






Qualitative Assessment of Surgical Repair of Three Types of Unilateral Cleft Lip

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Academic Editor: Alidianne Fábila Cabral Cavalcanti

Received: 28 April 2021 / **Review:** 17 September 2021 / **Accepted:** 02 November 2021

How to cite: Adetayo AM, Taiwo AO, Adetayo MO, Akinola MA, Adeyemo WL. Qualitative assessment of surgical repair of three types of unilateral cleft lip. *Pesqui Bras Odontopediatria Clín Integr.* 2022; 22:e210085. <https://doi.org/10.1590/pboci.2022.032>

ABSTRACT

Objective: To assess the effect of the three types of unilateral cleft lip (UCL) [cleft lip only, cleft lip and alveolus, and cleft lip alveolus and palate] on the outcome of the repair. **Material and Methods:** This study was a case series of effect of types of UCL on the outcome of the repair. Fifteen subjects each were in three UCL phenotypes groups. Evaluation of the scar, lip, and nose was done qualitatively by both parents/guardians and professionals using a modified form of the criteria described by Christofides et al. (2006). **Results:** In the assessment of the surgical scar, the parents found a difference between the three types of cleft in terms of texture, shape, and width of the scar and presence of columella deviation. The professional assessors, however, only found the three types of cleft to be different in the presence of alar flattening. **Conclusion:** Differences truly exist in the outcome of surgical repair of the three types of unilateral cleft lip, especially in the aesthetics of the nose and in the width and shape of the residual lip scar. Thus, it is important to consider this in the assessment of UCL repair because putting the subtypes together might have a negative impact on the assessment.

Keywords: Congenital Abnormalities; Stomatognathic System Abnormalities; Cleft Palate.

Introduction

The goals of cleft lip repairs are to normalize the face with barely visible scars, symmetrical lips, nose, and nostrils with an open and functional airway that would allow normal speech development [1,2]. Therefore, the ideal operation for the repair of a unilateral cleft lip (UCL) should result in a symmetrical upper lip and nose with the equal philtral column length on either side [3]. Furthermore, the Cupid's bow should be of adequate proportions. These criteria should be obtainable in a single operation without multiple minor revisional procedures [3]. The range of outcomes of the treatment of cleft lip and palate can, however, be considerable due to many variables, including types/severity of cleft, variation in the sequence, timing and technique of treatment, the organization and delivery of care, as well as in the skills and experience in the individual surgeons [4,5].

The major phenotypes of UCL (cleft lip only, cleft lip and alveolus, and cleft lip alveolus and palate) are generally assumed to represent the extent of severity of UCL in that order [6]. The degree of tissue distortion in cleft lip and/or palate is dependent on the type of cleft [7]. As observed by Suzuki et al. [7], the degree of displacement of the tissues in the isolated cleft lip is minimal and the facial anatomy is very close to the normal population [7]. This, however, is worse in subjects with cleft lip and palate, especially in bilateral clefts [8]. And so, this degree of tissue distortion might affect the degree to which the tissue can be apposed in unilateral cleft lip repair, ultimately affecting the outcome of surgical repair.

The severity of unilateral cleft lip (UCL) has been correlated with the extent of facial tissue distortion by only a few studies [7,9], where measurements were made from dental casts [7] or where an index was used to quantify the extent of tissue distortion preoperatively and was also used to determine the aesthetics of the repaired cleft lip-nose postoperatively [9]. The assessment of facial attractiveness and nasolabial appearance, as seen in cleft lip repair, however, remains essentially a subjective opinion, which may be regarded as complex and highly individual [10]. Nicola and Jonathan [11] concluded that the general public and patient's perception is likely to reflect the true nature of facial impairment, and Trotman et al. [12] went further in their study that evaluation of cleft lip repair would be best done with a method that involves both professional and laypeople [12].

Nollet et al. [13] also affirm that the continuous audit of the outcome of surgical repair of the cleft lip and palate deformity serves as a benchmark for comparing the surgical outcome results, and it can expose critical areas that would require improvement. In addition, this audit might further facilitate adequate patient information about expected treatment outcomes after surgery [13].

This study is unique as it attempts to assess the effect of types (severity) of UCL on the outcome of surgical repair using evaluation by professionals (maxillofacial surgeons) and laypeople (parents/guardians). The aim was to evaluate the effect of types of unilateral cleft lip on treatment outcome, following repair of unilateral cleft lip.

Material and Methods

Study Design

This study was a prospective case series study of the effect of the three types of unilateral cleft lips (cleft lip only, cleft lip and alveolus, and cleft lip alveolus and palate) on the treatment outcome of surgical repair of unilateral cleft lip.

Ethical Clearance

It was carried out from 1st of January 2013 to 31st of July 2014. The study was approved by the Health Research and Ethics Committee on 9th October 2012 (IRB number 34512). Written informed consent was obtained from parents/guardians of all subjects before enrolment in the study. Prior to this, detailed information and explanations of the study were given to the parents or guardians. Every one of them was given an opportunity to ask questions concerning the study, and appropriate clarifications were given before the commencement of the study. The opportunity to withdraw at any stage of the study was also made known without victimization or denial of treatment.

Sampling

The sample size for this study was determined by using the formula for cohort and case-control study as proposed by Schlesselman [14]. The attrition rate was 10% to cater to dropouts, so the sample size was 27.5, approximated to 28; nevertheless, 45 were used. This was statistically stratified into three to make each group (cleft lip only, cleft lip and alveolus, and cleft lip alveolus and palate) contain 15 subjects. Subjects were recruited from the cleft clinic of the University Hospital.

The following inclusion criteria were adopted: 1) Subjects with complete unilateral cleft lip with or without alveolus and palate; 2) Subjects who were 3 months old and above. In addition, as exclusion criteria, the following were established: 1) Subjects with bilateral cleft lip with or without palate; 2) Subjects with syndromic cleft of the lip and/or palate; 3) Subjects who were less than 3 months old; 4) Subjects who required cleft lip revision following primary cleft lip repair and 5) Subjects who were not fit for general anaesthesia.

Data Collection and Preoperative Evaluation

The following data were recorded preoperatively on a proforma: age, sex, weight, height, and type of clefts. Routine preoperative blood investigations, including haemoglobin estimation, electrolyte, urea and creatinine level, and electrocardiography, were done for each subject. Echocardiography was also done when indicated. Subjects were referred to the paediatrician for clinical evaluation to rule out congenital cardiovascular anomalies, upper respiratory tract infections, ear infections and other congenital anomalies that may be of clinical significance. Subjects were at least 3 months old, 4.5kg (10 pounds), with a minimum haemoglobin concentration of 10g/dl.

Operative Procedure

All subjects had their surgical repair done under general anaesthesia with endotracheal intubation. Two Oral and Maxillofacial surgeons skilled in the Millard-Rotation advancement technique of cleft lip repair with the same number of years of experience performed the operation. When the depth of anaesthesia was judged to be adequate, the important landmarks usually present on unilateral cleft lip, viz-a-viz, peak of the Cupid's bow, lowest point of the Cupid's bow, either sides of the columella at its junction with the lip, and the mid-point of the alar base, among others, were marked and surgical site was infiltrated with adrenaline (1:200,000), before making an incision. Primary rhinoplasty was not done as it was delayed till the time of secondary alveolar grafting.

Surgical outcome was assessed by using the qualitative method. The qualitative method was a modified form of the criteria described by Christofides et al. [3]. This method of assessment has also been used by Christofides [15] in 2009 and by Adetayo et al. [16]. This evaluation was carried out by both the subjects/guardians and independent assessors. The scoring indices essentially assessed the surgical scar, lip, and nose.

The evaluation by the assessors was carried out by three experienced surgeons (different from the operating surgeons). Initially, the assessment was done independently and then together by the three assessors to resolve any differences in their results. The final results were reached by consensus. The three assessors met before the commencement of the project to study the modalities of the scoring index. This evaluation was done by means of clinical evaluation using the modified form of the criteria {symmetry of nostrils, and centrality of the columella, thickness of the lip scar, thickness of the scar at the nasal sill, peaking, notching} as described by Christofides et al. [3] and as shown in the evaluation form.

For the 2nd part of the qualitative assessment, the parents/guardian completed a questionnaire to assess satisfaction with the treatment of his/her ward. The questionnaire was interpreted to the patient/guardian, where he/she was not literate. The questionnaire consisted of an evaluation of satisfaction with scar and nose appearance. The colour, shape and thickness of the scar were used to assess the residual lip scar by the patients/guardians, while the presence or absence of flattening of the nose at the cleft side, as well as deviation of the columella, were used to assess the nose.

The pre- and post-operative pictures for each group (CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus, and Palate) are shown in Figure 1.



Figure 1. (A) Cleft lip only; (B) Cleft lip and alveolus; and (C) Cleft lip alveolus and palate.

Data Analysis

Data analysis was performed using the Statistical Package for Social Sciences (SPSS) for Windows (version 23.0, SPSS Inc., Chicago, IL, USA). Proportions and percentages of the variables assessed were compared with each other with the use of Chi-square. An inter-rater reliability analysis using Cohen's kappa statistic was also performed to determine coherence among raters (The inter-rater reliability for the raters was 0.85, 95% CI). A significance level of $p \leq 0.05$ was used. Statistical significance was $p \leq 0.05$.

Results

Forty-five subjects requiring repair of unilateral cleft lip were enrolled for the study and analysed. Fifteen subjects each were in cleft lip, cleft lip and alveolus, and cleft lip, alveolus and palate groups. Of the 45, 25 (55.6%) were males, and 20 (44.4%) were females, in a ratio of 1.3:1.

In the colour and thickness evaluation, the majority (more than 80%) were either very happy or happy with the colour and thickness of the scar. The comparison between the three groups was not significant ($p > 0.05$). However, there is a difference between the three groups in terms of texture, shape and width of the scar. Fifteen (100%) were very happy or happy with the scar texture in the cleft lip only, compared with 11 (73%) in CLA group; 13 (86.6%) were very happy with the scar shape in the cleft lip only group compared with 11 (73%) in CLA group, and 15 (100%) were very happy or happy with the scar width in CLO group compared with 12 (80%) in the other two groups ($p = 0.003$, $p = 0.037$, and $p = 0.003$) (Table 1).

Table 1. Parents/guardians evaluation of the surgical scar in CLO, CLA and CLAP groups.

Surgical Outcome	CLO N (%)	CLA N (%)	CLAP N (%)	p-value
Colour of Scar				
Very Happy	13 (86.7)	14 (93.3)	15 (100.0)	0.343
Happy	2 (13.3)	1 (6.7)	0 (0.0)	
Okay	0 (0.0)	0 (0.0)	0 (0.0)	
Unhappy	0 (0.0)	0 (0.0)	0 (0.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Texture of Scar				
Very Happy	11 (73.3)	11 (73.3)	13 (86.7)	0.003
Happy	4 (26.7)	0 (0.0)	0 (0.0)	
Okay	0 (0.0)	3 (20.0)	1 (6.7)	
Unhappy	0 (0.0)	1 (6.7)	1 (6.7)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Thickness of Scar				
Very Happy	13 (86.7)	11 (73.3)	12 (79.9)	0.322
Happy	2 (13.3)	1 (6.7)	1 (6.7)	
Okay	0 (0.0)	2 (13.3)	1 (6.7)	
Unhappy	0 (0.0)	1 (6.7)	1 (6.7)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Shape of Scar				
Very Happy	13 (86.7)	11 (73.3)	12 (79.9)	0.037
Happy	0 (0.0)	2 (13.3)	1 (6.7)	
Okay	2 (13.3)	2 (13.3)	1 (6.7)	
Unhappy	0 (0.0)	0 (0.0)	1 (6.7)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Shape of Scar				
Very Happy	13 (86.7)	12 (79.9)	9 (60.0)	0.003
Happy	2 (13.3)	0 (0.0)	3 (20.0)	
Okay	0 (0.0)	2 (13.3)	3 (20.0)	
Unhappy	0 (0.0)	1 (6.7)	0 (0.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

The largest number of parents/guardians was recorded to be very happy or happy with the Cupid's bow in CLO group (n=10; 66.7%), while the least number 7 (46.7%) was recorded in CLAP group. The comparison was not significant (p=0.833) (Table 2).

Table 2. Parents/guardian evaluation of Cupid's bow.

Surgical Outcome	CLO N (%)	CLA N (%)	CLAP N (%)	p-value
Cupid's Bow				
Very Happy	6 (40.0)	6 (40.0)	6 (40.0)	0.343
Happy	4 (26.7)	2 (13.3)	1 (6.7)	
Okay	4 (26.7)	5 (33.4)	6 (40.0)	
Unhappy	1 (6.7)	2 (13.3)	2 (13.3)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

The highest number, 14 (93.3%) of nostril was taken to be flattened by the parents/guardians in CLAP group compared with 10 (66.7%) in the CLO group. Therefore, the comparison was not significant (p=0.066). However, there was a difference in the evaluation of the columella with CLA and CLAP groups having 12 (80%) columella deviated compared with 8 (53.3%) in the CLO group (p=0.050) (Table 3).

The assessors adjudged the scar on the lip to be levelled with the surrounding in 9 (60%) in CLO group but only 7 (46.7%) of the CLA group, while the thickness of the scar at the nasal sill was taken to be

levelled in 12 (80%) in the CLA group but only 8 (53.3%) in both CLO and CLAP group. The comparison did not show any statistically significant difference between the three groups for either the lip scar ($p=0.333$) or the nasal scar ($p=0.324$). Similarly, keloid/hypertrophic scar was found in 2 (13.3%) in the CLO group compared to 4 (26.7) in the CLAP group. There was no statistically significant difference between the three groups ($p=0.306$) (Table 4).

Table 3. Parents/guardian evaluation of the Nostril.

Surgical Outcome	CLO	CLA	CLAP	p-value
	N (%)	N (%)	N (%)	
Presence of Nasal Flattening at Cleft Side				
Yes	10 (66.7)	13 (86.7)	14 (93.3)	0.060
No	5 (33.3)	2 (13.3)	1 (6.7)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Columella Deviation				
Yes	8 (53.3)	12 (80.0)	12 (80.0)	0.050
No	7 (46.7)	3 (20.0)	3 (20.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

Table 4. Assessors' evaluation of the scar in CLO, CLA and CLAP groups.

Surgical Outcome	CLO	CLA	CLAP	p-value
	N (%)	N (%)	N (%)	
Thickness of Scar				
Level with Surrounding	9 (60.0)	7 (46.7)	8 (53.3)	0.333
Depressed	0 (0.0)	1 (6.7)	1 (6.7)	
Elevated	6 (40.0)	7 (46.7)	6 (40.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Nostril Scar				
Level with Surrounding	8 (53.3)	12 (80.0)	8 (53.3)	0.324
Depressed	1 (6.7)	0 (0.0)	1 (6.7)	
Elevated	6 (40.0)	3 (20.0)	6 (40.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Keloid or Hypertrophic Scar				
Yes	2 (13.3)	2 (13.3)	4 (26.7)	0.306
No	13 (86.7)	13 (86.7)	11 (73.3)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

There were 3 (20%) lips that were taken to have peaking in the CLO group compared to 7 (46.7%) in the CLAP group. Similarly, nothing was found in 3 (20%) lips in the CLO group compared to 5 (33.3%) in the CLAP group. There was no statistically significant difference in the comparison for peaking ($p=0.067$) or for lip notching ($p=0.361$) (Table 5).

Table 5. Assessors' evaluation of the lip in CLO, CLA and CLAP groups.

Surgical Outcome	CLO	CLA	CLAP	p-value
	N (%)	N (%)	N (%)	
Peaking				
Yes	3 (20.0)	7 (46.7)	7 (46.7)	0.067
No	12 (80.0)	8 (53.3)	8 (53.3)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Notching				
Yes	3 (20.0)	5 (33.3)	5 (33.3)	0.361
No	12 (80.0)	10 (66.7)	10 (66.7)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

The assessors adjudged 6 (40%) nostrils to be symmetrical in the CLO group but only 3 (20%) in the CLAP group. Meanwhile, 13 (86.7%) of columella were said to be central in the CLO group compared to 9 (60%) in the CLAP group. The comparison did not show any significant difference between the groups for a number of symmetrical nostrils ($p=0.063$) or for centrality of columella ($p=0.055$). However, 6 (40%) alae were adjudged flattened in the CLO group compared to 11 (73.4) in the CLAP group. There was a significant difference between the three groups ($p=0.036$) (Table 6).

Table 6. Assessors' evaluation of the nostril in CLO, CLA and CLAP groups.

Surgical Outcome	CLO N (%)	CLA N (%)	CLAP N (%)	p-value
Nasal Symmetry				
Yes	6 (40.0)	8 (53.3)	3 (20)	0.063
No	9 (60.0)	7 (46.7)	12 (80)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Centrality of Columella				
Yes	13 (86.7)	9 (60.0)	9 (60.0)	0.055
No	2 (13.3)	6 (40.0)	6 (40.0)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	
Alae on Cleft Side				
Normal	9 (60.0)	8 (53.3)	4 (26.7)	0.036
Flattened	6 (40.0)	7 (46.7)	11 (73.3)	
Total	15 (100.0)	15 (100.0)	15 (100.0)	

CLO: Cleft Lip Only; CLA: Cleft Lip and Alveolus; and CLAP: Cleft Lip, Alveolus and Palate.

Discussion

In this study, the evaluation of the color and thickness of the residual scar did not show any difference between the three types of UCL. This might not be unexpected as color and thickness seem to be an intrinsic attribute of an individual [17]. The comparison of texture, shape and width, however, showed a difference between the three UCL types. A plausible explanation might be that the force required in bringing the medial and lateral segments in CLA and CLAP is likely to be higher than that required in CLO, and this will create tension that tends to increase the width or alter the shape of the scar from a normal thin line. The physical and biological characteristics of a surgical scar depend on incision designs and accurate intraoperative techniques, such as the absence of tension and accurate approximation, among others [17]. As stated previously, tension along the suture line increases with increased severity (width and distortion) of UCL [9]. Another possible explanation is the unequal width of the lateral and medial cleft segments that worsens with increased tissue distortion associated with severe clefts. This might also play a role in determining the shape, width and texture of the final scar [18,19].

Tension along the wound edges is known to intensify all the phases of wound healing leading to a more prominent surgical scar [17,20]. However, in contrast to this assertion, the assessors did not see any significant difference between the three groups as regards the thickness of the scar on the lip and nasal sill and the presence of keloid/hypertrophic scar, even though CLAP group had a higher number of scars not level with the surrounding skin and also had more keloid/hypertrophic scar than were seen in the CLO and CLA group. The reason for this might be because the three surgeons are highly skilled and could compensate for the differing severities of the UCL with different tissue manoeuvres.

The comparisons of the cupid's bow in the three groups by the parents did not also reveal any difference between the three groups, even though most parents/guardians were either very happy or happy in

the CLO group compared to other groups. Similarly, the assessors' opinion on the presence of peaking and notching (a feature of a repaired Cupid's bow) also did not reveal any significant difference between the three groups. The explanation might be because of the prominent central position of the Cupid's bow, and so surgeons would try as much as possible to reproduce the cupid's bow as near-normal as possible. This finding is also echoed in a previous study by Adetayo et al. [16] in that surgeons try to reproduce a near-normal Cupid's bow, but this is in contrast to the findings by Hoods et al. [21] and Hoh and Sulaiman [22] that the outcome of the cupid's bow worsens with increased preoperative cleft severity.






The nasal assessment by the parents/guardians showed no significant difference between the three groups in the presence of nasal flattening, even though the CLO group recorded the lowest number. Surprisingly, the professional assessment showed that types of cleft have an effect on the presence of nasal flattening, with the CLAP group having the most flattened nose. This picture is reversed for columella deviation with parents/guardian assessment of the three groups showing a significant difference between the three groups. The result of nasal repair is agreed to become worse as the severity of the cleft deformity increases, as pointed out by Abdurrazaq et al. [23]. This is also echoed by Campbell et al. [9] and Gundlach et al. [24], even when primary rhinoplasty and nasoalveolar moulding was done. The disagreement between the two groups of assessors could be explained that an experienced and skilful surgeon would be able to produce a nasal repair with a good result in the eyes of the laymen, but professional eyes would be able to detect little unseen errors by the laymen.

It is agreed that significant differences exist between the various forms of UCL, as found by Hoods et al. [21], Honda et al. [25], and Gosman [26]. These differences were reported to be responsible for the various facial forms seen in different types of UCL/P.

Conclusion

This study has shown that differences truly exist in the outcome of surgical repair of the three types of unilateral cleft lip, especially in the aesthetics of the nose and in the width and shape of the residual scar. Thus, it is important to consider this in the assessment of UCL repair because putting the subtypes together might have a negative impact on the assessment.

Authors' Contributions

AMA		https://orcid.org/0000-0002-7318-0810	Conceptualization, Methodology, Formal Analysis, Investigation, Writing - Original Draft and Writing - Review and Editing.
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All authors declare that they contributed to critical review of intellectual content and approval of the final version to be published.			

Financial Support

None.

Conflict of Interest

The authors declare no conflicts of interest.

Data Availability

The data used to support the findings of this study can be made available upon request to the corresponding author.

Acknowledgments

We acknowledge the support given to the Dental unit by the theater staff during the cleft repair.

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