

Clinical Paper
 Cleft lip and palate

An anatomical subunit-based outcome assessment scale for bilateral cleft lip and palate

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K. Bonanthaya, P. N. Shetty, P. S. Fudalej, D. D. Rao, S. Bitra, M. Pabari, M. Rachwalski: An anatomical subunit-based outcome assessment scale for bilateral cleft lip and palate. *Int. J. Oral Maxillofac. Surg.* 2017; xxx: xxx–xxx. © 2017 International Association of Oral and Maxillofacial Surgeons. Published by Elsevier Ltd. All rights reserved.

Abstract. As there is currently no internationally accepted outcome measurement tool available for complete bilateral cleft lip and palate (CBCLP), the goal of this prospective study was to develop a numerical evaluation scale that allows reliable scoring of this cleft deformity. Our cohort comprised 121 Indian subjects with CBCLP who underwent surgical repair (mean age at time of surgery 6.53 months) using a modified Millard technique. A panel of three professionals evaluated each subject's outcome of bilateral cleft lip repair 6 months postoperatively on two-dimensional (2D) full-face photographs in the frontal view and worm's eye view. A simple two-point rating system was applied to separately analyse a total of 12 components of lip, nose, and scar. The results and mean scores for the analysed anatomical areas were 2.2 ± 1.01 (max = 3) for nose, 5.4 ± 1.54 (max = 8) for lip, and 1.9 ± 1.3 (max = 3) for scar, with a total score 7.7 ± 2.21 (max = 12) indicating a good surgical outcome. The inter-examiner ICC for nose, lip, scar, and total score was calculated at 0.836, 0.889, 0.723, and 0.927 respectively and indicated a strong level of repeatability and reliability that was highly significant ($P < 0.001$). In conclusion, we were able to develop and test a scoring system for measuring outcomes in CBCLP that warrants simplicity of use, reliability and reproducibility.

Key words: bilateral cleft lip and palate; bilateral cleft lip; binary scale; outcome assessment.

Accepted for publication

Although there is consensus among healthcare providers that evaluation of nasolabial morphology in cleft lip and palate (CLP) is one of the key elements in measuring treatment success, to date there remains controversy regarding a

commonly accepted rating system. A number of previous studies on subjects with unilateral cleft lip and palate (UCLP) have included direct and indirect anthropometrics of hard- and soft tissues, panel-based evaluations of professionals and

laymen, linear and area analyses of two-dimensional (2D) photographs, and more recently three-dimensional (3D) images, primarily measuring and comparing the symmetry of the cleft- to the non-cleft side^{1–3}.

Outcome evaluation in bilateral cleft lip and palate (BLCLP) poses a somewhat greater challenge to the assessor, primarily because of the absence of a normal side to compare with. Because of the multidimensional complexity of the initial cleft deformity this patient sub-group is after all the most likely to require multiple revision surgeries until adulthood⁴.

There is currently no scale available which is “tailored” for the purpose of evaluation of the bilateral cleft deformity and which is devoid of expensive technology, time consuming and complicated quantitative and anthropometric measurements of angles and landmarks.

To overcome these shortcomings, the aim of our study was to develop and test a binary scoring system and assessment scale that warrants simplicity of use, reliability, and reproducibility, and that allows for the analysis of 12 relevant components of the nasolabial area of the bilateral cleft deformity in a time efficient manner.

Materials and methods

During the period of February 2007 until February 2014, a total of 121 consecutive Indian patients (89 males, 32 females) with non-syndromic complete bilateral cleft lip and palate (CBCLP) were selected for this prospective study. All subjects underwent primary lip repair without nasal correction using a modified Millard technique until the age of 12 months (mean age at time of surgery 6.53 months, range 3–12 months) performed by two senior surgeons (K.B. and P.N.S.) at the Smile Train

Cleft Palate Centre, Bhagwan Mahaveer Jain Hospital, Bangalore, India. Two-dimensional (2D) full-face photographs in the frontal view and worm’s eye view were acquired 6 months postoperatively by the same experienced photographer using a Canon EOS 500D digital camera (Canon Inc., Tokyo, Japan). Both views were taken with the head in a rest position against a green background. The frontal view was taken with both ears visible to minimize rotation and least nostril show to minimize tilt. The worm’s eye view was taken with nasal tip projected between the medial canthi and eyebrows (Fig. 1). The photographic records were stored as JPEG files and further processed through ImageJ software.

Reformatted and equal sized images in the frontal and the worm’s eye view were printed on high-quality photographic paper and distributed among professional panellists for evaluation. The panel consisted of three former cleft surgery fellows, with 1 year of postgraduate experience, who were not involved in the treatment of the patients enrolled in this study.

Assessment of the outcome of bilateral cleft repair was conducted by a binary numerical evaluation scale of three major evaluation areas including lip, nose, and scar, subdivided into a total of 12 anatomical subunits and items, of which each was separately analysed for 15 seconds and scored. A simple two point rating system was applied, where a score of 1 was given if the parameter was found to be acceptable (normal) and score of 0 was given when the postoperative result was consid-

ered not to be satisfactory for that particular parameter (Table 1).

Statistical analysis

All statistical analysis was performed with SPSS 16.0 software (Chicago, IL, USA). To evaluate the inter-examiner reliability, the agreement between three professional raters regarding the scoring of our assessment scale, an intra-class correlation coefficient (ICC) was calculated. Higher ICC values indicate greater inter-examiner reliability, with an ICC estimate of 1 indicating perfect agreement while 0 indicates only random agreement. Negative ICC values indicate systematic disagreement. Cicchetti⁵ provides commonly-cited cut-offs for qualitative ratings of agreement based on ICC values, which can be interpreted as follows: inter-examiner reliability is poor for ICC values <0.40, fair for values between 0.40 and 0.59, good for values between 0.60 and 0.74, and excellent for values between 0.75 and 1.0.

Pilot study

Initially, a pilot study was conducted on 10 CBCLP cases for training and calibration purposes and to test the inter-examiner reliability of the assessment scale among three professional panellists (former cleft surgery fellows). The results of the pilot study showed statistically significant intra-class correlation coefficient (ICC) values for the inter-examiner reliability for nose, lip, scar, and total scores, which were 0.4977 ($P = 0.005$), 0.8334 ($P = 0.001$), 0.3237 ($P = 0.047$), and

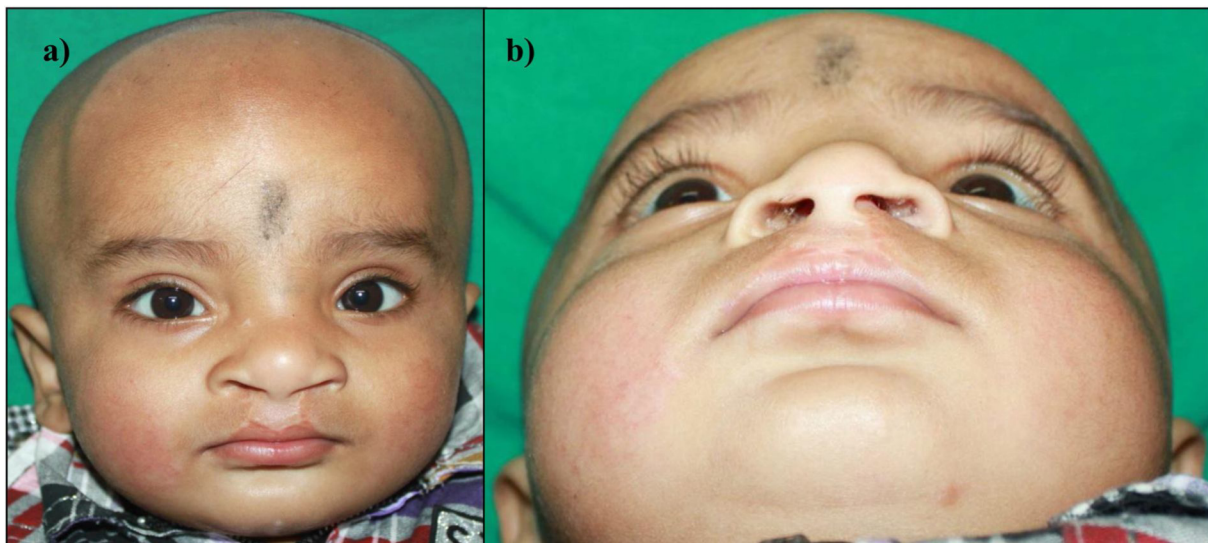


Fig. 1. Full-face photographs for the assessment of the bilateral cleft lip repair outcome, taken six months postoperatively in (A) frontal view and (B) worm’s eye view.

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