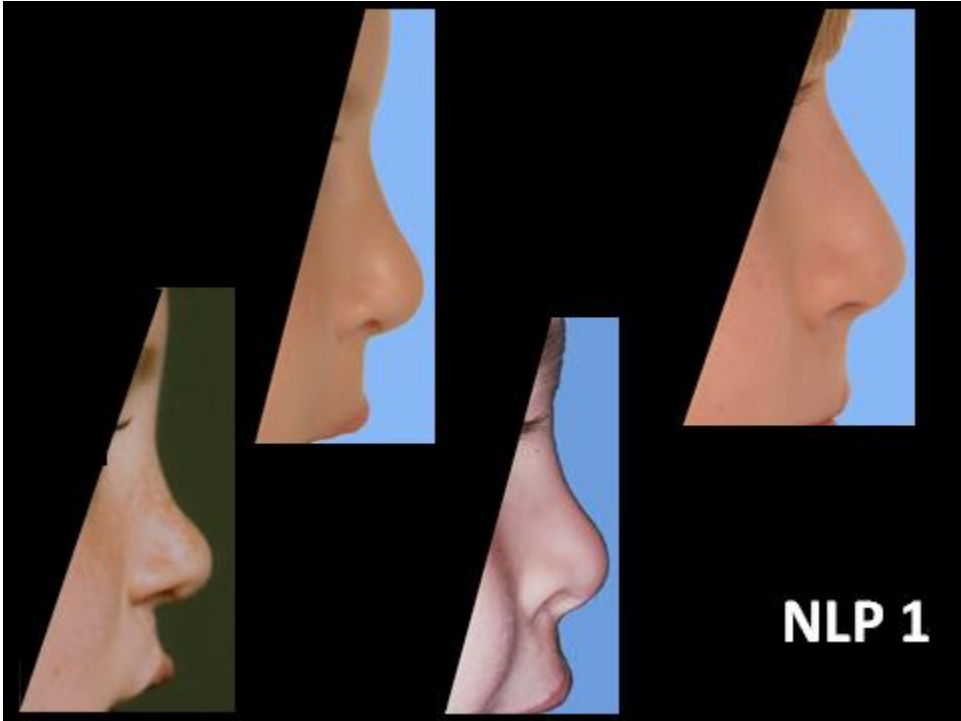




Nasal Frontal: Rating 5



Nasolabial Profile: Rating 1



Nasolabial Profile: Rating 2



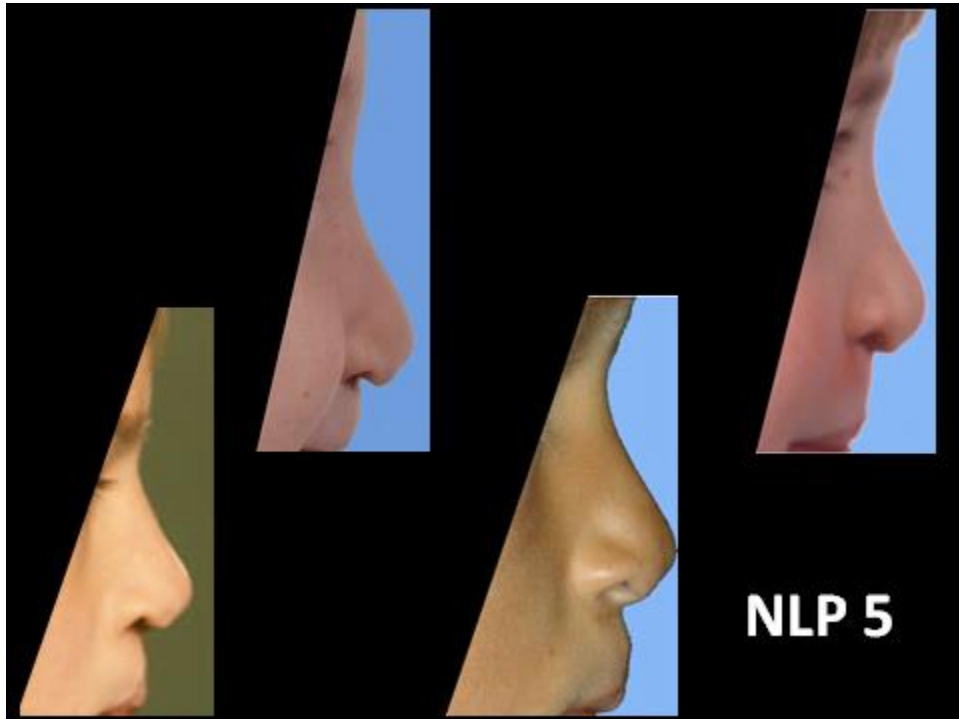
Nasolabial Profile: Rating 3



Nasolabial Profile: Rating 4



Nasolabial Profile: Rating 5



**13) Recording of ratings**

- Raters will be given blank recording sheets. The following is an example of a table to circle the ratings from a single patient.

<b>CASE # 1</b>		<b>Very Good</b>	<b>Good</b>	<b>Fair</b>	<b>Poor</b>	<b>Very Poor</b>
	<b>Vermillion border</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	<b>Nasolabial frontal</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>
	<b>Nasolabial profile</b>	<b>1</b>	<b>2</b>	<b>3</b>	<b>4</b>	<b>5</b>

**14) Statistical Analysis**

- The group means of the different centers for each nasolabial feature will be compared using analysis of variance, assuming normal distributions. If distributions cannot be confirmed normal, the Kruskal-Wallis test with multiple comparisons and Bonferroni correction is a better method for use with these categorical data. Weighed kappa statistics will be performed to evaluate inter-examiner and intra-examiner agreement.

## PUBLICATIONS

1. Mercado AM, Russell KA, Hathaway RR, Daskalogiannakis J, Sadek H, Long Jr RE, Cohen MA, Semb G, Shaw W: The Americleft Study: An intercenter study of treatment outcomes for patients with unilateral cleft lip and palate. Part 4 – Nasolabial esthetics. Cleft Palate-Craniofacial Journal, 48:259-264, 2011.
2. LongJr RE, Mercado AM, Daskalogiannakis J, Hathaway RR Russell KA, Stoutland A, Singer E, Semb G, Shaw WC, Gregory J. The Americleft Project: A modification of Asher-McDade method for rating nasolabial esthetics in patients with CUCLP. Transactions of the 12<sup>th</sup> International Congress on Cleft Lip/Palate and Related Craniofacial Anomalies, Orlando, FL, May 5-10, 2013.
3. Mercado AM, Russell KA, Daskalogiannakis J, , Hathaway RR, LongJr RE, Semb G, Shaw WC, Ozawa T, Smith A, Lin AY, Gregory J. The Americleft Project: A proposed expanded nasolabial appearance yardstick of 5-year old patients with CUCLP. Transactions of the 12<sup>th</sup> International Congress on Cleft Lip/Palate and Related Craniofacial Anomalies, Orlando, FL, May 5-10, 2013.
4. Mercado AM, Russell KA, Daskalogiannakis J, Hathaway RR, Semb G, Ozawa T, Smith A, Lin A. The Americleft Project: A proposed expanded nasolabial appearance yardstick for 5 year old patients with CUCLP. Cleft Palate-Craniofacial Journal, 53:30-37; 2016.
5. Stoutland A, LongJr RE, Mercado A, Daskalogiannakis J, Hathaway RR, Russell KA, Singer E, Semb G, ShawWC. The Americleft Project: A Modification of Asher-McDade Method for Rating Nasolabial Esthetics in Patients with CUCLP using Q-SORT, J of Craniofacial Surgery, 28:1911-1917.
6. Jones CM, Roth B, Mercado AM, Russell, KA, Daskalogiannakis D, Samson TD, Hathaway RR, Semb G, Smith A, Makay DR, LongJr RE. Comparison of ratings using 2D vs. 3D images for evaluation of nasolabial appearance in patients with CUCLP. J of Craniofacial Surgery, 29:105-108, 2018.
7. Peanchitlertkajorn S, Mercado AM, Daskalogiannakis J, Hathaway RR, Russell KA, Semb G, Shaw WC, Lamichane M, Fessler, J, LongJr RE. An inter-center comparison of nasolabial esthetics including a center using nasoalveolar molding. Cleft Palate Craniofacial J, 55:655-663; 2018.

8. Kornbluth M, Campbell RE, Daskalogiannakis J, Ross EJ, Glick PH, Russell KA, Doucet JC, Hathaway RR, Long Jr RE, Sitzman TJ. Active presurgical infant orthopedics for unilateral cleft lip and palate: Intercenter outcome comparison of Latham, modified McNeil, and nasoalveolar molding. Cleft Palate Craniofacial J, 55:639-648, 2018.
9. Singer E, Daskalogiannakis J, Russell KA, Mercado A, Hathaway RR, Stoutland A, Long Jr RE, Fessler J, Semb G, Shaw WC. Burden of care of various infant orthopedic protocols for improvement of nasolabial aesthetics in patients with CUCLP. Cleft Palate Craniofacial J, 55:1236-1243, 2018.

## **PRESENTATIONS**

### **2011 ACPA San Juan, PR**

THE AMERICLEFT PROJECT: A MULTICENTER RETROSPECTIVE STUDY OF PATIENTS WITH CUCLP FROM 5 NORTH AMERICAN CENTERS

Peachitlertkajorn, Daskalogiannakis, Lamichane, Mercado, Hathaway, Russell, Long, Gregory

AN EXPANSION OF THE AMERICLEFT INTERCENTER COMPARISON OF NASOLABIAL APPEARANCE OUTCOMES TO INCLUDE A CENTER USING NAM AS PART OF ITS PRIMARY PROTOCOL

Mercado, Peachitlertkajorn, Daskalogiannakis, Hathaway, Lamichane, Russell, Semb, Long

### **2014 ACPA Indianapolis, IN**

THE AMERICLEFT PROJECT: COMPARISON OF RATINGS USING 2D VS 3D IMAGES FOR EVALUATION OF NASOLABIAL APPEARANCE IN PATIENTS WITH CUCLP

Jones, Mercado, Russell, Daskalogiannakis, Samson, Hathaway, Semb, Smith, Fessler, Long

THE AMERICLEFT PROJECT: A MODIFICATION OF ASHER-MCDADE METHOD FOR RATING NASOLABIAL ESTHETICS IN PATIENTS WITH CUCLP

Russell, Daskalogiannakis, Mercado, Hathaway, Long, Semb, Shaw, Fessler

### **2015 ACPA Palm Springs, CA**

COMPARISON OF CUCLP NASOLABIAL APPEARANCE BETWEEN 4 CENTERS WITH INFANT MANAGEMENT PROTOCOLS +/- USE OF NAM, GPP, OR INFANT ORTHOPEDICS

Glick, Beals, Sitzman, Semb, Daskalogiannakis, Hathaway, Russell, Long, Fessler, Muller

**2016 ACPA Atlanta, GA**

THE AMERICLEFT PROJECT: A COMPARISON OF NASOLABIAL AESTHETICS AMONG FIVE CENTERS USING DISTINCT TYPES OF ACTIVE PRESURGICAL ORTHOPEDICS.

Sitzman, Campbell, Kornbluth, Daskalogiannakis, Ross, Glick, Beals, Russell, Doucet, Mercado

**2017 ACPA Colorado Springs, CO**

THE AMERICLEFT PROJECT: LONG TERM EFFECTS OF NASOALVEOLAR MOLDING IN PATIENTS WITH COMPLETE UNILATERAL CLEFT LIP AND PALATE.

Reyhani, Daskalogiannakis, Glick, Beals, Russell, Doucet, Mercado, Hathaway, Long

**2018 ACPA Pittsburgh, PA**

LONG-TERM CHANGES IN CUCLP NASOLABIAL APPEARANCE RATINGS AT 5,8, AND 11 YEARS OF AGE WITHOUT SECONDARY REVISION SURGERY.

Dabbagh, Long, Horst, Daskalogiannakis, Hathaway, Russell, Mercado, Beals, Weaver, Doucet, Hall, Beals

CHANGES IN CUCLP NASOLABIAL APPEARANCE RATINGS FOLLOWING SECONDARY REVISION SURGERY.

Dabbagh, Long, Beals, Horst, Mackay, Samson, Weaver, Doucet, Hathaway, Russell, Daskalogiannakis, Hall

