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Original Article

# Cleft Lip Surgery in Sudan: Clinical Presentations, Early Outcomes, and Patient and Professional Satisfaction: A sub-Saharan African experience

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## ABSTRACT

**Background:** Cleft lip and palate are the most common congenital craniofacial anomalies. They account for approximately 13% of all congenital anomalies.

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**Keywords:**

Cleft lip and palate  
Surgery  
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**Objectives:** To study the presentation of cleft lip and the early results of surgical repair among patients who presented to our centers.

**Methods:** This was a hospital-based prospective cohort study of 72 patients who underwent cleft lip repair in Sudan.

**Results:** The commonest age group was between 10–18 months. The male-to-female ratio was 2:1, and a family history of cleft lip was found in 2.8% of patients. The cleft lip was complete in 81.9%, incomplete in 12.5%, and hybrid in 5.6% of patients. Associated cleft palate was observed in 54 patients. Associated syndromes were found in 10 patients. The surgery was carried out in most patients at 9 months or less; in 4 patients, it was more than 18 months. Achievement of reasonable lip repair was moderate (50% collectively). High achievement was observed for criteria, such as accurate union (90.3%), and sub-moderate achievement in even vermilion border and cupid's bow (44%), low nose symmetry (30.6%), and quality of scar (18.1%). Early complications were reported at the rate of 13.9%. Patient satisfaction was 59.7%; however, the professionals showed higher satisfaction levels (66.7%). The anthropometric measurements of normal infants were moderately similar to those of the infants who underwent surgery.

**Conclusion:** The patients with cleft lip showed early presentation, with a predominance of the male gender and left side pattern. The preliminary outcome of cleft lip repair was moderate, with variations in different criteria. Patient and professional satisfaction were above average.

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## Introduction

A cleft lip (CL) is an opening in the upper lip that can extend into the base of the nostril. It is a birth defect that occurs when the tissues of the lip of the fetus do not fuse early in the first trimester of pregnancy. A CL is caused by failure of union between the medial nasal process and maxillary prominence during the 4th to 10th week of life.<sup>1</sup>

Clefts of lip and palate (CLP) are the most common congenital craniofacial anomalies. Accounting for approximately 13% of all congenital anomalies, CL with or without a cleft palate occurs in approximately 1 in 1,000 live births.<sup>2–4</sup> The highest frequencies are observed in the Asian or Amerindian populations, often at 1/500 or higher, followed by the Caucasian population, and African-derived populations having the lowest frequency at 1/2500.<sup>5,6</sup> CL repair significantly impacts an infant's future psychosocial well-being and follows these children over the formative years of their lives and this impact extends to their parents as well. Modern cleft surgical techniques, preoperative orthodontics, and specialized multidisciplinary team care has enabled more consistent and favorable primary surgical results.<sup>7</sup> In the traditional timeline, the repair is performed between 3 and 6 months.<sup>8</sup> The measurement of treatment outcome is essential in estimating the success of cleft management. Secondary lip and nose surgery is of prime importance in patients with CL and for their satisfaction. Most patients with a repaired CLP are satisfied with their facial appearance and dental function after surgery.<sup>9,10</sup> However, some patients may need further treatment.

In sub-Saharan Africa, CLP deformities have been generally neglected even though they have a significant impact on the lives of the patients and their families, with spiritual implications and societal stigmatization associated with them.<sup>11</sup> In Sudan, according to a study by Suleiman et al. (2005), the

prevalence of CL is 0.9 per 1,000. Girls outnumber boys by a ratio of 3: 10. The study reported 54 cases of CLP, 30% cases of cleft palate alone, and 16% for CL alone.<sup>12</sup> According to our knowledge, no previous local study has addressed CL presentation and surgical repair results from an aesthetic point of view. This study aimed to examine the presentations of CL (including syndromic CL) and preliminary results of surgical repair among patients who attended our plastic surgery departments.

## **Materials/Patients and Method**

### *Study design and area*

This was a multi-center hospital-based (White Nile Hospital and Soba University Hospital) prospective cohort study conducted over one year from August 2018 to August 2019.

### *Study population*

All patients with CL anomalies who underwent surgical repair during the study period were included. Patients who refused to be included and those who did not receive surgical repair were excluded. The total coverage sample size of 72 patients with CL was collected during the study.

### *Data collection*

Data were collected through an interview with the patients and their guardians. Written and verbal consent were obtained from the patient's guardian. Withdrawal at any time is reported. Personal data and clinical evaluation of the patient, including the post-surgical repair evaluation to evaluate for the CL achievement criteria and evident undesirable outcome, were assessed and recorded in the questionnaire. A 5-point Likert scale (employed to measure the subjective quality of life) for patients, parents, and professional was used to evaluate their level of satisfaction. A score of 1 indicates that the respondent is very dissatisfied, 2 is dissatisfied, 3 is unsure, 4 is satisfied, and 5 is very satisfied. Finally, a photo was captured via a software measurement program for anthropometric analysis of the patients' lip length, lip height, vermilion thickness, nasal width, hemi nasal width, and columellar length. The patient was followed up immediately after surgery, in the first 10 days, and 3 months after surgery to clinically assess early and late post-operative outcomes. Each patient was evaluated either by the researcher, a plastic surgery registrar, or at a higher level.

### *Preoperative evaluation*

The patient demographic data and type of clefts were recorded preoperatively. Every patient underwent a full clinical assessment to identify the associated anomalies. Routine blood investigation and electrocardiography were performed for every patient if possible. Our timing protocol followed the rule of 10s, which states that the procedure should be performed when the patient weighs 10 pounds at 10 weeks of age and when hemoglobin levels reach 10 g/dL.

### *Operative technique*

This procedure was performed under general anesthesia and endotracheal intubation. The operation was performed by a plastic surgeon experienced in the Millard-Rotation advancement technique to treat CLs. The important landmarks were marked, and the surgical site was infiltrated with adrenaline (1:200,000) before the incision was made. The procedure was then carried out, and in most cases, primary rhinoplasty was delayed until after secondary alveolar grafting.

### *Data management*

All collected data were processed via the SPSS software version 25.

**Table 1**

Baseline data of patients (N = 72) with cleft lip anomaly at Soba University Hospital (SUH) and White Nile Hospital (WNI).

Baseline data	Frequency	Percentage
Center		
Soba	35	48.6
White Nile Hospital	37	51.4
Residence		
Khartoum State	27	37.5
Central Sudan	25	34.7
Northern Sudan	5	6.9
Western Sudan	14	19.4
Eastern Sudan	1	1.4
Home of Origin		
Khartoum	7	9.7
Central Sudan	28	38.9
Northern Sudan	12	16.7
Western Sudan	25	34.7
Tribe:		
Arabic Origin	54	75.0
Nubian Origin (North)	1	1.4
Nuba (West)	10	13.9
Fur	4	5.6
Non Sudanese Origin	3	4.2
Age groups:		
0-3 months	2	2.8
4-6 months	12	16.7
7-9 months	4	5.6
10-18 months	50	69.4
>18 months	4	5.5
Sex:		
Male	48	66.7
Female	24	33.3

Mean±SD of patient age (months): 13.01±20.48 months

### Ethical consideration

Ethical approval from the ethical committee was obtained, an official letter to both centers was sent, and permission was taken. Verbal and written consent from the guardians were obtained as the purpose and study details were explained, and the right to withdraw at any time was settled.

### Results

The current study recruited 72 patients, aged <15 years, who presented with CL and underwent CL repair at Soba University Hospital and White Nile Hospital. There were 35 (48.6%) patients with CLs from Soba University Hospital and 37 (51.4%) from the White Nile Hospital. Males in the study were 48 (66.7) versus 24 (33.3%) females, with a male-to-female ratio of 2:1. Other patients' demographic data are shown in Table 1. Positive family history of CL was found in 16 (22.2%) patients, with 2 (2.8%) of them being siblings, and in 14 (19.4%) patients, other relation (neither first-degree nor second-degree). Among the total patients included in the study, 37 (51.4%) patients first presented to plastic surgery at <1 month, 20 (27.8%) patients between 1-3 months, and the rest presented after 3 months. Thirty-six patients had a left-sided CL, right-sided CL in 20 patients, and a bilateral CL in the others. After the presentation, the nearest appointment for surgery in 68.1% of the patients was ≤6 months, 9 months in 11.2%, and >9 months in the remaining patients. This surgical appointment was the cause for the delay in surgery in 39 (54.2%) patients. The delay was attributed in 15 (20.8%) patients to the ignorance of caregivers, who are unaware of where to refer those patients, and being unfit for anesthesia owing to repeated upper respiratory tract infections. Moreover, 9 (12.5%) patients mentioned that doctors misdirected them to other surgical units such as pediatrics and gen-

**Table 2**  
Pattern of cleft, associated cleft palate, presurgical molding, and date of surgery.

	Frequency	Percentage
<b>Pattern of Cleft</b>		
Complete	59	81.9
Incomplete	9	12.5
Hybrid	4	5.6
<b>Associated cleft palate</b>		
Yes	54	75.0
No	18	25.0
<b>Associated disease or syndrome</b>		
No anomaly	62	86.1
Diagnosed syndrome	5	6.9
Undiagnosed syndrome	5	6.9
<b>Presurgical molding:</b>		
No molding	<b>66</b>	<b>91.7</b>
Strapping	<b>6</b>	<b>8.3</b>
Total	<b>72</b>	<b>100.0</b>
<b>Age during surgery, months</b>		
0–3	8	11.1%
4–6	25	34.7%
7–9	15	20.8%
10–18	20	27.8%
>18	4	5.6%

eral surgery, 8 (11.1%) reported no delay, and 7 (9.7%) patients cited their financial status for their delay. The pattern of cleft, associated cleft palate, presurgical molding, and date of surgery are shown in [Table 2](#).

All patients in our series underwent Millard's type of repair ([Figure 1](#)). The achievement of reasonable lip repair, as assessed in terms of accurate skin, muscle, and mucous membrane union, was 65 (90.3%). Early post-operative complications recorded were wound dehiscence in 8 (11.1%) patients and infection in 2 (2.8%) patients. Late post-operative complications observed in this report were alar malposition in 33 patients, vermilion problems in 20, muscle problems in 9, prominent premaxilla in 8, long lip in 5, tight lip in 4, and 0 for short upper lip. Lateral vertical length malposition of ala was reported in 31 patients, medial vertical length malposition of ala was reported in 2, whereas 8 had no alar malposition. The alar malposition is significantly associated with early complications ( $P=0.034$ ). Among the patients with early complications, 8 (11.1%) had lateral vertical length alar malposition and 2 (2.8%) had medial vertical length alar malposition. All the patients with no alar malposition had no early complications.

Anthropometric measurements of all patients were compared to those of normal children. The mean lip length was 12.44 mm in patients versus 13.7 mm in their normal counterparts (healthy group), and the mean lip height was 12.1 mm in patients versus 9.4 mm in the healthy group. The vermilion thickness was 5.2 mm in patients versus 6.1 mm in the healthy group, nasal width was 24.9 mm versus 19.4 mm, and mean hemi nasal width was 13.8 mm versus 9.7 mm. The columellar length was 4.8 mm in patients versus 3.8 mm in the healthy group. The correlation between the prominent premaxilla and side of the CL showed a statistically significant association ( $P<0.001$ ), and alar malposition was significantly associated with the prominent premaxilla ( $P=0.034$ ). [Figure 2](#) summarizes these anthropometric measurements. The satisfaction of the patients or parents and professionals following CL surgery is shown in [Table 3](#)

## Discussion

The current study recruited 72 patients who were 15 years old or less with CL deformity and attended the referred clinic or were in the operating list at the 2 centers included in the study. The study addressed this wide range in age to capture the sporadic cases in which late presentations to



**Figure 1.** Preoperative (A) and postoperative (B) photographs

medical care occurred, and this was due to illiteracy and lack of nearby medical services and remote areas. That resulted in a mean age of  $(13.01 \pm 20.48)$  months. Most of our patients were presented at a reasonable time, as more than half of the participants presented before 6 months of age. However, the time of primary surgery showed some delay owing to a long waiting list, as 33 (45.8%) patients underwent surgery at the age  $\leq 6$  months. This long waiting list could be explained by the decreased number of centers providing the service compared to the country's population. Distribution according to gender revealed a predomination of the male gender with a male-to-female ratio of 2:1, which is consistent with that in the literature.<sup>11,13,14</sup> A family history of CL was reported at a noticeable rate of 22.2%. Two (2.8%) patients were siblings and the others were third-degree or further relatives. In our finding, the left: right: bilateral CL ratio was 2.3: 1: 1.3%, whereas David et al. reported a different ratio of 6: 3: 1.<sup>13</sup> Notably, patients with bilateral CLs are strongly associated with a cleft palate and, therefore, have more frequent attendance and follow-up. Cleft palate associated with CL was found to be very frequent in the current study; it was observed in three-quarters of the patients. This is higher than that reported in the literature.<sup>6,7,15,16</sup> The higher frequency of cleft palate in the current study

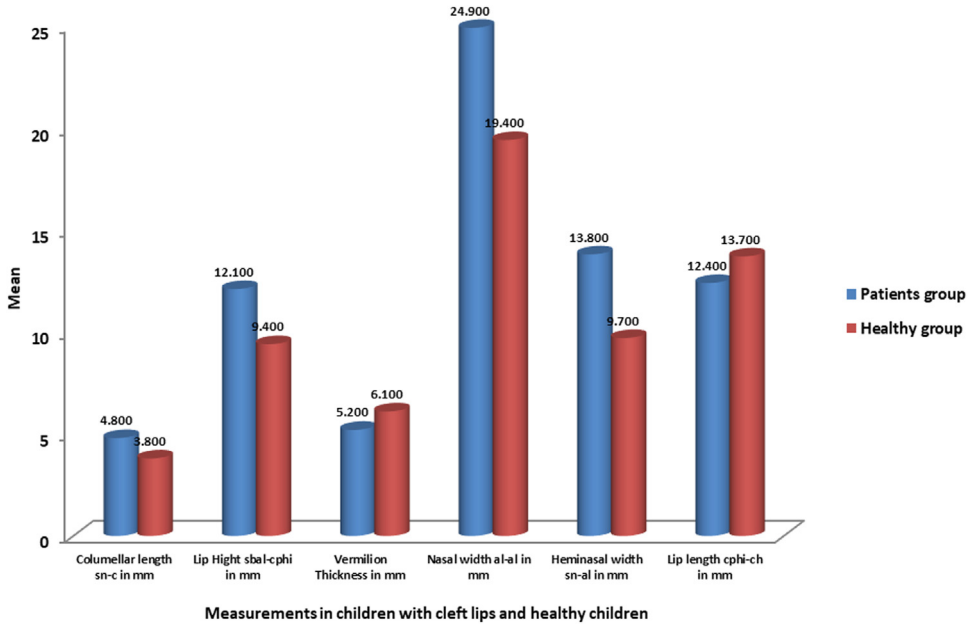


Figure 2. Anthropometric measurements in children with cleft lips and normal children (healthy group)

Table 3 Patient or parents and professional satisfaction.

	Level of satisfaction	Frequency	Percentage
Patient or parent satisfaction	Satisfied	43	59.7
	Neither satisfied nor dissatisfied	23	31.9
	Unsatisfied	6	8.3
Professional satisfaction	Satisfied	48	66.7
	Neither satisfied nor dissatisfied	14	19.4
	Unsatisfied	10	13.9
	Total	72	100.0

can be attributed to the fact that most patients from the clinic return to seek surgical treatment for palate deformity.

Associated syndromes were found among several patients (13.8%) with CL. They were equally distributed into diagnosed and undiagnosed syndromes (6.9% for each), which conforms with that in the literature.<sup>17,18</sup> Among the 10 patients with associated malformations, 5 were reported to have cardiovascular malformation, of them 1 had prune belly syndrome, 1 had Treacher Collins syndrome, 1 had xeroderma pigmentosum, and 1 had Van der Woude syndrome.

Multidisciplinary cleft care is very important for achieving satisfactory outcome in managing CL. Individuals born with CL and/or palate require coordinated care from multiple specialties to optimize the treatment outcomes. Typical cleft team members include audiologists, dentists, geneticists, nurses, nutritionists, oral surgeons, orthodontists, pediatricians, plastic surgeons, psychologists, social workers, and speech pathologists. Attentive team care in the first few months of life will increase the success of primary surgeries by preparing the infant and family medically, physically, and psychologically. The emphasis is on coordinating subspecialized experts to minimize the number of surgeries performed while maximizing the benefit.<sup>1</sup> However, the multidisciplinary cleft care concept is not well established in our setting. Furthermore, orthodontists and pediatricians are involved in cleft case management, sometimes through referral.

Repairing a CL should result in a symmetrical upper lip of equal length on both sides of the philtral column. A key component of the aesthetic outcome of surgery is the severity of the primary CL/nose deformity.<sup>19</sup> If possible, the scar should mirror the opposite side and should not reach the philtral column.<sup>16</sup> The Millard-Rotation advancement was introduced in 1957 and has been the most widely used procedure for repairing CLs as most of the scar is placed along the natural CL-philtral border and is more flexible than other techniques. Additionally, the Millard technique completely repairs the muscles, and lesser amount of normal tissue is discarded. Most studies have shown improvement in nasal width on the cleft side compared to the non-cleft side. However, significantly increased nasal width continues to be observed compared to normal controls.<sup>20</sup> All patients in this study underwent the Millard repair.

Assessing the overall achievement of reasonable lip repair among patients with CLs indicated a moderately acceptable mean of achievement, among which accurate skin, muscle, and mucous membrane union and proper rotation of the orbicularis oris into a horizontal position were both high up to 90.3%. This finding is comparable to other regional reports.<sup>21</sup> Other criteria such as even vermilion border with reproduction of cupid's bow (44%) and symmetric nostril floor and tip (30.6%) were sub-moderate. Symmetric nostril floor and tip are mostly impacted by the fact that only 38.9% of patients in the current study underwent primary nose repair at the time of the primary surgery. Conway et al. reported a different result in a retrospective review to assess the outcomes of CL repair in Africa, where most patients underwent primary repair of the nose deformity.<sup>6</sup> Some studies reported nose repair performed in one-third of the patients.<sup>8</sup> Few studies achieved good quality of their scars, most probably due to the African ethnicity among the Sudanese; this was supported earlier in the study by Muir, who reported that the Africans, Asians, and Orientals tend to have more prominent scars than the Caucasians.<sup>22</sup> Early complications reported in our series were wound dehiscence and infection at a rate of 13.9% collectively; dehiscence was more common and was reported in 8 patients, among whom 1 patient experienced direct physical trauma that led to wound dehiscence. Some studies agree with our findings regarding the early outcome of CL repair; Balaji reported that immediate visible outcomes such as dehiscence and scarring were the most common outcomes.<sup>23</sup> Two consecutive cleft missions were conducted in Guwahati, northeastern India, by Schönmeier et al., and their findings showed that among the 298 patients who underwent CL repair, 3.7% were diagnosed with lip wound infection and 9.6% with lip dehiscence.<sup>24</sup> The study by Khan et al. in Pakistan reported fewer rates of complications (1.18%); our findings conform to theirs in reporting that the most common complication was stitch sinus (0.71%), but unlike our findings, they reported some cases of nasal hematoma (0.24%) and severe lower respiratory tract infection (0.24%).<sup>25</sup> The late post-operative complication in the current study indicated the predominance of alar malposition, which was observed in 45.8% of patients who underwent CL repair. It was mostly lateral vertical length in 31 patients. Other late complications were vermilion problems, muscle problems, and prominent premaxilla. In comparison, long upper and tight lips were less frequent, with no cases of shortened lip deformity. In our study, alar malposition was associated with early complications ( $P=0.034$ ), which may have contributed to the high rate of nasal asymmetry. A systemic review by Adeola and Oladimeji reported similar adverse outcomes; they classified the deformities as nasal and oral ones and among the 200 post-operative cases of cleft patients reviewed, the commonest lip deformities were vermilion irregularity followed by muscle bulk deficiency, but their results disagreed with our findings by reporting some cases of shortened and notched lip. Alar asymmetry was reported among the most common nasal deformities.<sup>26</sup> The tight lip showed no significant association with the side of the CL. Yet, it was more important among patients with bilateral CL (71.4%,  $P=0.088$ ). Prominent premaxilla was found to be significantly more common among patients with bilateral CL (78.6%,  $P=0.000$ ), whereas the vast majority of patients without alveolus had left or right CLs (50% and 40.9%, respectively).

Anthropometric measurements of the noses and lips of patients with CLs were compared to those of normal children, matching the same mean of age (Figure 2). It was revealed that the mean nasal and hemi nasal widths were wider among patients compared to their normal counterparts, and the lip length and vermilion thickness were lesser among patients compared to that of the normal group of children. However, the mean columellar length and lip height increased among patients compared to those in healthy children. Concerning columellar length, the apparent results might be due to the inclusion of unilateral clefts in the total number.



Patient/parent and professional satisfaction was measured in our report using the Likert scale. Patients showed moderate satisfaction toward CL repair; however, nearly a third of the participants could not determine their level of satisfaction. These findings are comparable to those in the literature.<sup>27</sup> Moreover, professionals showed higher satisfaction than patients. The discrepancy between patient and clinician ratings of satisfaction may be explained by the fact that patient satisfaction appears independent of the appearance alone, and it might be impacted by realistic self-perception and expectation. A study by Thittiwong et al. in Thailand used the same Likert scale to assess satisfaction and reported similar findings; they revealed that the patients were moderately satisfied with their appearance. When compared to the clinician ratings, the patients were less satisfied.<sup>25</sup> This is also in accordance with results from earlier studies by Marcusson et al. and Sinko et al., which indicated a trend toward less satisfaction by the parents compared to that of the clinicians.<sup>28,29</sup>

## Conclusion

Assessing the overall achievement of reasonable lip repair among patients with CLs indicated a moderate level of achievement. The outcome of repair of CL in our series was satisfactory in our setting and comparable to those in the regional reports. A large-scale study is needed to address this problem and obtain more evaluation for the rate and pattern of CL. Establishing a well-trained multidisciplinary team is required to improve the outcome of CL management.

## Declaration of competing interest

No conflict of interests.

## Availability of data and materials

The report contains all pertinent information.

## Author contributions

The conception and design of the study, acquisition of data, or analysis and interpretation of data were carried out by all authors.

Drafting the article or revising it critically for important intellectual content were performed by all authors.

All authors provided final approval of the version to be submitted.

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## Ethics approval and consent to participate

This study was approved by the institutional review board of the Sudan Medical Specialization Board Ethical Committee. Moreover, ethical clearance was obtained from the ethical committee in the participating centers. Consent was obtained for participation in this study.

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