PATTERN OF SECONDARY CLEFT LIP AND PALATE DEFORMITIES IN PATIENTS SEEN IN SELECTED HOSPITALS IN NAIROBI, KENYA.

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A RESEARCH PROJECT SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE DEGREE OF MASTERS OF DENTAL SURGERY IN ORAL AND MAXILLOFACIAL SURGERY OF THE UNIVERSITY OF NAIROB

DECLARATION OF ORIGINALITY

DECLARATION OF ORIGINALITY

I, Odhiambo Bati of registration number V60/88145/2016 of the Department of Oral and Maxillofacial Surgery, School of Dental Sciences, College of Health Sciences of University of Nairobi, declare that this research work titled, "Pattern of secondary cleft lip and palate deformities on patients seen in selected hospitals in Nairobi, Kenya." is my original work.

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SUPERVISORS'APPROVAL

SUPERVISORS'APPROVAL

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LIST OF ABBREVIATIONS

CL – Cleft lip

CP – Cleft palate

CLP – Cleft lip & palate

CLPD – Cleft lip & palate deformities

QOL – Quality of life

US – United States

SCLP – Syndromic Cleft Lip and Palate

NSCLP – Non Syndromic Cleft Lip and Palate

IUL – Intrauterine Life

AED - Antiepileptic drugs

NTDs - Neural tube defects

OCs - Oral clefts

KNH – Kenyatta National Hospital.

UoN – University of Nairobi

ENT – Ear Nose and Throat

PRAS – Plastic Reconstructive and Aesthetic Surgery

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ABSTRACT

Study background

Cleft lip and palate (CLP) deformities are the commonest congenital anomalies affecting orofacial structures, usually found in one in every 700–1000 of the new-borns worldwide. Whereas most deformities are surgically corrected, there is often residual deformity that may need additional correction. The demographics and characteristics of these secondary deformities remain largely undocumented in Kenya.

Main objective

Main objective was to determine the pattern of secondary CLP deformities in patients seen in selected hospitals in Nairobi, Kenya.

Study design and sites

This was a descriptive hospital based, cross-sectional study of patients presenting with secondary CLP deformities seen at selected hospitals in Nairobi, Kenya.

Participants and method

Convenience sampling technique was used. Study population consisted of patients diagnosed with CLP who had undergone at least one corrective surgery. All patients who meet the criteria for inclusion and consented to participate were enrolled to the study.

Data collection

Data collection was done using a questionnaire. Data collected included social and demographic characteristics of the patients, primary CLP deformities, age of the initial corrective surgeries and the secondary cleft lip and palate (SCLP6) deformities. The incidence and pattern of the secondary deformity was described and clinical photographs taken.

Analysis of the data

The data was analysed using SPSS 25th version.

Results

A total of seventy six (76) secondary cleft cases were enrolled. Forty one (41) being males and thirty five (35) females. The most common primary cleft type was the combined bilateral cleft lip and palate (BCL+P) constituting 22 (28.9%) of all cleft deformities. Of the 76 participants recruited, 69 had primary CL deformities while 7 had isolated cleft palate deformities. Of the 69, forty one (59.4%) had some form of secondary cleft deformity while twenty eight (40.6%) did not have. A total of 39 participants had had their cleft palates repaired. Thirty two (78%) had clinically observable secondary deformities while seven (22%) had no secondary deformities. Some of participants had more than one secondary cleft lip or palate deformities occurring concurrently.

There was a slight male preponderance among the participants with male to female ratio of 1.2:1. Age distribution was between 5 months to 27 years with majority being below 4 years 34 (44.7%). They were from urban areas (51.3%), semi urban regions (27.6%) and rural areas (21.1%).

Discussion

There was a higher proportion of younger patients with mean age of 10 months which is consistent with study by Onyango JF et al (1) Kenyan studies. More than half the number of participants had secondary deformity of the lips (59.4%), this is consistent with the study by Musgrave HR et al (39) who observed that this occurrence may be due technique of repair or post-surgical complications like infection and dehiscence. Most common deformity being scarring (42.4%), a finding consistent with the preponderance of Africans to scar and keloid formation. The most common secondary cleft palate deformity was oronasal fistula in 50%. The more complex the primary deformity the more likelihood of developing secondary deformity. This is consistent with other studies (46-48) that showed the fistula formation rate to be higher in more severe degree of cleft palates.

Conclusion

Secondary CL +P deformity is a prevalent phenomenon that requiring proportionate attention. It should be addressed early and in a multidisciplinary manner to minimise secondary deformities.

CHAPTER ONE

INTRODUCTION AND LITERATURE REVIEW

1.1 Introduction

Offering care to children born with cleft lip and palate (CLP) is a challenging task and especially when faced with difficult secondary deformities. Making correct diagnosis of the underlying problem is an important step in evaluating such patients. More often than not, it requires a good understanding of the original deformity and the technique of repair that was performed.

CLP deformities are the commonest congenital anomalies affecting orofacial structures, usually affecting one in every 700–1000 of the new-borns worldwide. The risk factor for CLP include familial genetic predisposition, maternal nutrition, medication especially folate antagonists, and exposure to teratogens. (1). The anomaly is depicted by break of continuity of soft or hard tissues forming the lip and palate.(2)(3) In Kenya, CLP is the third most prevalent congenital malformation after congenital talipes equinovarus and neural defects compared to U.S where it is the second most common of congenital birth defect after Down's syndrome (4). In the US, 3.79 million babies are born annually, and 7,000 of the infants have craniofacial clefts. (5)

When CLP appears clinically together with other, identifiable malformations in a defined pattern, it is referred to as a syndromic cleft lip/ palate (SCLP). If it occurs as a sole deformity, it is referred to as non-syndromic cleft lip/ palate (NSCLP). Among the syndromes associated with CLP are Apert syndrome, Crouzon syndrome, Hemi-facial microsomia, Pierre Robin Syndrome and Treacher Collins syndrome.

Secondary CLP are deformities that manifest in previously repaired CLP. (6) The presentation largely depends on the nature, severity of the primary deformity, timing of the primary repair,

technique and expertise of the surgeon and the extent of multidisciplinary collaboration.(7) The secondary defects may present as physical deformities or functional insufficiencies. The deformities range from: hypoplastic lips, notching on the lips, lip asymmetry, nasal asymmetry, velopharyngeal insufficiency, oronasal fistulae, hypoplastic maxilla, and anomalies of dentition and scarring, among others. Other than physical defects on the patient, CLP deformities have a great psychological and socio-economic effects on the affected patients and their families. Negative effect on psychosocial life and lower quality of life are reported effects. Increased mortality from causes such as suicide has also been reported. (8) It also has substantial healthcare costs impact.(5)(9)

A number of techniques for secondary CLP repair have been advanced with the goal of constructing the philtral column, getting rid of bad scars, augmenting lip volume, fistula closure, pharyngeal surgery to improve speech among others. Still, no single technique yields a completely satisfactory results. Additionally, the timing for surgical corrections of the secondary cleft lip is still under debate.(6) Subsequent surgeries are avoidable burden on patients and their families when it is possible to achieve a good outcome through primary surgery alone. (10)

Despite the secondary CLP being common, there is scarcity of literature with regard to SCLP deformities in Kenya.

Three hospitals in Nairobi will be chosen for this study. The hospitals attract patients from all over the republic of Kenya both for primary surgical care and referrals for repair of secondary CLP deformities. The study therefore aims to describe the incidence and pattern of deformities in secondary CLP in patients presenting at three hospitals in Nairobi, Kenya.

1.2 Review of literature

1.2.1 Embryology

Thorough understanding of the embryology of the lip and palate is essential for comprehensive management of CLP. The face is formed from many primordial processes which form about the primordial oral cavity known as stomodaeum. By week 4 of IUL, five pharyngeal arches develop at the future cervical region. The first branchial also known as the mandibular arch grows to form the nasomaxillary complex whereas the upper boundary of the stomodaeum arises as a frontal prominence. The stomodaeum is later separated from the foregut by the buccopharyngeal membrane. Maxillary process forms from the dorsal end of the first arch.(11)

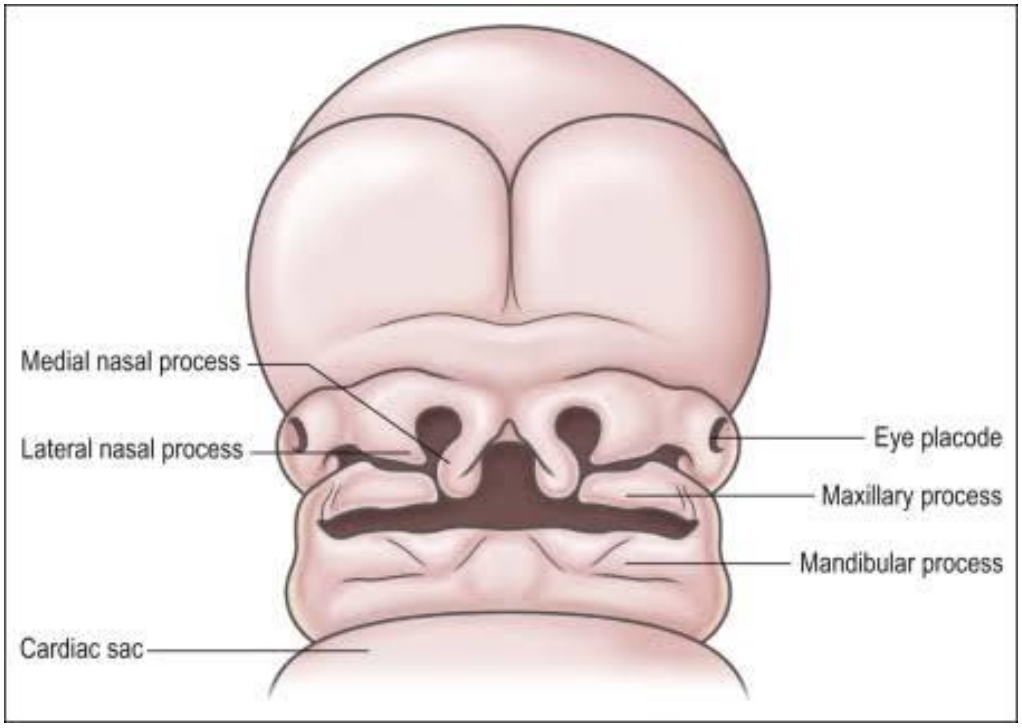

Plate 1 Maxillary and mandibular processes in human embryo of week 5 IUL (Adopted from Gulabivala K 2014) (12)

1.2.2 Development of the primary palate

The primary palate is also known as the premaxilla. It develops from union of the two medial nasal processes and the frontonasal prominence. It forms the anterior one-third of the final palate. It is anterior to the incisive foramen. It contains the maxillary incisors.

At 5th and the 6th weeks of IUL, the maxillary process undergoes rapid growth. It integrates with the nasal process at 7th week IUL to form the intermaxillary segment. The philtrum of the upper lip is formed from the labial component. Failure of or inadequate proliferation of these processes may lead to clefting.

1.2.3 Development of the secondary palate

It includes the soft palate and the hard palate posterior to the incisive foramen. It is formed from the palatal shelves by the 6th week IUL. The palatal shelves grow medially and downwards on either sides of the tongue. The tongue prevents premature union of the palatal shelves. Thus growing vertically down and approximate by week 8 IUL. The interposing epithelial lining thereafter degenerates. After that the underlying mesenchyme from the shelves integrate in the midline, forming be palatal raphe. Final fusion is completed by week 10 IUL. The fusion is slightly delayed in males. Failure of union of the shelves, and with the frontonasal processes results in CP.

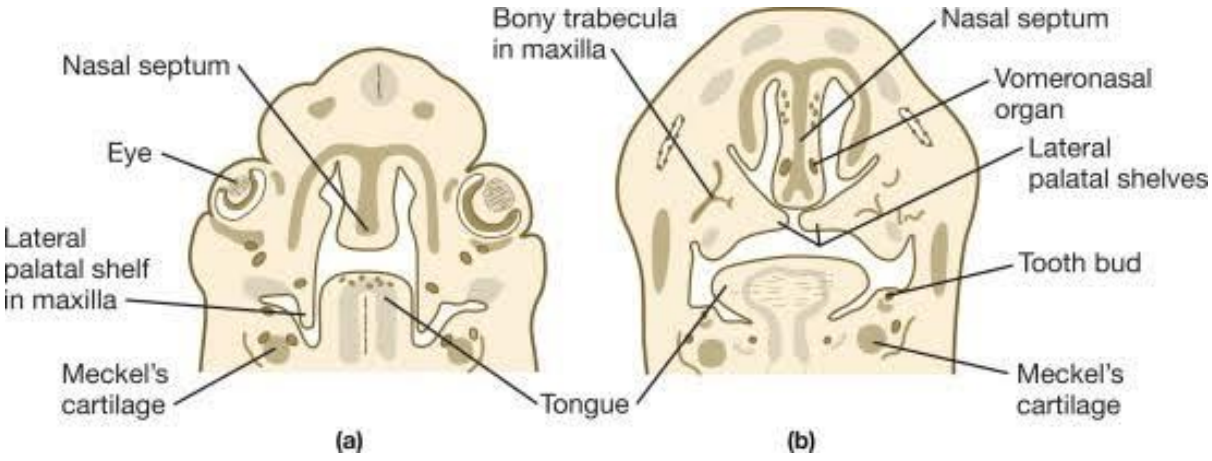

Plate 2 Development of the palate, week 4 IUL (a), and week 6 IUL (b)

(Taken from the developing human clinically oriented embryology 8th edition.*(13)*)

1.2.4 Causes of CLP

Studies are ongoing to determine the epidemiology and aetiology of CLP. Several risk factors have been identified such as parental age, smoking, nutritional inadequacy and liquor consumption. There is increasingly convincing findings that folic acid supplements may lower the incidence of orofacial clefts. Smoking is the only consistent common risk factor. (14)

1.2.4.1 Genetic basis

The aetiology of CLP is complex, having genetic component. A number of genes implicated in SCLP have been described - T- box transcription factor- 22 (*TBX22*), interferon regulatory factor- 6 (*IRF6*) and poliovirus receptor- like- 1 (*PVRL1*) are among the genes responsible for X- linked CLP. The variability of these genes is wide, indicating the high vulnerability in the developmental pathways in the craniofacial region.(15)

1.2.4.2 Environmental Factors

i. Smoking

Maternal smoking increases the risk of CLP. Surveys have consistently indicated a relative risk of about 1.3–1.5 (16). There is a synergistic effect of maternal smoking and a positive genetic background. Von Rooij *et al*. (2001) found that a maternal gene, glutathione s- transferase (*GSTT1*), combined with tobacco smoking, significantly increase the risk of CLP with odds ratio=4.9.(17). Beaty K. *et al*. (2002) found that maternal tobacco smoking and infant *MSX1* gene acting together, increases the risk for CLP by 7.16 times.(18)

ii. Consumption of alcohol

Heavy maternal alcohol consumption, may increase the risk of developing CLP. Lamar *et al*. (1999) found that alcohol intake by the mother increases the risk for CLP 1.5–4.7 fold. The risk was observed to be dose- dependent.(19). Lisa *et al*. (2008) noted increased risks of orofacial clefting in infants whose mothers were frequent alcohol drinkers, of an average of 5

or more bottles per sitting, during the first trimester of pregnancy compared to non-drinkers. (20) (21)

1.2.4.3 Medications

Usage of certain medications by expectant mothers especially during the first trimester has been linked to CLP deformities. (22) (23) Medications that have been associated with development of CLP defects include: some anticonvulsants like valproic acid, carbamazepine, and topiramate; anticoagulants especially warfarin; antidepressants and some anxiolytics especially diazepam. Data from the National Birth Defects Prevention Study compiled by Martha *et al*. (2012) assessed use of anti-seizure drugs and the risk of spina bifida, oral clefts (OCs), congenital heart defects, urethral defects in males, among other major birth defects. They looked at the specific agent, duration of usage, timing, and indication. There was drug-specific increased risk. Valproic acid seem to be more implicated in occurrence of OCs with odds of 4.4 at 95% confidence interval. For carbamazepine in relation to OCs 5.0 at 95% CI. Study done by Odhejo *et. al*. (2012) on ability of the antipsychotics to cross the placenta found that, the largest percentage was for olanzapine with mean=72.1%, SD=42.0%. Second is haloperidol with mean=65.5% at SD=40.3%), the least was quetiapine (7)(22). This propensity of the antipsychotic drugs to cross the foetal-placental barrier shows that they can potentially cause birth defects. Meta-analysis by Einarson et al (2009) found no risk of developing CLP or teratogenicity with the use of typical antipsychotics.(24). Risperidone, one of the commonly used atypical antipsychotic was found to cause foetal malformations like, Pierre-Robin sequence, CLP among others. (7)

1.2.4.4 Nutrition

Nutritional imbalance like folate deficiency has been identified as a cause of CLP. The analysis of data from the registry in Hungarian regarding congenital anomaly, Czeizel *et al*. observed that the use of folic acid (average of 6 mg) in the first trimester of pregnancy lowered cleft

palate risk among other congenital anomalies by averagely 50%. (2). Shaw *et al*. in a survey conducted in California reported a 50% decrease in CLP incidences upon introduction of folic acid containing multivitamins to expectant women. Van Rooij *et al*. reported a similar reduction in CLP incidence with use of folic acid containing medication in a survey done in the Holland. The study also indicated a 74% decrease in CLP incidence when using the folic acid containing supplements alongside a folate rich diet. Wilcox *et al*, reported a 39% reduction in CLP incidence when using folic acid supplements. Even a lower incidence when women used multivitamin/ folic supplements with folate rich diets.

In a meta-analysis of a number of recent surveys, Johnson et al (2008) observed a decrease of about 18% in the incidence of CLP with the use of folic acid containing supplements (25). This meta-analysis also noted a decrease by about 23% in CLP risk with usage of multivitamins fortified with folic acid

1.2.5 Classification

Different systems have been introduced to classify CLP.

1.2.5.1 Veau classification of 1931

Veau (1931) classified OCs into four groups according to the anatomical regions of the oral cavity as below:

- **I.** Unilateral/ midline cleft of soft palate.
- **II.** Clefting of the secondary palate
- **III.** Complete unilateral cleft of both the soft palate and hard palate
- **IV.** Complete bilateral cleft from the incisive foramen through the alveolus. The primary maxilla remains attached to the nasal septum.

Cleft lips are also classified into four groups using this system:

I. Unilateral clefting of the lip not reaching the mucocutaneous junction

II. Unilateral clefting of the lip sparing the floor of the nose

III. Unilateral clefting of the lip involving the floor of the nose

IV. Bilateral CL

1.2.5.2 Classification according to the International Confederation for Plastic and Reconstructive Surgery of 1966

They classified oral cleft into three groups:

I. Clefts of the primary palate; affecting the lip and alveolus.

II. Clefts of the hard palate.

III. Clefts of the posterior palate.

1.2.5.3 Kernahan and Stark classification (1958)

It is based on the embryological development.

It classifies oral clefts into two main groups:

I. Cleft of primary palate. This involves alveolus to the incisive foramen.

II. Cleft of secondary palate. This involves the soft palate and hard palate extending to incisive foramen.

In either category, it may be either complete or incomplete, or on one side or bilaterally. This classification was widely accepted because of its simplicity and embryological soundness.(11)

1.2.5.4 Kernahan striped “Y” classification (26)

It is illustrated as a stripped “Y” with labelled areas representing the regions affected in the cleft defect.

Table 1 Kernahan stripped Y classification of CLP

Block	**Area represented**
1 & 4	Lip
2 & 5	Alveolus
3 & 6	Primary palate
7 & 8	Secondary palate
9	Soft palate

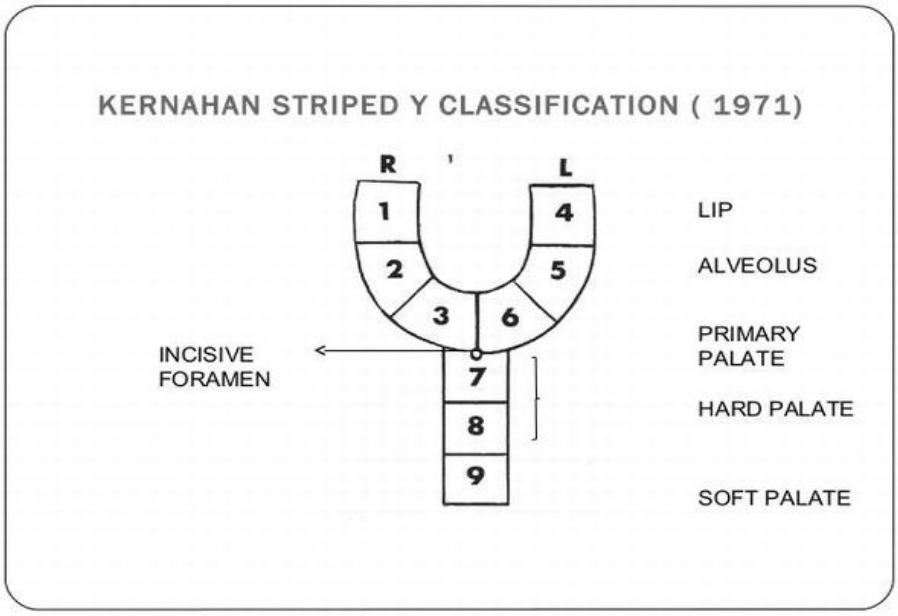

Figure 1.1 Kenaharn stripped Y classification of CLP

(Taken from the Art of Cleft Lip and Palate Repair, 2nd Edition)

1.2.5.4 Extended ”Y” classification

Similar to Kernahan striped Y classification but with representation of nose and nasal floor as modified by Millard. It is the most commonly used currently because it comprehensively describes the CLP defects.

key

1-5: Nose –Alar/ Floor

2-6: Lip

3-7: Alveolus

4-8: Premaxilla

9: Hard Palate

10: Soft Palate

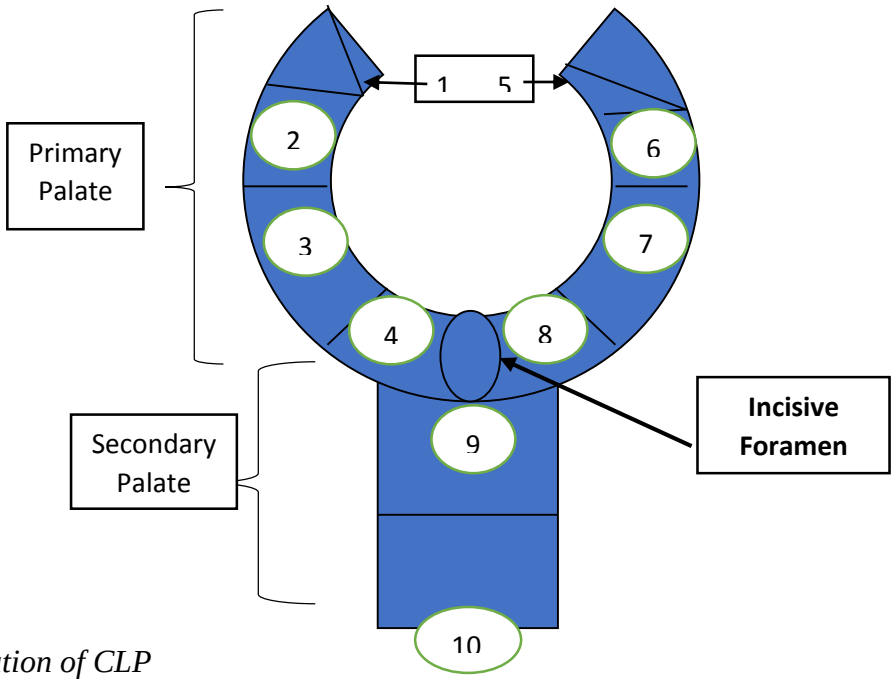

Figure 2 Extended Y classification of CLP

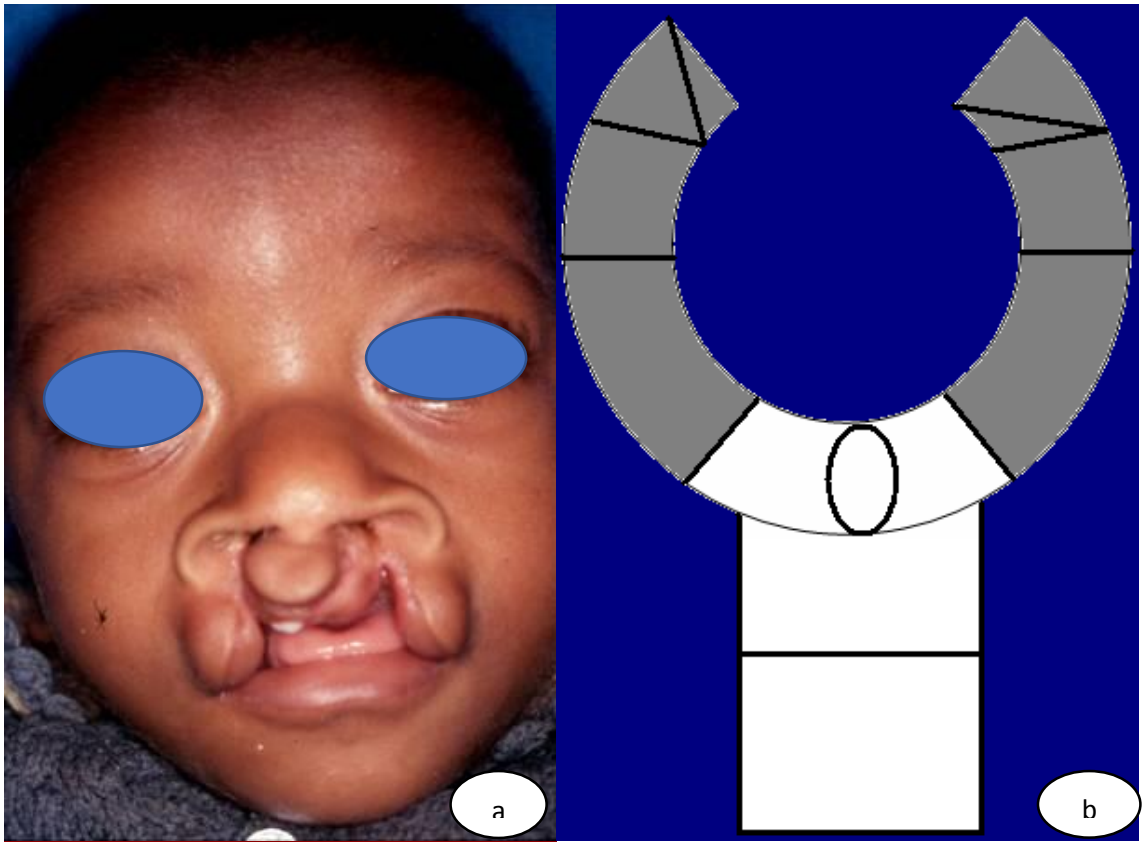

Plate 3 Demonstration of extended Y classification of CLP

(Photo courtesy of Professor Symon Guthua, Professor of maxillofacial surgery, University of Nairobi.)

1.2.5.5 The Iowa classification (26)

Iowa classification divides CLP into five groups. It is a descriptive classification and considered a variation of Veau classification.

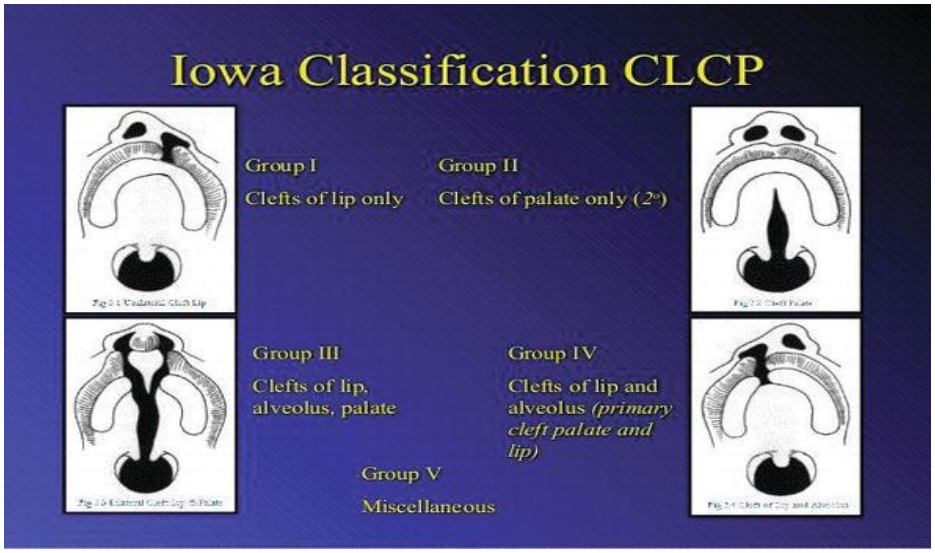

Plate 4 Iowa classification of CLP

(Taken from the Art of Cleft Lip and Palate Repair, 2nd Edition)

1.2.6 Complications related to CLP

Population based studies done in Scandinavia have found increased risk of psychiatric diseases and change in behaviour in people with CLP deformities compared to normal control. This is also associated with increased morbidity due to functional deficiencies. (27)

Almost all children with CP develop middle-ear complications, otitis media being the most prevalent. The abnormality of the palatopharyngeous muscle interferes with the operation of the Eustachian tube resulting in glue ear. Often there is fluid effusion in the middle ear causing conductive hearing loss. (28)

Children with CLP will suffer dental related problems like malocclusion and poor phonation. Swallowing is also a challenge owing to the inability to create an oral seal.

1.2.7 Management

Management of CLP requires collaboration of all relevant specialities to ensure a wholesome approach to the care of patients. Counselling is an important component of treatment especially for cases which have unfavourable risk-benefit projections. Successful management of patients with CL demands an organized multidisciplinary effort entailing both surgical and supportive management. These include disciplines of ear nose and throat (ENT) surgeons, plastic, reconstructive and aesthetics surgery (PRAS), maxillofacial surgery, orthodontics, speech therapy, paediatrics dentistry, counsellor, audiology, psychology and social worker. The desired goals are to optimize feeding, ensure best achievable facial growth, and enhance speech development as well as addressing the psychosocial development and physical appearance of the child.

1.2.7.1 Supportive therapy

i. Counselling

The occurrence of a cleft in an infant often cause feelings of stress and guilt in the parents. Extensive clefts are sometimes discovered intrauterine on ultrasound at week 18 and above. In some countries, intrauterine examination is done to identify foetal abnormalities among them CLP. Parents can then be informed earlier during pregnancy. (3). If a cleft is discovered at child delivery, the parents or caregiver should immediately receive guidance, counselling and necessary support. There is also need for awareness and training of the care givers at delivery.

ii. Nutrition after birth

Feeding an infant with CLP is difficult especially in the first weeks after childbirth. For successful suckling, the infant should create a negative pressure in the oral cavity. CP in particular prevent this making breastfeeding a nightmare.(2) Bottle feeding can be considered for such infants. Often, a feeding bottle with large teats coupled with squeezing the plastic bottle or base of the teat according to the child's feeding rhythm suffices. Mothers should still

be encouraged to breastfeed the baby. In severe cases and in neonatal period, the patient can be fed using nasogastric tube.

1.2.7.2 Surgical Management

Traditionally the rule of 10s as described by surgeons Wilhelmmensen *et. al*. (1969) advocated that the patient should be to the minimum 10 weeks of age, have weight of at least 10 pounds and have haemoglobin of at least 10g/dl. However it is now clear that surgery can be performed even as soon as at birth if the benefit outweighs the perceived risks. (29) The desired outcome for the surgical management of clefts are good appearance, and acceptable function in terms of speech and mastication.

Bone graft procedure may be necessary if there is significant alveolar bone defect, usually at 8 – 12 years with bone graft sources being primarily autologous especially iliac crest cancellous bone as well as maxillary tuberosity and mandibular symphyseal region. (30) The purpose of the procedure is to augment the bony defect in the tooth bearing region and base of the nose in order to secure the eruption of permanent teeth in the cleft region. Pre-surgical orthodontics is often indicated to align the teeth and post-surgical orthodontics to ensure proper occlusion is achieved. (3) (30). Severe jaw discrepancies may warrant correction with orthognathic surgery. Fistulas are a common occurrence after cleft palate repair with a prevalence of 0% to 77.8% globally.(31). Small defects can be closed with local flaps. Large ones usually require more definite flaps like a tongue flap.(32) The tongue flap is a 2-staged procedure and is usually preferred in complicated and large fistulas.

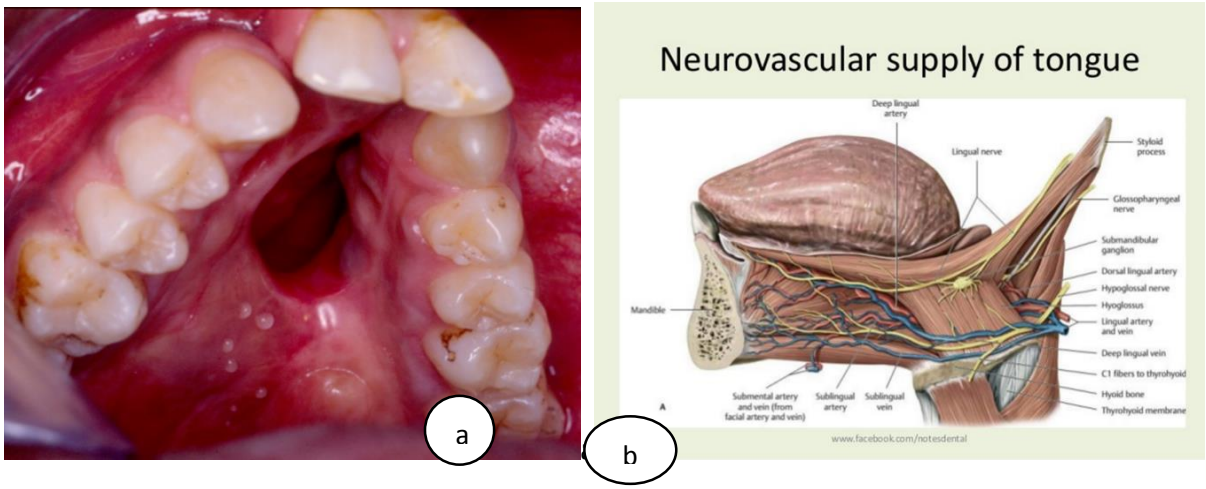

Plate 5 Palatal fistula from a repaired CP (a) and Neurovascular supply of the tongue (b) (Plate (a) is a photo courtesy of Professor Symon Guthua, Professor of maxillofacial surgery, University of Nairobi. Plate (b) - Rich neurovascular supply of the tongue, taken from Gray's anatomy 39th Edition. (33))

The rich neurovascular supply of the tongue, makes it a preferred flap for closing large palatal defects.

As documented by Shaw *et al*, the technique for surgical treatment of clefts at different centres is highly varied, since very few controlled studies have been conducted on the matter. Good results have been achieved through various techniques and programmes though the optimal surgical procedure and timing remains unsynchronised. They concluded that it would be extremely difficult to come up with guidelines for surgical management of clefts.(3) Guthua *et al*. observed an increase in patients presenting very late for correction of facial clefts. This presents a challenge in management of these patients. They demonstrated, in the form of case reports of 8 cases, an alternative surgical technique for repair of severe bilateral CP deformities by utilizing readily available and affordable materials and techniques to provide the best repair rehabilitation of the patient while utilizing as few operations and as short in-patient care as possible thereby relieving the financial constraint which is the major drawback to the majority of patients. (34)

1.2.8 Secondary defects

Secondary CLP are deformities that manifest in previously repaired CLP. Examples include; collapsed maxilla, fistula, residual defects, scars, lip asymmetry among others. (35) Secondary deformities are quite common. These deformities leave patients with stigma and wounded self-esteem

A French study revealed a varying incidence and pattern of occurrence of secondary CLP depending on the extent of the primary defect and method and timing of the initial repair. (36). Another survey done in Norway through self-reported concerns and concerns regarding aesthetics on psychosocial coping in patients who were subjected to standardised surgical treatment for complete CLP revealed that significant number of people with CLP compared to control subjects who had no CLP expressed concerns about their facial aesthetics. The study did not however consider the incidence and pattern of SCLP. They were also prone to anxiety and depression and were found to have fewer close friends. The subjects believed that their health status had influenced their career choices and reported to prefer jobs that do not entail direct contact with clients. Of the 233 participants who were interviewed, 221 responded to the question about whether they desired additional treatment. 35% of which expressed desire of additional treatment. Surgical correction was the treatment most often desired, then dental treatment and speech therapy.(27)

In certain cases of CLP, further operations are rarely required after the initial surgery. CP often require additional operations compared to CL. Good primary surgery can significantly reduce the need for secondary corrective surgery. Over time the surgical burden for patients born with CLP has considerably decreased in comparison to previous decades as reported in the Norwegian survey. Those born with unilateral CLP around 1960s and 70s required about eight surgeries by 18 years of age. Currently, the number of surgeries has been halved. The modern

surgery seeks to minimise of the treatment burden thereby saving public funds and sparing patient the long hospital experiences(3)

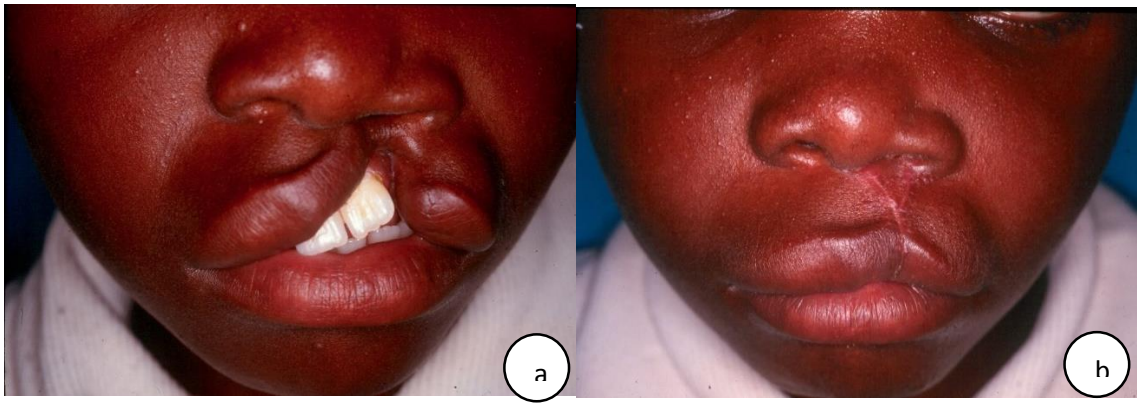

Plate 6 Photograph of a child with a left sided CL (a). Scar and lip asymmetry (b).
(Photos courtesy of Professor Symon Guthua, Professor of maxillofacial surgery, University of Nairobi.)

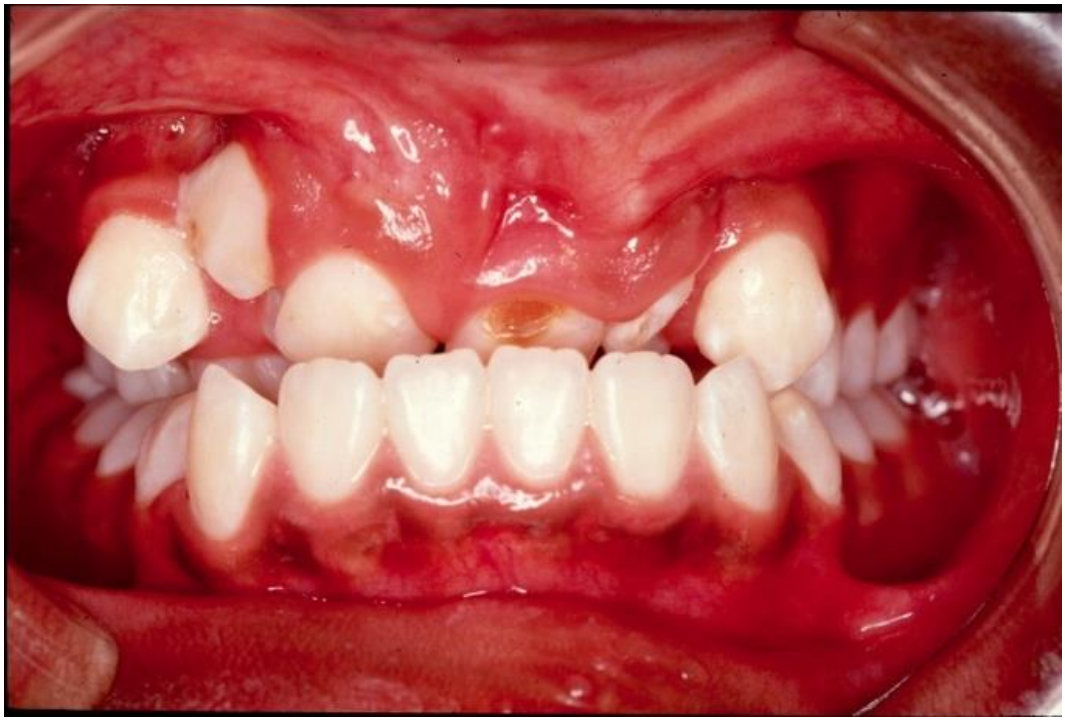

Plate 7 Photograph of a patient with a collapsed pre-maxilla after correction of CP

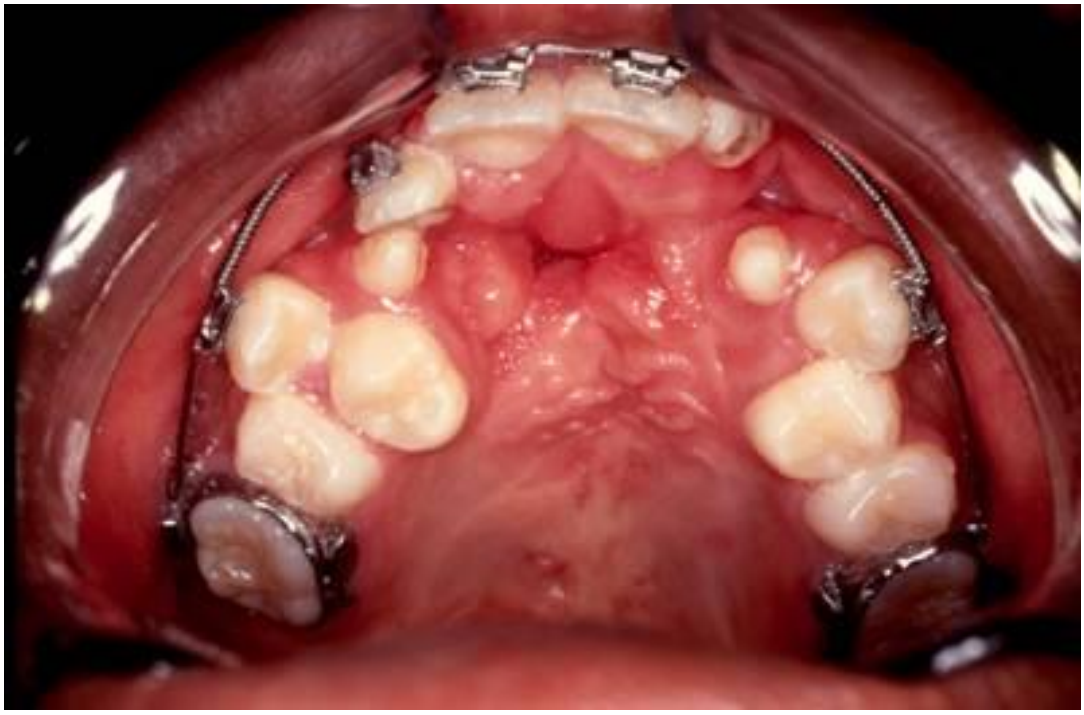

Plate 8 Photograph of the patient undergoing orthodontic treatment.
There is a residual defect at the junction of primary and secondary palate. (Photos courtesy of Professor Simon Guthua, Professor of maxillofacial surgery, University of Nairobi.)

I have not located any published work on incidence and pattern of secondary CLP.

Several methods for correction of secondary CLP have been described, but a single treatment modalities has not been agreed upon. (10)

It has been suggested that the degree of secondary CLP deformities is largely a factor of the primary deformity as well as the expertise of the surgeon who performed the initial surgery. (37)

1.3 Problem statement

CLP forms a big portion of congenital defects of the craniofacial region and causes significant disability and even death globally. Locally, a number of people can receive surgical management of the primary CLP through the non-governmental organizations' led programs and in faith based institutions at subsidised or at no cost. The economic and social implications of such birth defects have triggered research in many countries concerning incidence,

aetiology, characteristics and pattern of occurrence and social impact of primary CLP. Data on SCLP deformities is scanty and the follow up of patients after primary surgical correction is not well documented. The post primary surgical repair concerns of patients are largely ignored. Patients do not have sufficient awareness on the possibility of revision surgeries. This makes them to resign to fate as they suffer psychological torture and huge negative socio-economic effect owing to their condition. Majority of SCLP deformities are correctable, therefore, there is need to develop a protocol for their management. It is also necessary to allocate resources towards management of SCLP deformities. Such a protocol can only be formulated and resources allocated proportionally, if justified by a credible data on the occurrence of the deformities.

1.4 Study justification

This study describes the characteristics of soft and hard tissue deformities in secondary CLP. It also establishes the burden of SCLP deformities in the society. The data obtained will be useful in formulating management protocol of the deformities for better outcome of management of patients with CLP.

The data also creates a broader awareness of such deformities among all stakeholders and to influence policy on resource allocation towards management of secondary CLP deformities.

1.5 Objectives

1.5.1 Main objective

To determine the pattern of secondary CLP in patients seen in selected hospitals in Nairobi, Kenya.

1.5.2 Specific objectives

1. To describe the pattern of secondary CL deformities.
2. To describe the pattern of secondary CP deformities.

3. To describe the factors that may have contributed to secondary CLP

1.6 Study variables

1.6.1 Demographics

Age: years

Gender: male or female

1.6.2 Independent variables

a) Primary deformity

b) Age at first surgical repair: months

c) Family socioeconomic status

1.6.3 Dependent variable

a) Pattern of secondary soft and hard tissue deformities

b) Number of revision surgeries

CHAPTER TWO

METHODOLOGY

2.1 Study area

The study was carried out in three hospitals; Gertrude's Children Hospital-Muthaiga, which has a huge traffic of patients with CLP owing to the NGO sponsored program of smile train. Kenyatta National Hospital (KHN) given the good number of patients with CLP managed in the oral and maxillofacial surgery unit and plastic surgery division. University of Nairobi dental hospital because of the many referrals of complicated cases of CLP they receive.

2.2 Study population

The study population consisted of all patients of any age with SCLP visiting the three stated hospitals during the period of this study, and who met the inclusion criteria, as well as gave consent to participate in the study for those who were above 18 years of age. For minors, consent was obtained from parents / guardians.

2.3 Study design

It was a hospital based descriptive cross-sectional study.

2.4 Study period

Period of the study was between November 2020 and July 2021.

2.5 Sample size determination (38) (39)

The sample size was calculated using Fischer's formula**:**

$$n = \frac{Z^2 P(1-P)}{I^2}$$

n= Sample size (where population is greater than 10,000)

Z= Normal deviation at the desired confidence interval. It was be taken at 95%, of which the Z-value was 1.96

P= Proportion of the population with secondary CLP.

I^2 = Degree of precision; it was taken at 5%.

The proportion of the population with the desired population was taken to be 50%.

The calculation of the sample size was as below:

$$n = \frac{Z^2 P(1-P)}{I^2}$$

$$n = \frac{1.96^2 \times 0.5(1-0.5)}{0.05^2}$$

$$n = 384$$

The sample size was adjusted using Finite population correction for proportion as below.(38)

$$nf = \frac{n}{(1 + \frac{n}{N})}$$

Where:

- nf= is the desired sample size for population <10,000
- n= is the calculated sample size
- N = is the total population.

$$nf = \frac{384}{(1 + \frac{384}{83})}$$

$$nf = 73$$

2.6 Sampling method

Convenience sampling method (non-probability) was used to recruit the study participants. All patients who met the inclusion criteria and consented to take part in the survey were included.

2.7 Inclusion and exclusion criteria

2.7.1 Inclusion criteria

i. Patients with CLP seeking surgical correction or have had surgical correction.

ii. Patients with SCLP

iii. Patients who consented or whose parents/ guardians will give consent to participate in the study

2.7.2 Exclusion criteria

i. Those who have not had surgery as the management modality.

2.8 Data collection

Data collection was done using data collection forms and by physical examination of the participants from patients who present to the hospitals with the clinical characteristics under investigation.

All the data was collected by the principal investigator.

The data was recorded in a predesigned data collection form (Appendix 3).

Both the data forms and the photographs were coded to remove identifiers and identity sealed.

2.9 Data management and analysis

Data was entered onto a Microsoft Excel and transferred to SPSS version 25 for analysis. Double check was done to ascertain accuracy of data entry. The data set was also checked for typographical errors.

The data was be described using frequencies and percentages for categorical data and means and standard deviations for continuous data. These results were presented in either tabular or

graphical format by gender and age categories. Findings of the study was presented in form of statements, tables and graphs.

2.10 Quality assurance protocol

1. The data collection tools were cross-checked for completeness and errors prior to data entry.
2. Once data entry had been done, 15% of the questionnaires were sampled to check that the entry had been done correctly.
3. Additionally, the data set was checked for any typographical errors.

2.11 Data presentation

The data is be presented in form of graphs, tables and charts.

2.12 Ethical consideration

Clearance was be sought from the KNH/UON Research Ethics and Standards Committee before commencement of the study (P305/06/2020). Permission and clearance to collect data was also be sought from Gertrude's Children Hospital (GCH105/2021), University of Nairobi dental hospital and KNH before data collection.

CHAPTER THREE:

RESULTS

3.1 Introduction

Between September 2020 to July 2021 patients presenting in the clinics at Getrudes Children hospital, Muthaiga, Kenyatta National Hospital and University of Nairobi Dental Hospital for follow up after repair of cleft lip and palate were recruited in the study. Convenience sampling method (non-probability) was used to recruit the study participants. None of the people who were invited to participate in the study declined. They were examined for presence of clinically observable secondary cleft lip and palate deformities.

3.2 Demographic Characteristics of the respondents

Demographic characteristics considered included gender, age in completed years, and place of residence, education and occupation. (Table 3.1)

A total of 76 secondary cleft cases were seen during the study period. The most common primary cleft type was the combined bilateral cleft lip and palate (BCL+P) constituting 22 (28.9%) of all cleft deformities. Right sided CL and palate (LCL+P) and the left sided CL and palate (LCL+P) were 11.8% and 15.7% respectively. Right sided and left sided cleft lip were in the ratio of 1:2.3. Isolated CP were 9.2%.

There was a male preponderance among the secondary CL+P deformities with female to male ratio of 1:1.2. Age distribution was between 5 months to 27 years. Majority 34 (44.7%) were below 4 years, followed by 19 (25%) who were between 11 to 16 years, 14 (18.4%) were between 5 to 10 years, 5 (6.6%) were between 17 to 22 years and 4 (5.3%) were above 23 years.

The other demographic considered was the place of residence. Majority were from urban areas (51.3%), followed by semi urban regions (27.6%) then rural areas (21.1%). Majority were pre-school (64.5%) while those with tertiary education were the least in number (7.9%)

Table 2 Demographic Characteristics: Gender

Variables		**Number**	**Percentage**
	Male	41	53.9
Gender	Female	35	46.1

Other Demographic Characteristics

Variables			Male (%)	Female (%)
	< 4	34 (44.7%)	15(44.2)	19(55.8)
	5-10	14 (18.4%)	6(42.9)	8(57.1)
	11-16	19 (25%)	8(42.1)	11(57.1)
	17 - 22	5 (6.6%)	3(60)	2(40)
Age in years	23+	4 (5.3%)	3(75)	1(25)
	Urban	39 (51.3%)	18(46.1)	21(53.8)
	Semi Urban	21 (27.6%)	12 (57.1)	9(42.8)
Place of Residence	Rural	16 (24.1%)	9(56.2)	7(43.8)
	Primary	12 (15.8%)	7(58.3)	5(41.7)
	Secondary	9 (11.8%)	4(44.4)	5(55.6)
	Tertiary	6 (7.9%)	4(66.7)	2(33.3)
Education level	pre school	49 (64.5%)	22(44.9)	27(55.1)
	Casual worker	2 (2.6%)	2(100)	0(0.0)
Occupation	School going	74 (18.4%)	34(45.9)	40(54.1)
	Dental School	19 (25%)	10(52.6)	9(47.4)
	KNH	18 (23.7%)	8(44.4)	10(55.6)
Facility	Getrudes	39 (51.3%)	18(46.2)	21(53.8)
Total		**76**		

3.3 Primary Deformities

Table 3 Primary deformity

		Gender		Total		P-VALUE
		Male (%)	Female (%)		X^2	
	BCL+P	18(43.9)	11(31.4)	29(38.2)		
	LCL	2(4.9)	4(11.4)	6(7.9)		
	LCL+P	12(29.3)	15(42.9)	27(35.5)		
	RCL	2(4.9)	0(0.0)	2(2.6)		
Primary deformity	RCL+P	7(17.1)	5(14.3)	12(15.8)	5.353	0.253
Total		**41**	**35**	**76**		

There was no significant statistical relationship between gender and the pattern of primary cleft lip and palate deformity (P-value = 0.253)

3.4 Pattern of Secondary CL Deformities

Of the 76 participants recruited, 69 had primary CL deformities of which 41 (59.4%) had some form of secondary cleft deformity and the rest, 28 (40.6%) did not have. (Table 3.2)

Table 4 Prevalence of secondary cleft lip among the subjects seen

Variable		**Frequency**	**Percent**
Presence of secondary deformity	Yes	41	59.4
	No	28	40.6
Total		69	100

A total of 66 deformities were noted, of which were grouped into six. Scarring 28 (42.4%), lip notching 19 (28.8%), asymmetry of the vermilion border 12 (18.2%), short columela of the nose 5 (7.6%), hypoplastic lip and blocked nose each at 1.5% representing one case each. Examples of these deformities are listed in plates 9 to 11 below.

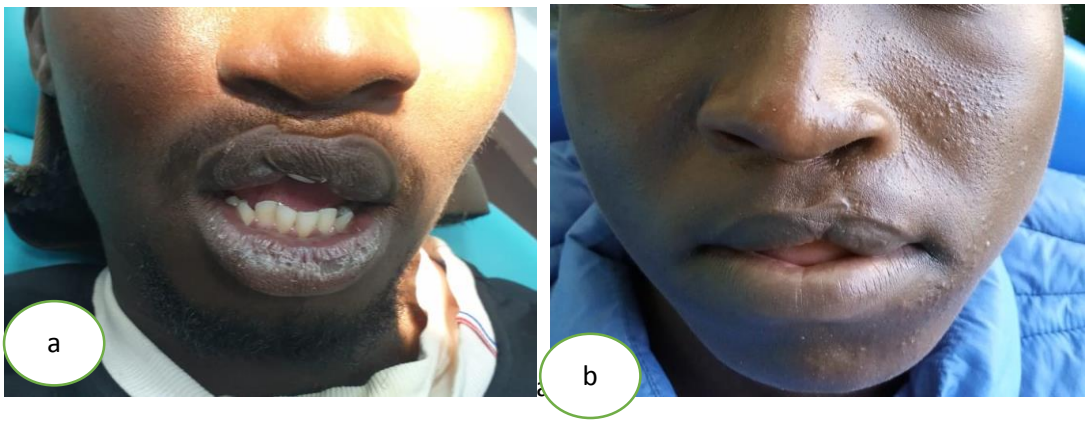

Plate 9 Asymmetry of the vermilion border after repair of right sided (a) and left sided (b) CL

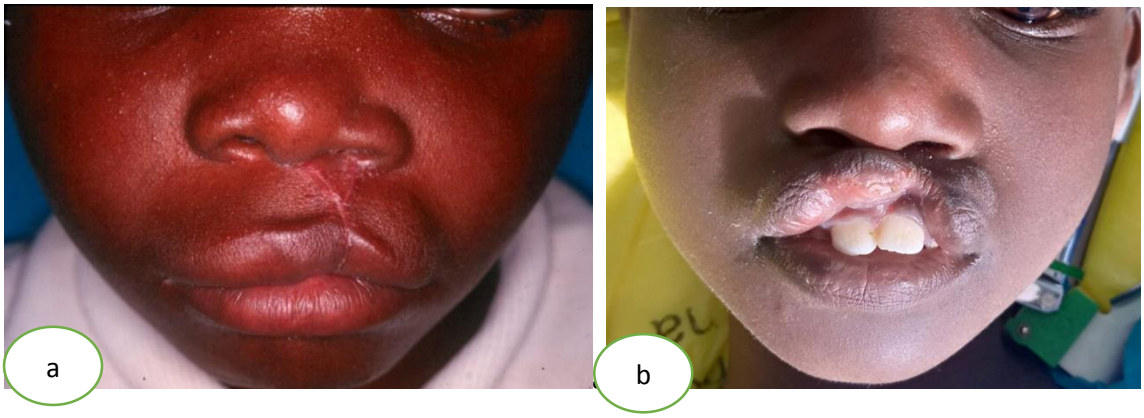

Plate 10 Lip notching after repair of left sided cleft lip (a) and a bilateral cleft lip (b)

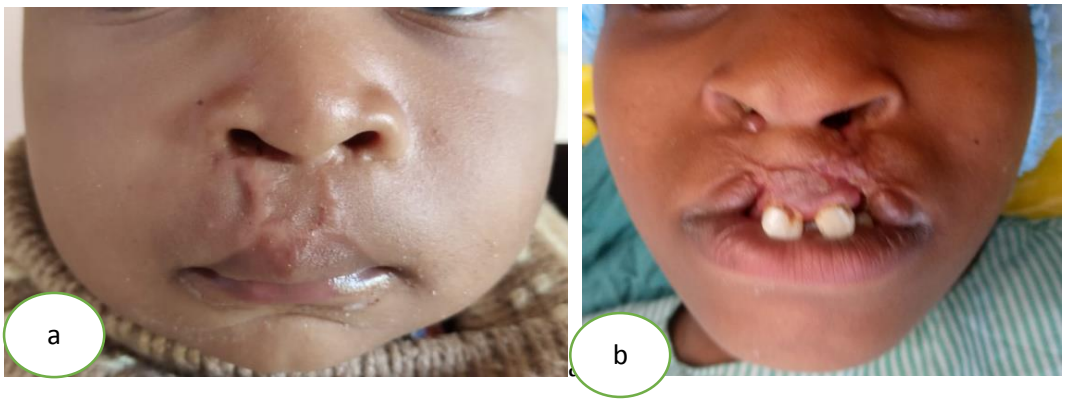

Plate 11 Scarring (a) and hypoplastic (b) after repair of bilateral. CL

Table 5 Secondary cleft lip deformities seen.

	Frequency	**Percentage**	**Male (%)**	**Female (%)**
Blocked nostril	1	1.5	1(100)	0(0.0)
Lip asymmetry	12	18.2	5(41.7)	7(58.3)
Lip notching	19	28.8	11(57.9)	8(42.1)
Scarring	28	42.4	13(46.4)	14(53.6)
Short columela	5	7.6	2(40.0)	3(60.0)
Hypoplastic lip	1	1.5	0(0.0)	1(100)
Total	66	100		

A number of participants had more than one lip deformity. Single deformity was found in 53.6% of all the participants, 34.1% had two concurrent deformities while 12.3% had three concurrent secondary lip deformities.

Table 6 Number of secondary deformities of the lip per subject

		Age when CL was repaired (Months)					
		<= 4.00	5.00 - 14.00	15.00+	Total	X^2	P-VALUE
Number of secondary lip deformities	0	14(48.3)	15(42.9)	5(45.5)	34(45.3)		
	1	11(37.9)	9(25.7)	3(27.3)	23(30.7)		
	2	3(10.3)	8(22.9)	2(18.2)	13(17.3)		
	3	1(3.4)	3(8.6)	1(9.1)	5(6.7)	3.236	0.779
Total		29	35	11	75		

There was significant statistical relationship between age at which the first surgical repair of the lip was done and the number or severity of the secondary cleft lip deformities (P-value = 0.779)

3.5 Pattern of secondary CP deformities.

A total of 39 participants had had their cleft palates repaired. 32 (78%) had clinically observable secondary deformities while 7 (22%) had no secondary deformities. (Figure 3.5 and table 3.6)

Table 7 Incidence of secondary palate deformities among the participants

		Frequency	Percentage	Male (%)	Female (%)
CP	Yes	32	78.0	15(46.9)	17(53.1)
	No	7	22.0	4(57.1)	3(42.9)
	Total	**39**	**100.0**	**19**	**20**

The secondary cleft palate were divided in three categories, oronasal fistula 16 (50%), scarring 9 (28.1%) and dehiscence at the soft palate 7 (21.9%). Examples of these secondary deformities have been illustrated in plates 12 and 13

Table 8 Pattern of secondary deformities observed.

Variables		Frequency	Percent
Patterns of SCP	Dehiscence at the soft palate	7	21.9
	Oronasal Fistula	16	50.0
	Scarring	9	28.1
Total		32	100.0

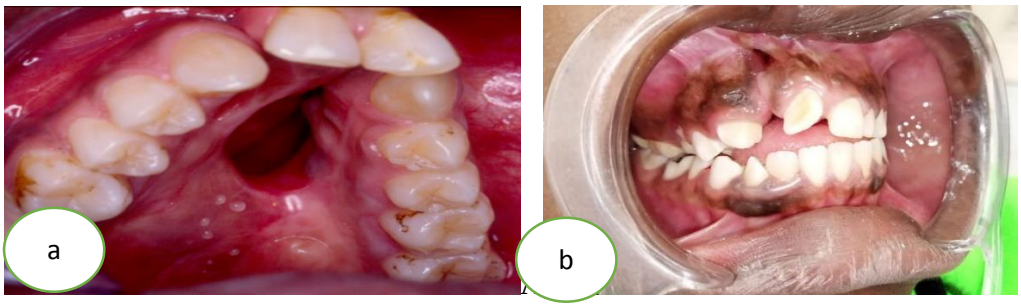

Plate 12 Oronasal fistula (a). Fistula at alveolar region (b) after repair of CP

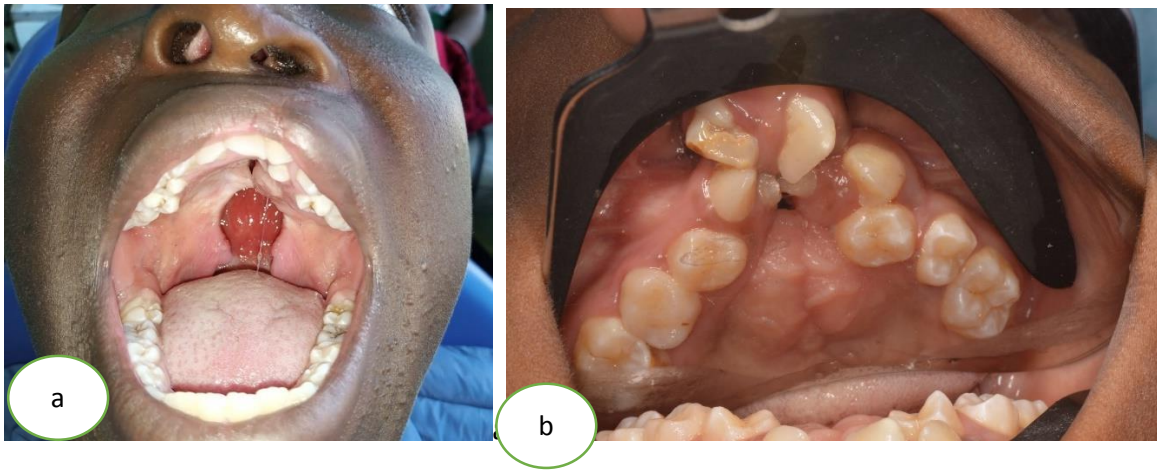

Plate 13 Dehiscence at the soft palate and oronasal after repair of CP (a). Severe scarring of the palate following multiple repairs of CP (b)

Some of participants had more than one secondary palate deformity. Single deformity was found in 23 (59.4%) of all the participants, 9 (23.1%) had two concurrent deformities while 7 (17.9%) had no secondary palate deformities.

Table 9 Number of secondary deformities of the palate per subject

		Age When CP was repaired (months)						
		<= 24.00	25.00 - 36.00	37.00 - 54.00	55.00+	Total	X^2	P-VALUE
Number of CP	0	4(30.8)	0(0.0)	1(20.0)	2(25.0)	7(17.9)		
	1	7(53.8)	5(83.3)	1(20.0)	6(75.0)	23(59.4)		
	2	2(15.4)	1(16.7)	3(60.0)	0(0.0)	9(23.1)	11.685	0.069
Total		**13**	**6**	**5**	**8**	**39**		

There was significant statistical relationship between age at which the first surgical repair of the palate was done and the number of secondary palate deformities (P-value = 0.069)

3.6 To describe the factors that may have contributed to secondary CLP

Factors which were investigated as possible modifiers of outcome of CLP surgery included; age at first surgery, the severity of the primary cleft and number of surgeries. Among these factors, only severity of primary deformity affected the outcome of surgical management. The other factors had no significant bearing on the outcome of surgical management.

CHAPTER FOUR:

DISCUSSION

4.1 Pattern of secondary CL deformities

Patients in this study came majorly Getrudes Children Hospital, this appears to be because of the NGO sponsored cleft lip and palate programs offered in the institution. Majority of the patients came from urban areas, especially which appears to be influenced by the accessibility to the hospitals. There was a wide range of age at presentation, however, it was notable that most of the cases were below four years with an average age of five years. A study on presentation of primary cleft lip and palate deformities in Kenya revealed a higher proportion of younger patients with mean age of 10 months (1). A similar study in Uganda, a country with a similar ethnic and socioeconomic profile, revealed a higher proportion of adult patients with a mean age of 13 years (12).

In contrast to reports in other African series (40-42), CL + P was the most common primary cleft type constituting 68.3% of all cleft types. CL was the second most common cleft deformity with 22.5% of cases while CP was the least common contributing 9.2% of the cases. In the previous African series (40-42) CL was reported as being the most common cleft type and this was regarded as a major departure from the pattern of clefting reported for the Caucasian populations**.**

More than half the number of participants had secondary deformity of the lips (59.4%). Most common deformity being scarring (42.4%). Whereas all the patients were Africans, therefore no other races to compare the predisposition to scaring, the finding seemed consistent with other findings (43-45) that Patients with darker skin, have a higher prevalence of scar formation than those with lighter pigmentation. There was no significant gender parity in scar formation. Asymmetry at the vermilion border was also observed in a significant number of patients

(18.2%) which might be attributed to repair technique. Notching of the lip was also significantly high (28.8%) across all the hospitals, this could be attributed repair technique and insufficient muscle development in the upper lip.

Many patients had more than one lip deformity occurring concurrently. Some having up to three deformities. Sex or time of repair of the lips were not significant factors in occurrence of these deformities.

4.3 Pattern of secondary CP deformities

A total of 41 participants had had their cleft palates repaired. A big number (78%) had clinically observable secondary deformities. The most common secondary cleft deformity was oronasal fistula (50%). The common site of fistula was at the junction of premaxilla and secondary palate. The period of observation ranged from 6 months to 10 years. According to other studies, prevalence of oronasal fistula after repair of cleft palate is highly variable. Findings by Phua and de Chalain (46) in a study of 211 patients collectively operated in one centre found an overall fistula rate of 12.8% over a mean follow-up period of four years 10 months. Amaratunga NA et al 2008 (49) reported oronasal fistula prevalence of 42%. The primary cause of development of oronasal fistula is hypothesised to be repair under tension especially those palatal clefts which are quite wide and the available tissue to repair the palate seems inadequate and also possibility of post-operative infection though wound infection is reported to be surprisingly rare (47)

In this study, oronasal fistula was more prevalent in bilateral cleft palate cases compared to unilateral cases. This is consistent with other studies (46-48) that concluded that fistula rates were higher for the more severe degree of clefting but were not affected by gender or type of surgical repair.

A number of participants had more than one secondary palate deformity. Single deformity was found in 19 (46.3%) of all the participants, 6 (14.6%) had two concurrent deformities while 7 (17.2%) had three concurrent secondary palate deformities.

4.4 CONCLUSION

1. Most of the patients who came for treatment were from urban region, majority being below 4 years of age.
2. More severe primary cases had higher propensity to develop secondary deformities.
3. Scarring was the most prevalent secondary cleft lip deformity while oronasal fistula the most prevalent palatal secondary deformity.

4.5 RECOMMENDATIONS

1. There be a center for comprehensive management of patients with cleft lips and palates where all the specialties needed can be found.
2. Multi centre studies should be done to audit the outcome of the repairs of cleft lip and palate.

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6.0 APPENDIX

6.1 Consent

6.1.1 Study participant's consent form

Title of study: Incidence and pattern of secondary cleft lip and palate deformities in patients seen in selected hospitals in Nairobi, Kenya.

Principal Investigator and institutional affiliation: DR. Odhiambo Bati, a post graduate student in Oral and Maxillofacial Surgery at the University of Nairobi.

Study purpose: The study seeks to describe the incidence and pattern of secondary cleft lip and palate deformities. Many patients present with cleft lip and palate that are managed surgically with varying outcome, some being secondary deformities. Some of these deformities are still correctable surgically.

Study procedure: The information will be acquired by administration of a questionnaire and taking of clinical photographs. The principal investigator will ask questions and record your response. The questions will cover primary defect you had, when and the number of surgical treatments done. The principal investigator will also take a photograph of you.

Voluntariness of the participation: Participation is voluntary and one is at the liberty to decline to participate or withdraw at any stage without loss of any benefits.

Confidentiality: The information obtained will be treated with utmost confidentiality. No personal details like name will be taken. The photographs will not be used or disseminated for any purpose other than for the purpose of this study.

Benefits of participation: This study will help to understand better the secondary cleft lip and palate deformities. The information will be used to influence policy and resource allocation to management of secondary cleft lips and palate.

Risks of participation in the study: There is no expected risk of psychological manner or bodily harm to the participants.

Participant's statement

I, ……. (Initials), have read this consent form or had the information read to me. My questions have been answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

If you agree to participate in this study, please sign your name.

I (child), _____, want to be in this research study.

_____ _____

(Sign your name here) (Date)

I…….. (Parent/guardian in case of a minor) give consent of participation and accept willingly to provide information regarding my dependant to be used in the research.

Sign……date……

Thank you.

Researcher's statement

I, Dr. Odhiambo Bati, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has willingly and freely given his/her consent.

Signature…… Date…….

In case of any clarifications or concerns regarding the study you may contact the investigator, the lead supervisor or secretary KNH/UON ethics , research and standards committee using the following contacts:

1. Dr. Odhiambo Bati (principal investigator)

   Tel 0737271655; odhiambo.b.s@student.uonbi.ac.ke

2. Dr. Tom Osundwa

   Tel 0724703678 tomosundwa@yahoo.com

3. KNH-UoN ERC

   Tel 2726300 Ext. 44102; uonknh_erc@uonbi.ac.ke

6.2 Fomu ya ridhaa na maelezo ya mshiriki

Mada ya utafiti: Matukio na haina ya mdomo sungura baina ya wangonjwa tayari kufanyiwa upaswaji katika mahospitali yaliyoteuliwa jijini Nairobi Kenya.

Mtafiti mkuu: Daktari Odhiambo Bati, mwanafunzi wa uzamili chuo kikuu cha Nairobi anayesomea masomo ya upasuaji wa uso, kinywa shingo na kichwa.

Lengo la utafiti: Utafiti huu unakusudia kutambua uneneaji na aina ya mdomo sungura uliosalia baada ya upasuaji. Wagonjwa waliyo na mdomo sungura hutibiwa kupitia upaswaji ilhali kwa matokeo mbalimbali ikiwemo kusalia kwa alama au tundu. Haya masalio ya hili tatizo la kimaumbile inaweza kurekebishwa bado

Mpangilio wa utafiti: Maelezo yatapatikana kwa kuuliza maswali. Mtafiti mkuu atakuuliza maswali na kurekodi majibu yako na kuchukua picha ya uso na mdomo wako. Utaulizwa maswali kuhusiana na tatizo lako la mdomo sungura na majibu kunakiliwa.

Kujitolea kwa mshiriki: Mshiriki anashiriki katika utafiti huu kwa hiari na ana uhuru wa kujiondoa pasipo na hasara yoyote.

Siri: Maelezo yatakoyopeanwa na mshiriki yatakuwa ya siri. Jina lake Litabanwa.

Manufaa ya kushiriki: Utafiti huu utatusaidia kujua changamoto ambazo wagonjwa hupitia wakati wanatafuta matibabu ya saratani ya shingo na kichwa. Majibu tutakayopata hapa yatatusaidia kuboresha matibabu ya ugonjwa wa saratani na pia yatasaidia kuugundua ugonjwa wa saratani mapema.

Kuna madhara yoyote ya kushiriki katika utafiti huu: Hamna madhara yoyote yanayotarajiwa kuwapata watakaoshiriki

Fomu ya ridhaa

Kauli ya mshiriki,

Mimi,…… (Majina), Nimeisoma fomu hii ya ridhaa au nimesomewa ujumbe ulipo kwenye fomu hii. Nilipata fursa ya kujadiliana kuhusu utafiti huu na mtafiti. Maswali yangu yamejibiwa kwa lugha ambayo naielewa. Nimeelezewa manufaa na hatari zilizopo. Naelewa kwamba ushiriki wangu katika utafiti huu ni wa hiari na naweza kujiondoa wakati wowote. Nimekubali kwa hiari kushiriki katika utafiti huu. Naelewa kuwa habari zangu za kibinafsi zitahifadhiwa vyema.

Kwa kutia sahihi fomu hiiya ridhaa,sijatupilia mbali haki zangu zxa kisheria kama mshiriki katika utafiti huu.

Sahihi ya mshiriki / Alama ya kidole ……..…T**arehe** …...……

Kauli ya mtafiti

Mimi daktari Odhiambo Bati, nimetoa maelezo kamilifu kuhusiana na utafiti huu kwa mshiriki ambaye ametajwa katika utafiti huu na naamini kwamba mshiriki ameelewa na akatoa ridhaa yake kwa hiari.

Sahihi…… Tarehe…….

Iwapo utahitaji ufafanuzi zaidi kuhusu utafiti huu zungumza na mkuu wa uchunguzi, msimamizi mkuu au katibu wa kamati ya maadili na utafiti ya KNH/UON kupitia kwa nambari zifuatazo:

1. Dr. Odhiambo Bati (principal investigator)

   Tel 0737271655; odhiambo.b.s@student.uonbi.ac.ke

2. Dr. Tom Osundwa

   Tel 0724703678 tomosundwa@yahoo.com

3. KNH-UoN ERC

   Tel 2726300 Ext. 44102; uonknh_erc@uonbi.ac.ke

6.3 Data collection tool

Demographic data

1. Date/ Tarehe……. Study serial number/ Nambari ya siri ….....

2. Age/ umri (years)……....

3. Gender/ jinsia: Male/ mwanamme ☐ Female / mwamke ☐

5. Residence/ makao: Rural/ shambani ☐ Urban/mjini ☐ Semi urban: ☐

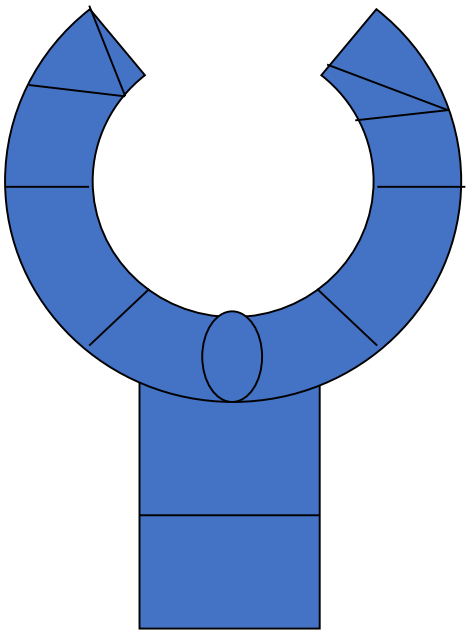
6. Educational level/ kiwango cha elimu: Primary/ msingi ☐ Secondary/ upili ☐

Tertiary/ chuo ☐

7. Occupation/ ajira (Indicate the specific job).....

Primary CLP deformity/ Mdomo sungura kabla ya upaswaji

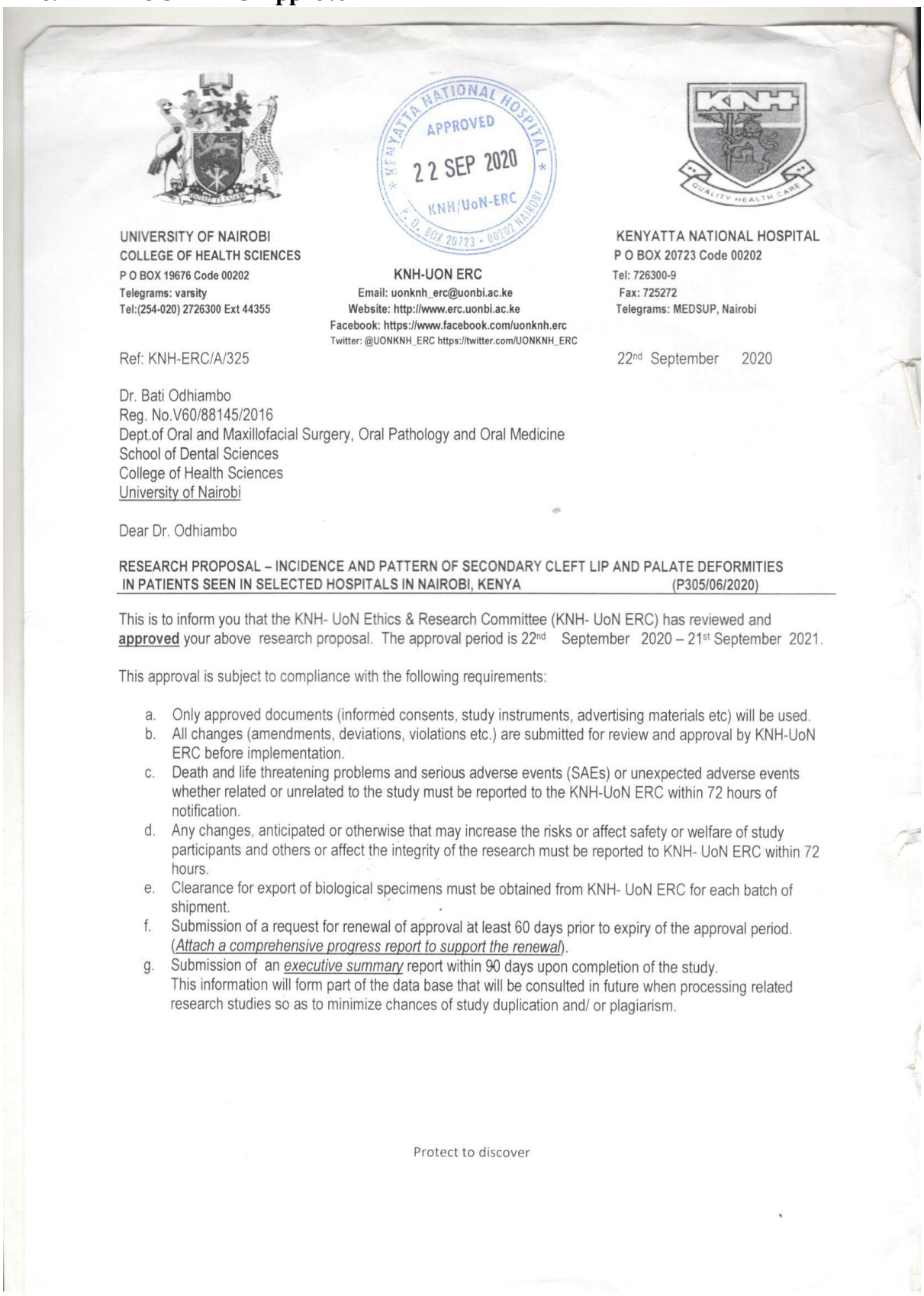
Using extended Y classification



1. Age at first correction of the deformity/ Umri wakati wa upaswaji wa awali (yrs): ……
2. Number of corrective surgeries/ Idadi ya upaswaji …….....
3. Current secondary CL/P deformity/ shida iliyosalia (describe) …….....
   .....
   .....
   .....
   .....
   .....
   .....
   .....
   .....
   .....
4. Take pictures/ chukua picha.

Thank you.

6.4 KNH-UON ERC Approval



KENYATTA NATIONAL HOSPITAL
APPROVED
22 SEP 2020
KNH/UoN-ERC
P. O. BOX 20723 - 00202 NAIROBI

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Ref: KNH-ERC/A/325

22nd September 2020

Dr. Bati Odhiambo
Reg. No.V60/88145/2016
Dept.of Oral and Maxillofacial Surgery, Oral Pathology and Oral Medicine
School of Dental Sciences
College of Health Sciences
University of Nairobi

Dear Dr. Odhiambo

RESEARCH PROPOSAL – INCIDENCE AND PATTERN OF SECONDARY CLEFT LIP AND PALATE DEFORMITIES IN PATIENTS SEEN IN SELECTED HOSPITALS IN NAIROBI, KENYA (P305/06/2020)

This is to inform you that the KNH- UoN Ethics & Research Committee (KNH- UoN ERC) has reviewed and **approved** your above research proposal. The approval period is 22nd September 2020 – 21st September 2021.

This approval is subject to compliance with the following requirements:

a. Only approved documents (informed consents, study instruments, advertising materials etc) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KNH-UoN ERC before implementation.
c. Death and life threatening problems and serious adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KNH-UoN ERC within 72 hours of notification.
d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KNH- UoN ERC within 72 hours.
e. Clearance for export of biological specimens must be obtained from KNH- UoN ERC for each batch of shipment.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period. (*Attach a comprehensive progress report to support the renewal*).
g. Submission of an *executive summary* report within 90 days upon completion of the study. This information will form part of the data base that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.

For more details consult the KNH- UoN ERC website http://www.erc.uonbi.ac.ke

Yours sincerely,

PROF. M. L. CHINDIA
SECRETARY, KNH-UoN ERC

c.c. The Principal, College of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Dean, School of Dental Sciences, UoN
The Chair, Dept. of Oral and Maxillofacial Surgery, Oral Pathology and Oral Medicine
Supervisors: Dr.Tom Osundwa Mulama, Dept.of Oral and Maxillofacial Surgery, Oral Pathology and Oral Med.UoN
Dr. Eunice Kihara,Dept.of Oral and Maxillofacial Surgery, Oral Pathology and Oral Med. UoN
Prof.Symon W. Guthua, Dept.of Oral and Maxillofacial Surgery, Oral Pathology and Oral Med. UoN

6.5 Getrude's Hospital ERC Approval

Gertrude's Children's Hospital

Final Decision Certificate

This document certifies that the study:

"INCIDENCE AND PATTERN OF SECONDARY CLEFT LIP AND PALATE DEFORMITIES IN PATIENTS SEEN IN SELECTED HOSPITALS IN NAIROBI, KENYA"

Principal Investigator: Dr. ODHIAMBO , STEPHEN BATI OTIENO
Reference number: GCH105/2021
Was reviewed and received the following status:
"done"
"Additional Comments:"
Final decision: **approved-minor-mod-req**
Comments sent:

Approved with Minor Amendments
1. Anonymization of photos is required.
2. Clarification of compensation of "additional costs" to be catered for study
Please note that this approval is only to conduct the study and is not an appr
On behalf of the Hospital we wish you a fruitful research.
This certificate has been issued with the permission from the Chair and the Se

Regards,

Dr. Thomas Ngwiri
Secretary - Ethical Review Board

Dr. Vankwa Indeche
Chair-Ethical Review Board