Modified Cleft Lip Evaluation Profile (Mclep) Index For Unilateral Cleft Lip Repair Outcome Assessment In Surabaya Clp Center

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ABSTRACT

Background: Cleft lip and/or palate is the most common craniofacial congenital anomaly encountered by the plastic surgeon. Both reconstruction and outcome assessment are challenging. This study aimed to assess the outcome of unilateral cleft lip repair in the Surabaya CLP Center.

Methods: All patients who underwent unilateral cleft lip repair in 2017 were included in the study. Those without complete photographs at minimally 52 weeks after surgery were excluded. The photographs of patients taken at least one-year post-surgery were assessed using a modified cleft lip evaluation profile (MCLEP) index. The data were then analyzed using statistical software.

Results: There were 38 subjects included in the study. There was no significant difference in the final scores obtained based on completeness of the cleft lip and the presence of alveolar cleft. The total nose score was significantly better in the left side cleft ($p = 0.002$). When palate cleft was absent, the total lip score ($p = 0.038$), the total nose score ($p = 0.008$), and total score ($p = 0.000$) were also significantly better.

Conclusions: The unilateral cleft lip repair in CLP Center Surabaya yielded good and symmetrically acceptable results. The study failed to observe the different outcomes of unilateral cleft lip repair based on completeness of the cleft lip and the presence of alveolar cleft. However, the unilateral cleft lip repair outcome was significantly better in the absence of palate cleft.

INTRODUCTION

The fact that cleft lip and/or palate is the most common congenital craniofacial abnormality, challenges plastic surgeons to carefully and skillfully manage it to avoid increasing morbidity (1). In Indonesia, the national incidence of CLP has not been reported but reports from various hospitals in major cities in Indonesia described the incidence to be around 0.49 – 1.23 per one thousand live births (2). Many of these patients had surgeries performed during charity missions since integrated cleft management is only available in major cities (3).

Unilateral cleft lip, in particular, demands high surgical skills aiming at restoring anatomical landmarks, bringing up symmetry between the medial and lateral lip

elements, and achieving normal facial movements (4,5). The features of the unilateral cleft lip are as follow: asymmetry of the nose due to the gap in the maxilla, abnormality of the orbicularis oris muscle attachment at the alar base on the side of the cleft and the base of the columella on the side of the cleft, and the lips in the unilateral cleft are shorter on the medial side with a more horizontal philtrum ridge and thinner vermillion, than on the lateral side (6–8).

The most popular technique used by surgeons to repair a unilateral cleft lip is the rotation-advancement technique from Millard (6,9,10). Among the popular modifications of the rotation-advancement techniques were those published by Mohler (11), Cutting (12), and Fisher (13).

There are several methods which

qualitatively assess the outcome of unilateral lip repairs such as the Asher-McDade system (14), the cleft lip evaluation profile index system (CLEP) (15), the aesthetic index (16), the unilateral cleft lip surgical outcome evaluation / UCL SOE scale (17), and the VLS system (18). There are quantitative measurement systems also, such as the craniofacial proportion measurement system (12,19). Of these various methods of measurement, only the Asher-McDade system has been validated (17,20,21). The CLEP, in particular, is interesting since it very simple and can be done not only by a plastic surgeon but also by other cleft care personnels.

Surabaya CLP Center has been providing integrated cleft care in Surabaya, which began in the year 2000 in collaboration with the Department of Plastic Reconstructive and Aesthetic Surgery Faculty of Medicine Universitas Airlangga and Dr. Soetomo General Academic Hospital. The technique for unilateral cleft lip repair in Surabaya CLP Center has been Millard's technique with Djo modification, or simply the "Djo technique" (22). This is the first study to assess the outcome of unilateral cleft lip repair in Surabaya CLP Center. This study aimed to assess qualitatively the outcome of unilateral cleft lip repair.

METHOD

Study Design

This was an observational study with a retrospective cohort design. Inclusion criteria in this study were photos of all patients who underwent unilateral cleft lip repair from 1st January 2017 to 31st December 2017, at CLP Center Surabaya. Only subjects whose clefts were repaired by plastic surgery residents in their fourth year of training were included in the study. Exclusion criteria were patients over 2 years old (104 weeks) at the time of the first surgery, those who were followed up less than 52 weeks, who underwent revision cleft lip surgery in less than one year after the first surgery, who underwent nasoalveolar molding (NAM), those with incomplete and substandard photographs, with

postoperative infections, and clefts repaired by junior plastic surgery residents under supervision. We assessed all subject characteristics: age, sex, completeness of the cleft, presence of alveolar cleft, and/or of cleft palate.

Unilateral Cleft Lip Repair

The technique applied all cases of unilateral cleft lip repair in Surabaya CLP Center was the "Djo technique". It was a modification of the Millard technique where an additional flap from a de-epithelized lateral segment of vermillion called the "Djo flap" was inserted subcutaneously underneath the thin vermillion to augment the philtral vermillion (22).

The unilateral cleft lip repair was followed with primary nasal correction using the Djo technique. The incision started transversely through the columella then moved toward the columella-alar angles always parallel to nostril rims. The skin was dissected superiorly to expose the lower lateral cartilages. The medial crus of the cleft side is repositioned and fixated to that on its contralateral side. This is followed by excision of any excess skin at the nasal rim (22).

CLEP Index Assessment

Cleft lip repair assessment used Modified CLEP Index (MCLEP) from the photographs database of Surabaya CLP Center. The difference between CLEP and MCLEP is summarized in **Table 1**.

Statistical Analysis

All data were processed with Microsoft Excel® for Mac version 14.6.9 (Microsoft Corporation) spreadsheet software. Statistical analysis was performed with the GNU PSPP (available at <https://www.gnu.org/software/pspp/>) version 1.2.0, free software under the terms of the GNU general public license (Free Software Foundation, Inc.). We used a 95% confidence interval for all statistical analysis purposes.

Table 1. The difference between CLEP and MCLEP

Subject	CLEP	MCLEP
Assessment Process	The patients select the CLEP standard images that resemble the patients' condition with the aid of cleft surgeon	Assessor chooses the outcome of unilateral cleft lip repair by comparing the patients' photographs with CLEP standard images
Lip Assessment	Scar Symmetry Philtral edge Volume of the upper lip Lip muscle function/ movement Volume-relation upper-lower lip	Scar Symmetry Philtral edge Volume of the upper lip
Nose Assessment	Symmetry tip of the nose Nostril symmetry Nostril size (area) cleft/non cleft side Nasal wing symmetry Tip of the Nose Size and form of the alae Position of the caudal septum	Symmetry tip of the nose Nostril symmetry Nasal wing symmetry
Scoring	0: Good 1: Acceptable Result 2: Clearly Visible Deformity	1: Good 2: Acceptable Result 3: Clearly Visible Deformity
Total Score	Best possible: 0 Worst possible: 26	Best possible: 7 Worst possible: 21

Table 2. Characteristics of the subjects

Characteristic		n	Percentage
Sex	Male	19	50%
	Female	19	50%
Cleft side	Left	21	55.3%
	Right	7	44.7%
Completeness of the cleft lip	Complete	16	42.1%
	Incomplete	22	57.9%
Alveolar cleft	Present	29	76.3%
	Absent	9	23.7%
Palate cleft	Present	20	52.6%
	Absent	18	47.4%

RESULT

Seventy-nine subjects were excluded from the 117 patients who underwent unilateral cleft lip repair in Surabaya CLP Center during the period. The exclusions were due to the incomplete and substandard photographs due to less than 52 weeks of follow up ($n = 48$), the age of the patients at the time of surgery exceeding 104 weeks old ($n = 12$), and under-supervision surgery by the second year plastic surgery trainees ($n = 19$). Thus, a total of 38 subjects were included in the study with the mean age at the time of surgery was 21.29 weeks (± 12.13) and the mean follow-up time was 61 weeks (± 9.49).

The characteristics of the subjects were presented in Table 2 and the assessment score results of unilateral cleft lip repair were presented in Table 3.

After completing the scoring process, the score of the lip, nose, and total was presented in the table and was statistically analyzed using independent t-test. Significant mean differences were found in the mean of total nose score between right and left cleft lip. When analyzed due to the presence of palate cleft, significant differences were also found in the mean of total lip score, mean of total nose score, and mean of total score as presented in Table 4. Using the chi-square test, significant differences in the presence of palate cleft were found in nostril symmetry ($p = 0.021$) and nasal wing symmetry ($p = 0.007$).

Table 3. Assessment of unilateral cleft lip repair

Assessment	Mean Score
Lip Scar	1.87 ± 0.47
Lip Symmetry	1.84 ± 0.49
Philtral Edge	1.97 ± 0.37
Lip Volume	1.55 ± 0.60
Total Lip Score	7.24 ± 1.30
Nose Tip Symmetry	1.58 ± 0.50
Nostril Symmetry	2.24 ± 0.59
Nasal Wing Symmetry	2.16 ± 0.64
Total Nose Score	5.97 ± 1.46
Total Score	13.21 ± 1.95

DISCUSSION

Presently this is the first study to analyze the outcome of unilateral cleft lip repair in Indonesia which were done by the fourth year trainees of Plastic Surgery Training Center in Surabaya. Furthermore, there has been a minimal quantitative study done in assessing the outcome of unilateral cleft lip repair in South East Asia. Outcome assessment of unilateral cleft lip repair is important not only for comparing one technique to another but also for refining the technique. Even Millard himself published revisions to his operating techniques after examining the results of his unilateral cleft lip repair (6).

The results of this qualitative assessment showed that unilateral cleft lip repair by the technique of Millard with Djo modification yielded acceptable scar and symmetry. However, the symmetry of the nose showed a significant difference, particularly in the right side cleft and in the presence of palate cleft.

A similar study in Taiwan showed that the best nose symmetry can be achieved by *nasoalveolar molding* and primary rhinoplasty with overcorrection (23). When done primarily with the repair of the cleft lip, a more symmetry in nasal cartilage may be yielded to shape a better appearance in early school years and maybe secondary repaired in the teens (24). Surgeons are advised to correct nasal deformity to achieve better nasal symmetry (22).

However, primary nasal correction is not always satisfactory. In a 15-year retrospective study in Indonesia, a primary nasal correction was not a guarantee that a secondary correction won't be needed when reaching puberty (25). A more popular advise was to do overcorrection with inverse-U incision (23,26,27). The subjective assessment in this study was not strong evidence to advise primary nasal correction with an overcorrection in unilateral cleft lip repair in CLP Center Surabaya.

The scar assessment in this study was probably the most significant finding. The repair showed good results a year after the surgery. Scar post unilateral cleft lip repair may be caused by intrinsic made by the surgeon's stitch, extrinsic stretch, and

individual response to tissue trauma (28). A surgeon may alter the stretch but not the individual response to tissue trauma.

Table 4. Total score of unilateral cleft lip repair outcome based on independent variables

Independent Variable		n	Mean of Total Lip Score	Mean of Total Nose Score	Mean of Total Score
Cleft Side	Right	7	6.71 ± 1.50	7.43 ± 0.98	14.14 ± 2.04
	Left	31	7.35 ± 1.25	5.65 ± 1.36	13.00 ± 1.90
		<i>p</i>	0.246	0.002	0.164
Cleft Lip	Complete	16	7.69 ± 1.58	6.19 ± 1.47	13.88 ± 2.03
	Incomplete	22	6.91 ± 0.97	5.82 ± 1.47	12.73 ± 1.78
		<i>p</i>	0.094	0.449	0.072
Alveolar Cleft	Present	29	7.41 ± 1.32	6.10 ± 1.50	13.52 ± 1.90
	Absent	9	6.67 ± 1.12	5.56 ± 1.33	12.22 ± 1.86
		<i>p</i>	0.135	0.332	0.081
Palate Cleft	Present	20	7.65 ± 1.35	6.55 ± 1.50	14.20 ± 1.70
	Absent	18	6.78 ± 1.11	5.33 ± 1.14	12.11 ± 1.60
		<i>p</i>	0.038	0.008	0.000

Photograph assessment was the main strength of this study. In limited resources and distant residence of the subjects, photographs assessment may provide data to measure the outcome of cleft surgery. The MCLEP index was not a complex measurement and all cleft care workers may be easily adapt to the assessment if necessary.

However, a subjective measurement was the main weakness of this study. Only one assessor involved in this study. It is advised to do the interrater assessment to further study the feasibility of the MCLEP index to assess unilateral cleft lip repair outcomes.

CONCLUSION

The unilateral cleft lip repair in CLP Center Surabaya yielded good and acceptable results. The study failed to observe the different outcomes of unilateral cleft lip repair based on completeness of the cleft lip and the presence of alveolar cleft. However, the unilateral cleft lip repair outcome was significantly better in the absence of palate cleft. In particular, the outcome of the nose was significantly better in the left side cleft, hypothetically due to a small number of right side cleft. A further

REFERENCES

1. Hopper RA. Cleft Lip and Palate: Embryology, Principles, and Treatment. In: Thorne CH, Chung KC, Gosain AK, Gurtner GC, Mehrara BJ, Rubin JP, et al., editors. Grabb and Smith's Plastic Surgery. 7th Ed. Philadelphia: Lippincott Williams & Wilkins; 2014. p. 173–99.
2. Kadri N, Ismael S, Raid N, Surhono A, Harianto A. Congenital Malformations and Deformations in Provincial Hospitals in Indonesia. Congenit Anom (Kyoto). 1995;35(4):411–23.
3. Ruslin M, Dom L, Tajrin A, Yusuf ASH, Arif SK, Tanra AH, et al. Establishing cleft services in developing countries: Complications of cleft lip and palate surgery in rural areas of Indonesia. Arch Plast Surg. 2019;46(6):511–7.
4. Trotman CA, Faraway JJ, Phillips C. Visual and statistical modeling of facial movement in patients with cleft lip and palate. Cleft Palate-Craniofac J. 2005;42(3):245–54.
5. Mulliken JB, LaBrie RA. Fourth-dimensional changes in nasolabial dimensions following rotation-advancement repair of unilateral cleft lip. Plast Reconstr Surg.

- 2012;129(2):491-8.
6. Millard DR. Cleft Craft: the Evolution of its Surgery, Vol 1: The Unilateral Deformity. Boston: Little, Brown & Co; 1976.
 7. Tse R. Unilateral cleft lip: Principles and practice of surgical management. *Semin Plast Surg.* 2012;26(4):145-55.
 8. Ettinger RE, Buchman SR. Cleft Lip and Palate: Embryology, Principles, and Treatment. In: Chung KC, editor. *Grabb and Smith's Plastic Surgery.* 8th Editio. Philadelphia: Wolters Kluwer; 2020.
 9. Sitzman TJ, Giroto JA, Marcus JR. Current Surgical Practices in Cleft Care: Unilateral Cleft Lip Repair. *Plast Reconstr Surg.* 2008;121(5):261e-270e.
 10. Roussel LO, Myers RP, Giroto JA. The Millard rotation-advancement cleft lip repair: 50 years of modification. *Cleft Palate-Craniofacial J.* 2015;52(6):e188-95.
 11. Mohler LR. Unilateral Cleft Lip Repair. *Plast Reconstr Surg.* 1987;80(4):511-6.
 12. Cutting CB, Dayan JH. Lip height and lip width after extended Mohler unilateral cleft lip repair. *Plast Reconstr Surg.* 2003 Jan;111(1):16-7.
 13. Fisher DM. Unilateral cleft lip repair: An anatomical subunit approximation technique. *Plast Reconstr Surg.* 2005;116(1):61-71.
 14. Asher-McDade C, Roberts C, Shaw WC, Gallagher C. Development of a Method for Rating Nasolabial Appearance in Patients with Clefts of the Lip and Palate. *Cleft Palate-Craniofacial J.* 1991;28(4):385-91.
 15. Ohannessian P, Berggren A, Abdiu A. The cleft lip evaluation profile (CLEP): A new approach for postoperative nasolabial assessment in patients with unilateral cleft lip and palate. *J Plast Surg Hand Surg.* 2011;45:8-13.
 16. Johnson N, Sandy J. An aesthetic index for evaluation of cleft repair. *Eur J Orthod.* 2003;25:243-9.
 17. Campbell A, Restrepo C, Deshpande G, Tredway C, Bernstein SM, Patzer R, et al. Validation of a Unilateral Cleft Lip Surgical Outcomes Evaluation Scale for Surgeons and Laypersons. *Plast Reconstr Surg - Glob Open.* 2017;5(9):1-7.
 18. Assuncao AGA. The V.L.S. classification for secondary deformities in the unilateral cleft lip. *Br J Plast Surg.* 1992;45(4):288-92.
 19. Edler R, Abd Rahim M, Wertheim D, Greenhill D. The use of facial anthropometrics in aesthetic assessment. *Cleft Palate-Craniofacial J.* 2010;47(1):48-57.
 20. Asher-McDade C, Dahl E, Molsted K, Prah Andersen B, Shaw WC. A Six-Center International Study of Treatment Outcome in Patients with Clefts of the Lip and Palate: Part 4. Assessment of Nasolabial Appearance. *Cleft Palate-Craniofacial J.* 1992;29(5):409-12.
 21. Mercado A, Russell KA, Hathaway R, Daskalogiannakis J, Sadek H, Long RE, et al. The Americleft study: An inter-center study of treatment outcomes for patients with unilateral cleft lip and palate part 4. Nasolabial aesthetics. *Cleft Palate-Craniofacial J.* 2011;48(3):259-64.
 22. Marzoeke D. Repositioning of the Nose in Primary Unilateral Cleft Lip Closure (Dissertation). Surabaya: Airlangga University Press; 1989.
 23. Chang CS, Por YC, Liou EJW, Chang CJ, Chen PKT, Noordhoff MS. Long-term comparison of four techniques for obtaining nasal symmetry in unilateral complete cleft lip patients: A single surgeon's experience. *Plast Reconstr Surg.* 2010;126(4):1276-84.
 24. Byrd HS, Salomon J. Primary correction of the unilateral cleft nasal deformity. *Plast Reconstr Surg.* 2000 Nov;106(6):1276-86.
 25. Sulaiman FK, Haryanto IG, Hak S, Nakamura N, Sasaguri M, Ohishi M. Fifteen-year follow-up results of presurgical orthopedics followed by primary correction for unilateral cleft lip nose in Program SEHATI in Indonesia. *Cleft Palate-Craniofacial J.* 2013;50(2):129-37.
 26. Tajima S, Maruyama M. Reverse-U Incision for Secondary Repair of Cleft Lip Nose. *Plast Reconstr Surg.* 1977;60(2):256-61.
 27. Lonic D, Morris DE, Lo LJ. Primary overcorrection of the unilateral cleft nasal deformity: Quantifying the results. *Ann Plast Surg.* 2016;77(00): S25-9.

28. Narayanan P V., Adenwalla HS. Unfavourable results in the repair of the cleft lip. Indian J Plast Surg [Internet]. 2013;46(2):171. Available from: <http://www.ijps.org/text.asp?2013/46/2/171/118591>