

## THE INFLUENCE OF CLEFT LIP AND PALATE SEVERITY ON SURGICAL OUTCOMES

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### ARTICLE INFO

**Keywords:** Cleft lip and Palate, labioplasty, craniomaxillofacial, good health and well-being, maternal health

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#### History:

Received: September 25, 2023

Revised: October 26, 2023

Accepted: November 16, 2023

Published: December 1, 2023

#### JRE : Jurnal Rekonstruksi dan Estetik

e-ISSN:2774-6062; p-ISSN: 2301-7937

DOI: 10.20473/jre.v8i2.47682

#### Open access :

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#### Available at:

<https://e-journal.unair.ac.id/JRE/>

#### How to cite:

Asparini, R. R., Nur

Khalida Zia, Sidharta, B. ., Sakthivel, J.

., & Naga, B. S. THE INFLUENCE OF

CLEFT LIP AND PALATE SEVERITY

ON SURGICAL OUTCOMES. Jurnal

Rekonstruksi Dan Estetik,2023. 8(2):

95-105.

### ABSTRACT

**Introduction:** An orofacial cleft is a congenital abnormality in which an abnormal opening or cleft of the lips and/or palate. There are three main types of orofacial clefts, specifically cleft lip (CL), cleft palate (CP), and cleft lip and palate (CLP). Data in 2017 showed that the most encountered characters are patients with cleft lip and palate. The distribution of the incidence of cleft lip and palate at Cleft Lip and Palate (CLP) Center Faculty of Medicine University of Muhammadiyah Malang was dominated by the complete unilateral type, which was 45.22%. Generally, the severity of cleft lip and/or palate is influenced by the severity of the preoperative cleft.

**Methods:** This study used a retrospective cohort design taken from 40 medical records at Cleft Lip and Palate (CLP) Center Faculty of Medicine University of Muhammadiyah Malang. The preoperative photo data were categorized according to the severity of the cleft, then postoperative photos were assessed according to the Visual Rating Chart (VRC) indicator.

**Results:** The intraclass correlation coefficient (ICC) reliability test between evaluators has a strength of > 0.8 on the outcome of lip and nose surgery and also > 0.9 on the outcome of the palate, indicating that there was no perception gap between evaluators. The Mann-Whitney non-parametric test had a significance of  $p < 0.05$ , indicating that there was a positive correlation between the severity of unilateral cleft lip and palate and the outcome of surgery.

**Conclusion:** There is a correlation between the severity of the unilateral cleft lip and palate and the surgical outcome.

### Highlights:

1. The severity of unilateral CLP was assessed by categorizing preoperative photo data based on the severity of the cleft, and this severity was then correlated with the surgical outcomes.
2. The research identified a positive correlation between the severity of unilateral cleft lip and palate and the outcomes of surgery.
3. This connection is associated with the way wounds heal, where the width of the gap and the precise tension of sutures are pivotal factors influencing surgical outcomes.

## INTRODUCTION

An orofacial cleft is a congenital abnormality resulting in an abnormal opening or cleft of the lips and/or palate. Asia has been reported to have the highest number of cleft lip incidences along with the most severe deformities.<sup>1</sup> Cleft lip and palate malformations remain the most prevalent congenital abnormalities, presenting significant challenges for Indonesia's healthcare system.<sup>2</sup> The annual incidence comprises 7,500 individuals born with cleft lip malformation and/or accompanied by a new palate.<sup>3</sup> Analysis of data from the Cleft Lip and Palate (CLP) Center at the Faculty of Medicine, University of Muhammadiyah Malang, reveals that the distribution of cleft lip and palate cases is predominantly the complete unilateral type, accounting for 45.22%, followed by the incomplete unilateral cleft at 18.41%.<sup>4</sup>

Assessment of surgical outcomes, based on severity, is imperative to provide feedback to the medical team, minimizing the occurrence of complications that may impact oral function, aesthetic appearance, nutritional intake, and speech development. Cleft lip and palate severity is categorized into two classifications: mild and severe. The evaluation employs a measurement of the ratio between cleft width and normal nostril width, objectively determined through the nostril width ratio (NWR) method, introduced by Campbell et al.<sup>5,6</sup> Mild severity is indicated by a cleft width ratio of less than 2, while the severe category encompasses a cleft width ratio exceeding 2.<sup>5</sup> Post-surgery, the severity assessment outcome for unilateral cleft lip and palate is divided into three assessments: lip, nose, and palate outcomes.<sup>7</sup> These are respectively categorized as good, moderate, and poor outcomes based on the visual rating chart. The good category shows almost no visible cleft and fistula so they do not require re-surgery. The moderate category shows cleft asymmetry and fistula formation requiring minor reconstructive procedures. The poor

category is described in the form of visible asymmetry and significant gap formation so needs a requires corrective surgery.

## METHODS

### Study Design

This study employs an observational analytic approach using a retrospective cohort method, utilizing medical record photos from the Cleft Lip and Palate (CLP) Center of the Medical Faculty at the University of Muhammadiyah Malang, Malang Indonesia. The study's sample comprises patients with unilateral cleft lip and palate who underwent surgery at the CLP Center of the Faculty of Medicine, University of Muhammadiyah Malang, during the period of 2019-2020. The study encompasses a cohort of 40 patients, all of whom underwent surgical interventions using a single fixed technique and under the care of a designated operator. The study protocol was approved by the Health Research Ethics Committee University of Muhammadiyah Malang to conduct this study (No.E.5a/264/KEPK-UMM/XII/2021).

### Preoperative Assessment

Preoperative cleft severity was graded utilizing the Unilateral Cleft Lip and Palate Severity Index. This assessment tool is based on defined guidelines that evaluate the overall appearance of the primary deformity and separates patients into 2 categories according to the progressive degree of lip and nose involvement (Figure 1).

The "complete cleft lip" category represents a condition where there is a total cleft in the lip, characterized by a nostril width ratio (NWR) of less than 2. This deformity is further characterized by a short hemicolumella, deviation of the columella and tip, posterior displacement of the alar base, and a slumping of the lower lateral cartilage. On the other hand, the "severe complete cleft lip" category describes a more severe form of a

complete cleft lip, with an NWR greater than 2, indicating that the width of the cleft side nostril is more than twice that of the noncleft side. In this case, there is a substantial gap between the medial and lateral elements, allowing for easy passage of the tongue or an endotracheal tube. This condition is accompanied by a significant nasal deformity where the alar is completely spread across the cleft, often resulting in a complete distortion of the normal alar curvature. The determination of the NWR can be observed in Figure 2.<sup>5</sup>



Figure 1. Unilateral Cleft Lip and Palate Severity Index<sup>5</sup>

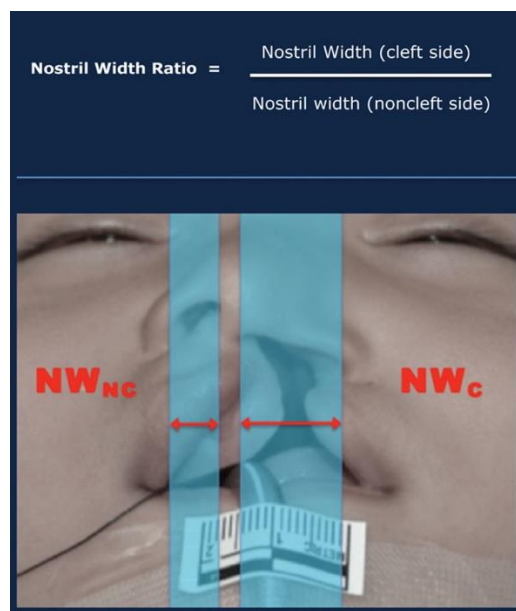


Figure 2. Calculation of Nostril Width Ratio (NWR)<sup>5</sup>

### Praoperative Assessment

An illustrative depiction of each distinct outcome was created, accompanied by a succinct textual description, resulting in the formulation of the Visual Rating Chart (VRC) (Figure 3). To simplify, the researchers categorized values 1 and 2 as "good" outcomes, value 3 as "moderate," and values 4 and 5 as "poor," indicating the need for additional surgical procedures. The assessment of surgical outcomes for unilateral cleft lip and palate cases took place at least 6 months after the surgery, involving a clinical examination. Acknowledging the subjectivity in outcome assessment, the researchers involved a panel of five evaluators to minimize potential bias, ensuring a thorough evaluation of the 40 photographic samples. (Figure 4).

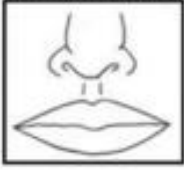











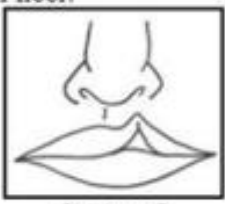


LIP REPAIRS	NASAL REPAIRS	PALATAL REPAIRS
<p><b>L I</b> - Lip is continuous in bulk, no notching at both vermilion borders i.e the white roll (WR) and the red line (RL).</p>  <p><b>Score = 1</b></p>	<p><b>N I</b> - Nostril is not flared, alar base symmetrically positioned and restoration of alar dome.</p>  <p><b>Score = 1</b></p>	<p><b>P I</b> - Complete palatal closure with a well formed 'U' shaped uvula.</p>  <p><b>Score = 1</b></p>
<p><b>L II</b> - Malalignment of WR, and/or differential lip bulk at surgical site.</p>  <p><b>Score = 2</b></p>	<p><b>N II</b> - Nostril not flared, dome restored, alar base asymmetry.</p>  <p><b>Score = 2</b></p>	<p><b>P II</b> - Complete palatal closure with clefting, disfigurement or shrinkage of the uvula.</p>  <p><b>Score = 2</b></p>
<p><b>L III</b> - Lip notched at either or both borders (i.e. WR and RL) without exposure of underlying teeth or gingiva.</p>  <p><b>Score = 3</b></p>	<p><b>N III</b> - Nostril not flared, dome not restored, ± alar base asymmetry.</p>  <p><b>Score = 3</b></p>	<p><b>P III</b> - An isolated hard palatal dehiscence between the incisive foramen and vibrating line.</p>  <p><b>Score = 3</b></p>
<p><b>L IV</b> - Isolated lip/nasal floor dehiscence.</p>  <p><b>Score = 4</b></p>	<p><b>N IV</b> - Nostril is flared.</p>  <p><b>Score = 4</b></p>	<p><b>P IV</b> - An isolated hard palatal dehiscence anterior to the incisive foramen.</p>  <p><b>Score = 4</b></p>
<p><b>L V</b> - Notching of lip involving at least 1/3 of lip length but not up to the nasal floor.</p>  <p><b>Score = 5</b></p>	<p><b>N V</b> - Shortened columella</p>  <p><b>Score = 5</b></p>	<p><b>P V</b> - Dehiscence involving the soft palate.</p>  <p><b>Score = 5</b></p>

Figure 3. The Visual Rating Chart - A Diagrammatic Description of the Outcome of Cleft Lip and Palate Repairs<sup>7</sup>



No	Pre Operative	Post Operative of lip and Nose	Post Operative of Palate
1	 <p>Mild</p>	 <p>- Lip: Good - Nose: Good</p>	 <p>Good</p>
2	 <p>Severe</p>	 <p>- Lip: Moderate - Nose: Poor</p>	 <p>Poor</p>
3	 <p>Severe</p>	 <p>- Lip: Poor - Nose: Moderate</p>	 <p>Moderate</p>

Figure 4. Postoperative Photographs Assessed by All Evaluator

### Statistical Analysis

The data analysis for this study involved two phases of reliability testing between assessors and a chi-square correlation test. In cases where the chi-square correlation test did not meet the criteria, it was followed by the Mann-Whitney non-parametric test. The ICC Test was used to assess reliability, aiming to reduce the inherent subjectivity in the evaluation of cleft lip and palate repair outcomes conducted by researchers and evaluators.

### RESULTS

In this study, the labioplasty procedure utilized the Noordhoff surgical technique, while the palatoplasty procedure employed the Von Langenbeck technique. When analyzing data collected between 2019 and 2020 from a sample size of 40 cases, it became apparent that the assessment of the severity of unilateral cleft lip and palate was primarily concentrated in the severe category. This severe category accounted for 22 cases, representing 55% of the total, in contrast to the mild category,

which consisted of 18 cases, amounting to 45% of the cases under investigation (Table 1).

Table 1. Distribution of Unilateral Cleft Lip and Palate Preoperative

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	Mild	18	45.0	45.0	45.0
	Severe	22	55.0	55.0	100.0
	<b>Total</b>	<b>40</b>	<b>100.0</b>	<b>100.0</b>	

In the assessment of individuals with unilateral cleft lip and palate, the data reflects varying outcomes across three key categories: lip, nose, and palate. Regarding lip outcomes, the majority of subjects, comprising 65.5% of cases, were categorized in the "good" category, indicating favorable results. A significant proportion, at 22.5%, fell into the "moderate" category, suggesting acceptable outcomes. The "poor" category had the lowest representation at 15%, indicating that a smaller number of individuals had less favorable lip outcomes. Moving on to the assessment of the nose, the data demonstrates that the "good" category was still the most frequent, with 42.5% of cases falling within this favorable outcome range. The "moderate" category accounted for 37.5% of cases, reflecting moderately positive results. The "poor" category, though less common, was represented by 20% of cases, signifying individuals with less favorable nose outcomes.

Finally, the palate assessment exhibited the highest frequency in the "moderate" category, encompassing 50% of cases. This suggests that a significant portion of individuals had satisfactory palate outcomes. The "good" category accounted for 32.5% of cases, indicating positive results, while the "poor" category was the least common, with 17.5% of cases showing less favorable palate outcomes.

The data reveals that "good" outcomes were predominant in both lip and nose assessments, while the "moderate" category was most prevalent in palate

assessment. "Poor" outcomes were the least common across all three categories, underscoring a generally favorable trend in the assessment of individuals with unilateral cleft lip and palate (Table 2).

Table 2. Characteristic Outcome of Unilateral Cleft Lip and Palate

Indicator Outcome	Mild	Valid Percent	Moderate	Valid Percent	Poor	Valid Percent
	Lip	25	62.5	9	22.5	6
Nose	17	42.5	15	37.5	8	20.0
Palate	13	32.5	20	50	7	17.5

The inter-rater reliability among assessors was assessed using the ICC reliability tests (Table 3). The significance of lip and nose assessments yielded values >0.8, signifying a robust and highly significant agreement among evaluators. The significance of palate assessment displayed values >0.9, indicating an almost perfect agreement among evaluators.

The initial step involved conducting a Chi-square correlation test to investigate the connection between the severity level of unilateral cleft lip and palate and the outcomes of surgical procedures. Since the expected count values were greater than 20%, the analysis was continued with the use of the non-parametric Mann-Whitney test. The Mann-Whitney test revealed that the  $p < 0.05$  for each surgical outcome, indicated a notable association between the severity of unilateral cleft lip and palate and the results of the surgical procedures, as shown in Table 4. The Mann-Whitney non-parametric test shows the value of each of the results of the operation is  $p < 0.05$  which means there is a significant relationship between the severity of unilateral cleft lip and palate and the outcome of surgery (Table 5).



Table 3. The Result of Intraclass Correlation Coefficient

		Intraclass Correlation	95% Confidence Interval		F Test with True Value 0			
			Lower Bound	Upper Bound	Value	df1	df2	Sig
Lip	Single Measures	.502	.359	.651	6.032	39	160	.000
	Average Measures	.834	.737	.903	6.032	39	160	.000
Nose	Single Measures	.545	.404	.687	6.980	39	156	.000
	Average Measures	.857	.772	.917	6.980	39	156	.000
Palate	Single Measures	.666	.541	.781	10.974	39	156	.000
	Average Measures	.909	.855	.947	10.974	39	156	.000

Table 4. The Crosstabs of Chi Square Test

Severity		Lip			Nose			Palate		
		Good	Moderate	Poor	Good	Moderate	Poor	Good	Moderate	Poor
		Mild	Frequency	16	0	2	11	6	1	11
	Expected Count	11.3	4.1	2.7	7.7	6.8	3.6	5.9	9.0	3.2
Severe	Frequency	9	9	4	6	9	7	2	14	6
	Expected Count	13.8	5.0	3.3	9.4	8.3	4.4	7.2	11	3.9

Table 5. The Result of the Mann-Whitney Test

	Test Statistics		
	Lip	Nose	Palate
Mann-Whitney U	112.000	114.500	84.000
Wilcoxon W	283.000	285.500	255.000
Z	-2.715	-2.444	-3.390
Asymp. Sig. (2-tailed)	.007	.015	.001
Exact Sig. [2*(1-tailed Sig.)]	.019	.022	.001

## DISCUSSION

A range of studies from various Asian countries, including the Palestinian Territories (35 births with CLP (1.01/1,000 live births))<sup>8</sup>, Thailand (784 patients with CL/CP (59.8%)), Singapore (16.72% per 10,000 live births)<sup>9</sup>, China (1.4 OFCs per 1000 live births)<sup>10</sup>, Pakistan (1574 instances of CLP)<sup>11</sup>, India (0.73 per 1,000 and 0.10 per 1,000 respectively)<sup>12,13</sup>, and Nepal (220 orofacial clefts)<sup>14</sup>, provide insights into the prevalence of cleft lip and palate (CLP) in different populations. In these studies, the incidence of CLP varies, with some showing a higher prevalence in males and different types of CLP, such as CL/CP, CPO, and CL.<sup>15</sup> For instance, Indonesia also faces a significant incidence of CLP, with 1,596 recorded cases.<sup>16</sup> These findings highlight the importance of

understanding and addressing CLP in diverse populations.

The results of this study showed that the incidence of cleft lip and palate unilateral weight category is more dominant than the mild category. This study is relevant to several studies in Asia that the incidence of cleft lip and palate complete more often found.<sup>6</sup> Many factors can contribute, one of which is the genetic factor of the TGF Gene and the Msx1 Gene.<sup>17</sup> Moreover, familial genetic evidence suggests an augmented likelihood of severity in siblings of individuals with cleft lip.<sup>18</sup>

In developed nations, most scientists hold the belief that cleft lip and palate (CLP) cases result from a combination of genetic and environmental factors, which include maternal illnesses, medication use, and malnutrition. In these countries, CLP is

typically detected prior to birth through ultrasonography. This early identification provides an opportunity for educating parents about potential causes and necessary post-birth procedures. Timely and age-appropriate treatment is essential for individuals with orofacial cleft deformities to ensure both functional and aesthetic well-being. The treatment process is intricate and demands a multidisciplinary and interdisciplinary approach. The occurrence of clefts in the lip and/or palate takes place in a critical orofacial region, typically before birth, rendering it a complex congenital deformity.<sup>19,20</sup>

The utilization of the ICC reliability test, involving a panel of five evaluators who meticulously examined 40 photographs, effectively curtailed subjectivity in evaluating surgical outcomes. This underscores the efficacy of the visual rating chart (VRC) introduced by Adeola and Oladimeji (2015) as a robust standard for assessing surgical results. This standardized VRC approach holds promise in furnishing patients with comprehensive information regarding treatment strategies and the management of primary and secondary enhancements.<sup>7</sup>

Labioplasty surgical outcomes at mild severity resulted in the output of good category surgery results that are very dominant, but there is an even distribution related to severe severity. Research by Abidin et al. (2015) revealed that it can occur as a result of the surgeon in charge being very experienced and skilled in handling cases of unilateral cleft lip. The study also revealed that mild cases will give better results.<sup>21</sup> Skillful operator selection and technique implementation contributed to favorable outcomes, with the Noordhoff technique proving effective in restoring function, symmetry, and aesthetic.<sup>22</sup>

Remarkably, the outcomes of lip surgery surpassed those of nose surgery in terms of percentages. This phenomenon is common in both unilateral and bilateral cleft lip and palate cases, attributed to the

transverse nasal muscle's incomplete insertion into the anterior nasal spine, which leads to medial alar cartilage dislocation and skin insertion posterior to the nasal ala due to columella length discrepancies.<sup>23</sup> Another study also explained that the results of the asymmetrical rhinoplasty are often associated with the width of the gap in both unilateral and bilateral cases although lip and nose surgery is performed at one time, so secondary rhinoplasty-related repairs are more recommended after facial growth has been completed to avoid scarring that affects the aesthetic and long-term adverse prognostic.<sup>24</sup>

Palatoplasty surgery outcomes demonstrated significant strength. This means that at mild severity it will produce better surgical output than at severe severity. Notably, the outcomes of palatoplasty exhibited a pronounced significance, suggesting that mild severity cases yielded superior surgical outcomes in contrast to severe severity cases. This aligns with research by Rossell-Perry et al. (2014), highlighting the link between cleft palate severity and palate fistula incidence.<sup>25</sup> The significance between severity and surgical outcomes on the palate frequently hinges on gap width, surgeon proficiency, appropriate procedure selection, and surgical technique. The von Langenbeck technique, employed in this study, is recognized for its simplicity and avoidance of palate lengthening attempts. Notably, modifications have been made to preserve the major Palatine vascular pedicle, thereby curbing scar formation that could impede facial growth and contribute to velopharyngeal incompetence.<sup>24</sup>

The study's limitations include a retrospective design with potential biases, focusing on a single center, a two-year analysis timeframe, subjectivity in outcome assessment, reliance on a single operator and technique, absence of adjustments for confounding variables, limited follow-up



duration, and scope limitations due to excluding speech development and patient satisfaction. These aspects call for careful interpretation, emphasizing potential gaps and the need for broader research.

The study boasts several notable strengths. This study lies in its approach to evaluating the relationship between cleft severity and surgical outcomes in a comprehensive manner, covering lip, nose, and palate categories using standardized techniques. This approach contributes to a deeper understanding of the factors that influence surgical success in cleft lip and palate patients. This study employed standardized surgical techniques, encompassing Noordhoff and Von Langenbeck procedures, ensuring uniform treatment approaches. The inclusion of a substantial sample of 40 patients undergoing unilateral cleft lip and palate surgery enhances the study's robustness. Comprehensive outcome evaluation across lip, nose, and palate categories provides a holistic perspective on surgical results. Furthermore, the clinical relevance of addressing the pertinent issue of cleft lip and palate repairs, coupled with the exploration of the relationship between severity and surgical outcomes, amplifies the study's practical implications. These combined strengths collectively bolster the study's credibility, potential for yielding valuable insights, and relevance within the realm of cleft lip and palate surgeries. The unique aspect of this study lies in its comprehensive evaluation of surgical outcomes for cleft lip and palate (CLP) patients, particularly those with unilateral cleft lip and palate. It differentiates itself from other studies by exploring the relationship between the severity of the cleft and the surgical results, covering lip, nose, and palate categories. This comprehensive approach allows for a more holistic understanding of the outcomes.

## CONCLUSION

The conclusion of this study has a significance value of  $p < 0.05$  with the non-parametric Mann-Whitney test. This study shows that there is a positive correlation between the severity of the unilateral cleft lip and palate to the output of surgery results. This correlation is rooted in the intricate dynamics of wound healing, influenced by intrinsic factors. Notably, a broader gap width is associated with a deteriorating prognostic trajectory of surgical outcomes. The meticulous tension applied to sutures is a key determinant, intricately intertwined with the wound healing process and tissue oxygenation. Oxygenation is the most important factor that can affect the wound healing process, where oxygenation is related to vascularization. Disruption to the wound healing process carries implications that reverberate through the outcome of surgical Interventions.

## ACKNOWLEDGMENTS

We would like to thank CLP Center FK UMM and the Faculty of Medicine University of Muhammadiyah Malang for their kind assistance and help during the research period.

## CONFLICT OF INTEREST

The authors declare no conflict of interest.

## FUNDING DISCLOSURE

This study received no external funding.

## AUTHOR CONTRIBUTION

RRA contributed to the study conception and design, analysis, and interpretation of the data, drafting of the article, critical revision of the article for important intellectual content, and final approval of the article. NKZ contributed to research concepts, statistical analysis, data

collection, and administrative, technical, or logistic support. BS contributed to the research concept, statistical analysis, and data collection. JS and BSN designed the research and contributed to critical revision of the article for important intellectual content. All authors approved the manuscript submission.

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