Original Article

Factors Affecting the Outcome of Unilateral Cleft Lip Repair Assessed Through Photographic Analysis

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ABSTRACT

The surgical outcome of unilateral cleft lip (UCL) helps clinicians evaluate symmetry and aesthetics. Hence, this study aims to evaluate the factors associated with the outcome of UCL repair based on photographic analysis. This study comprised 125 patients with UCL who underwent primary surgery (cheiloplasty) and were followed for 1 month. Clinical outcomes were as follows: 1. No correction was required; 2. Corrections of the lip were only 3. Redo Cheiloplasty. Factors affecting treatment outcomes, such as time of surgery, surgical technique, centers, cleft side, and severity, were evaluated. Standardized digital photographs of the patients' full face were considered for outcome assessment. Postoperative outcomes varied significantly by surgical technique, center, and case severity. Millard's technique yielded superior results, with 44.3% requiring no correction compared to 21.1% for Afroze, while lip-only corrections were more frequent with the Afroze technique (47.3%) ($p=0.019$). Center 2 achieved the best institutional performance (46.2% no correction), whereas Center 3 had the highest rate of lip-only corrections (47.4%) ($p=0.031$). Severity was a major determinant, with mild cases showing 64.4% without correction and only 11.1% requiring redo cheiloplasty, whereas severe cases had 50.0% undergoing redo cheiloplasty ($p<0.001$). The present investigation revealed that the outcomes of UCL reconstruction are influenced by the surgical technique, the surgical facility, and the severity of the UCL injury. These findings help practitioners to evaluate symmetry and aesthetics.

Key words: Afroze technique, Unilateral cleft lip, 2D photographic analysis, Treatment outcomes.

Introduction

The cleft lip (CL) is the most prevalent congenital abnormality [1, 2]. CL needs to be addressed through an interdisciplinary approach to address abnormalities in appearance and speech, as well as swallowing difficulties. Numerous varieties of cleft lip deformities frequently coexist with cleft palate [3, 4]. Patients can have a unilateral cleft lip (UCL) or a bilateral cleft lip. Infants with cleft lips frequently require numerous operations and multidisciplinary care [5, 6].

Parents and affected patients worry about aesthetic and functional limitations, especially when they become self-conscious because of an untreated abnormality or substandard treatment [7, 8]. Numerous psychological aspects are affected, including problems with peer integration, discrimination, feelings of inferiority, reduced confidence, and functional disruption. This condition affects overall health-related quality of life [9, 10]. Only solutions that are both cosmetically and functionally desirable can reduce this burden. Individuals with UCP may have full-thickness defects involving all tissue layers or defects limited to the vermilion [11, 12].

Owing to these differences in cleft lip appearance, several repair methods have been developed over time and are used to treat unilateral cleft lip. Ideal surgery for unilateral cleft lip/palate (UCL/P) aims to produce a symmetrical upper lip, with both sides having equal philtral column lengths [13, 14]. The scarring should avoid crossing the philtral column and should mirror the opposite side. Additionally, avoid cutting the vermilion or revealing the Cupid's bow on the cleft side. Furthermore, the Cupid's bow should be the right size. These requirements should be met in a single process, avoiding the need for several minor revision rounds [4, 15, 16].

The outcomes of UCL/P treatment can vary significantly depending on the timing and sequence of procedures, as well as the skills and experience of the surgeons involved [17, 18]. Therefore, assessing therapy outcomes is essential for selecting and applying the right level of care. [19, 20]. Because nasolabial presentation allows the midface to develop naturally and harmoniously while correcting the malformation, it may be one of the most important indicators of successful UCL therapy [21, 22]. Methods for assessing nasolabial presentation generally fall into two categories: quantitative and qualitative techniques. The former techniques use facial dimensions to objectively evaluate the magnitude of asymmetry and amount of aberrant morphology [23, 24].

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In qualitative approaches, scoring, ranking, indices, and scales are employed, as these methods tend to be more subjective when evaluating impairments related to appearance and facial aesthetics [25-28]. Although subjective evaluation of appearance and attractiveness is challenging, it usually reflects how the patient and broader society view facial disability [29, 30]. The present study aims to investigate the factors associated with the outcome of unilateral cleft lip repair using photographic analysis.

Materials and Methods

A retrospective comparative study was conducted using patients' clinical and facial photographic records from the repositories of a well-known center specializing in multiple cleft lip and palate cases. These centers maintained identical photographic standards.

Source of study population
Clinical records and facial photographs of non-syndromic patients were obtained from the archives of a renowned multiple cleft lip and palate center. Demographic data were collected from the centers between 2011 and 2019.
Center 1: St Thomas Hospital Chengannur
Center 2: BMES MG Hospital, Mumbai.

Center 3: Amar Facial Plastic Surgery Center and Dental Hospital, Gulbarga.

Inclusion criteria
- Non-syndromic CL children
- Subjects with unilateral CL
- Individuals aged > 3 months.
- Cheiloplasty had been performed

Exclusion criteria
- CLP is associated with syndromes.
- Subject with bilateral CL
- Secondary surgeries were performed.

Sampling method
A simple random sampling procedure was used to select 125 samples that met the study's inclusion or exclusion criteria. To avoid selection bias, an online "random number generator" application randomly assigned numbers to each UCL participant from all centers.

Research tools
- History and Examination record review of various centers' CLP children.
- Extraoral two-dimensional photographs.
- Adobe Photoshop CS6 software.
- Visual and measurable parameters

Data collection procedure
A medical information database was searched to identify patients with UCL who visited the study centers. Random sampling was applied when selecting all participants from the record repository of each center, adhering to strict eligibility and exclusion requirements. If all the requirements were satisfied, the patient was chosen. Data were collected from patients' folders.

The study population included 125 patients with UCL who had undergone primary surgery (cheiloplasty) and were followed for a month. Clinical outcomes were as follows: 1. No corrections were required; 2. Corrections of the lip were only 3. Redo Cheiloplasty. Factors that can influence treatment outcomes were assessed: time of surgery (6 months, more than 6 months), type of surgery (Millard, Afroze), different centers (center 1, center 2, center 3), cleft side (right or left).

Cleft severity index
The Cleft Lip Cleft Severity Index divides individuals into four groups based on the degree of their primary malformation and relies on established standards that assess the abnormality's visual appearance.

Mild incomplete cleft lip
When less than 50 percent of the lip height is cleft, moderate partial CL is classified as a grade one deformity. A minor nasal malformation and a muscle dip above the cleft are typical.

More severe incomplete cleft lip
A more serious incomplete cleft lip that extends upward beyond more than 50 percent of the lip height is referred to as a grade two deformity. It is easier to observe a nasal malformation. The floor of the nasal cavity is unharmed, though.

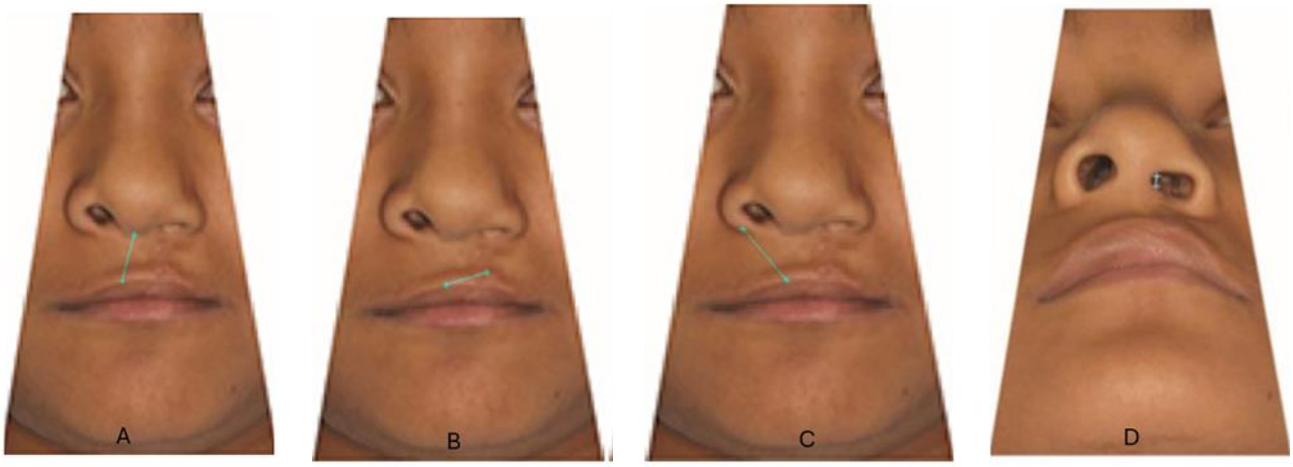
Complete cleft lip
When the nostril width ratio (NWR) is < 2, the entire cleft lip is classified as a grade 3 deformity.

Severe complete cleft lip
A severe complete cleft lip with an NWR greater than 2, or a cleft-side nostril width more than twice that of the non-cleft side, is referred to as a grade 4 deformity. The medial and lateral elements are widely spaced apart, making it easy for the endotracheal tube or tongue to fit. Additionally, there is a significant malformation of the nose, in which the alar is stretched across the cleft and is frequently entirely distorted from its usual curve, as stated by Campbell *et al*. [12].

Photography protocol
The camera type, distance, head position, lighting conditions, and background color were standardized in all three centers.

Visual parameters
Digital images of patients' faces, profiles, submental oblique views, and nasolabial regions were standardized for

aesthetic evaluation of the nasolabial region. To enhance contrast and minimize shadows, a light-coloured background was used as shown in **Figure 1**. The grading methodology followed that of Johnson and Sandy [13].



a) b) c) d)

Figure 1. Shows representative digital images used for the measurement of Various Parameters: a) Philtral height, b) Cupid's bow width, c) Lip height, and d) Columella

Intra-inter examiner reliability

A sample of 20 photographs was utilized to calculate intra-examiner reliability. The ICC value was 0.85, indicating good reliability. Similarly, adequate inter-examiner reliability was obtained (0.86).

Statistical analysis

All data were processed with IBM SPSS Statistics version 25 (Armonk, NY, USA). Frequency distributions and percentages were computed for the categorical variables. The data were organized into tables, and associations were assessed using the chi-square test at the five percent level.

Results and Discussion

This study evaluated 125 patients with unilateral cleft lip. 26 (20.8%), 80 (64.0%), and 19 (15.2%) patients were observed at the Kerala, Mumbai, and Gulbarga centers, respectively. Most patients were six months old (63.2%). The patients were followed up for 12 months (12%) and 24 months (11.2%). Males constituted 56.0% of the total study population. In 42.4% of patients, the cleft lip was on the right side, and in 42.4% on the left side. Millard's technique was used in 84.8% of patients, whereas the Afroze technique was used in 15.2%. All the patients had a Class I profile. **(Table 1)**.

Table 1. Characteristics of unilateral cleft lip patients

Characteristics		n	%
Centre	Center 1	26	20.8%
	Center 2	80	64.0%
	Center 3	19	15.2%
Age at surgery	6 months	79	63.2%
	>6 months	46	36.8%
Gender	Male	70	56.0%
	Female	55	44.0%
Cleft side	Right side	53	42.4%
	Left side	72	57.6%
Technique	Mullard's Technique	106	84.8%
	Afroze Technique	19	15.2%
Profile	**Class I**	**125**	**100.0%**

There were 79 patients with surgical care time of 6 months, and 46 with more than 6 months. Based on the evaluation of 2D clinical photographs, no correction was required in 34 (43.0%) patients, corrections at the lip only in 18 (22.8%) patients, and repeat cheiloplasty was required in 27 (34.2%) patients after 6 months of surgical care. On the other hand, no correction was required in 17 (37.0%) patients, corrections at the lip only in 11 (23.9%) patients, and redo-

cheiloplasty was required in 18 (39.1%) patients after more than 6 months of surgical care. The findings showed no statistically significant difference between patients who had surgery at different times (p=0.788). The surgical outcome did not show a significant link to the length of the procedure. **(Table 2)**.

Table 2. Factors associated with cleft lip surgical outcomes

Time of surgery	6 Months		>6 months		χ^2	df	p
	n	**%**	**n**	**%**			
No correction	34	43.0	17	37.0	0.478	2	0.788
Corrections at the lip only	18	22.8	11	23.9			
Redo Cheiloplasty.	27	34.2	18	39.1			
Total	79	100	46	100			
Surgical technique	**MIllards**		**Afroze**		**χ^2**	**df**	**p**
	n	**%**	**n**	**%**			
No correction	47	44.3	4	21.1	7.904	2	**0.019**
Corrections at the lip only	20	18.9	9	47.3			
Redo Cheiloplasty.	39	36.8	6	31.6			
Total	106	100	19	100			
Cleft side	**Right side**		**Left side**		**χ^2**	**df**	**p**
	n	**%**	**n**	**%**			
No correction	19	35.8	32	44.4	1.586	2	**0.453**
Corrections at the lip only	15	28.4	14	19.4			
Redo Cheiloplasty.	19	35.8	26	36.2			
Total	53	100	72	100			

Centre	**Centre 1**		**Centre 2**		**Centre 3**		**χ^2**	**df**	**p**
	n	**%**	**n**	**%**	**n**	**%**			
No corrections	10	38.5	37	46. 2	4	21.1	10.646	4	**0.031**
Corrections at the lip only	8	30.8	12	15.0	9	47.4			
Redo Cheiloplasty.	8	30.7	31	38.8	6	31.5			
Total	**26**	**100**	**80**	**100.0**	**19**	**100**			

In this study, 106 patients were managed using the Millard technique, whereas 19 patients were managed using the Afroze technique. No correction was needed in 47 (44.3%) patients, and correction at the lip was required in 20 (18.9%) patients. Redocheiloplasty was required in 39 (36.8%) patients managed using the Millard technique. On the other hand, no correction was required in four (21.1%) patients, corrections at the lip only in nine (47.3%) patients, and repeat cheiloplasty was required in six (31.6%) patients managed with the Afroze technique. The proportion of patients in whom no correction was performed was greater in the Maillard technique group. These findings were statistically significant. The proportion of patients requiring correction only at the lip was greater with the Afroze technique. The surgical technique was also notably linked to the surgical outcome. (p=0.019) **(Table 2)**.

It was observed that no correction was required in 10 (38.5%) patients, corrections at the lip only in eight (30.8%) patients, and repeat cheiloplasty was required in eight (30.8%) patients at center 1. Similarly, no correction was observed in 37 patients (mean age: 46. 2%), corrections at the lip only in 12 (15.0%) patients, and repeat cheiloplasty was required in 31 (38.8%) patients at center 2. Again, no correction was observed in 4 (21.1%) patients, corrections were limited to the lip in 9 (47.4%) patients, and repeat cheiloplasty was required in 6 (31.6%) patients at Center 3. The proportion of patients requiring no correction was highest at Center 2, followed by Centers 1 and 3. The proportion of patients requiring lip corrections was highest at Center 3, followed by Centers 1 and 2. There was a significant association between the surgical outcomes and the center where the surgery was performed. years (p=0.031), respectively **(Table 2)**.

In this study, 53 patients had a right-sided cleft lip, and 72 had a left-sided cleft lip. No correction was required in 19 (35.8%) patients, corrections at the lip only in 15 (28.4%) patients, and reoperation was required in 19 (35.8%) patients with cleft lip on the right side. On the other hand, no correction was required in 32 (44.4%) patients; corrections at the lip were required in 14 (19.4%) patients; and repairs were required in 26 (36.2%) patients with left-sided cleft lip. The difference in surgical outcomes between the right and left sides was not significant. Surgical results showed no significant link to which side of unilateral cleft lip was affected. (p=0.453) **(Table 2)**.

The proportions of surgical outcomes for patients with right- or left-sided cleft lip were similar across various centers,

with no statistically significant differences. (p=0.055, 0.533) **(Table 3)**. Analysis of sex disparity for surgical outcomes at various centers for cleft lip revealed that the impact of sex and center on surgical outcome was non-significant. (p=0.081 and p=0.393) **(Table 4)**.

Table 3. Surgical outcomes based on cleft sides in different centers

Side	Outcomes	Centre 1		Centre 2		Centre 3		Total		χ^2	p
		n	%	n	%	n	%	n	%		
Right	No correction	5	38.5	12	41.4	2	18.2	19	35.8	8.983	0.055
	Corrections at lip only	4	30.8	4	13.8	7	63.6	15	28.3		
	Redo Cheiloplasty	4	30.8	13	44.8	2	18.2	19	35.8		
	Total	13	100	29	100	11	100	53	100		
Left	No correction	5	38.5	25	49.0	2	25.0	32	44.4	3.209	0.533
	Corrections at lip only	4	30.8	8	15.7	2	25.0	14	19.4		
	Redo Cheiloplasty.	4	30.8	18	35.3	4	50.0	26	36.1		
	Total	**13**	**100**	**51**	**100**	**8**	**100**	**72**	**100**		

Table 4. Surgical outcomes based on gender in different centers

Gender	Outcomes	Centre 1		Centre 2		Centre 3		Total		χ^2	p
		n	%	n	%	n	%	n	%		
Male	No correction	4	25.0	17	39.5	1	9.1	22	31.4	8.291	0.081
	Corrections at lip only	7	43.8	8	18.6	6	54.5	21	30.0		
	Redo Cheiloplasty.	5	31.2	18	41.9	4	36.4	27	38.6		
	Total	16	100	43	100	11	100	70	100		
Female	No correction	6	60.0	20	54.1	3	37.5	29	52.7	4.094	0.393
	Corrections at lip only	1	10.0	4	10.8	3	37.5	8	14.6		
	Redo Cheiloplasty.	3	30.0	13	35.1	2	25.0	18	32.7		
	Total	**10**	**100**	**37**	**100**	**8**	**100**	**55**	**100**		

This study involved 45 patients with complete cleft lip and 80 with severe complete cleft lip. No correction was needed for 29 patients (64.4%), while 11 patients (24.4%) received corrections solely on the lip. Redocheiloplasty was required in 5 (11.1%) patients with complete cleft lip. On the other hand, no correction was required in 22 (27.5%) patients; corrections at the lip were only required in 18 (22.5%) patients, and repeat cheiloplasty was required in 40 (50.0%) patients with severe complete cleft lip. It was observed that the proportion of patients requiring cheiloplasty was greater in those with severe complete cleft lip. There was a significant association between cleft lip severity and surgical outcomes. (p <0.001). Moreover, the proportion of patients with negative surgical outcomes, such as redo cheiloplasty, was higher among those with severe complete lip at all centers where cleft lip was managed surgically. However, different centers did not affect surgical outcomes **(Table 5)**.

Table 5. Surgical outcomes based on cleft severity treated in different centers

Severity/Centres	Outcomes	Complete cleft lip		Severe complete cleft lip		χ^2	p
		n	%	n	%		
Severity	No correction	29	64.4	22	27.5	21.780	<0.001
	Corrections at lip only	11	24.4	18	22.5		
	Redo Cheiloplasty.	5	11.1	40	50.0		
Centre 1	No correction	6	66.7	4	23.5	4.484	0.099*
	Corrections at lip only	2	22.2	6	35.3		
	Redo Cheiloplasty.	1	11.1	7	41.2		

Centre 2	No correction	21	70.0	16	32.0	16.893	<0.001
	Corrections at lip only	6	20.0	6	12.0		
	Redo Cheiloplasty.	3	10.0	28	56.0		
Centre 3	No correction	2	33.3	2	15.3	1.346	0.695*
	Corrections at lip only	3	50.0	6	46.2		
	Redo Cheiloplasty.	1	16.7	5	38.5		
***Fisher's exact test**							

This study assessed surgical treatment outcomes using photographic analysis and examined how factors such as timing of surgery, surgical technique, treatment center, UCL side, sex, and UCL severity relate to these outcomes. In this study, 106 patients were managed with the Millard technique, and 19 with the Afroze technique. The proportion of patients in whom no correction was performed was higher in the Millard technique group. These findings were statistically significant. The proportion of patients requiring correction only at the lip was higher with the Afroze technique. The surgical technique was also significantly associated with the surgical outcome (p=0.019). In this study, the difference in findings between patients who underwent surgery at different times was not statistically significant (p=0.788). This showed that the surgical outcome was not significantly associated with the duration of surgery.

Several studies, including Tse [9], have also reported that the surgical technique significantly affects the outcomes of UCL procedures. Adetayo *et al*. [23] reached a similar conclusion in their study. These findings were similar to those of the present study. Comparisons of the results of various repair procedures for unilateral cleft lip have not been extensively studied [19, 22]. Fewer studies have compared the two most popular techniques [28, 29]. The appearance of the nasal cavity is among the most crucial indicators of the effectiveness of cleft lip repair therapies. In line with earlier research by Tan *et al*. [30] and Zaleckas *et al*. [22], nasolabial appearance was used to evaluate treatment outcomes in this investigation. Similarly, several authors have utilized an existing scar in the nasolabial area following cleft surgery to evaluate the efficacy of cleft lip repair [7, 23]. Most research has found that having more assessors increases reliability and reduces inter-examiner bias [29, 30].

It was observed that the proportion of patients requiring cheiloplasty was greater in those with severe complete cleft lip. There was a significant association between CLP severity of cleft lip and surgical outcomes. When assessing the results of cleft repair, the patient's perspective on the procedure is a crucial factor. Most trial participants expressed great satisfaction with the appearance of the scar and, consequently, with the repair, in both the Millard and Afroze groups. This suggests that surgical correction of a unilateral cleft lip is important and may offer hope to patients and their parents. This is consistent with earlier research by Christofides *et al.* [4], where parents/patients rated most repairs made using either technique as good. One possible reason for this could be the patients' or parents' perception that the correction significantly improves the deformity [23, 24]. Additional factors contributing to this situation include the trust parents and patients place in caregivers, as well as their anxiety that their criticism would be interpreted as a lack of appreciation. Another possible explanation for the high patient/parent satisfaction percentages documented is respect for caregivers [21-26].

The proportion of patients requiring no correction was highest at Center 2, followed by Centers 1 and 3. The proportion of patients requiring lip corrections was highest at Center 3, followed by Centers 1 and 2. There was a significant association between the surgical outcomes and the center where the surgery was performed. This shows that treatment outcomes vary depending on the expertise and training of individual surgeons. The difference in the proportions of different surgical outcomes between the right and left sides was not significant. Surgical outcomes were not significantly associated with the side of the unilateral cleft lip. Analysis of sex disparity for surgical outcomes at various centers for cleft lip revealed that the impact of sex and center on surgical outcome was not statistically significant (p=0.081 and p=0.393)

A previous study by Adetayo *et al*. [23] reported that the wider the cleft deformity, the worse the outcome of nasal repair. However, a skilled and experienced surgeon can still produce an excellent nasal appearance in cases with broad cleft abnormalities. Nonetheless, several authors have suggested a presurgical orthopedic method for large cleft deformities. The findings of this study are similar to those of our study, which also revealed different treatment outcomes across centers for surgical repair.

Conclusion

The present study reported surgical treatment outcomes based on photographic analysis and found a significant association between factors such as surgical technique, center of surgical management, and UCL severity and treatment outcomes. Mild UCL cases treated with Miller's technique in center 2 showed better outcomes.

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Conflict of interest: None

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Ethics statement: This study was conducted in accordance with the guidelines of the Declaration of Helsinki and was approved by the Research Center of Universiti Sains Malaysia, Kubang Kerian, Kelantan 16150, Malaysia (USM/JEPem/21080534).

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