DETERMINANTS OF EARLY SURGICAL OUTCOMES AND COMPLICATIONS FOLLOWING PRIMARY CLEFT LIP AND PALATE REPAIR IN SELECTED HOSPITALS IN KENYA.

Principle investigator

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A research proposal submitted as partial fulfilment of the requirements of the University of Nairobi for the award of the degree of Master of Medicine in Plastic, Reconstructive and Aesthetic Surgery (MMED-PRAS)

DECLARATION

This research proposal is presented in partial fulfilment of the requirements for the award of the degree of Master of Medicine in Plastic, Reconstructive and Aesthetic Surgery (MMED-PRAS) at the University of Nairobi.

I, **Dr Nang'andu A Malungo**, declare that this proposal is my original work. No part of it has been presented for the award of a degree at any other University.

Signed:..... Date …….

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The research proposal has been presented at the surgical department dissertation clinic and is hereby approved for presentation to the Kenyatta National Hospital Ethics and Research Committee.

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ABBREVIATIONS

BCL/P	Bilateral Cleft lip and palate
BCL	Bilateral cleft lip
CL	Cleft Lip
CPO	Isolated Cleft Palate
CL/P	Cleft lip and Palate
CI	Confidence Interval
CTEV	Congenital Talipes Equinovarus
GPP	Gingivoperioplasty
Hb	Haemoglobin
KNH	Kenyatta National Hospital
ONF	Oronasal Fistula
NAM	Nasal alveolar moulding
PLAN	Pennsylvania Lip and nose score
SPSS	Statistical Package for social sciences
UCL	Unilateral Cleft lip
UCL/P	Unilateral Cleft lip and palate
L/UCL	Left Unilateral cleft lip
R/UCL	Right Unilateral cleft lip
VPI	Velopharyngeal insufficiency

Operational Definitions

The following definitions have been used in this research proposal

- **Cleft Lip** (cheiloschisis.)- a congenital split in the upper lip on one or both sides of the midline
- **Cleft palate** (palatoschisis) - congenital fissure of the roof of the mouth produced by failure of the two maxillae to unite during embryonic development
- **Cupids bow** is defined by the horizontal double curve of the lip and has two peaks
- **Mucosa** is the pink lining of the oral mucosa compose of non-keratinised squamous epithelium
- **Philtrum** central depression flanked by philtral columns on both sides
- **Primary palate -** consists of the lip, alveolus and anterior palate back to the incisive foramen.
- **Secondary palate** – consists of the hard and soft palate from the incisive foramen back to the uvula
- **Sub-mucous cleft palate** – a triad of deformities : a bifid uvula, a notched posterior hard palate ,and muscular diastasis of the velum
- **Hard (bony) palate** - The hard palate is approximately anterior 4/5 of the palate and covered with mucous membrane.
- **Soft (Velum) palate** –A fibro-muscular sling attached to the posterior border of the hard palate and consisting of five paired muscles; the palatoglossus, palatopharyngeus, levator veli palatini, tensor veli palatine and musculus uvulae.
- **Level 5 hospital**- Level 5 Hospitals in Kenya are regional centres which provide specialised care, including intensive care, life support and specialist consultations
- **Red line** is the junction between the vermillion and mucosa

- **Wound dehiscence** is a surgical complication in which a wound ruptures along a surgical incision.
- **Vermillion** is the red part of the lip that is exposed and dry. It is composed of keratinized squamous epithelium and has an abundance of superficial capillaries
- **White roll** is the shiny convex prominence above the vermillion that is characterised by sparse vellus hair
- **Vermillion border** is the junction between the vermillion and white roll. It represents the change in the epidermis from highly keratinised external skin to less keratinised mucous membrane

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ABSTRACT

BACKGROUND: Cleft lip and palate is the most common congenital craniofacial anomaly managed by plastic surgeons. Its surgery has revolutionised over the last half century. However, there is no consensus with respect to the protocol, timing and the ideal technique of cleft lip and palate repair among surgeons. The goal of cleft surgery is to repair the affected structures to restore functional impairments and facial aesthetics. The best approach to cleft management is through multidisciplinary team approach through dedicated cleft and craniofacial centres. Many developing countries, however, still lack cleft centres making patient follow-up erratic. In Kenya, several patients undergo cleft surgery each year. The complication rates and the determinants of complications and outcomes following surgical repair are not known in our setting. Cleft lip and palate repairs may result in complications such as surgical site infection, dehiscence and fistulas. Poor outcomes and complications contribute significantly to the burden of care in these patients, as there arises further need for secondary procedures.

OBJECTIVE: To evaluate determinants of early surgical outcomes and complications following primary cleft lip and palate repair in selected Hospitals in Kenya.

STUDY DESIGN: This was a descriptive cross sectional study

MATERIALS AND METHODS: The study was carried out from November 2019 to June 2020 at hospitals where cleft surgeries were carried out, that is, Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenyatta University Teaching, Referral and Research Hospital (KUTRRH), Meru level 5 Hospital, Kapenguria level 5 Hospital, Kitale level 5 Hospital, Machakos level 5 Hospital. Consenting patients above 18 years, assenting minors and consenting parents/guardians with patients requiring primary cleft lip or palate surgery were recruited into the study. Ethics approval was obtained for this study. Permission was sought from the participating study sites.

One hundred and forty-one (141) consecutive consenting participants meeting the inclusion criteria were included in this study and assessed at 4 weeks post operatively to determine the surgical outcomes and complications of repair. Patient's demographics, pre-operative status that is., Haemoglobin, weight, type of cleft, presence of other congenital anomalies and intra-operative data on method of repair was collected using a researcher administered questionnaire. Photos were taken pre-operatively and post-operatively, analysed and scored using the PLAN score by 3 senior plastic surgeons to assess the cleft lip repair outcomes. The outcome of Cleft palate repairs was determined based on the integrity of repair that is, on the presence or absence of fistula. A good palate repair was defined as one without a fistula.

Data collected were put into SPSS version 23 from where percentages and frequencies were derived. Cross tabulations between the outcomes (presence of fistula), patient factors (haemoglobin, weight, type of cleft, presence of other congenital anomalies and intra-operative data) was then done. Mann Whitney and Kruskal Wallis tests were run to assess for statistical significant differences. Spearman correlation test was run between different variables and presence of fistula among the palatal cohort, and different variables and scores for the lip cohort. To assess for reliability of the scores among the different raters on for the PLAN scores, coherence among raters was determined using Cohen's kappa inter-rater reliability analysis. P-value of ≤ 0.05 was considered significant at 95% CI. Data were presented in tables and photographs.

RESULTS: Left cleft lip and palate deformity was the most common pattern of presentation. The male to female ratio was 1:1.2. The ethnic groups from the central region of Kenya were the largest population in this study. Seventy nine percent (79%) of the patients had sporadic clefts with only 30% reporting a family history of clefts. Most patients had primary palate repair at 1-3years (mean 18 months) of age while the majority of cleft lip patients were below one year (mean 5.4months) at primary repair. Bardach's two flap palatoplasty was the most common method of repair for Cleft palate. A relatively high rate of palate fistula formation of

37% was noted. Lower fistula rates occurred where vomer flaps were used to augment the nasal mucosal layer. Millard rotation and advancement or its modifications, was commonly used for cleft lip repair. The most common complication of cleft lip repair was hypertrophic scarring in 20% of the patients. In this study, there was no difference in outcome between use of Dermabond and sutures in cleft lip repair. Seventy percent (70%) of the patients were said to have good outcomes based on the PLAN score that showed significant inter-rater reliability.

CONCLUSION: This study demonstrated a low complication rate and high patient satisfaction following cleft lip and palate surgery in Kenya. Intra-operative complications occurred more with palate repair and these increased the risk of ICU admission and prolonged hospital stay. The most significant factors determining cleft surgery outcome were the surgical technique and cleft severity. Surgeons with extensive experience in cleft surgery had good outcomes even with wide cleft lips in the absence of pre-surgical orthodontics.

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CHAPTER 1: INTRODUCTION AND LITERATURE REVIEW

1.1 INTRODUCTION

Cleft lip and palate is a congenital condition where there is a defect in the continuity of the architecture of the tissues that form the normal lip and palate. Management involves multiple disciplines and the length of treatment spans from infancy to adulthood. Individuals with CL/P have challenges with feeding, hearing, speech and psychosocial integration (1-2). It is common for these patients to suffer poor weight gain in infancy associated with difficult feeding (3). Adjunctive treatment to surgery may include, but not limited to, genetic counselling, nutritional consultations, speech therapy and substantial orthodontic and dental interventions (4-5)

1.1.1 History of Cleft lip and palate repair

The first recorded cleft repair was in 390 BC in China(6). From the middle ages, cleft lip closure with butter coated bandages by Albucasis was attempted. Repair with muscle approximation was documented Von Pfolsprundt in 1460. Alveolar bone grafting was later introduced by Skoog who also modified Veau's method of repair in the 1930s (7).

Over the last half a century, CL(Cleft Lip) repair has revolutionised with the introduction of Millard's popular 'cut as you go' method that forms the basis for many other repair techniques used today (8). Manchester in 1965 introduced a technique for bilateral cleft lips whose application in current practice continues today alongside Millard's bilateral cleft lip repair technique.

Repair of cleft palates was not documented till 1816 when Graefe first described a successful repair. This is probably because without anaesthetics, cleft palate repair was immensely difficult and painful (6).

1.1.2 Epidemiology

In Kenya, CL/P (cleft lip and palate) is a significant congenital craniofacial malformation(9). There is a higher occurrence of associated congenital malformations and familial inheritance than reported elsewhere according to a study by Wanjeri (10).

Worldwide of CL/P ranges between 1/300 and 1/2500 births with higher rates seen in Native Americans and Asians, followed Caucasians, lowest in the black population (11,12). The incidence of CPO (isolated cleft palate) is approximately 1/1500 birth. It is reported CPO has a predilection for females, while CL/P is more common in males (13). Similarly, a retrospective study conducted in selected hospitals in Kenya from 2005 to 2009 showed CL/P occur more frequently in males with a male to female ratio of 1.3: 1(9).

1.1.3. Functional Anatomy

Understanding the anatomy and patho-physiology of CL/P has an influence on successful treatment outcome (14,15). The orbicularis oris, the main muscle of the lip, is functionally made up of two components; superficial fibres contribute to facial expression while the deep fibres aid in swallowing and oral sphincter control (1,2). It is important to approximate the muscle layer during Cleft lip repair to restore these functions(7).

Cleft lip repair should include correction of the distorted nasal tissues to improve outcome. Definitive rhinoplasty is usually done at a later stage during teenage years (4,16). Cleft lip nasal deformities include a collapsed ala dome and larger nares on the side with cleft. In BCL, the nasal tip is larger, flattened and bifid with both alae spread apart and rotated inferiorly (1,5).

The soft palate (or velum) is vital in swallowing and speech. Of the muscles of the soft palate, the Levator veli palatini is the largest; it elevates the soft palate and secondarily opens the Eustachian tube(1). Patients with CL/P may present with frequent episodes of secretory

otitis media in infancy (17). During cleft palate repair, the muscle fibres must be redirected for appropriate restoration of palate function (15).

The greater palatine artery is the main blood supply to the palate, entering the region via the greater palatine foramen. The viability of the muco-periosteal flaps raised during surgery depend on this vessel(13).

1.1.4. Surgical approach

At about 10 to 12 weeks of age, primary lip repair can be done safely, with or without primary rhinoplasty though patient safety during pregnancy takes precedence(18). Gingivoperiosteoplasty (GPP) may be considered at primary surgery for segments ≤ 2mm part (3). Some authors have suggested the "Rule of 10s" as a crude way to determine if surgery can proceed that is, at 10 weeks, 10lbs of body weight, and Hb of at least 10g/dL (7). In unilateral cleft lip repair, Millard's rotation and advancement is a popular repair technique. In a retrospective study done in Kenya between 2005 and 2009 by Nangole almost all CL repairs were operated using Millard technique (9).

Bilateral cleft lip (BCL) repair is generally considered more difficult than UCL repair partly due to the delicate pre-maxilla tissues that make handling difficult (19).The Millard, Manchester-Garcia and Mulliken methods of repair have been described. In the absence of NAM, a multistage repair is usually more realistic is severe cases of BCL as is the case in most developing countries (19,20)

The timing of palate is highly variable. It can be a single stage or a two staged repair. It is recommended that the timing of repair should strike a balance between speech development and facial growth(21). The latter is affected by early surgical trauma demonstrated by restricted maxillary growth(13). Some researchers argue that impaired maxillary growth is independent of CP repair suggesting these patients have an intrinsic maxillary growth restriction. Midface hypoplasia would eventually occur with or without palate repair(15).

Based on these arguments, CP repair may be carried out as early as nine months to one year to facilitate speech development. Some advocate for early soft palate repair at six to nine months and hard palate repair is delayed as long as possible to accommodate facial growth (13). Staged repair has become less common because it is associated with increased oronasal fistula risk and worse speech and sound results compared to the single stage(22,23). Theoretically, the best technique of palate repair is one which results in good speech execution with no effect on the growth of the maxillofacial tissues(24)

In cleft repair, techniques are based on the principle of raising oral mucosal flaps based on the greater palatine vessles and tension free three layer closure of the nasal mucosa, muscle layer (inter-velar-veloplasty) and the oral mucosa layer(15). Repair of cleft palate using Pushback procedure (Veau-Wardill-Kliner V-Y palatopharyngoplasty), Furlow's z-plasties and Von-langenbeck two-flap plasty are documented and widely used(25). The choice of technique depends on the surgeons' preference. Fistula occurrence is usually higher for the Furlow procedure than for the von Langenbeck(26).

1.2 LITERATURE REVIEW

1.2.1 Measuring surgical outcomes

Facial appearance is subjective and complex. Generating a reproducible and reliable scoring system for measuring nasolabial aesthetics post repair is an on-going challenge for cleft surgeons. Many outcome measure scoring systems have been described but yet to be validated(14). The Asher-McDade is a 5-point system that forms the basis of many of the proposed system. Three dimensional assessments are more objective however such complex cephalometric measurements are not readily available or accessible(3,27).

The PLAN scoring system has been described and has been found to be reproducible in evaluating nasolabial appearance after cleft lip repair. The hallmark of this system is its simplicity making it usable by cleft surgeons and laymen alike(28). In the PLAN index, surgical outcome is good when the average score from lip and nose assessment is 1 (no revision is necessary), fair if it is 2 (minor revision is indicated), and poor if it is 3 (complete revision of the surgery is deemed necessary). Cropped photographs are more representative than full face.

Compared with cleft lip repair, a successful cleft palate repair takes years to assess and cannot be evaluated definitively until commencement of speech and completion of facial growth. However, short term outcomes can be evaluated by the presence or absence of an oronasal fistula(22). The reliability of ONF classification between surgeons remains unclear despite oronasal fistula being an important surgical outcome. Among the most used classification is the Pittsburgh fistula classification system that has been found to be reliable when used by a single surgeon but with less reliable inter-rater correlation(29). It is based on the anatomical location of the fistula and numbered (I) to (VII) from the uvula to the labial alveolar respectively(30).

Velopharyngeal insufficiency may occur if there is a short palate. Lack of transverse orientation of the levator mechanism may also contribute to VPI(13). Further surgeries are required to correct VPI post cleft palate repair for the patient to attain near normal phonation.

1.2.2 Complications of Repair

CL/P surgical complications are rare though several debilitating complications and unfavourable outcomes have been reported (27,31,32). Mortality related to cleft surgery is negligible (0.01%). Approximately 3% of the patients may develop acute complications like airway failure, haemorrhage, infection or wound disruption(33). Brain injury peri-operatively has been reported in very few cases(27).

There are important factors that contribute to poor surgical outcome and complications after cleft surgery. Patient factors leading to oronasal fistula include the age at time of repair, malnutrition and severity of cleft(34). In a study undertaken in paediatric patients planned for CL/P surgery, Hb levels of 7-10g/dL were associated with hypoxemia during airway management but the general peri-operative morbidity was the same as in the patients with Hb >10g/dL(35). Other studies have shown that the body weight at time of repair has a direct correlation to the risk of peri-operative complications(31).

The type of cleft may affect surgical outcome. Wider cleft palates have a higher rate of oronasal fistula formation post operatively (22) Though rarely indicated, the use of biomaterials, such as a cellular cadaveric human dermis, has been described as a reinforcing layer on top of the nasal closure for wide clefts(13). Various fistulae locations have been reported in literature commonly at the hard and soft palate junction, incisive foramen and the uvula (22,29,30). Fistula rate, in experienced hands, is currently twice to thrice less than previously reported(25)

Symptomatic oronasal fistulas are repaired with local mucosal flaps. Asymptomatic fistulas are left unrepaired until the time of another surgery, such as alveolar bone grafting(20). Some of the fistulae may narrow or close spontaneously(36).

Relatively wide cleft lips may also present a challenge during repair. This is particularly worse in wide bilateral clefts with small prolabium. Bilateral CL repair can be twice harder to execute with results half as good compared to Unilateral CL (9). Cleft width can be mitigated by Nasal alveolar moulding from birth(16). This is not a common intervention in resource limited settings like ours.

Other Patient factors like presence of malnutrition, low weight and very young age at repair, may lead to complications (22,36). Previous studies have shown that body weight at time of repair has a direct correlation to the risk of peri-operative complications (31). Most surgeons wait till a child is about 10lbs before surgery but this is variable depending on the surgeons 'experience. The age and weights of patients seen in our cleft clinics was quite variable (37).

Many methods of cleft palate repair may have an impact on the surgical outcome. In a 2011 study by Williams *et al*, fistula occurrence was noted to be higher for the Furlow procedure than for the von Langenbeck(26). Tennison Randal straight line closure in cleft lip has been associated a longer lip after repair (3). By far, the Millard technique, or its modifications, is quite popular with plastic surgeons in Kenya (9). Outcomes with this method are not well studied locally.

An ideal repair should include tensionless closure. Schönmeyr and colleagues in 2015 demonstrated that excessive tension tends to be a significant cause of complications such as dehiscence (24).

Wound infection and dehiscence may occur after cleft lip repair. These constitute different entities with different aetiologies, though an infected wound can undergo dehiscence or the other way round(38). Excessive wound tension eventually tends to dehiscence.

Surgeon skill, operative technique, single layer repair, tension closure, single-layer repair and post-operative management contribute to the development of oronasal fistula post-operatively (39). Use of peri-operative antibiotics and the surgeon's familiarity with the peri-operative team, may have a bearing on the palate surgery outcome(33)

Some studies have suggested that visiting surgeons may have a higher complication rate in cleft lip repair rate due to unfamiliar work environment particularly where pre-operative NAM is no done(32).

CHAPTER 2: PROBLEM STATEMENT, JUSTIFICATION, SIGNIFICANCE, RESEARCH QUESTION, HYPOTHESIS AND SIGNIFICANCE

2.1 PROBLEM STATEMENT

Approximately 100 patients annually undergo surgical repair provided by Kenya Society of Plastic, Reconstructive and Aesthetic Surgeons (KSPRAS) outreach programs(40). Many more patients around Kenya receive care facilitated by providers from other surgical disciplines including ENT and Maxillofacial surgeons(41). Based on pilot surveys, it is generally noted that patients, parents and guardians are satisfied with the dramatic change following repair in the immediate post- operative interval. There is a paucity of local data regarding the outcomes and complications following surgical repair in terms of infection rate, fistula formation, surgical scarring requiring revision and quality of life thereafter.

2.2 JUSTIFICATION AND SIGNIFICANCE

Cleft lip and palate is a common congenital surgical condition(33). The complication rates and the determinants of these complications are not known in our setting. There are fewer studies in Africa on the outcomes encountered following surgery compared to the west. The timing and best method of repair in clefts remains controversial. Most of the protocols adopted are based on western studies where the healthcare systems and access to care differ significantly with our setting. Patients presenting with cleft surgery complications often require additional procedures that tend to be costly for both the patient and the healthcare system(17). This study will therefore indirectly reduce the cost of cleft care as it will be a source of educational material helping surgeons identify and reduce risk factors leading to poor outcomes. Ultimately, information from the study could be used to formulate appropriate treatment protocols for cleft patients in the region and beyond.

2.3 RESEARCH QUESTION

What are the determinants of early post-operative outcomes and complications following primary cleft lip and palate repair?

2.4 NULL HYPOTHESIS

i. Patients undergoing cleft lip and palate have good early post-operative outcomes
ii. There are no complications following surgical cleft repair

2.5 BROAD OBJECTIVE

To evaluate the factors contributing to outcomes and complications following primary cleft lip and palate surgery.

2.5.1 SPECIFIC OBJECTIVES

I. To determine the outcomes of surgical cleft lip and/or palate repairs
II. To determine the relationship between the factors and surgical outcomes
III. To determine the complication rates and factors related to these complications following primary cleft lip/palate surgery

CHAPTER 3: MATERIALS AND METHODS

3.1 STUDY DESIGN

This study was a descriptive cross sectional study

3.2 STUDY AREA AND TIME

The study was carried out at select hospitals where cleft surgeries are offered either as part of routine surgical procedures or as part of cleft camp outreaches conducted by the Kenya Society of Plastic, Reconstructive and Aesthetic Surgeons (KSPRAS). The selection of cleft camp surgery site is an interactive process between KSPRAS and the hosting hospital. Once they have several patients requiring cleft surgery, an outreach program is planned.

The sites included three Teaching and referral hospitals (also called Level 6 hospitals) that is, Kenyatta National Hospital (KNH), Moi Teaching and Referral Hospital (MTRH), Kenyatta University Teaching and Referral and Research Hospital (KUTRRH), Several level 5 Hospitals including, Meru level 5 Hospital, Machakos level 5 Hospital, Kapenguria level 5 Hospital and Kitale level 5 Hospital,

The following were the specific study settings;

I. **Kenyatta National Hospital** - The hospital is located in the area to the immediate west of Upper Hill in Nairobi, the capital and largest city in Kenya. Its location is about 3.5 kilometres west of the city's centre and is the largest public referral hospital in Kenya receiving patients from all over the country. The primary contact with patients to be recruited into the study was in the plastic surgery clinic 24, situated on the ground floor of the hospital and conducted every Tuesday between 8am to 1pm and in the wards. Data were further collected during the surgical procedures conducted in theatre.

II. **Moi Teaching and Referral Hospital**: Started in 1916 serves as a level six Hospital offering outpatient, inpatient and specialized healthcare services. It is located along Nandi Road in Eldoret Town, Uasin Gishu County (310 Kilometers Northwest of Nairobi). The Hospital serves residents of Western Kenya, parts of Eastern Uganda and Southern Sudan. It operates a Training School offering a range of courses. Patient recruitment was done in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures.

III. **Kenyatta University Teaching, Referral and Research Hospital**- located along Northern Bypass Rd. near Kahawa West, Nairobi, is a leading National Referral Hospital with a 650 bed capacity and equipped with state-of-art medical amenities. The hospital is well equipped to offer Oncology, Trauma & Orthopaedics, Renal among other services. Patient recruitment was carried out in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures

IV. **Kapenguria County Teaching and Referral Hospital-**: Located in Mwotot Sub Location, (Kitale Lodwar Road at Kapenguria town near DC's office) Kapenguria Location in Kapenguria Constituency, West Pokot County, Kenya. Patient recruitment was carried out in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures

V. **Kitale District Hospital:** Kitale District Hospital is a Ministry of Health district hospital located in Naisambu Sub Location Kibomet in Saboti Constituency, Trans Nzoia County, Kenya. Patient recruitment was carried out in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures

VI. **Meru Level 5 Hostipal -** Meru Level 5 Hospital is a public hospital with a bed capacity of 306. It is located in Imenti North Easthern Township, Miriga Mieru East Division, North Imenti Constituency in Meru County. Patient recruitment was carried out in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures

VII. **Machakos Level 5 Hospital-** Machakos Level 5 Hospital is a public hospital located in Machakos Town, Machakos County. Patient recruitment was carried out in the out-patient clinic areas as per hospital guidelines, in the surgical wards and intra-operative information was obtained in the theatres during the procedures

The study duration was approximately eight (8) months from November 2019 to June 2020

3.3 STUDY POPULATION

Consenting patients above 18 years, assenting minors and consenting parents or guardians presenting with patients requiring primary cleft lip or palate surgery were recruited into the study within the given study period. Patient's demographics; age at repair, sex, history of clefts in the family was obtained. Pre-operative status that is, Haemoglobin, weight, type of cleft, presence of other congenital anomalies and intra-operative data on method of repair was collected. Patients were reviewed at four weeks for complications.

3.4 SAMPLE SIZE

According to a study by Abdurrazaq *et al*(28), 68.8% of participants who underwent cleft lip and palate surgery had good surgical outcomes. Assuming similar numbers for our study, we can calculate sample size by applying Cochran equation for sample size calculation given by:

$$n_o = \frac{\mathrm{Z}^2 \text{ x p x } (1 - \mathrm{p})}{\mathrm{d}^2} = \frac{1.96^2 \; x \; 0.69(1 - 0.69)}{0.05^2} = 328.7 \; cases$$

However on average, 246 cases of cleft lip and palate are undertaken each year during outreach activities by plastic surgeons and other surgeons involved in cleft care (25-26,28) . Therefore applying the finite population correction factor, the adjusted sample size will be calculated as:

$$\text{n} = n_o/(1 + \left(\frac{n_o - 1}{N}\right) = \frac{329}{1 + \frac{329 - 1}{246}} = 141\ cases$$

Total sample size = 141 cases

3.5 SAMPLING PROCEDURE

In this study, participants were selected via a convenient sampling procedure where consecutive patients meeting the criteria were sampled till the sample size was reached.

3.6 SELECTION CRITERIA

3.6.1 Inclusion criteria

i. All consenting patients above the age of 18 with cleft lip and/or palate requiring primary surgery

ii. All children (below 18) with cleft lip and/or palate undergoing primary surgical repair with consenting parents or guardians

3.6.2 Exclusion criteria

i. Non-consenting patients

ii. Patients with severe syndromic presentation where surgical repair presents a significant risk to a patients' life

iii. Patients with cleft lip and/or palate who have had previous surgical repair

iv. Patients with acquired cleft lip and palate defects

3.7 DATA COLLECTION

3.7.1 Recruitment

Ethics approval was obtained prior to commencing the study. Permission was sought from every participating study site before data collection.

The recruitment of patients was carried out in specific study areas during normal hours of operation either in the out-patient clinics or in the respective ward. The patients were recruited based on the inclusion and exclusion criteria from their files.

Data from the patients were collected through researcher administered questionnaire by the principal investigator or research assistant.

The research proposal was explained to them by Principal investigator/assistant. Thereafter, the research study consent form was presented to the patient detailing the specifics of the research project and any clarifications about the consent document made. Consenting patients were asked questions based on researcher administered questionnaire and any clarifications were made during the process.

The data collection was conducted in the private consultation rooms in the clinic or in the wards in order to ensure confidentiality. In the event of language barrier or inability to fully comprehend the consent/assent form, or the questions presented in the questionnaire, a third party was included to translate and relay the information to the patient.

The questionnaire was used by the principal investigator or research assistant to obtain relevant information

Consenting patients planned for cleft lip and palate surgery underwent routine surgical preparation including counselling for the procedure and consent for the procedure by patient, parent or guardian.

Surgical repair was performed under general anaesthesia in all cases. A pre-operative, intra-operative and post-operative data form was filled and analysed for each patient. Standard WHO pre-operative checklist was done before all procedures. All patients received intra-op loading antibiotic dose with a minimum 3 days duration oral antibiotic post-operatively.

3.7.2 Photography

Patient's photos were taken pre-operatively and post-operatively at four (4) weeks for analysis and scoring using the PLAN score by three senior plastic surgeons and the principle investigator. Standardised photography with comparison of before and after photos for meaningful observation was undertaken. Clinical photographs were taken with the same equipment and procedure. The lighting, camera, magnification, framing and patient position was consistent. A clear, non-reflective background on a wall, or other flat surface with the camera to patient distance of one (1) meter was used. Minimum camera screen resolution of 640 X 480 pixels was used. Anterior, oblique and worm's eye views were taken pre-and post-operatively at four weeks.:

3.7.3 Scoring

The PLAN (Pennsylvania lip and nose score) is a qualitative clinical assessment with the following components**:**

Lip scoring

1. Mild- almost undetectable at conversational distance. Does not need further treatment.
2. Moderate- some asymmetry of lip noted at conversational distance, may need minor revision

3. Severe- Remarkable asymmetry of the lip needing complete revision.

Nose scoring

1. Mild – Almost undetectable at conversational distance. Does not need further treatment
2. Moderate – asymmetry of nasal tip seen on worm's eye tip, needing rhino-plasty
3. Severe – Nasal asymmetry on Antero-posterior view, at conversational distance, crooked nose, needing reconstructive rhino-plasty or grafts to achieve correction

Pre-assessment training prior to using this tool was carried out where the average from the lip and nose score was good when the score is 1 (will not need revision), Fair when the score is 2 (minor revisions needed) and Poor if the score is 3 (complete surgical revision)

The outcome of cleft palate repairs was be judged based the presence or absence of fistula. A good surgical outcome consisting absence of a fistula. A fair or poor outcome, if fistula diameter was less or more than 1cm respectively, as calibrated and validated by a Vernier calliper.

3.8 ETHICAL CONSIDERATIONS

This proposal was subjected to review by the Kenyatta National Hospital/University of Nairobi Ethics Review Committee (KNH/UON-ERC) and procedures conformed to the World Medical Association Declaration of Helsinki.

Prior to data collection, permission was obtained from each participating study site.

Informed consent/ assent (Appendix-A) was sought from all the participants pre-operatively. The patients understood that participation was voluntary and they were free to withdraw from the study at any time without stating the reason and without affecting the quality of care that they received.

The participants were interviewed in private, and their identities and personal particulars were kept strictly confidential. Identity codes were used for the questionnaires in order to keep the data anonymous. Translation, via a third party, was considered where language barrier or inability to fully comprehend the questions presented during the pre-operative assessment.

The findings were treated with utmost confidentiality, for the purpose of this research only. The data collected from this study will be used to provide information aimed towards development of protocols that will help optimize treatment outcomes for other cleft lip and palate patients.

Non-participation did not affect a participants' care in the hospital. Participation in this study did not attract extra cost to the medical care of the participants. Participants' hospital file number was included into the data sheet to facilitate easy tracing and capture of missed information during data collection.

3.9 DATA MANAGEMENT

3.9.1 Data entry

Photographs were identified via a systematic numbering system that corresponded with the filled data collection forms and stored on an external hard drive, Google drive and laptop. These images were password protected. The images were shared with the supervising consultant and two senior plastic surgeons with experience in cleft surgery. The PLAN scoring was then done for each of the 68 (sixty-eight) cleft lip patients.

All completed research administered questionnaires (Appendix-B) were completed for each patient and included for data analysis. Data entry was done by the principal investigator and her trained assistant(s) onto an Ms excel sheet and encrypted for safety. All the entered data was checked for consistency and validity by the principle investigator before analysis

3.9.2 Data analysis

Data collected were put into SPSS version 23 from where percentages and frequencies were derived. Cross tabulations between the outcomes (presence of fistula), patient factors (haemoglobin, weight, type of cleft, presence of other congenital anomalies and intra-operative data) was then done. Mann Whitney and Kruskal Wallis tests were run to assess for statistical significant differences. Spearman correlation test was run between different variables and presence of fistula among the palatal cohort, and different variables and scores for the lip cohort. To assess for reliability of the scores among the different raters on the PLAN core, coherence among raters was determined using Cohen's kappa inter-rater reliability analysis. P-value of ≤ 0.05 was considered significant at 95% CI. Data was presented in tables and photographs.

CHAPTER 4: RESULTS

4.1 DEMOGRAPHICS

One hundred and forty-one (141) consecutive patients meeting the inclusion criteria were included in this study. The gender distribution was 55% female (n=78) and 45% male (n=63).

Age

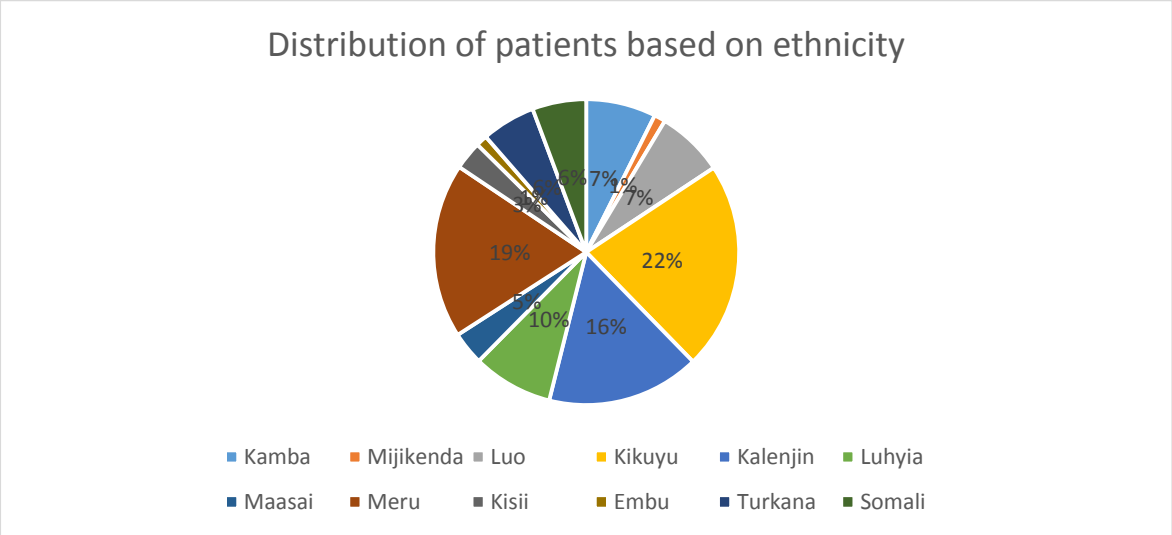
The age distribution ranged from 1 month to 70 years old. The majority (62%) were aged between 0-3 years old, then 3-5 years (13%), 5-7 years (11.3%), older than 9 years (8.2%) and finally 7-9 years (5.5%). This is summarised as below:

Age group	**Frequency (percentage) *n=141***
0-3	87 (62%)
3-5	18 (13%)
5-7	16(11.3%)
7-9	8(5.5%)
>9	12(8.2%)

Table 1: Table showing distribution of age groups

Ethnicity

The majority of patients were from central Kenya region



Piechart 1: Chart showing the distribution of participants based on ethnicity

Family history of clefts

Most of the patients (79%) had sporadic clefts, for those who had a family history, the family member associated with the defect was mostly from the extended family (23 out of 30) compared to nuclear family (7 out of 30).

Associated syndromes

Of the patients assessed, most did not have any other congenital anomaly (91.7%) whereas the rest had. The noted anomalies associated with cleft palate included: club foot, heart defects (Atrio-ventricular septal defect, Patent ductus arteriosus-PDA), Treacher Collins, CTEV and cerebral palsy. For cleft lip associations included club foot, Van der woude syndrome and Down syndrome. Similarly, majority (96.5%) did not have any medical illness on admission. Of those who had, cough was most noted (3 cases). Other conditions like cervical fungal infections, mild eczema and arthritic knee pain were noted.

Type of cleft

The most common pattern of cleft deformity was Left cleft lip with or without a palate representing 45% of the study population. This was followed by Right cleft lip with/without palate at 26% and Bilateral cleft lip with/without a palate at 21%. The least common pattern was isolated cleft palate representing 8% patients. The graph below shows the distribution by cleft deformities

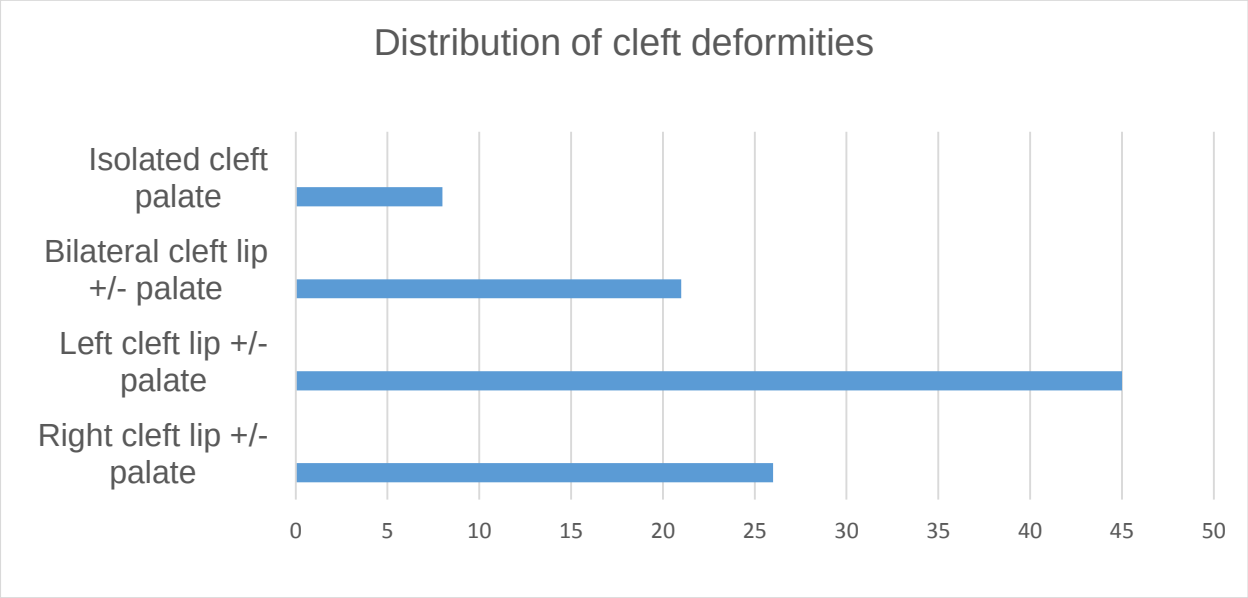


Chart 1: Chart showing the distribution of cleft deformities

Operating surgeon

Most of the patients were attended to by consultants (87%) as compared to the registrars (13%). The registrars were consultant assisted or supervised. Bilateral cleft lip was predominantly repaired by senior consultants with more experience in cleft surgery.

4.2 PALATAL REPAIR

Seventy three (73) patients presented with cleft palate of which 57% were female (n= 42) and 43% were male (n= 31).

Age

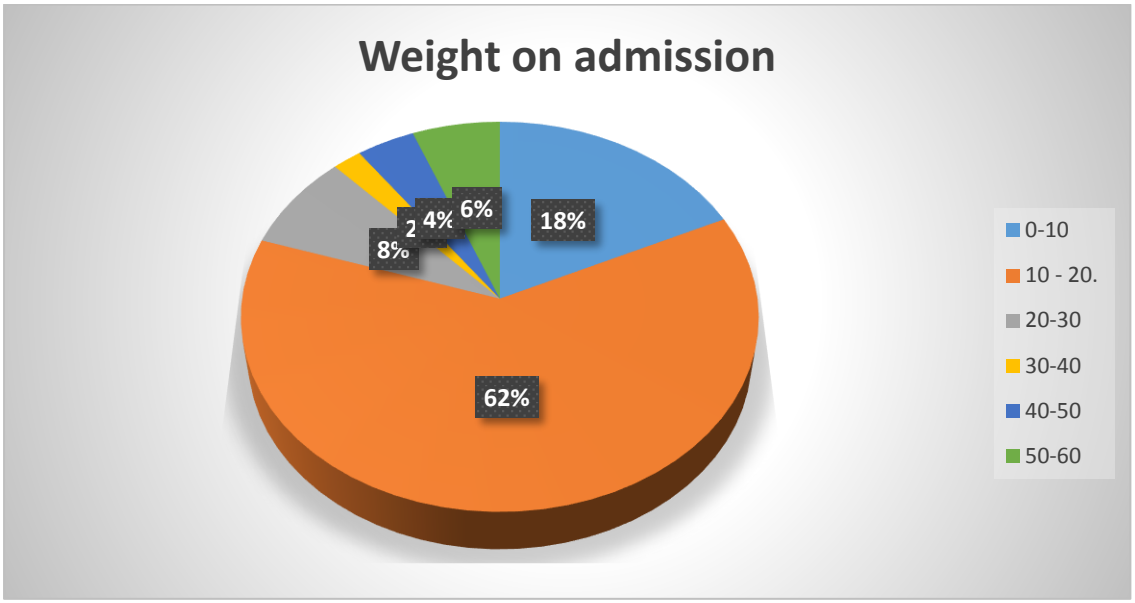
The mean age was five years (Range between 9months – 33 years). However the majority of patients was between the ages of 1-3 years (54%).

Age group	**Frequency (percentage) *n=73***
1-3	39(54%)
3-5	11(15.1%)
5-7	10(13.1%)
7-9	6(8.2%)
>9	7(9.6%)

Table 2: Table showing distribution of age groups

Weight

On admission, most of the patients weighed between 10-20 Kgs (62%), 0-10kgs (18%) and 20-30kgs (8%) (Graph 2)



Piechart 2: Pie chart showing distribution of weight on admission

Haemoglobin level

Mean Haemoglobin levels on admission were 11.7g/dL (range 7.9 – 14.4g/dL). Approximately ninety percent (90.5%) patients had an Hb level above 10g/dL compared to 7 out of 73 patients that had Hb lower than 10g/dL. Only one patient had an Hb below 9g/dL (Hb -7.9g/dL).

Cleft width

Most of these deformities constituted cleft widths more than 15mm (39 out of 73) as compared to those less than 15mm. Of those that were more than 15mm, the mean size was 12.09mm (8 – 14.99mm) whereas in those larger than 15mm, the mean was 18.63mm (16 – 24mm).

Method of repair

The main methods of cleft repair used by cleft surgeons in this study were Von Langenbeck technique or its modification, Bardach two flap palatoplasty (with or without vomer flaps for hard palate closure of the nasal lining). Of the total of 28 of 73 (38%) patients with fistula, the following was the distribution by method of repair

Presence of fistula	Type of Procedure			
		Vomer +2 flap Palatoplasty n=19	2 flap Palatoplasty n=44	Von langenbeck n=10
	Yes	5 (26%)	19(43%)	4(40%)
	No	14(74%)	25(57%)	6(60%)
Significance	P value = 1.000			

Table 3: Cross tabulation between presence of fistula and procedure of repair.

There was no statistical significant difference noted among the groups who underwent repair using the three techniques. The group with two flap palatoplasty with vomer flap for hard palate had less frequency for fistula formation 26%. The majority group of 1-3 years were further analysed as follows:

		Technique of repair		
		Palatoplasty + VOMER n=16	Palatoplasty n=27	Von Langenbeck n=2
Fistula presence	Yes	4(25%)	14(52%)	1(50%)
	No	12(75%)	13(48%)	1(50%)
Significance		P value = 0.001		

Table 4: Cross tabulation for age 1-3 years, Statistical significant difference between the groups who underwent the different procedures by Kruskal Wallis test revealed statistical significant difference among the groups

Perioperative Complications

No peri-operative mortality was recorded in the current study. Intra-operative complications with cleft palate were largely anaesthetic in nature ranging from Cardiac arrest on induction (n=1), Post-operative hypoxia after ex-tubation (n=8) and intra-operative bleeding. Of these patients 8 required ICU or HDU admission. Intra-operative complication were associated with a longer hospital stay of four to five days. The average length of hospital stay was two days.

Palatal fistula

When palatal scoring was done, in majority of the cases, the score was good (62%), or fair (30%). In 8%, it was poor (fistula >1cm). On assessment of the location of the palatal fistula, it was summarised as below.

Fistula Location	Frequency (n=27)	Percentage
Uvula	2	7%
Soft palate	2	7%
Soft and hard palate junction	13	48%
Hard Palate	6	22%
Pre maxilla	4	15%

Table 5: Table showing the distribution of fistulas based on location

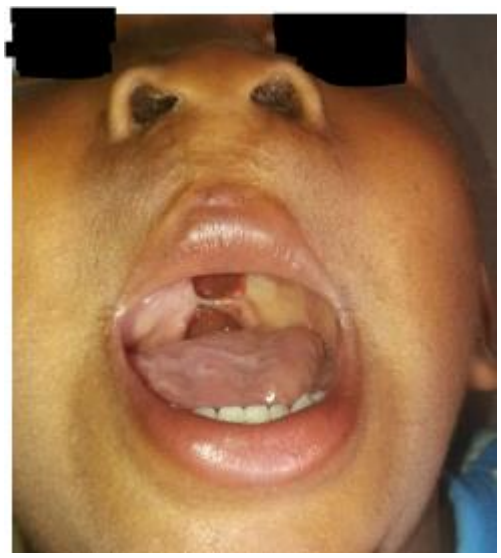


Figure 1: 18 month old patient with post-operative fistula (>1cm) on the soft palate

Correlation between factors and fistula formation

To assess the role of age of patients, Hb, width of cleft, blood loss, cleft type and medical illness on outcome (being presence or absence of fistula), the above variables were cross tabulated and has been summarized (Table 6-10). Similarly, Spearman's correlation was done between the variables and has been tabulated (Table 11). Of all the variables assessed, cleft width, blood loss and Hb were noted to affect the outcome significantly (r values = 0.389, -.565 and -.316 respectively; p value = 0.001, 0.000; 0.006 respectively).

Presence of fistula	Age grouping(in years)					
		1-3 n=39	3-5 n=11	5-7 n=10	7-9 n=6	>9 n=7
	Yes	14(35))	4(36)	4(40)	2(33)	3(42)
	No	25(65)	7(64)	6(60)	4(67)	4(58)
Significance	P value = 1.0000					

Table 6: Cross tabulation between presence of fistula and age grouping. There was no statistical significant difference noted among the age-groups for presence of fistula

Presence of fistula	Type of cleft					
		L/CLP n=27	R/CLP n=16	BCL/P n=17	CPO soft n=4	CPO Hard&soft n=8
	Yes	11(40%)	7(43%)	7(41%)	1(25%)	2(25%)
	No	16(60%)	9(57%)	10(59%)	3(75%)	6(75%)
Significance	P value = 1.000					

Table 7: Cross tabulation between presence of fistula and type of cleft. There was no statistical significant difference noted among the cleft type for presence of fistula

Presence of fistula	Blood loss (mls)										
		0-10	10-2	20-30	30-40	40-50	50-60	60-70	70-80	80-90	90-100	100-110
	Yes	0	0	2	3	11	3	7	1	1	1	2
	No	1	10	10	10	8	4	0	0	0	0	0
Significance	P value = 1.000											

Table 8: Cross tabulation between presence of fistula and blood loss

There was no statistical significant difference noted among the blood loss group for presence of fistula

Presence of fistula	Cleft width (mm)		
		<15 n=34	>15 n=39
	Yes	7(20)	20(52)
	No	28(80)	19(48)
Significance	P value = 1.000		

Table 9: Cross tabulation between presence of fistula and cleft width. Those below 1.5mm width had less fistula formation. To further evaluate the effect of cleft width, the majority group aged between 1- 3years was further analyzed as below:

		Cleft width 1-3 year old	
		<15mm n=23	>15mm n=22
Fistula presence	Yes	4	15
	No	19	7
Significance		P value=0.010	

Table 10: Statistical significant difference between the groups with difference widths of fistula by Mann Whitney test revealed statistical significant difference among the groups p value = 0.010)

On assessing correlation between presence of fistula to its associated factors (age, cleft width, blood loss, medical illness, cleft type and Hb), only the variables age and cleft width showed positive correlations. Furthermore, significant correlations were noted for blood loss, Hb and cleft width. This is summarised in the table below

	Correlations						
Presence of fistula		Age	Cleft width	Blood loss	Medical illness	Cleft type	Hb
	Spearman correlation value	0.094	0.389	-0.565	-0.108	-0.221	-0.316
	P value	0.431	0.001	0.000	0.365	0.062	0.006

Table 11: Correlation results on presence of fistula with age, cleft width, blood loss, medical illness, cleft width and Hb

4.3 LIP REPAIR

Out of the 68 patients that presented with cleft lip, 37 (54%) were female and 31 (46%) were male. The majority of patients were below one year, with the mean age at surgery at 5.4 months. The range was from 1 month-70 years (Table 9).

Age group	**Frequency (percentage)** *n=68*
< 1year	36(53%)
1-3	12(17%)
3-5	7(10%)
5-7	5(7%)
7-9	4(6.5%)
>9	4(6.5%)

Table 12: Table showing distribution of participants based on age**.**

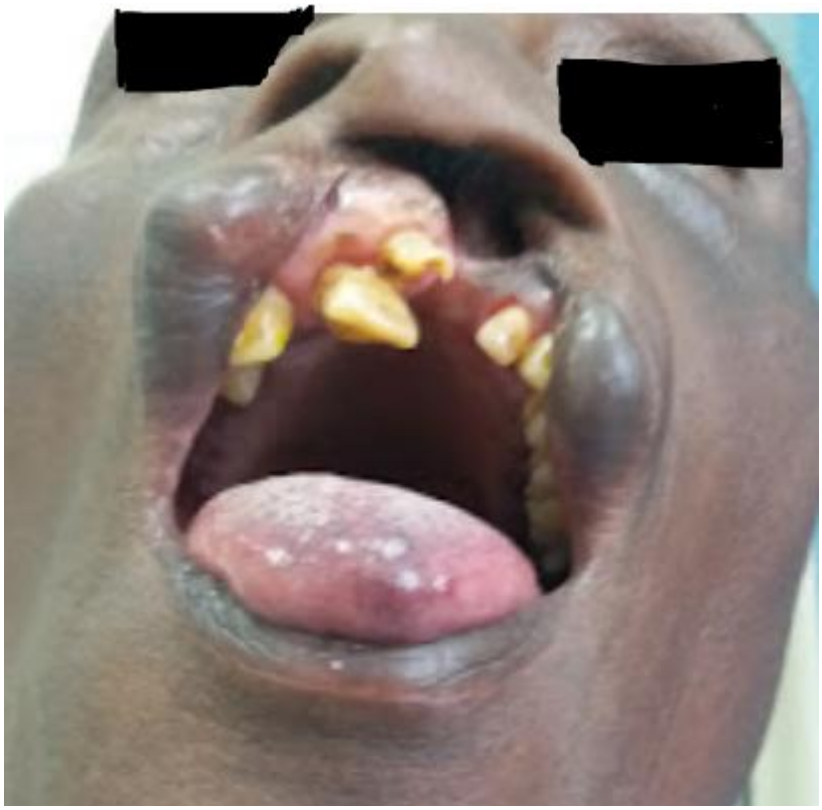


Figure 2: 70 year old patient with Left complete cleft lip and alveolus

The most common deformity observed was Isolated Left cleft lip (32%), followed by Left cleft lip and palate (19%) and Right cleft lip and palate (19%)

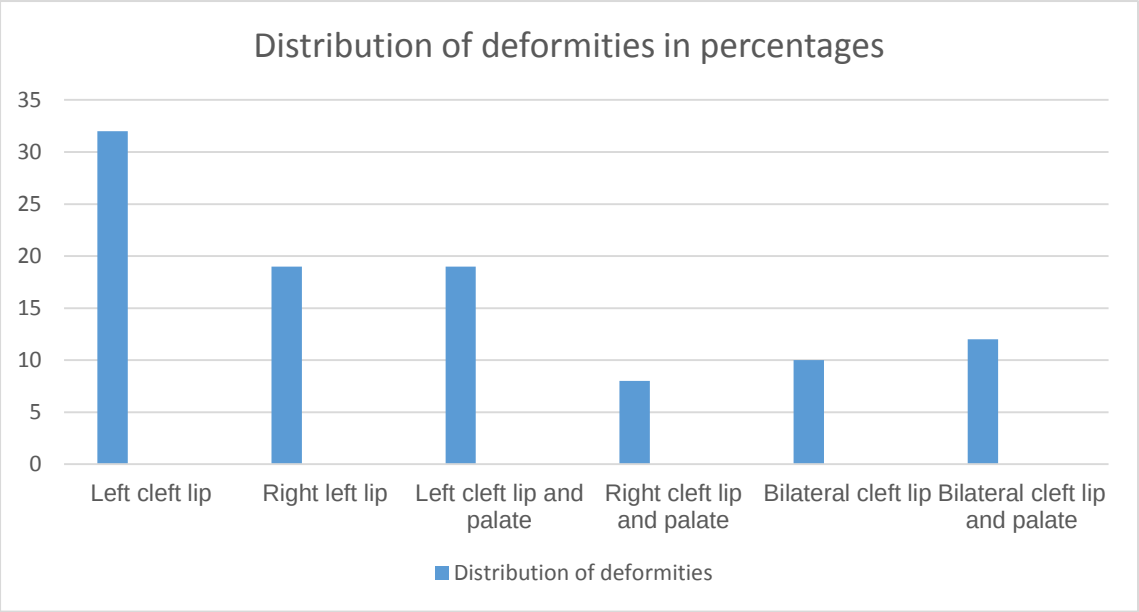


Chart 3: Chart summarizing distribution of cleft deformities.

Below is cross tabulation for type of cleft deformity against the lip scoring. Bilateral cleft lip and palate was not associated with a worse score.

Lip+nose score	Cleft deformity							
		L/UCL	R/UCL	L/UCL/P	R/UCL/P	BCL	BCL/P	P value
	1	8	5	3	1	1	5	1.00
	2	10	3	9	1	3	3	1.00
	3	3	3	1	1	0	1	1.00

Table 13: Cross-tabulation of Lip/Nose score on cleft deformity. When all the cleft deformity groups were assessed for differences on score, their differences were noted to not be significant.

Averages from the lip and nose scores showed no difference based on Cleft width (r= -.002) or cleft lip deformity (r= - 0.086) significant

Correlation between lip and nose scoring and factors

The surgery in most cases, lasted for 1 hour (30minutes – 2 hours), with average blood loss of 19mls (4 – 50mls).During surgery, the suture utilized in most instances for skin closure was the 5/0 vincryl (70%) as compared to the 4/0 and 6/0 vincryl (10%, 10% respectively). The vicryl 4/0 was used on older patents while 6/0 vicryl or moncryl was preferred for the very young patients below two years of age. The surgeons who used 6/0 vicryl also used tissue glue for a suture less skin closure proximal to the vermillion stitch.

Lip score	Sutures				
		4/0 vicryl n=7	5/0 vicryl n=44	6/0 vicryl + tissue glue n=10	P value
	1	2	16	5	1.00
	2	4	20	5	1.00
	3	1	8	0	1.00

Table 14: Cross-tabulation of Lip/Nose score on suture type. The various sutures used did not significantly affect the early surgical outcomes (Spearman's correlation r= - 0.183, sig= 0.136) as shown below

Cleft Lip complications

Following surgery, 50% of the patients did not report complications. In those with complications, scarring was noted (20%), followed by whisling (10%), alveolar fistula (7%), lip shortening (3%), infections (3%), dehiscence (2%), asymmetry (2%), and nasal mal-rotation (2%).

Spearman's correlation	Age	Cleft deformity	Cleft width	Hb	Sutures	Duration	Blood loss
Lip complications(correlation coefficient)	-0.077	0.048	0.150	-0.044	0.00	0.123	0.016
P value	0.530	0.698	0.226	0.724	1.000	0.319	0.898

Table 15: Table showing the correlation between lip complications and associated factors

Spearman correlation test between the complications and associated factors (age, cleft deformity, cleft width, Hb levels, sutures type used, duration and blood loss) did not reveal any significant correlation r values. These factors therefore did not have any influence on the presence of complications as shown by the table.

4.4 SCORING SYSTEMS

When lip scoring was done, in majority of the cases, the score was 1 (80%) and 2 (20%). In nose scoring, it was 1 in 60% of patients, 2 in 35% and 3 in 5%. Results of the reliability analysis of the different scores assigned by the 3 senior raters for both the nose and lip outcomes, revealed intra-class correlation coefficient values of 0.708 and 0.658 respectively. The PLAN score is therefore reproducible method of evaluating both cleft lip and palate repair.

Figure 4: Good outcome after bilateral cleft palate

Patient satisfaction

On satisfaction based on postoperative patient or care-giver response, 97% were either very satisfied or satisfied with the surgical outcome even in the presence of complications. The other 3% comprised of dissatisfied respondents or those who were neither satisfied nor dissatisfied.

CHAPTER 5: DISCUSSION, CONCLUSION AND LIMITATIONS

5.1 DISCUSSION

Cleft lip and palate is a common craniofacial deformity treated by multiple disciplines with the bulk shared between plastic and maxillofacial surgeons in Kenya. Most of the patients were attended to by consultants (87%) and the rest by senior residents (13%) under consultant supervision or assistance. A Study conducted by Losken W. *et al* noted that Plastic surgery residents can contribute to safe palatoplasty with low fistula rates (25).

The most common pattern of clefting was Left CL/P (45%) while the right CL/P and Bilateral CL/P had similar frequency. This pattern is similar to what has been found in previous studies in Kenya (30-31). Contrary to previous local studies, there was a predominance of female participants in this study. The Female to male ratio was 1: 1.2. A Study conducted in Sudan and Nigeria found female predominance with a M:F ratio of 3:10 and 1.1.1 respectively(13,32). Ethnic groups from central Kenya presented most frequently with cleft lip and palate, the most common being Kikuyu as previous studies have reported (37). The mean age for cleft palate repair was five years (range 9 months to 33years) though the majority of patients were operated on between one to three years of age. The majority of cleft lip patients were those below one year (mean 5.4months) but late presentation is a reality in poor resource setting (42)(43).

No peri-operative mortality was recorded in our study. Intra-operative complications increased risk of admission to ICU with increased hospital stay. The rate of fistula formation after cleft palate repair was 37% in this study. The majority, 22 out of 28 patients had fair palatal scores (that is, fistula less than 1cm). This is slightly more than values reported elsewhere (13, 21, 22, 37-38). In Uganda, similar rates of 35% were reported at a single centre(36). Fistula rates could be lower among individual surgeons. The factors to consider in this study were that the outcomes were from surgeries conducted by multiple surgeons in

various hospitals and with a short length of follow up compared to some studies where follow up was up to three months post-operatively(44). Spontaneous closure of a fairly small palatal fistulas may occur over time(28). Generally, developing countries reported the higher fistula rates compared to centres in developed countries(39). Among populations in developed countries, patients from low social economic status tend to have poorer cleft outcomes and longer hospital stay (45). The majority of patients in this study come from rural areas hence are already at high risk of complications. In terms of fistula location, the most common site in this study was at the hard and soft palate junction and supported by previous literature (13, 22). The next most common site was the hard palate.

The most common complication after cleft lip repair was hypertrophic scarring. It is not uncommon following cleft lip repair with rates in literature ranging from 1 to 50%(46). It often requires later revision to improve the aesthetic appearance of the upper lip particularly in female patients The risk factors for this complication are not well studied(46). These included race, lip closure with tension and infection. The various skin closure techniques did not significantly change the outcome on lip scoring (r= - 0.183, sig= 0.136). Other studies have shown that tissue glue (also called suture less skin closure) can be safely used for skin closure in cleft lip repair equally good outcomes and perhaps more superior aesthetics (45-46). The limitation to use of tissue glue is the cost but compared to sutures, there's no need of removal after four to five days (47).

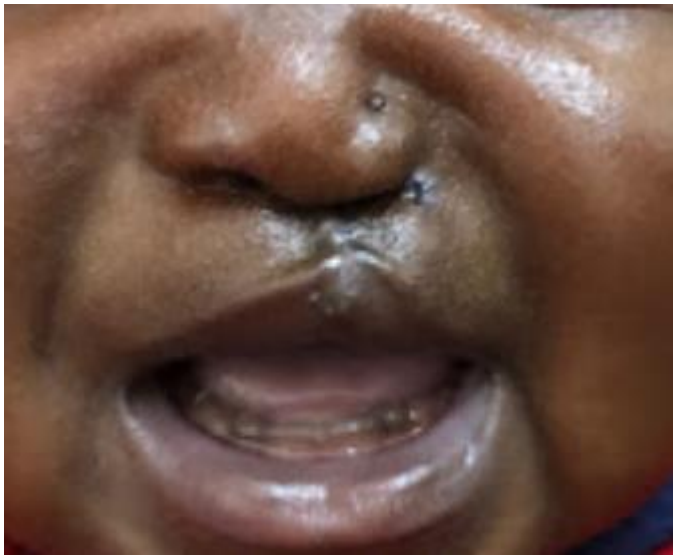


Figure 7: Hypertrophic scarring post-operatively in a 6 month old child

Ethnicity is a significant predictor of hypertrophic scarring with Caucasian patients having lower rates compared to Hispanics and Asians (46). Treatment of lip scaring may include intra-lesional steroids, silicon sheets and massage therapy (13, 20). Botulinium toxin may be used to prevent scarring in susceptible populations (48).

The PLAN (Pennsylvania lip and nose score) is a qualitative clinical assessment which from this study and others(28) has been found to be quick, easy to perform and reproducible by various raters (inter-rater correlation coefficient values of 0.708 and 0.658 respectively for nose and lip scores respectively). The rater average outcome from the lip and nose scoring was 70%. The remaining 30% patients may later have revision procedures for the aforementioned complications while others may opt not to undergo more surgery.

In terms of the patient factors affecting outcome, age, weight and classification of cleft did not affect the outcome, while the severity of the cleft affected outcome significantly. In our study, 54% patients were operated on at one to three years of age (Minimum nine months). The age and weight of the patient at time of repair did not affect the early outcome in terms of fistula formation (r value=0.094). The advantage of early cleft repair (9-12 months) is improvement of speech (6-7). The hole-in-one repair (one stage cleft and palate repair) was

not observed in this study though some authors report comparable results to the staged approach(23). Approach to cleft palate repair remains controversial especially in terms of timing, staged repair and method of repair (45). In this study it was noted that 99% of patients had a one stage repair and one patient had staged repair of the soft palate at 10 months based on the surgeons' preference with cleft width as the main factor.

Cleft width affects fistula formation as seen in the study where the frequency of fistulas increases above 15mm cleft width ($r=0.389$, $p=0.001$). Of note in this study, 53% of patients presented with cleft width above 15mm. From literature, cleft severity has been noted to independently increase adverse outcomes (6, 18, 21).

For cleft lip patients, the width was less impactful on the outcome of repair. Pre-operative NAM for all complete UCL and BCL is recommended to reduce tension during the repair (23-24). In this study, none of the participants were treated with pre-operative NAM hence most of them presented with relatively wide clefts, particularly in BCL. Senior cleft surgeons were able to get relatively good outcomes in these patients as seen in this study. This is consistent with previous local observations (19). In this study, junior consultants and residents did not operate on wide bilateral cleft lips. The surgeons' experience therefore was an important factor.

Figure 3: five month old patient with anteriorly displaced pre-maxilla in Bilateral cleft lip and palate

Millard rotation and advancement and Millard forked flap technique were the most common for unilateral cleft lip and bilateral cleft lip repair respectively. Similarly, Nangole and Khainga in their study found that the Millard technique was popular among Kenyan surgeons and is commonly used to teach residents cleft lip repair(9).

For the factors age, medical illness, cleft width, blood loss, cleft type and Hb, the present study demonstrated that the larger the cleft width, the higher the chances of having a fistula. For the Hb, the lower the Hb the higher the chances of postoperative fistula formation. The age has a weak correlation to presence of postoperative fistula formation and is less likely to affect the outcome.

The method of repair affected the outcome in the present study. Bardach two flap palatoplasty was commonly used by surgeons and has been reported elsewhere in literature (6,8).It has been previously recommended for relatively wide clefts and has been shown to have low fistula rates (29,41). Furrows opposing z-plasty technique was not used in this study, instead inter-velar-veloplasty was used to approximate in the soft palate. Surgeons who used Vomer flaps as part of the technique had less incidence of fistula formation in this study. Fistula formation rates for two flap palatoplasty with Vomer flaps was 27%, and without vomer flaps 43%. The Vomer flaps are relatively simple to raise, safe and available in the region of the palate making them a good choice tissue to augment the nasal mucosal lining during repair (42-43).

The overall satisfaction rate by either the patient or Parent/guardian was either very satisfied or satisfied with the outcome, even in patients who develop complications. Dissatisfaction was noted in an adult patient after cleft palate repair despite lack of fistula formation due to persisting speech problems post-operatively.

5.2 STUDY STRENGTHS

This is study is one of the few local studies that estimates the fistula rates after cleft surgery. The factors affecting the complications after repair have been well demonstrated. This information is important for every cleft surgeon to help prevent adverse outcomes

The study validated the use of the PLAN score as an easy tool to evaluate outcomes in our local settings. This is the first local study that demonstrates that there is no difference in outcome between use of tissue glue (dermabond) and sutures in cleft lip.

5.3 STUDY LIMITATIONS

- The duration of patient follow up was relatively short. Though the main focus was to evaluate the early complications, Long term complications like speech and facial growth could not be evaluated.
- The study utilised two dimensional evaluation after repair which may not give a comprehensive facial assessment
- The dropout rate was high due to patients missing review appointments for various reasons.

5.4 CONCULSION

This study demonstrated a low complication rate and high patient satisfaction following cleft lip and palate surgery in Kenya. Intra-operative complications occurred more with palate repair and these increased the risk of ICU admission and prolonged hospital stay. The most significant factors determining cleft surgery outcome were the surgical technique and cleft severity. Surgeons with extensive experience in cleft surgery had good outcomes even with wide cleft lips in the absence of pre-surgical orthodontics.

5.5 RECOMMENDATIONS

- Studies with longer duration at a single centre should be conducted to evaluate speech outcomes, VPI and facial growth
- More local studies using 3-D models to characterise defects or evaluate outcomes may be required
- A follow up study to evaluate patient and caregiver rated outcomes and satisfaction based on a validated CLEFT-Q tool would be recommended.
- It is important to set up a cleft centre of excellence to standardise treatment across Kenya and to improve teaching, skill transfer and patient follow up and care
- To improve patient and healthcare personnel education about cleft care through media programs and local community initiatives

CHAPTER 6: REFERENCES

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CHAPTER 7: APPENDICES

APPENDIX A: PATIENT INFORMED CONSENT FORM

This Informed Consent form is for patients planned for cleft lip with or without cleft palate surgery and will be administered to the eligible patients or patient's next of kin. We are requesting these patients to participate in this research project titled **"Determinants of early surgical outcomes and complications following primary cleft lip and palate surgery in selected hospitals in Kenya"**

Principal Investigator: Dr. Nang'andu Amanda Malungo

Institution: Department of Surgery, School of Medicine, University of Nairobi.

This Informed Consent Form has five parts:

1) Information Sheet (to share information about the research with you)

2) Certificate of Consent (for signatures if you agree to take part).

3) Certificate of assent

4) Photography consent

5) Statement by the researcher/person taking consent.

You will be given a copy of the full informed consent form.

PART I: Information Sheet

Introduction

My name is Dr. Nang'andu A. Malungo, a post graduate student in Plastic and Reconstructive and aesthetic Surgery at the University of Nairobi. I am carrying out a

research to determine the factors that affect surgical outcome after primary cleft lip and palate surgery in selected hospitals in Kenya.

Purpose of the Research

Cleft lip and palate are the most common congenital craniofacial anomalies treated by plastic surgeons. Previous studies show that cleft lip and palate are significant congenital anomalies in Kenya. Individuals affected by this condition have multiple challenges including feeding, speech difficulties, dental, emotional, facial growth and social stigmatisation. Most patients with access to surgical facilities end up undergoing cleft surgery to repair the defect. The purpose of this study is to understand the factors affecting the surgical outcome and complications following cleft lip and palate surgery in order to come up with standardised treatment guidelines that prevent poor outcome.

Type of Research Intervention

This research will involve asking questions as part of history taking, examination of your pre-surgical malformation and photography before, immediately post-operatively and 4 weeks after repair. This Photography is intended for medical use only.

Study Procedure

On presentation to the study site, I will introduce myself to you and explain the nature of this research project, its justification and the benefits the data obtained will provide. I will then guide you through a consent form taking questions and making clarifications at any point you deem necessary. After you have consented to participate in the study by signing this form, I will conduct an interview that comprises several questions that you will answer truthfully to the best of your ability. The questions in the interview are tailored to address the laid out objectives of the study. The interview will be conducted in a private and confidential manner in a private consultation room in the outpatient clinic or ward. The data collected from this

interview will be analysed and used to draw conclusions and later presented as a research paper for publication. Throughout the study your confidentiality and anonymity will be preserved. A follow-up interview may be conducted at later stages during the post-operative hospital visits as may be deemed necessary and with your consent.

Voluntary Participation/Right to Refuse or Withdraw

Your participation is entirely voluntary. Whether you choose to participate or not, all the services you receive at this hospital will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this hospital for your condition. You have a right to refuse or withdraw your participation in this study at any point.

Confidentiality

The information obtained will be treated with confidentiality and only be available to the principal investigator and the study team. Your name will not be used. Any information about you will have a number on it instead of your name. We will not be sharing the identity of those participating in this research.

Sharing the Results

The knowledge that we get from this study will be shared with the policy makers in the Ministry of Health and doctors through publications and conferences. Confidential information will not be shared.

Benefits

You may get no direct benefit from the information you provide for this study. However, the results will greatly contribute towards the advancement of health science by providing knowledge on better management of patients undergoing a similar treatment process such as yours.

Risks

There are no direct risks anticipated in this study as it only seeks observe the surgical outcomes and complications that may occur following surgery. The risks, if any, are from the surgical intervention, the consent of which will be collected separately preoperatively.

Cost and Compensation

There will be no extra cost incurred for participating in this study nor will there be any compensation offered. This proposal has been reviewed and approved by UoN/KNH Ethics Committee, which is a Committee whose task is to make sure that research participants are protected from harm.

Who to Contact

If you wish to ask any questions later, you may contact:

1. Principal Researcher: Dr. Nang'andu Amanda Malungo, Department of Surgery, School of Medicine, University of Nairobi P.O. Box 19676 KNH, Nairobi 00202. Mobile no. 0700711301

If you have any ethical concerns, you may contact:

Kenyatta National Hospital/ University of Nairobi Ethics and Research Committee College of Health Sciences P. O. Box 19676 Code 00202 Nairobi Tel. (254-020) 2726300-9 Ext 44355 E-mail: uonknh_erc@uonbi.ac.ke Website: www.erc.uonbi.ac.ke

PART II: Certificate of Consent

I have read the above information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Signature of Participant _____

Date _____

If Non -literate:

I have witnessed the accurate reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I confirm that the individual has given consent freely.

Thumb print of participant

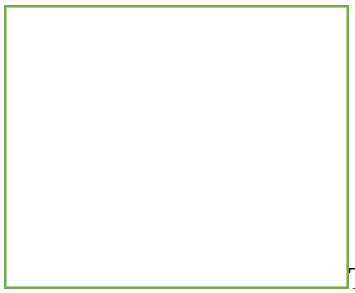
Signature of witness _____

Date _____

PART III: **Certificate of Assent (patients below 18years)**

I understand that I have been asked to take part in a study about cleft lip and palate results. I have read the above information, or it has been read to me. I have had the chance to ask questions about it and any questions that I have asked have been answered to my satisfaction. I understand that I do not have to enter this study. If I take part, I can quit at any time without giving a reason. My parent(s)/ guardian is aware of my willing participation in this study.

Signature of patient _____

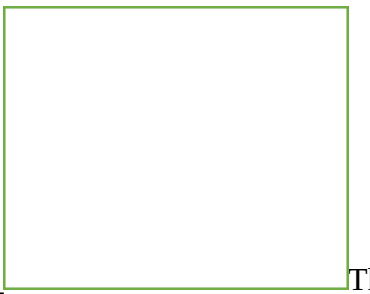
 Thumb print

Signature of parent/guardian/witness _____

Date _____

PART IV: <u>Photography Consent / Release form</u>

I, the undersigned, hereby give permission for the lawful use of my/my child's photographs as part of data collection in this cleft lip and palate study. I understand that it is for medical educational use e.g. conference presentations, publications and illustrations. I hereby release to the photographer all rights to exhibit this work in print and electronic form.

Signature_____  Thumb

Witness _____

Date_____

PART V: Statement by the Researcher

I have accurately read out the information sheet to the participant, and to the best of my ability made sure that the participant understands that the following will be done:

- Refusal to participate or withdrawal from the study will not in any way compromise the care of treatment.
- All information given will be treated with confidentiality.
- The results of this study might be published to facilitate better management of patients with cleft lip and palate

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this Informed Consent Form has been provided to the participant.

Name of researcher/person taking consent

_____

Signature of researcher/person taking consent _____

Date_____

FOMU YA MAELEZO

HATI YA RIDHAA YA MGONJWA KUSHIRIKI UTAFITI

Hati hii ya ridhaa ni kwa ajili ya wagonjwa waliopangiwa kufanyiwa upasuaji wa mpasuko wa mdomo wa juu bila au pamoja na upasuaji wa mpasuko wa mdomo wa chini na kisha itawasilishwa kwa watu wa karibu wa wagonjwa hao. Tunawaomba wagonjwa hawa kushiriki katika mradi huu wa utafiti unaoitwa "**Mambo yanayopelekea matokeo na changamoto na changamoto za upasuaji wa uwaji wa mdomo wa juu na mdomo wa chini katika hospitali teule Kenya"**

Mtafiti mkuu: Dr. Nang'andu Amanda Malungo

Taasisi: Idara ya Upasuaji, Kitivo cha Afya, Chuo Kikuu cha Nairobi.

Hati hii ya ridhaa ina sehemu tatu:

1) Karatasi ya taarifa (kushirikishana taarifa za utafiti na wewe)

2) Cheti cha ridhaa (kwa ajili ya kutia sahihi ikiwa utakubali kushirki).

3) Maelezo ya mtafiti/mtu anayepokea ridhaa.

Utapewa nakala ya hati ya ridhaa yenye maelezo.

SEHEMU: Karatasi ya taarifa

Utangulizi

Jina langu ni Dr. Nang'andu A. Malungo, mwanafunzi wa shahada ya uzamiri ya Plastic and Reconstructive Surger Katika chou kikuu cha Nairobi. Ninafanya utafiti kubaini mambo yanayoathiri matokeo ya upasuaji wa uwazi wa mdomo wa juu na mdomoa wa chini katika hospitali teule za Kenya.

Kusudi la utafiti

Tafiti zilizotangulia zinaonesha kuwa muachano mapsuko katika mdomo wa juu na wa chini ni are significant congenital anomalies in Kenya. Watu walioathiriwa na tatizo hili hupatwa na changamoto mbalimbali ikiwemo kushindwa kula, kutamka vizuri, athari za meno, hisia na muonekano na kutengwa na jamii. Waathiriwa wengi wa tatizo hili wanaofanikiwa kupata matibabu hushia kufanyiwa upasuaji wa mdomo wa juu au wa chini ili kurekebisha athari. Kusudi la utafiti huu ni kubaini mambo yanayoathiri matokeo na changamoto za upasuaji wa mpasuko wa mdomo wa juu na mdomo wa chini ili kuweza kufikia njia-elekezi rasmi za matibabu zitakazoondoa matokeo hasi.

Aina ya uhusika wa utafiti huu

Utafiti huu utahusisha uulizaji wa mamswali kama hatua ya kupata historia, uchunguzi wa athari kabla ya upasuaji na piacha za awali, na hali halisi mara baada ya uapasuaji na wiki nne baada ya upasuaji. Picha hii imekusudiwa kwa ajili ya matuizi ya kitabibu tu.

Hatua za utafiti

Katika eneo la utafiti, nitajitambulisha kwako/ kwenu na kuelezea sifa ya utafiti huu, sifa hizo ndizo faida ambazo tutazipata kutoka kwenye taarifa zenu. Kisha nitawaongoza katika swala zima la ridhaa nikipokea amswali kutoka kwenu na kuweza kufafanua jambao lolotea litakalohitaji ufafanuzi. Baada ya kuridhia kushirikia utafiti kwa kutia sahihi hati hii,

nitaongoza usaili ambao utahusisha maswali kadhaa ambayo mtajibu kwa uwazi na ukweli kadiri muwezavyo. Maswali katika usaili yameandaliwa ili kuweza kufikia malengo ya utafiti huu. Usaili utaendeshwa kwa siri katika chumba binafsi na cha siri maalumu katika kliniki au wodi. Taarifa zitakazopatikana katika usaili huu ziatachambuliwa na kutumiwa kuandaa hitimisho na kisha baadaye kuwasilishwa kama jarida la utafiti kwa ajili ya usambazaji. Katika utafiti wote taarifa zako za binafsi na siri zitahifadhiwa salama. Usaili kwa ajli ya kufuatilia maendeleo unaweza kufanyika katika hatua za baadaye wakati kutembelea hospitali baada ya upasuaji ikilazmiu kufanya hivyo na kwa ridhaa yenu.

Ushiriki wa hiyari/ Haki ya kukataa au kujiondoa

Ushiriki wako ni wa hiari kabisa. Ikiwa utakubali kushiriki au la, huduma zote unazopata katika hospitali hii zitaendelea kama kawaida na hakuna kitakachobadilika. Kama ukikataa kushiriki katika utafiti huu, utaendelea kupatiwa matibabu kama kawadia katika hospitali hii kwa afya yako. Una haki ya kukataa au kujiondoa kwenye utafiti huu wakati wowote.

Usiri

Taarifa itakayopatikana itatumiwa kwa usiri na itahifadhiwa na mtafiti mkuu pamoja na watafiti wenza tu. Jina lako halitatumiwa. Kila tarifa utakayoitoa itakuwa na nambari badala ya jina lako. Hatutashirikisha taarifa binafsi ya watakaoshiriki katika utafiti huu.

Kushirikisha Matokeo

Maarifa yatakayopatikana katika utafiti huu yatashirikishwa kwa watunga sera ndani ya wizara ya afya na madktari kupitia warsha na makongamano. Taarifa za siri hazitashiirikishwa

Faida

Yawezekana usipate faida ya moja kwa moja kwa taarifa utakayoitoa katika utafiti huu. Hatahivyo, matokeo ya utafiti huu yatatoa mchango mkubwa katika kuboresha sayansi ya afya kupiti kutoa maarifa juu ya matibabu ya wagonjwa wanopitia mchakatowa matibabu kama unaopitia wewe.

Hatari

Hakuna hatari yoyote katika utafiti huu kwakuwa unalenga kujifunza matokeo ya upasuaji na changamoto zinazoweza kujitokeza. Hatari,kama zitakuwepo, ni katika ushirki mchakato wa upasuaji, ambapo ridhaa yake itaombwa kabla.

Gharama na Fidia

Hakutakuwa na gharama zaidi itakayotozwa kwa kushiriki wala hakutakuwa na fidia yoyote itakayotolewa. Ombi hili limepitiwa na kupitishwa na kamati ya Maadili ya UoN/KNH, ambayo kazi yake ni kuhakikisha washiriki wa utafiti wanalindwa kutoka ktika hatari.

Mtu wa kuwasiliana naye

Ikiwa utahitaji kuuliza swali lolote baadaye, waweza wasiliana na:

1. Mtafiti Mkuu: Dr. Nang'andu Amanda Malungo, Idara ya Upasuaji, Kitivo cha Afya, Chuo kikuu cha Nairobi P.O. Box 19676 KNH, Nairobi 00202. Simu ya mkononi 0700711301

Ikiwa una shaka yoyote kuhusu mambo ya maadilli, wasiliana na:

Hospitali ya Taifa ya Kenyatta/ Tume ya maadili ya Chuo kikuu cha Nairobi, Kitivo cha Sayansi ya Afya P. O. Box 19676 Code 00202 Nairobi Simu. (254-020) 2726300-9 Ext 44355

E-mail: uonknh_erc@uonbi.ac.ke

Website: www.erc.uonbi.ac.ke

SEHEMU: Cheti cha Ridhaa

Nimesoma taarifa hapo juu, au imesomwa kwangu. Nilipata nafasi ya kuuliza maswali kuhusu taarifa hiyo na maswali yote niliyouliza yamejibiwa na nimeridhika. Ninaridhia bila kwa hiyari yangu kushiriki kama mshiriki katika utafiti huu.

Sahihi ya mshiriki _____

Tarehe _____

Kama hufahamu kusoma wala kuandika:

Nimeshuhudia usomaji sahihi wa hati ya ridhaa kwa mshiriki, naye alipata nafasi ya kuuliza maswali. Nathibitisha kuwa mshiriki ametoa ridhaa kwa hiyari.

Alama ya dole gumba ya mshiriki

Sahihi ya shuhuda _____

Tarehe _____

SEHEMU: Maelezo ya mtafiti

Nimesoma kwa usahihi hati ya taarifa kwa mshiriki, na kwa kadiri ya uwezo wangu nimehakikisha mshiriki anaelewa kwamab yafuatayo yatafanyika:

• Kukataa kushiriki au kujiondoa hakutaathiri matibabu ya mginjwa kwa namna yoyote.

• Taarifa zote ziattumiwa kwa siri.

• Matokeo ya utafiti huu yaweza sambazwa kwa ajili ya kutoa huduma nzuri kwa wagonjwa wa mpasuko wa mdomo wajuu na wa chini.

Nathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali kuhusu utafiti huu, na maswali yote yaliyoulizwa na mshiriki yamejibiwa kwa usahihi kwa kadiri ya uwezeo wangu. Nathibitisha kuwa mshiriki hajashurutishwa kutoa ridhaa yake, na ridhaa imetolewa bure na kwa hiyari.

Nakala ya hati hii ya ridhaa amepewa mshiriki.

Jina la mtafiti / mtu anayepokea ridhaa

_____

Sahihi ya mtafiti/ mtu anayepokea ridhaa

_____

Tarehe _____

APPENDIX B: RESEARCH TOOLS

Questionnaire

Determinants of early surgical outcomes and complications in the early postoperative period following primary cleft lip and palate repair in selected hospitals in Kenya

Preoperative Data

Section A (Epidemiology)

Number of Client……

Contact phone…….

Hospital number……

Sex - Male [ ] Female [ ]

Date of birth……

Age at the time of surgery……

Ethnic group……..

Family history of clefts……

- If yes to above, specify……..

Birth history……Term……..Preterm……

Maternal illness during pregnancy……..Epilepsy ( ), Smoking ( ), Alcohol ( )

Section B (clinical status of client)

Type of cleft deformity

Unilateral cleft lip -/+ alveolus

- Right [ ] Left [ ]
- Complete [ ]
- Incomplete [ ]
- Simmonart band [ ]

Unilateral cleft lip and palate: Right [ ] Left [ ]

Bilateral cleft lip +/- alveolus ……..

Median cleft lip……

Bilateral cleft lip and palate……

Isolated cleft palate:

- Hard [ ]
- Soft [ ]
- Both hard and soft [ ]
- Microform [ ]
- Unilateral [ ]
- Bilateral [ ]
- Submucous [ ]

Diameter of cleft: Narrow [ ] Wide [ ] (wide cleft: medial edges >1.5cm)

Other congenital anomalies present

1. ……

2. ……

Weight on admission…….

MUAC on admission……..

Hb on admission…….

Other health problems on

admission……

Section C (Intraoperative Data)

Date of surgery…….

Surgical checklist done- Yes ( ) No ( )

Operating surgeon:

- Consultant plastic surgeon……
- Resident plastic surgeon…….. …….

Surgical procedure:

-Unilateral cleft lip

- Millard [ ]
- Tennison-Randall [ ]
- Others……

-Bilateral cleft lip

- Millard [ ]
- Manchester [ ]

- Others [ ]……..

-Cleft palate

- Von-langenbeck [ ]
- Furlow [ ]
- Others [ ]…….

Sutures used for skin closure……..

Duration of surgery……

Estimated blood loss……..

Complications intra-op (please specify)……

Section D (Post-operative outcome and complications)

Length of hospital stay……

Client/Parent/Guardian surgical outcome satisfaction:

- ✓ Very satisfied [ ]
- ✓ Satisfied [ ]
- ✓ Dissatisfied [ ] ……(elaborate if possible)

PLAN (Pennsylvania Lip and nose) score:

- Lip: Good (1) Fair (2) Poor (3)
- Nose: Good (1) Fair (2) Poor (3)

Quantitative palatial score:

-Good (No fistula)……

-Fair (fistula <1cm)…….

-Poor (fistula>1cm)……

Complications

Infection……..

Dehiscence……. Partial [ ], complete [ ]

Whistling deformity……

Others……

Location of fistula if present:

-Pre maxilla…….

-Anterior hard palate…….

-Junction of hard and soft palate……..

Soft palate….. Uvula.....