University of Nairobi, College of Health Sciences School of Medicine

HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA

DR. MICHAEL ONGAS (H58/11538/2018)

A dissertation submitted in partial fulfilment of the requirements for the award of the degree of Masters of Medicine in Plastic, Aesthetic and Reconstructive Surgery, University of Nairobi (M. Med-PRAS, UoN)

STUDENT'S DECLARATION

I, **Dr Michael Ongas,** declare that this dissertation is my original work and, to the best of my knowledge, has not been presented elsewhere for the award of a degree at any other institution.

Dr Michael Ongas, MBChB, M. Med PRAS **(H58/11538/2018)**
Department of Surgery, Faculty of Health Sciences
University of Nairobi
Email address: mikaelongas@gmail.com

Signed…… Date……..…

SUPERVISORS' APPROVAL

This dissertation is submitted for review with our approval as university supervisors.

Dr. Ferdinand Wanjala Nang'ole,

MB ChB (UoN), MMed Surgery (UoN), Fellow (EBOPRAS),

Consultant Plastic and Reconstructive Surgeon

Senior Lecturer- Department of Surgery, University of Nairobi.

Email address: nangole2212@gmail.com

Signed…… Date……..…

Dr. Joseph Kimani Wanjeri,

MB ChB (UoN), M. Med General Surgery (UoN), MPH (UoN), IPTM (Tel Aviv)

Consultant Plastic and Reconstructive Surgeon

Lecturer -Department of Surgery, University of Nairobi.

Email address: joseph.wanjeri@uonbi.ac.ke

Signed…… Date……..…

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UNIVERSITY OF NAIROBI

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Name of student: **Dr Michael Ongas,**

Registration Number: H58/11538/2018

Faculty/School/Institute: Faculty of Health Sciences

Department: Department of Surgery

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DEPARTMENTAL APPROVAL

This dissertation was approved by the Kenyatta National Hospital – University of Nairobi, Ethics and Research committee and hereby submitted for examination with my approval as the Chairman, Department of Surgery.

Dr Kiboi Julius Githinji,
MBChB, MMed Surg. (UoN),
Consultant Neurosurgeon,
Chairman- Department of Surgery, Faculty of Health Sciences
Senior lecturer- Department of Surgery, Faculty of Health Sciences
University of Nairobi

Signed…… Date……..…

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DEDICATION

I dedicate this dissertation to my parents **Mr. Fredrick Odhiambo Ongas** and **Mrs. Redepemtor Saidi Ongas**, my siblings **Sheila Achieng, George Tendwa** and **Collins Ochieng** and my nephew **Chiwo Otieno** all for their love and unwavering support.

I would also like to dedicate this dissertation to the love of my life **Nasidai Mruttu** for her support and walking this long journey with me.

COLLABORATING INSTITUTIONS

- Kenyatta National Hospital, Nairobi
- Moi Teaching and Referral Hospital, Eldoret
- Garissa Level V Hospital
- Meru Level V Hospital
- Nyeri Level V Hospital
- Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu
- Smile Train
- Operation Smile
- Cleft Kinder Hilfe

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ACRONYMS AND ABBREVIATIONS

CL – Cleft Lip

CP – Cleft palate

CLP – Cleft lip palate

KNH – Kenyatta National Hospital

QoL – Quality of Life

VPD- Velopharyngeal dysfunction

DFMT- Decayed, missing and filled teeth

HRQoL- Health-related quality of life

PROM- Patient-reported outcome measures

SPSS- Statistical Package of the Social Sciences

KSPRAS- Kenya Society of Plastic, Reconstructive, and Aesthetic Surgeons

OPERATIONAL DEFINITIONS

Cleft Lip / Palate - Common congenital craniofacial abnormalities characterized by failure of normal fusion of the palate and/or lip at the midline during development resulting in significant aesthetic facial deformity and communication between the oral and nasal cavities

Quality of Life- A subjective evaluation which aims to capture the well-being, whether of a population or individual, regarding both positive and negative elements within the entirety of their existence at a specific point in time.

Cheiloschisis- A congenital cleft of the upper lip; synonymous with isolated cleft lip

Uranoschisis- A congenital cleft of the hard palate.

SUMMARY

Background: Oro-facial cleft deformities usually exact a significant disease burden on patients and their families. A patient's emotions and social lives and their sense of self-worth may be impacted by several procedures, protracted supplementary therapies, and reduced cosmetic and physiological outcomes, lowering their Quality of Life. Using patient-centered measures such as the health-related quality of life (HRQoL) is crucial for estimating the true burden of a condition to an individual and determining patient outcomes of healthcare programs and interventions. This study aims to evaluate the health-related Quality of Life following cleft lip and/or palate surgery.

Methodology: Using an analytical cross-sectional research study design, patients who underwent cleft lip and palate repair were recruited using the consecutive sampling approach. Patients were sourced from the database of operations conducted over 20 years since 2000. Data were collected on demographic and clinical factors as independent variables. Quality of life measurement was derived from the CLEFT-Q tool comprising questions on speech, psychological and social parameters. Data analysis was done by SPSS. The significance level for all tests was 5% ($p<0.05$). Tables, charts, and graphs were used to present the data. To examine categorical data, frequencies and percentages were used. The students' T-tests and analysis of variance (ANOVA) was employed to examine the validity of the hypothesis for continuous variables. Multiple regression models were used to investigate predictors of health-related characteristics in multivariate analysis.

Results: out of a possible 100, the average score by the 114 participants was 86 in the test assessing psychological function, 83.1 in the test assessing social function, and 79.86 in the test assessing for speech distress. Female participants scored lower than male participants in all parameters, however this was not significant. Participants over 18 years old scored higher than participants under 18, with the difference in social function being statistically significant ($p=0.05$). The highest scores were seen in participants with unilateral cleft lip deformities in all scales, while the lowest CLEFT-Q scores were seen in participants with bilateral cleft lip and palate deformities in all scales, with that of speech and social function being statistically significant ($p=0.027$ and $p=0.044$ respectively).

Conclusion: This study demonstrates that the quality of life of female and younger patients who have undergone corrective cleft surgery is mostly affected by the psychosocial burden of this genetic defect. The demonstrated findings on psychosocial function as well as speech distress amongst patients with cleft lip and palate deformities provide insight into the mental aspects of the health condition which are often overlooked, and provide information on additional measures to be taken in order to improve the quality of life amongst patients with this genetic defect.

1.0 CHAPTER ONE: INTRODUCTION

1.1 Background Information

The most frequently encountered developmental orofacial defect with a worldwide impact is arguably cleft lip and cleft palate anomalies (Volk *et al*., 2020). Cleft lip and palate are splits within the typical anatomical structure of the upper lip, roof of the mouth or both. The failure of appropriate union of the palatal shelves and the forming lips from both sides in the middle during embryological development leads to clinically evident neonatal malformation (Tollefson *et al.*, 2008). Cleft lip and palate can significantly impact the patient's looks, articulation, or dentition, leading to a lesser health-associated quality of Life (Eckstein *et al*., 2011). The far more prevalent form of the congenital cleft is cleft lip coupled with cleft palate (CLP), which is followed by cheiloschisis (isolated cleft upper lip) and then uranoschisis (isolated cleft hard and/or soft palate); 92.6% of orofacial clefts occur bilaterally, with 5.5% being isolated to only the right side (Kianifar *et al.*, 2015; Pantaloni & Bryd HS. Cleft Lip, 2001). Cleft lip and palate (CLP) represent the most frequently diagnosed maxillofacial malformation, with an estimated worldwide occurrence rate of one case for every 700 births (World Health Organization, 2006).

The frequency of this disorder differs widely among nations and territories, with Kenya registering 1.7 babies born with congenital clefts per each cohort of 1000 births *(*Hlongwa *et al.*, 2019) and an estimated six hundred to seven hundred corrective procedures performed in the country each year (Waweru, 2019). Quality of life (QoL) is a significant wellness parameter growingly acknowledged in patients with potentially curable illnesses (Manchanda *et al.,* 2014). Cranio-facial cleft abnormalities have a significant illness burden due to their intricacy and impact on all elements of a patient's and their family's lives. For instance, Velo-pharyngeal Dysfunction (VPD), a disorder that arises when the patient's nose and mouth chambers cannot be separated while speaking due to misaligned soft-palate musculature, often leads to an unpleasant nasal tone that has the potential to distort speech (Woo, 2012). Multiple operations, additional long-term treatments, and decreased functional and cosmetic outcomes may negatively impact patients' social and emotional functioning and sense of personal identity, resulting in diminished well-being and, consequently, a lower QoL (Naros *et al.,* 2018).

Quality of life, when considered in the context of craniofacial defects, encompasses several areas: looks, speech articulation, facial development, and social interaction. Furthermore, the significance also rests on how these many domains could shift from childhood to adulthood. Clients' levels of satisfaction can differ depending on whatever components of care are

evaluated, and total body esteem is often not tied to assessments of facial aesthetics (Heliövaara *et al.*, 2020).

Cleft lip and cleft palate procedural interventions aim to improve facial look and functionality and enhance psychosocial wellness. Treatment outcomes have traditionally been evaluated objectively via patient-reported or provider-reported evaluations (Heliövaara *et al.*, 2020). The purpose of treatment for orofacial cleft defects is to help cultivate better conditions for a patient's overall well-being and quality of Life (Food and Drug Administration, 2009). Results, as reported by the patients themselves after the repair of their cleft lip and cleft palate defects, are crucial for the evaluation of care provided. Conventional surgical results are measured objectively using pictures, anthropometric proportionality assessments, complication rates, and death rates. Cosmetic, articulation, functionality, personal identity, and quality of life studies allow a much more comprehensive evaluation of therapeutic success and the surgeon's and the patient's satisfaction.

The patient-reported quality of life in Thailand after cleft repair surgery was high, though they still worried about their self-concept and psychological well-being (Augsornwan *et al.*, 2011). Cleft lip or cleft palate patients can use Patient-Reported Outcome Measures (PROMs) such as CLEFT-Q. The CLEFT-Q measures have received worldwide validation in numerous situations to assess patient outcomes in people with facial defects (Klassen *et al.*, 2018, 2021). There is no indication of bias based on age, gender, or language with these findings (Miroshnychenko *et al.*, 2021; Tsangaris *et al.,* 2017). The findings also back the global adoption of a standard scoring formula for each scale. The CLEFT-Q scales' cross-sectional construct validity supports the instrument's psychometric properties. The increasing popularity and adoption of CLEFT-Q scales in over 45 countries, their addition to the International Consortium for Health Outcome Measurement cleft standard set, and their translation into 22 languages and counting serve as proof of their usefulness, robustness, and applicability (Miroshnychenko *et al.*, 2021).

Smile Train, Operation Smile and Cleft Kinder are some nonprofit charitable organizations that fund and support the treatment of cleft lip and palate patients in low-income communities. Their vast and diverse client databases may provide evidence-based data to guide therapeutic approaches and further studies. Our investigation focused on the health-related quality of life outcomes after cleft lip and/or palate correction procedures. This was accomplished by using the CLEFT-Q, a novel patient-centered outcome questionnaire created to assess important patient outcomes.

2.0 CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of Cleft Lip and Palate Defects

The prevalence of cleft lip and palate varies widely among geographical regions. Asia and the Americas experience the highest prevalence of CLP, while Africa has the least. The sex ratio of cleft lip- and palate-affected children is generally unequal. CLP is twice as common in male than in female children, but isolated CP is more frequent among girls (IPDTOC Working Group, 2011). CLP frequencies were recorded in research undertaken by the International Perinatal Database of Typical Orofacial Clefts, created in 2003 by the World Health Organization's Human Genetics Program (WHO). Japan had the highest incidence of CLP, while South Africa had the lowest (IPDTOC Working Group, 2011; Owens *et al.*, 1985). According to Owens *et al.*'s study on the epidemiology of facial clefting in Liverpool, the frequency of CLP occurrence was 0.51 cases for every 1000 live births (Owens *et al.*, 1985). In Yazd, Iran, the proportion of cleft lip and palate among babies born was 0.86 in 1000 live births, including 46.4 per cent of those having both cleft lip and palate (Yassaei *et al.*, 2010). CLP has a relatively modest prevalence rate in Africa; for instance, Malawi reports just 0.7 cases for every 1,000 children born (Msamati *et al.,* 2000). Suleiman *et al.* observed a 54% prevalence of CLP in Sudan and Africa (Suleiman *et al.*, 2005). The South African public healthcare system reports an approximate prevalence of cleft lip and palate defects at 0.3 cases per 1,000 live births, with a 34.6% incidence rate for both cleft lip and palate cases (Hlongwa *et al.,* 2019).

Over one year in Kampala, Uganda, a CLP average incidence of 0.73 per 1000 babies born was discovered in 26,186 babies delivered (Dreise *et al.*, 2011). Cleft lip and/or cleft palate represent the most frequent birth abnormality in Kenya, as per Kenyatta University Hospital (KUH), a tertiary health institution, occurring once every 1300 births. This compares to a study demonstrating a CLP frequency of 1.7 per 1000 babies born in Kenya (Hlongwa *et al.*, 2019). Healthcare professionals must take preventative steps to reduce the number of children with orofacial clefts due to the disorder's higher regional prevalence and develop and refine therapeutic and diagnostic methods to lessen the effects of this condition on children.

2.2 Complications of Cleft Lip Palate

Dental abnormalities, notably abnormal tooth size, morphology, and positioning, are common in children with orofacial clefts. Most of these youngsters have cosmetic disfigurements, speech impairments, and feeding challenges and are stigmatized. Discontentment with one's

physical looks affects one's relationships with peers, identity, and reasoning ability (Kesande *et al.,* 2014). Some children born with CLP require continuing surgeries, orthodontics, and speech therapy, which could impact their quality of life (Zeytinoglu & Davey, 2012). Furthermore, certain children may have learning difficulties, low self-esteem, social anxiety, and peer stigmatization, necessitating further psychological help (Berger & Dalton, 2009). A likely consequence of CLP defects involves Velo-pharyngeal Dysfunction (VPD) (Inman *et al.*, 2005). VPD seems to be a disorder that arises when the patient's nose and mouth chambers cannot be separated while speaking due to misaligned soft-palate musculature. It leads to an unpleasant nasal tone that has the potential to distort speech.

Cleft patients often have dental disorders, including dental and segmental arch anomalies, and surgical scar concerns, all of which contribute to a higher rate of tooth decay. Zhu *et al.* studied three-year-old to twenty-five-year-old cleft patients in Western China. They discovered that tooth decay was considerably greater in individuals with CLP (Zhu *et al.*, 2010).

Recurring otitis media involving fluid exudates and hearing loss is correlated with CLP. It is widely acknowledged that kids with cleft palate have a greater likelihood of middle ear infections, estimated to be over 90% by age six. Recurrent ear infections will affect up to 45 per cent of these children (Sheahan *et al.*, 2003).

CLP has substantial psychological, social, and economic consequences on the child and their families, such as disturbance of psychological adjustment, social dysfunction, and poor QoL (Wehby & CH, 2010). According to Conway *et al.,* the shame and stigmatization of an unfixed dento-facial cleft severely limit a child's capacity to assimilate into social and cultural settings (Conway *et al*., 2015).

2.3 Treatment and Repair of Cleft Lip Palate

The method utilized to treat congenital orofacial cleft abnormalities depends on the extent of the deformity and the surgeon's preferences. Patients with complete unilateral CLP require multiple surgical procedures throughout their lifetimes (Chang *et al.*, 2017).

Soft-palate reconstruction approaches can be utilized alone or in conjunction with hard-palate surgeries. To achieve levator muscular relocation, most surgeons currently employ some variation of an intra-velar velo-plasty verses a two-flap palate-plasty with double opposed zplasty (Sitzman & Marcus, 2014). The aims of palatal repair must be to partition the oral from the nasal cavities and to establish a functional velo-pharyngeal valve for swallowing and articulation while retaining facial bone structure and soft-tissue growth, and physiological occlusion development (Friedman *et al.*, 2010).

Restoration has occurred anywhere from immediately following birth to as later as six years. Evidence suggests that beyond the age of seven, children do not benefit after palatal reconstruction surgeries since major speech skills have already evolved, and modifying the anatomy at around this point may impede speech advancement (Hopper *et al.*, 2006). Post cleft palate repair, the most common acute complications are hemorrhage, pulmonary obstruction, infections, and wound dehiscence. Although infrequent, bleeding and respiratory blockages that require re-intubation can happen soon after the surgery and are possibly fatal (Hopper *et al.*, 2006).

2.4 Outcome Measures in Cleft Lip Palate Treatment

There seem to be various outcome metrics that assess the overall effectiveness of any CLP therapies. Those are primarily centered on quality of life and therapeutic satisfaction. It is challenging to quantify significant results in CLP surgery. Aesthetic labial morphology, nasal morphology, lip scarring, articulation, postoperative complications, and facial maturation (Chang *et al*., 2017) are employed to assess the results of CLP patients and score "study" parameters against a collection of common standards or indices (Jones *et al.,* 2014). These indices include:

The GOSLON Yardstick- the most extensively used evaluation tool of the occlusal effects of primary surgery, is universally acknowledged to possess good validity and reliability.

The 5-Year-Olds' Index

Modified Huddart/Bodenham scoring system

The EUROCRAN Index

In the United Kingdom, an instrument for analyzing speech is employed for auditing reasons. However, it is lengthy because of the necessary consensus listening to validate the process. A variety of indexes have also been created to aid in the evaluation of speech in cleft patients (John *et al.*, 2006):

Great Ormond Street Speech Assessment (GOS. SP. ASS)

The cleft audit protocol for speech augmented (CAPS-A)

Amongst the most important determining indicators of effectiveness in the therapy of CLP is the appearance of the nasolabial folds. Assessment can be done directly or indirectly in a medical context using various methods (Al-Omari *et al.*, 2005). To evaluate cleft patients' nasolabial appearance, five main grading systems have been used these are;

The Asher-McDade system is- the most widely used scoring system

The VLS classification

The craniofacial proportion indices

The aesthetic Index

The cleft lip evaluation profile (CLEP) index.

CLP children's good oral health outcome metrics are like those used in every other child, including dental hygiene and periodontal and tooth decay status. One can employ the Decayed Missing Filled Teeth Index (dmft for milk teeth and DMFT for permanent teeth). This documentation keeps track of all teeth extracted, repaired, or showing any signs of decay. DMFT is unquestionably the most extensively employed oral healthcare outcome metric in both cleft and non-cleft individuals worldwide (Chang *et al.,* 2017).

Most outcome measures listed above are used to judge treatment outcomes immediately following treatment or during therapeutic intervention. The vast proportion of accessible outcome measurements emphasizes the complexities of auditing cleft results.

2.5 Quality of Life Measures after Cleft Lip Surgery

The quality of life that people experience is more difficult to assess objectively or over an extended period of time than many physical outcomes. Since it is a subjective state of mind, quality of life can mean various things to different people. In recent years, researchers have started to distinguish between various aspects of well-being, such as emotional well-being, which asks respondents about the quality of their regular emotional experiences, and life evaluation, which asks respondents to consider their lives generally and rate them using a scale. These and other scales and measurement methods have long been in use. There are numerous ways to assess quality of life, and numerous instruments have been created for various use cases and demographics. The "healthy days measure," "Patient-Reported Outcomes Measures" (PROMS), and "Quality-Adjusted Life Years" are three popular ones (QALYS) (Heath, 2020). Quality of life of patients with facial defects encompasses a range of multiple areas (aesthetics and cosmetics, articulation, facial maturity, and psychosocial interaction). Furthermore, the significance rests in how these many regions could shift from childhood to adulthood. For the best patient care, cleft lip and/or cleft palate defects must be corrected according to patient reports. Depending on the aspect of care that is evaluated, patient satisfaction levels can vary, and ratings of facial appearance are not always correlated with assessments of overall body image (Hunt *et al*., 2005).

Auditory issues and/or middle ear infections were likewise the most frequently encountered complications of CLP management. In one study on CLP, respondents described seeing their

family physician or ENT specialist several times each year. Even though this did not appear to impact adjustment significantly, it did raise the cost of care (Kappen *et al*., 2019).

2.5.1 Psychological

According to research conducted by Kappen *et al.* to investigate contentment with treatment and quality of life in individuals having had procedures to correct CLP, 55 per cent of the older patients examined had embraced their cleft, and many were content with the ultimate result of therapy (Kappen *et al.*, 2019). As per Latifa *et al.*, the general QoL rating for teenagers with CLP is 59.61%, whereas the rating for the subjects' families suffering from CLP is 60.58% (Latifa *et al.*, 2019).

2.5.2 Social

A high number of CLP-afflicted participants preferred speech results and intelligibility success over cosmetic outcome success, particularly as they grew older. Almost all participants reported receiving overwhelming parental assistance. Some participants talked frankly about their troubles and issues with their families, something they thought was crucial to their adjustment (Kappen *et al.*, 2019).

2.5.3 Speech

Much discussion about the protracted effects of cleft reconstruction focuses on the developmental aspects of speech and mid-facial growth. Researchers noted that the HRQoL of young people with labial/palatal clefts declined as speaking issues became more severe, and older children with CLP showed lower HRQoL than children with CLP (Damiano *et al.*, n.d.). There seem to be very few studies that show how patients feel following surgical correction procedures and how they estimate their quality of life. A complete, accurate, and comprehensive questionnaire for cleft lip and palate surgery is lacking (Grollemund *et al.*, 2010).

2.5 Gaps in Local Literature

There is a lack of adequate knowledge in this environment on patients' overall well-being following cleft lip/palate repair. This is occasioned by a lack of studies detailing the same in this environment. Such lack of knowledge hinders adequate assessment and provision of care for patients post cleft lip/palate surgery. Current tools assessing the quality of life may not apply in different geographical regions due to varying socio-cultural and economic circumstances.

Further research would be required in such areas. Specific measures to quantify Quality of Life in patients with congenital maxillofacial defects following repair have now been highlighted as a critical knowledge gap that must be addressed in the local setting. A tool that displays clinically relevant scientific data that the patient has self-reported and considers wellness issues in people with CLP is required to appropriately measure the HRQoL of subjects with CLP following surgical intervention. These would be evaluations of one's quality of life and/or other crucial outcome indicators, such as patient satisfaction, symptoms, and functionality.

2.6 Problem Statement

Cleft lip and cleft palate abnormalities are often typically encountered with greater frequency in developing countries. Dental issues, malocclusion, nasal distortions, feeding impairments, and auditory and speech disorders are all related to these defects. If left untreated, CLP causes cosmetic, physiological, social, and psychological problems and disrupts social connections. Several research studies have described the psychological and social burdens experienced by young people with congenital labial and/or palatal clefts. These individuals' exhibit significantly more behavioral issues, in addition to more depressive symptoms, while also being less pleased by the look on their faces.

Patient-Reported Outcome Measures (PROM) in correcting cheiloschisis and uranoschisis are crucial for patient care. Conventional surgical results are measured objectively using anthropometric proportionality, morphological assessments, complication rates, and fatalities. Aesthetic, speech, functionality, identity, and quality of Life studies allow a more comprehensive evaluation of surgical results, in addition to the surgeon's and the patient's contentment.

2.7 Justification

Cleft lip and palate (CLP) defects are not just aesthetic defects but can also cause severe physiological impairment in newborns if not appropriately treated. Currently, no local studies objectively focus on cleft individuals' quality of life in relation to their health. Many cleft correction procedures aim to improve looks and facial functionality. It is critical to include patient-reported outcomes tools that can assess particular aspects of suffering from a cleft lip and/or palate.

Study Utility: The study of Quality of Life can be employed to evaluate the everyday burden an individual with CL or CLP has to face. Moreover, the results of this investigation could aid in developing suitable intervention protocols for cleft patients locally and then beyond.

2.8 Study Objectives

2.8.1 Broad Objective

To assess the health-related Quality of Life following surgical correction for cleft lip and/or palate defects in Kenya

2.8.2 Specific objectives

i. To assess the psychosocial quality of life after cleft lip and palate surgery
ii. To assess speech distress after cleft lip and palate surgery
iii. To assess any sex differences in Health-related Quality of Life
iv. To assess any age differences in Health-related Quality of Life in people above and below 18 years of age
v. To assess any differences in Health-Related Quality of Life amongst different cleft lip and palate deformities

3.0 CHAPTER THREE: METHODOLOGY

3.1 Study Design

This was a descriptive cross-sectional study design.

3.2 Study Site

The study was undertaken at health institutions where orofacial cleft corrective procedures were provided as part of the regular surgical interventions or as part of the Kenya Society of Plastic, Reconstructive, and Aesthetic Surgeons (KSPRAS) surgical cleft camp outreaches. The choice of a surgical camp location was a cooperative process involving the KSPRAS and the host facility. An outreach effort was then established when there were a number of individuals who required cleft surgery.

Listed below were the study sites:

- **i.** Moi Teaching and Referral Hospital, Eldoret
- **ii.** Kenyatta National Hospital, Nairobi
- **iii.** Garissa Level V Hospital **iv.** Meru Level V Hospital
- **v.** Nyeri Level V Hospital
- **vi.** Jaramogi Oginga Odinga Teaching and Referral Hospital, Kisumu

3.3 Study Population

The study population encompassed consenting or assenting patients over ten who underwent cleft lip/palate surgery from 2000 to present. They were required to have been officially documented in either the Smile Train, Operation Smile or Cleft Kinder database

3.4 Selection Criteria

3.4.1. Inclusion Criteria

Children over the age of 10 years and adults

Patients with CLP who had undergone cleft lip/palate operations recorded within any of the Smile Train, Operation Smile or Cleft Kinder databases.

Participants who understood either English or Kiswahili enough to be able to fill in the questionnaire with little guidance

Patients who had had at least six months post cleft repair surgeries

3.4.2 Exclusion Criteria

Patients who failed to complete the questionnaire.

Participants who had their cleft lip and/or palate surgeries performed in another country (not Kenya)

Patients who presented with an unrelated chronic comorbid condition that may have also affect their quality of life e.g., diabetes, chronic heart conditions etc.

3.5 Sample Size Determination

Fischer's formula for determining sample size was used to determine the sampling size. According to Latifa *et al.* research, the percentage of teenagers who were content with their Quality of Life was 59(Latifa *et al.*, 2019). As a result, this figure was utilized to compute the sample size. The formula is:

n= (Z^2 P (1-P))/e^2

Here n represents the population sample

The normal curve's abscissa was Z2 (1.96) p was the approximate prevalence of teenagers who were content with the HRQoL after CLP surgery = (59 per cent) q was (1-p)- the proportion of a population trait that was missing (0.41) e denoted the study's margin of error (0.05)

As a result, for a significant population (>10000), the sample size was N = 372.

120 people every year multiplied by 20 years was 2400 people.

The formula (N *n) / (N +n) was employed for finite population correction.

As a result, a sample size of 114 patients was sought.

3.6 Sampling Procedure

Before the beginning of the clinic service for the day, the investigators reviewed the records and chose each suitable patient. The eligible individuals were chosen using a sequential sampling strategy based on the Smile Train, Operation Smile or Cleft Kinder repositories. Once the sample size was reached, every patient who met the eligibility requirements were enrolled after receiving a thorough explanation of the investigation and providing written informed consent.

3.7 Recruitment

Before commencing the investigation, ethical approval was sought and obtained. The potential participants were contacted using phone numbers obtained from Smile Train, Operation Smile or Cleft Kinder databases. Some study subjects were recruited on site if they met the inclusion

criteria. All costs incurred by the participants in the course of the study were fully reimbursed fully by the principal investigator. Each potential respondent in the research was also asked for their consent before collecting any data if they were adults. In the case of children, assent was sought from those above 10 years and informed consent also sought from their parents or guardians. The lead researcher or research assistant collected patient information and data using a questionnaire administered by the researcher. Two medical students from the undergraduate level, years 5 & 6, were recruited and trained as data collectors. They were trained for a day on how to implement the study protocol, including collecting data from the databases and aiding the principal investigator in guiding the participants, compiling the data and entering it into the data collection sheet. Consenting patients who had undergone the procedure were recruited for data collection.

3.8 Data Collection

A CLEFT-Q Questionnaire form was utilized to collate outcome data from the patients. The Health-Related Quality of Life Part of the CLEFT-Q questionnaire was used (Appendix 1).
The patients' files were cross-checked from the hospital's registry. The patients' sociodemographic data, including; sex, age at the time of repair, and familial history of congenital cleft defects, were obtained. The patients personally filled out both the socio-demographic questionnaire and the CLEFT-Q questionnaire.

3.9 CLEFT-Q Conceptual Framework

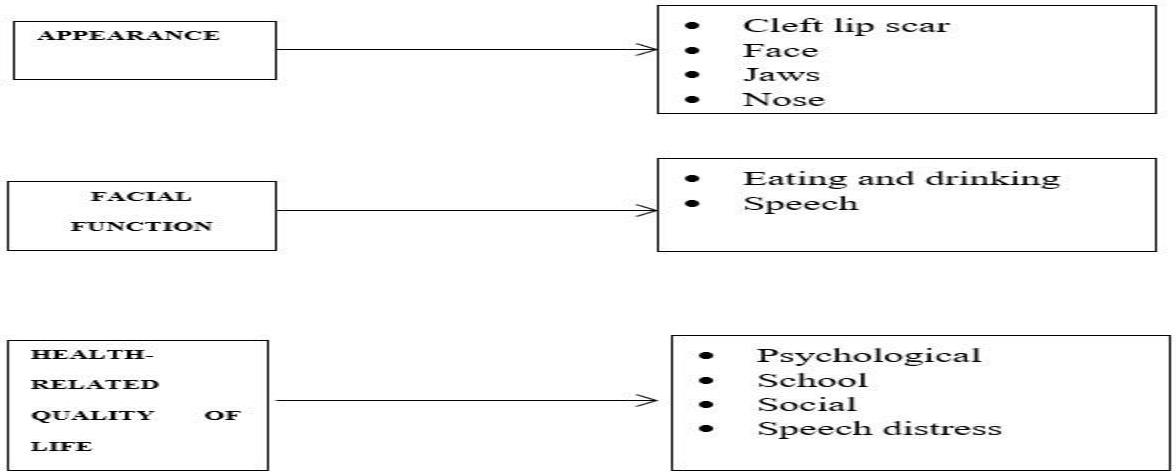

Figure 1:Cleft Q Conceptual Framework

(Scoring and scales are provided in the Appendix)
Scoring in each scale was out of a total possible 100.

3.10 Data Management and Analysis

Data analysis was done with version 25 of the SPSS software. At a p-value less than 0.05, the results were deemed significant. Charts, tables, graphs, and other suitable info-graphic elements were used to present the data. The significance level for all the statistical tests was defined at 95 per cent (p-values less than .05). To explore categorical data, frequencies and percentages were also utilized.

For hypothesis testing, the student t-test was used to assess differences in Cleft Q scores between the two groups regarding sex and age above or below 18 years. Comparisons were also made with similar studies in the published literature. Data was presented in frequency tables, bar charts, pie charts, and written reports.

3.11 Ethical Considerations

The ethical approval was received from the Kenyatta National Hospital & the University of Nairobi Ethics Review Committee (KNH/UON-ERC). Administrative authorization was also received from each enrolled research site before commencing data collection. All subjects' informed permission, assent, consent, or agreement was obtained prior to the scheduled surgery. The patient's involvement in the study was totally optional, and participants were given the option of leaving the research at any time.

The participants' identities and personal information was kept confidential during the private interviews. The questionnaires had identity codes to maintain the data's anonymity. When there was a language barrier or an inability to thoroughly understand the questions asked during the preoperative assessment, a third party's translation was used. The research results and findings were only used for this particular investigation and with the strictest secrecy. The information collected during the study was utilized to build protocols that aided in the creation of suitable treatment plans for cleft patients in the area and elsewhere.

Their decline to participate did not compromise in any way a participant's hospital care. The cost of the participant's medical care did not increase due to their participation in this study. Participants' hospital file numbers were provided in the datasheet to make it easy to find and gather missing data during data collection.

4.0 CHAPTER FOUR: RESULTS

4.1 Study Participants

A total of 114 participants submitted a response. Out of these, 62.8% (71) were male while 37.2% (42) were female. The average age of the respondents was 16 years old with the youngest being 10 and the oldest 70 years old. The mode age of the respondents was 10 with 26 out of 114 of the participants falling under this age. The average age at which surgery was performed was at 111 months with the earliest surgery done in 1970 and the latest in September 2022.

53.5% of the responders had undergone the surgery 10-14 years prior, 31.5% 5-9 years prior and 14.9% less than 5 years prior to the current study (Table 1).

Out of the 114 participants, more than half (51.8%) of the patients reported a unilateral cleft lip, 19.8% reported a bilateral cleft lip and palate, 16.7% reported a unilateral cleft lip and palate, 8% reported an isolated cleft palate and 3.5% reported a bilateral cleft lip. There was no recorded patient with a median cleft lip (Table 2). The details of the cleft lip and palate are summarized in Table 3 in regards to the type of unilateral cleft lip, type of unilateral cleft lip and palate and in the case of isolated cleft palate, the characteristic of the deformity reported. Among the participants, there was one incident of another congenital anomaly reported, which was hydrocephalus, and one incidence of a health problem on admission, being a form of motor deficit.

Table 1:Duration from last surgery till now

Duration from last surgery	**frequency**
<5 years	17 (14.9%)
5-9 years	36 (31.6%)
10-14 years	61 (53.5%)
>15 years	0

Table 2:Type of cleft deformity

Type of cleft deformity	**Frequency**
Unilateral cleft lip +/- alveolus	59 (51.8 %)
Unilateral cleft lip and palate	19 (16.7 %)
Bilateral cleft lip +/- alveolus	4 (3.5%)
Median cleft lip	0
Bilateral cleft lip and palate	22 (19.3%)
Isolated cleft palate	10(8%)

Table 3:Characteristics of the cleft lip and palate type

Cleft Lip and Palate Type	Characteristics	Number Of Patients
Unilateral cleft lip+/- alveolus	right	22
	Left	38
	Complete	25
	incomplete	32
	Simmonart band	0
Unilateral cleft lip and palate	right	10
	Left	7
Isolated cleft palate	Hard	1
	Soft	5
	Both hard and soft	4
	microform	0
	unilateral	0
	bilateral	0
	submucous	0

4.2 Patient Reported Health Related Quality of Life

4.2.1 Psychological Function

The average score for the psychological assessment of the health-related quality of life based on the question: “how do you feel” in relation to the surgery performed was 86.11 out of a possible 100 and was represented as follows (Fig 2and 3)

Figure 2:Responses to the first 5 questions of the psychological function scale in the CLEFT-Q questionnaire

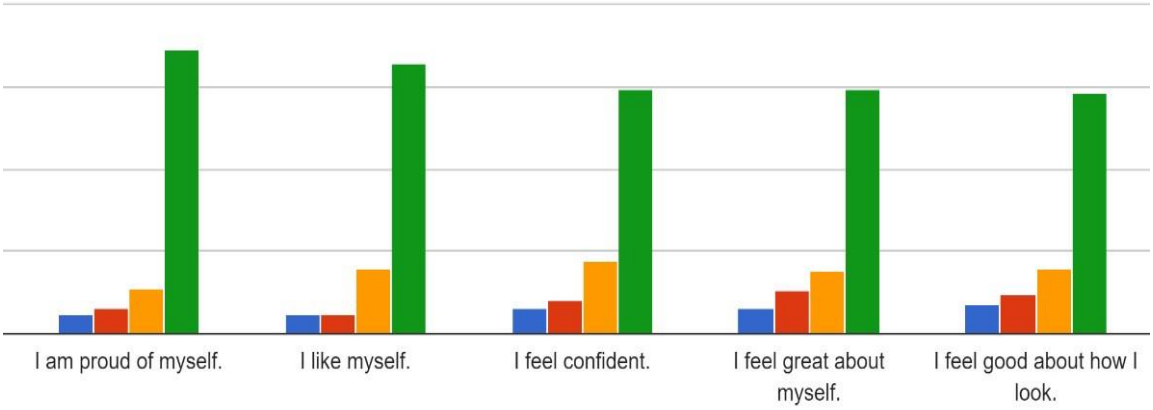

Figure 3:Responses to the last 5 questions of the psychological function scale in the CLEFT-Q questionnaire

4.2.2 Social Function

The average score for the social assessment of the health-related quality of life based on the question "how is your social life" was 83.1 out of a possible 100 and was represented as follows (Fig 4 and 5)

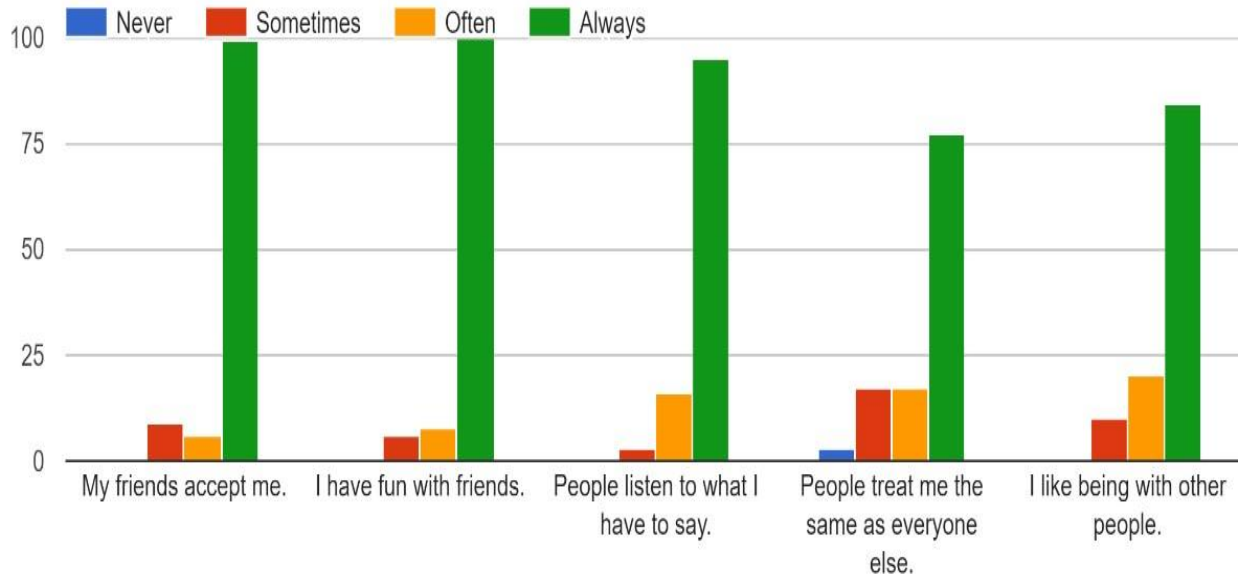

Figure 4:Responses to the last 5 questions of the psychological function scale in the CLEFT-Q questionnaire

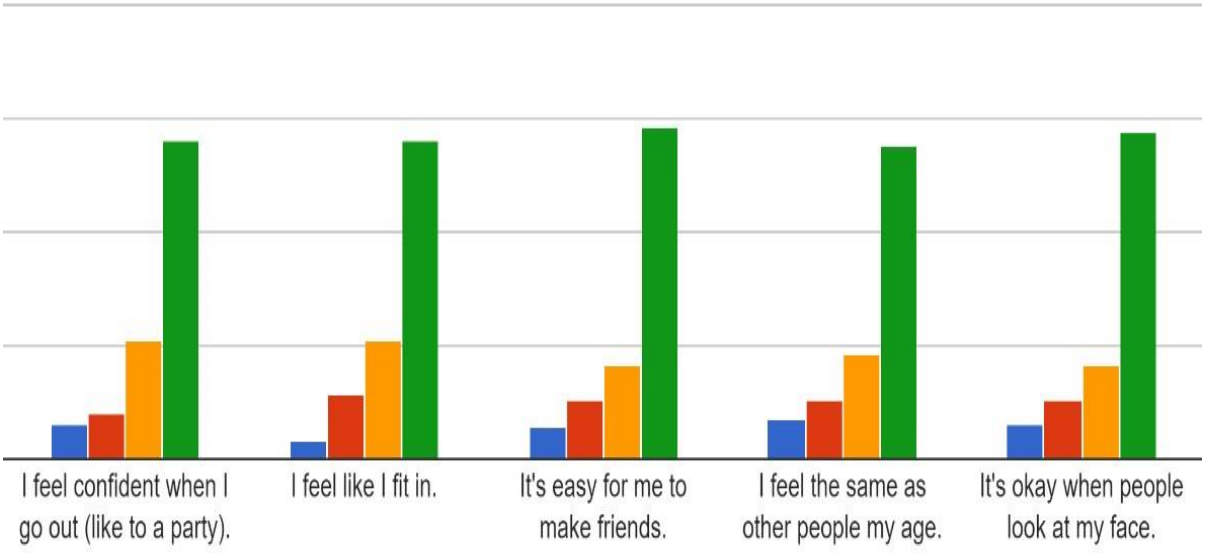

Figure 5:Responses to the last 5 questions of the social function scale in the CLEFT-Q questionnaire

4.2.3 Speech Distress

The average score for the speech assessment of the health-related quality of life based on the question "how do you feel about speaking" in regards to the week of data collection was 79.86 out of a total 100 and was represented as follows (Fig 6 and 7):

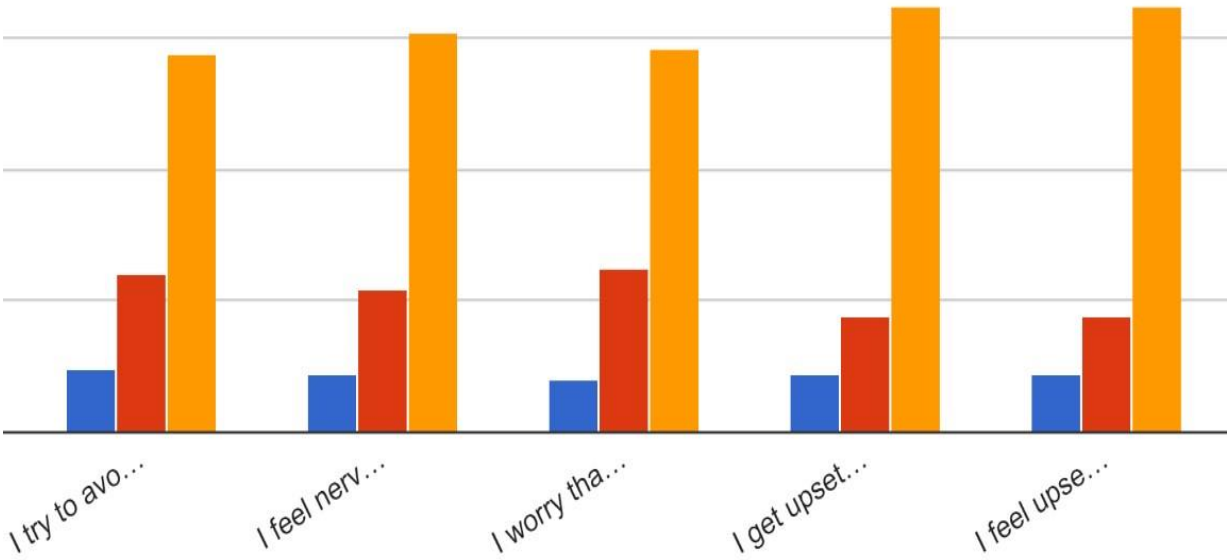

Figure 6:Responses to the first 5 questions of the speech distress scale in the CLEFT-Q questionnaire

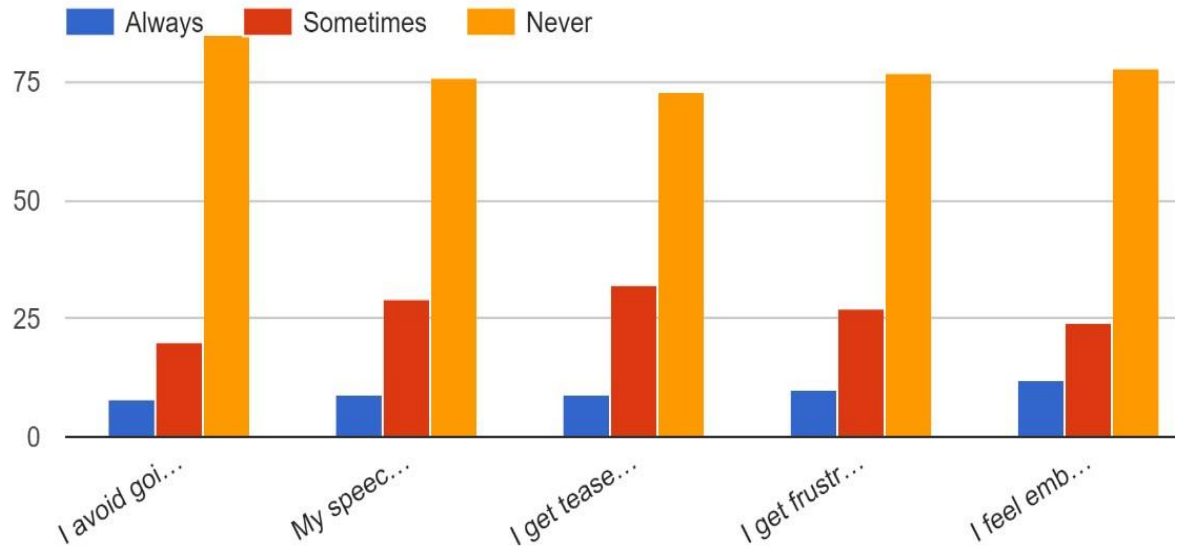

Figure 7:Responses to the last 5 questions of the speech distress scale in the CLEFT-Q questionnaire

4.3 Psychometric Findings

After running the Shapiro Wilk test for normality, it was determined that the data did not fall under normal distribution and thus the Mann-Whitney U test was used to compare the values across different groups.

4.3.1 Comparison Between Different Sexes

In the score assessing psychological function, the average score in male participants was 87 while the average score in female participants was 85. This difference however was not statistically significant (p=0.364). In the score assessing social function, the average score was 83 in males and 82 in female participants. This difference was not statistically significant (p=0.483). In the score assessing speech distress, the average score for male participants was 80 in males and 78 in female participants. This was also not statistically significant (p=0.532). Regression tests did not reveal any association between a particular gender and higher test scores.

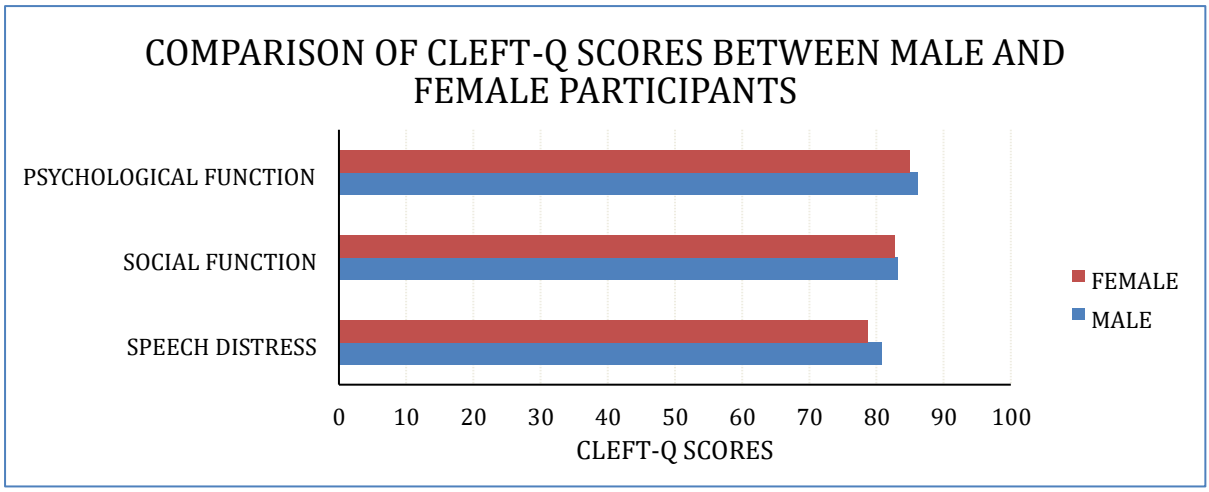

Figure 8:Comparison of CLEFT-Q scores between male and female participants

4.3.2 Comparison Between Different Ages

In the assessment of psychological function, the average test scores for the participants under 18 was 83 and 91 in participants over 18 years old. This was not statistically significant (p=0.183). In the assessment of social function, the average score was 80 in participants under 18 and 90 in participants over 18. This difference was statistically significant (p=0.05). In the assessment of speech distress, the mean score in those under 18 was 79 while the mean score in those over 18 was 82. This difference was not statistically significant (p=0.605). Regression tests revealed a 4% association between increasing age and increasing scores in the psychological function scale.

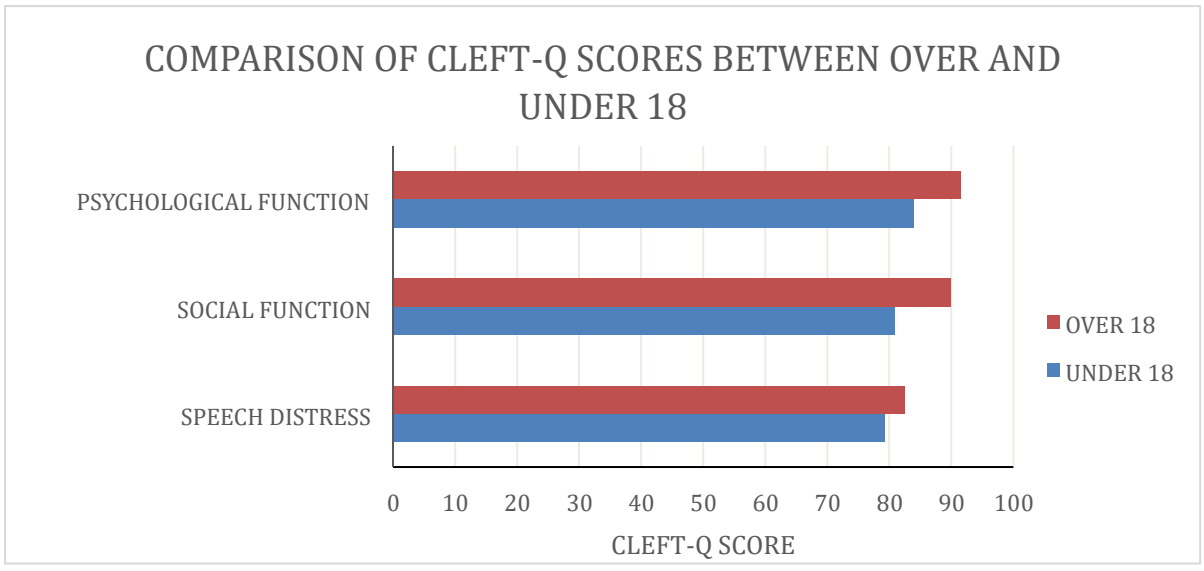

Figure 9:Comparison of CLEFT-Q scores between over and under 18 participants

Participants with unilateral Cleft lip deformities scored the highest in all 3 scales, with an average of 90.69, 87.98, and 87.3 in the psychological scale, social function scale and speech distress scale respectively. The lowest scores in the psychological and social function tests were by the participants with bilateral Cleft lip deformities, scoring 71.75 and 72.5 respectively. Participants with bilateral CLPs scored the lowest in the speech distress scale, with an average of 65.

Using the Kruskal-Wallis hypothesis test, it was determined that the average social function and speech distress test scores in participants with bilateral cleft lip and palate were significantly lower than in other CLP deformities, with a significance level of p=0.027 and p=0.044 for speech distress and social function respectively.

Table 4:CLEFT-Q scores among patients with different cleft lip deformities

Type Of CLP / **CLEFT-Q SCORES**	Unilateral Clef Lip	Unilateral CLP	Bilateral Cleft Lip	Bilateral Clp	Isolated Cleft Palate
Psychological Function	90.69	84	71.75	78.41	81.1
Social Function	87.98	79.36	72.5	77.77	75.7
Speech Distress	87.83	79.79	69.75	65	70.7

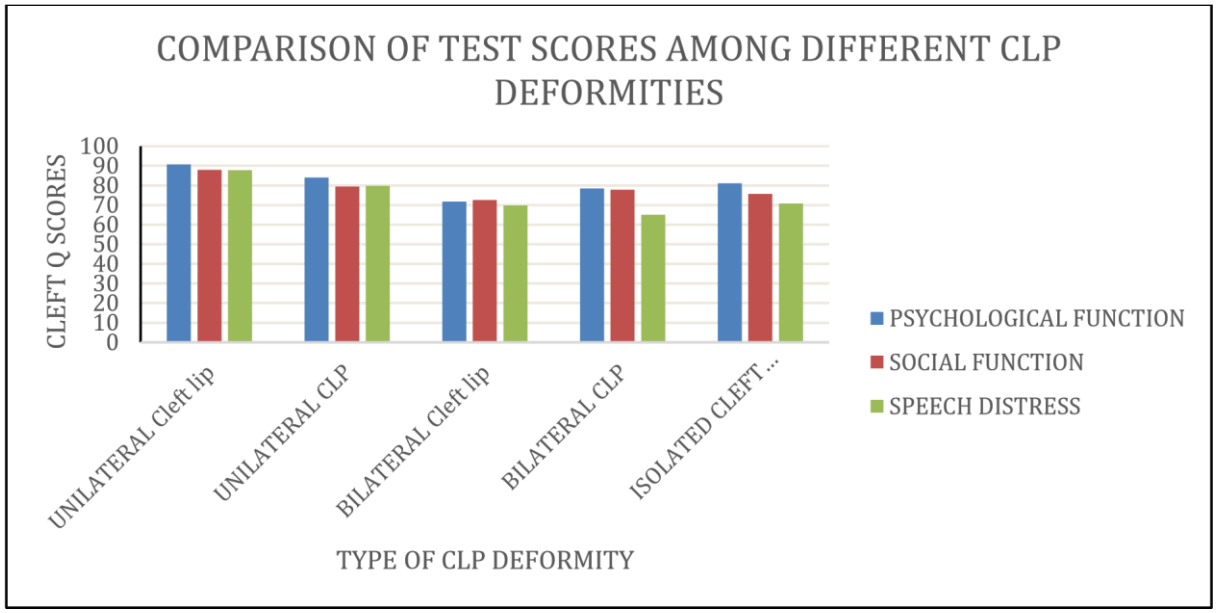

Figure 10:Comparison of CLEFT-Q scores among participants with different cleft lip deformities

5.0 CHAPTER FIVE: DISCUSSION, CONCLUSION & RECOMMENDATIONS

5.1 Discussion

5.1.1 Patient Reported Quality of Life

The assessment of patient reported health related quality life sought to measure psychological function, social function and speech distress amongst patients with cleft lip and palate who had undergone corrective surgeries. Amongst the three scales measured, the lowest scores were observed in the assessment of speech distress, followed by social function, while psychological function scored the highest in the assessment. Patients with unilateral cleft lip deformities scored highest while patients with bilateral cleft lip and palate deformities scored lowest in all 3 scales, with the difference being statistically significant.

Wong Riff *et al.*, using the CLEFT-Q scores assessed the patient reported health related quality of life in CLP patients and compared scores amongst different CLP deformities (Wong Riff *et al*., 2019). It was seen that patients with bilateral CLPs scored the lowest in all scales while patients with unilateral CLPs scored the highest scores, which was in line with our study findings. It was also seen that speech distress had the lowest scores as compared to the scores assessing psychological and social function, similar to this study (Wong Riff et al., 2019). Latifa *et al.,* reported an overall lower quality of life amongst CLP patients in all scores, reporting an average of 59.6 (Latifa *et al.,* 2019). This was in contrast to our findings and the findings of other studies utilizing the CLEFT-Q framework. In this study, there was a higher patient reported HRQoL. This may have been due to the fact that majority of the participants had unilateral cleft lip deformities, which have previously been documented to report a better quality of life (Wong Riff *et al.,* 2019). The observed lower scores in speech distress scale of the CLEFT-Q framework may have been due to velo-pharyngeal dysfunction post-surgery, delayed CLP surgeries or lack of speech therapy following corrective therapy (Safaiean *et al.*, 2017). The most common speech defect was unintelligibility, which is assessed by the speech distress scale of the CLEFT-Q framework. Corrective speech therapy is often inaccessible due to the lack of specialists in rural areas, inadequate funds, and poor outreach to lower income communities to provide the necessary specialists (Lockhart, 2003). Speech therapy as postsurgical practice should therefore be strengthened in the local communities and supported by the local public health system.

5.1.2 Sex Differences in Patient Reported Quality of Life

It was observed that female participants scored the lowest in all three scales as compared to the male participants; this was not however statistically significant. In other studies, on the HRQoL in CLP patients which used different scales, there was observed significant differences in scores between male and female participants, with female patients reporting a lower quality of life (Eslami *et al*., 2013, Sinko *et al*., 2005). Poor reported outcomes in female patients is purported to be due to the social expectation of physical attractiveness in females as compared to males, particularly in the adolescent age group (Sinko *et al.*, 2005). In order to assess this issue, targeted counselling for female patients may be helpful in order to enable these patients embrace their clefts and live more fulfilling lives.

5.1.3 Age Differences in Patient Reported Quality of Life

Participants over 18 scored significantly higher in all scales than participants under 18, with their difference in the score in the social function scale being statistically significant. Regression tests did not find significant association between gender and age with higher test scores, although analysis showed that slightly higher psychological function was seen in patients over 18 years than those under 18years of age.

Damiano *et al.*, 2007 saw that HRQoL amongst patients with CLPs was lowest in adolescent patients as compared to other age groups, attributing it to the fact that physical appearance was most important at this age group in regards to social interaction and self- evaluation (Damiano *et al.*, 2007). Latifa *et al.*, also reported lower scores amongst teenagers as compared to other age groups, synonymous with this study (Latifa *et al*., 2019).

The biggest difference in health-related quality of life between patients over 18 and under 18 years was in the social function scale which sought to measure the adjustment of CLP patients in society and their sociability, where younger patients had significantly lower scores. Lockhart, found that CLP patients at school-going ages tended to be more withdrawn, less socially adept and depressed as compared to their peers in the same age group (Lockhart, 2003). This may have been due to rejection, or in attempt to avoid rejection leading to poorer social function. Adults on the other hand, were less likely to suffer from the psychological disturbances associated with CLP but still reported difficulty in attaining many social expectations of society such as marriage and child bearing (Lockhart, 2003). Studies demonstrate that older CLP patients embrace their cleft and live a more fulfilling life and thus a support group to the younger patients by older patients would be beneficial to their self-esteem and create a needed community.

5.2 Conclusion

This study demonstrates that the quality of life of female and younger patients who have undergone corrective cleft surgery is mostly affected by the psychosocial burden of this genetic defect. The demonstrated findings on psychosocial function as well as speech distress amongst patients with cleft lip and palate deformities provide insight into the mental aspects of the health condition which are often overlooked, and provide information on additional measures to be taken in order to improve the quality of life amongst patients with this birth defect.

5.3 Recommendations

From our findings, we hereby front the following recommendations:

a) It was observed that speech distress was the most affected scale in the patient reported health related quality of life. We recommend that further research be conducted in this area which may include assessing how this disability affects different patients from different dialects, the correlation between speech distress and other otolaryngological illnesses in cleft lip and palate patients, among others.

b) The CLEFT-Q conceptual framework has proved useful in the assessment of the patient reported HRQoL. However, other tools that examine quality of life in cleft lip and palate patients exist which have been scarcely utilized in the local setting. We recommend additional studies utilizing these questionnaires and tools to assess post-operative patient reported social outcomes in order to compare findings and provide additional information that may have been overlooked by this scale.

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APPENDICES

Appendix I: Structured Data Tool

Form no:

Demographics & clinical factors Section A (Epidemiology)

Number of Clients…… Contact phone……..

Hospital……

Hospital number……

Sex Male [ ] Female [ ]

Current age……

Date of first surgery…….

Age when first surgery was done ……

Duration from last surgery to now

< 5 years	[ ]
5-10 years	[ ]
0-15 years	[ ]
> 15 years	[ ]

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. ……

3. Other health problems on admission ……

Section C (Intraoperative Data)

Date of surgery…….

Surgical procedure: Unilateral cleft lip

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

Bilateral cleft lip

- Millard [ ]
- Manchester [ ]
- Others [ ]……

Cleft palate

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

Cleft Q components PSYCHOLOGICAL FUNCTION

HOW DO YOU FEEL? Please answer thinking in relation to the surgery.

Points: Never (1), Sometimes (2), Often (3), Always (4)

	Never	**Sometimes**	**Often**	**Always**
1. I am happy with my life.				
2. I enjoy life.				
3. I feel happy.				
4. I feel okay about myself.				
5. I believe in myself.				
6. I am proud of myself.				
7. I like myself.				
8. I feel confident.				
9. I feel great about myself.				
10. I feel good about how I look.				

PSYCHOLOGICAL FUNCTION CONVERSION TABLE

Instructions: Higher scores reflect a better outcome. If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best).

SUM SCORE EQUIVALENT RASCH TRANSFORMED SCORE (0-100)

10- 0 11- 4 12- 11 13- 15 14- 19 15- 23 16- 26 17- 29 18- 32 19- 35 20- 38	21- 41 22- 44 23- 47 24- 49 25- 52 26- 54 27- 57 28- 59 29- 61 30- 63	31- 66 32- 68 33- 70 34- 73 35- 76 36- 79 37- 82 38- 86 39- 92 40- 100

SOCIAL FUNCTION

HOW IS YOUR SOCIAL LIFE?

Points: Never (1), Sometimes (2), Often (3), Always (4)

	Never	**Sometimes**	**Often**	**Always**
1. My friends accept me.				
2. I have fun with friends.				
3. People listen to what I have to say.				
4. People treat me the same as everyone else.				
5. I like being with other people.				
6. I feel confident when I go out (like to a party).				
7. I feel like I fit in.				
8. It's easy for me to make friends.				
9. I feel the same as other people my age.				
10. It's okay when people look at my face.				

SOCIAL FUNCTION CONVERSION TABLE

Instructions: Higher scores reflect a better outcome. If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best).

SUM SCORE to EQUIVALENT RASCH TRANSFORMED SCORE (0-100)

10- 0 11- 4 12- 11 13- 15 14- 19 15- 23 16- 26 17- 29 18- 32 19- 35 20- 38	21- 41 22- 44 23- 47 24- 49 25- 52 26- 54 27- 57 28- 59 29- 61 30- 63	31- 66 32- 68 33- 70 34- 73 35- 76 36- 79 37- 82 38- 86 39- 92 40- 100

SPEECH DISTRESS

HOW DO YOU FEEL ABOUT SPEAKING? Please answer thinking of the PAST WEEK.

Points: (1) Always (2) Sometimes (3) Never

	Always	**Sometimes**	**Never**
1. I avoid going out because of my speech (like to a party).			
2. My speech makes it hard for me to make new friends.			
3. I get teased about my speech.			
4. I get frustrated when I speak.			
5. I feel embarrassed when I speak.			
6. I try to avoid speaking in front of people.			
7. I feel nervous when I speak.			
8. I worry that my speech is hard to understand.			
9. I get upset when I need to repeat myself.			
10. I feel upset when I am not understood.			

SPEECH DISTRESS CONVERSION TABLE

Instructions: Higher scores reflect a better outcome. If missing data is less than 50% of the scale's items, insert the mean of the completed items. Use the Conversion Table below to convert the raw scale summed score into a score from 0 (worst) to 100 (best).

SUM SCORE EQUIVALENT RASCH TRANSFORMED SCORE (0-100)

10- 0 11- 12 12- 19 13- 24 14- 28 15- 32	16- 36 17- 39 18- 42 19- 46 20- 49	21- 52 22- 56 23- 60 24- 63 25- 68	26- 72 27- 77 28- 83 29- 90 30- 100

Appendix II: Structured Data Tool (Kiswahili Version)

Chombo cha data

Kichwa cha Utafiti: Ubora wa Maisha Unaohusiana na Afya katika Upasuaji wa Baada ya Kupasuka kwa Midomo na Palate nchini Kenya **Nambari ya fomu:**

Idadi ya watu na sababu za kimatibabu:

Sehemu ya A (Epidemiolojia)

Idadi ya Wateja……

Simu ya mawasiliano……..

Hospitali……

Nambari ya hospitali ……

Jinsia ya Kiume [ ] Mwanamke [ ]

Umri wako……

Tarehe ya upasuaji …….

Umri ambao upasuaji ulifanywa …… Muda kutoka kwa upasuaji wa mwisho

[ ] <Miaka 5

[ ] Miaka 5-10

[ ] Miaka 10-15

[ ]>miaka 15

Sehemu B (hali ya kliniki ya mteja)

Aina ya ulemavu wa mpasuko

Midomo iliyopasuka upande mmoja -/+ alveolus

Kulia[ ] kushoto [ ]

Kamilisha [ ]

Haijakamilika [ ]

Bendi ya Simmonart [ ]

Mdomo na kaakaa iliyopasuka upande mmoja:

Kulia [ ] Kushoto [ ]

Mdomo uliopasuka baina ya nchi mbili +/- alveolus ……..

Mdomo wa kati uliopasuka ……

Midomo na kaakaa iliyopasuka pande mbili ……

Kaakaa la mpasuko lililotengwa:

• Ngumu [ ]

• Laini [ ]

• Yote ngumu na laini [ ]

• Fomu ndogo [ ]

• Upande mmoja [ ]

• Nchi mbili [ ]

• Submucous [ ]

Kipenyo cha mpasuko: Nyembamba [ ] Pana [ ] (mpana mpana: kingo za kati >1.5cm) Kuna matatizo mengine ya kuzaliwa nayo?

(i). …….

(ii). …….

Matatizo mengine ya kiafya wakati wa kulazwa ……

Sehemu C (Data ya Uendeshaji)

Tarehe ya upasuaji …….

Utaratibu wa upasuaji:

Mdomo uliopasuka upande mmoja

• Millard [ ]

• Tennison-Randall [ ]

• Nyingine…….

Mdomo wa pande mbili uliopasuka

• Millard [ ]

• Manchester [ ]

• Nyingine [ ]……

Kaakaa iliyopasuka

• Von-langenbeck [ ]

• Furlow [ ]

• Nyingine [ ]……

KAZI YA KISAIKOLOJIA

UNAJISIKIAJE? Tafadhali jibu kufikiri kuhusiana na upasuaji.

	Daima	**Mara nyingi**	**Wakati mwingine**	**Kamwe**
1. Nina furaha na Maisha yangu.				
2. Ninafurahia maisha.				
3. Najisikia furaha.				
4.Ninahisi sawa juu yangu mwenyewe.				
5. Ninajiamini.				
6. Ninajivunia mwenyewe.				
7. Najipenda.				
8. Ninahisi kujiamini.				
9. Ninajisikia vizuri juu yangu mwenyewe.				
10. Ninahisi vizuri jinsi ninavyoonekana.				

KAZI YA KIJAMII

MAISHA YAKO YA KIJAMII YAKOJE?

	Daima	**Mara nyingi**	**Wakati mwingine**	**Kamwe**
1. Marafiki zangu wananikubali.				
2. Ninafurahiya na marafiki.				
3. Watu husikiliza ninachosema.				
4. Watu wananitendea sawa na kila mtu mwingine.				
5. Ninapenda kuwa pamoja na watu wengine.				
6. Ninajiamini ninapotoka (kama vile a chama).				
7. Ninahisi kuwa ninastahili.				
8. Ni rahisi kwangu kupata marafiki.				
9. Ninahisi sawa na watu wengine wa umri wangu.				
10. Ni sawa watu wanaponitazama usoni.				

MSIBA WA MAONGEZI

UNAONAJE KUZUNGUMZA? Tafadhali jibu ukifikiria WIKI ILIYOPITA.

	Daima	**Wakati Mwingine**	**Kamwe**
1. Ninaepuka kutoka nje kwa sababu ya hotuba yangu			
2. Hotuba yangu hufanya iwe vigumu kwangu kupata marafiki wapya.			
3. Ninataniwa kuhusu hotuba yangu.			
4. Mimi huchanganyikiwa ninapozungumza.			
5. Ninaona aibu ninapozungumza.			
6. Ninajaribu kuepuka kusema mbele za watu.			
7. Ninahisi woga ninapozungumza.			
8. Nina wasiwasi kwamba hotuba yangu ni ngumu kuelewa.			
9. Ninakasirika ninapohitaji kujirudia.			
10. Ninahisi kukasirika nisipoeleweka.			

Appendix III: Patient Consent Form (English Version)

Participant Information and Consent Form for Enrollment in the Study

This Informed Consent form is for patients managed for Cleft lip/palate at various institutions. It will be administered to eligible patients. We request you to participate in this research project titled "**HEALTH RELATED QUALITY OF LIFE IN CLEFT LIP AND/OR PALATE PATIENTS POST-CLEFT SURGERY IN KENYA**." **Principal Investigator: Dr. Michael Ongas**

Institution: Department of Surgery, Faculty of Health Sciences, University of Nairobi.

This Informed Consent Form has three parts:

Information Sheet (informs you in a brief overview about the research with you).

Certificate of Consent (to sign if you agree to participate).

Statement by the researcher/person taking consent. A copy of the informed consent form will be provided.

Part I: Information Sheet

Introduction

I am Dr. Michael Ongas, a postgraduate student in Plastics and Reconstructive Surgery at the University of Nairobi. I am conducting research to assess the quality of life after cleft lip/palate surgery in patients treated at varied hospitals in Kenya.

Purpose of the Research

I will provide information and invite you to participate in this research. There may be some words that you don't comprehend. Please ask me to explain as we go through the information, and I will explain. After receiving the information concerning the study, you are encouraged to seek clarification in case of any doubt. This study will elucidate the quality of life after surgery for cleft lip/palate to inform future treatment practices. The study will also aim to justify the establishment of appropriate management protocols for managing patients with cleft lip/palate.

Type of Research Intervention

This research will involve using questionnaires and medical records with your doctor's permission [or their representative].

You will be consenting to respond to questions on the quality of life. This is at no extra cost and forms part of triage.

Voluntary Participation/Right to Refuse or Withdraw

You decide to participate or not. Whether you choose to participate or not, all the services you receive at this hospital will continue, and nothing will change. If you decide against participating, you will be offered the treatment routinely provided in this hospital for your condition. You can refuse or withdraw your participation in this study at any point.

Confidentiality

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

Study Procedure

After agreeing and consenting to participate in the study, you will be asked questions according to the study protocol on your quality of life after treatment for cleft lip/palate.

Sharing the results

The knowledge obtained from this study will be shared with the policymakers in Kenya and doctors through publications and conferences. Confidential information will not be shared.

Benefits

The benefits of joining the study include the following:

Contribution to the advancement of patient management.

Risks

There will be no risk involved in enlisting for this study. Cost and Compensation. There will be no extra cost incurred for participating in this study, nor is compensation offered. This research proposal has been reviewed and approved by the UoN/KNH Ethics Committee, a committee whose task is to ensure that research participants are protected from harm.

Whom to Contact

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

Principal Researcher:

Dr. Michael Ongas,

Phone: 0720759366

Email: mikaelongas@gmail.com

Department of Surgery,

Faculty of Health Sciences,

University of Nairobi

Supervisors:

Dr. Joseph Kimani Wanjeri,

Phone: 0722708051

Email: joseph.wanjeri@uonbi.ac.ke

Dr. Ferdinand Nangole

Phone: 0714342214

Email: nangole2212@gmail.com

Or The Secretary,

UON/KNH-ERC,

P.O. Box 20723- 00202, KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

Part II: Certificate of Consent

I have read and understood the above information/the above information has been read out to me. I have had the opportunity to ask questions, and my questions have been answered satisfactorily. I voluntarily agree and consent to participate in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

If Non -literate:

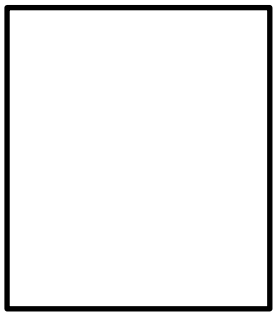
I have witnessed the reading of the consent form to the potential participant, and the individual has had the opportunity to ask questions. I can confirm that the individual has given consent voluntarily.

Print Name of witness_____

Signature of witness _____

Date _____

Thumbprint of participant



Part III: Statement by the Researcher

I have read out the information sheet to the participant and made sure that the participant understands that the following will be done:

A decision to refuse to participate or withdraw from the study will not compromise the care of treatment.

All information given will be handled with confidentiality.

The results of this study might be published to facilitate research and improved clinical guidelines. I can confirm that the participant was allowed to ask questions about the study, and all the questions 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 approval has been given voluntarily.

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

Name of researcher/person taking consent _____

Signature of researcher/person taking consent_____

Date_____

Appendix IV: Patient Consent Form (Kiswahili Version)

Fomu ya Ridhaa ya Mgonjwa Taarifa ya Mshiriki na Fomu ya Idhini ya Kujiandikisha Katika Utafiti

Fomu hii ya Idhini iliyoarifiwa ni kwa ajili ya wagonjwa wanaosimamiwa kwa Midomo/palate katika taasisi mbalimbali. Itasimamiwa kwa wagonjwa wanaostahiki. Tunauomba ushirika wako katika mradi huu wa utafiti unaoitwa " **UBORA UNAOHUSIANA NA AFYA KATIKA MIDOMO INAYOPASUKA NA/AU WAGONJWA WA UPASUAJI BAADA YA KUPASUA NCHINI KENYA** ."

Mpelelezi Mkuu: Dkt Michael Ongas

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

Fomu hii ya Idhini iliyo na Taarifa ina sehemu tatu:

Karatasi ya Taarifa (inakujulisha kwa muhtasari mfupi kuhusu utafiti na wewe).

Cheti cha Idhini (kutia saini ikiwa unakubali kushiriki).

Taarifa ya mtafiti/mtu anayekubali. Nakala ya fomu ya idhini iliyoarifiwa itatolewa.

Sehemu ya I: Karatasi ya Taarifa

Utangulizi

Mimi ni Dkt Michael Ongas, mwanafunzi wa shahada ya uzamili katika Upasuaji wa Plastiki na Urekebishaji katika Chuo Kikuu cha Nairobi. Ninafanya utafiti ili kutathmini ubora wa maisha baada ya upasuaji wa midomo/palate iliyopasuka kwa wagonjwa wanaotibiwa katika hospitali mbalimbali nchini Kenya.

Madhumuni ya Utafiti

Nitatoa taarifa na kukualika kushiriki katika utafiti huu. Kunaweza kuwa na maneno ambayo huelewi. Tafadhali naomba nifafanue tunapopitia taarifa, nami nitaeleza. Baada ya kupokea taarifa kuhusu utafiti, unahimizwa kutafuta ufafanuzi iwapo kuna shaka yoyote. Utafiti huu utafafanua ubora wa maisha baada ya upasuaji kwa midomo/palate iliyopasuka ili kufahamisha mbinu za matibabu za siku zijazo. Utafiti huo pia utalenga kuhalalisha uanzishwaji wa itifaki za usimamizi zinazofaa kwa ajili ya kusimamia wagonjwa wenye midomo/palate iliyopasuka.

Aina ya Uingiliaji kati wa Utafiti

Utafiti huu utahusisha kutumia hojaji na rekodi za matibabu kwa idhini ya daktari wako [au mwakilishi wao].Utakuwa unakubali kujibu maswali juu ya ubora wa maisha. Hii haina gharama ya ziada na ni sehemu ya utatuzi.

Kushiriki kwa Hiari/Haki ya Kukataa au Kujitoa

Unaamua kushiriki au la. Ukichagua kushiriki au la, huduma zote unazopokea katika hospitali hii zitaendelea, na hakuna kitakachobadilika. Ukiamua kutoshiriki, utapewa matibabu yanayotolewa mara kwa mara katika hospitali hii kwa ajili ya hali yako. Unaweza kukataa au kuondoa ushiriki wako katika utafiti huu wakati wowote.

Usiri

Taarifa zilizopatikana katika utafiti huu zitakuwa za siri na zinapatikana kwa mpelelezi mkuu na timu ya utafiti pekee. Jina lako halitatumika. Taarifa zozote za kibinafsi zitakuwa na nambari badala ya jina lako. Hatutashiriki utambulisho wa wale wanaoshiriki katika utafiti huu.

Utaratibu wa Masomo

Baada ya kukubali kushiriki katika utafiti, utaulizwa maswali kulingana na itifaki ya utafiti kuhusu ubora wa maisha yako baada ya matibabu ya midomo/kaakaa iliyopasuka.

Matokeo ya Kushiriki

Maarifa yaliyopatikana kutokana na utafiti huu yatashirikiwa na watunga sera nchini Kenya na madaktari kupitia machapisho na makongamano. Taarifa za siri hazitashirikiwa.

Faida

Faida za kujiunga na utafiti ni pamoja na Mchango katika maendeleo ya usimamizi wa wagonjwa.

Hatari

Hakutakuwa na hatari yoyote katika kujiandikisha kwa utafiti huu.

Gharama na Fidia.

Hakutakuwa na gharama ya ziada itakayotumika kwa kushiriki katika utafiti huu, wala fidia haitatolewa. Pendekezo hili la utafiti limekaguliwa na kuidhinishwa na Kamati ya Maadili ya UoN/KNH, kamati ambayo jukumu lake ni kuhakikisha kuwa washiriki wa utafiti wanalindwa dhidi ya madhara.

Nani wa Kuwasiliana

Ikiwa ungependa kuuliza maswali yoyote baadaye, unaweza kuwasiliana na:

Mtafiti Mkuu:

Dk Michael Ongas,

Simu: 0720759366

Barua pepe: mikaelongas@gmail.com

Idara ya upasuaji,

Kitivo cha Sayansi ya Afya,

Chuo Kikuu cha Nairobi **Wasimamizi:**

Dkt Joseph Kimani Wanjeri,

Simu: 0722708051

Barua pepe: joseph.wanjeri@uonbi.ac.ke

Dk Ferdinand Nangole

Simu: 0714342214

Barua pepe: nangole2212@gmail.com

Au Katibu huyo,

UON/KNH-ERC,

SLP 20723- 00202, KNH, Nairobi.

Simu: 020-726300-9 EXT 44355

Barua pepe: uonknh_erc@uonbi.ac.ke

Sehemu ya II: Cheti cha Idhini

Nimesoma na kuelewa habari hiyo hapo juu/habari hiyo hapo juu imesomwa kwangu. Nimepata nafasi ya kuuliza maswali, na maswali yangu yamejibiwa vya kuridhisha. Ninakubali kwa hiari na kukubali kushiriki katika utafiti huu.

Chapisha Jina la Mshiriki _____

Sahihi ya Mshiriki _____ Tarehe _____

Ikiwa Hajui kusoma na kuandika:

Nimeshuhudia usomaji wa fomu ya idhini kwa mshiriki anayetarajiwa, na mtu huyo amepata fursa ya kuuliza maswali. Ninaweza kuthibitisha kwamba mtu huyo ametoa idhini kwa hiari.

Chapisha Jina la shahidi_____ Alama ya kidole gumba ya mshiriki

Sahihi ya shahidi _____

Tarehe _____

Sehemu ya III: Taarifa ya Mtafiti

Nimesoma karatasi ya habari kwa mshiriki na kuhakikisha kuwa mshiriki anaelewa kuwa yafuatayo yatafanyika:

Uamuzi wa kukataa kushiriki au kujiondoa kwenye utafiti hautahatarisha utunzaji wa matibabu.

Taarifa zote zitakazotolewa zitashughulikiwa kwa usiri.

Matokeo ya utafiti huu yanaweza kuchapishwa ili kuwezesha utafiti na kuboresha miongozo ya kliniki. Ninaweza kuthibitisha kwamba mshiriki aliruhusiwa kuuliza maswali kuhusu utafiti, na maswali yote yamejibiwa kwa usahihi na kwa kadri ya uwezo wangu. Ninathibitisha kuwa mtu huyo hajalazimishwa kutoa idhini, na idhini imetolewa kwa hiari.

Nakala ya Fomu ya Idhini iliyoarifiwa imetolewa kwa mshiriki.

Jina la mtafiti/mtu anayepokea kibali _____

Sahihi ya mtafiti/mtu anayekubali kibali _____

Tarehe_____

Appendix V: Letter to Collaborating Institution Seeking Permission to Conduct the Study.

I, Dr. Michael Ongas, a registrar in the Department of Surgery, University of Nairobi, would like to seek consent from the Research and Administration department/Office of Director of the……..…….

Hospital, to Conduct a research study entitled, this study entails collecting data from patients formerly treated for cleft lip/palate.

No patient-identifying information will be collected. Covid -19 prevention measures shall be adhered to per the hospital's recommendations. The results of this study will be shared with the hospital management, among other stakeholders, to help improve local policies and guidelines on the management of cleft lip/palate.

…….

Hospital representative

……

Principal Investigator

Whom to Contact

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

Principal Researcher:

Dr. Michael Ongas,

Phone: 0720759366

Email: mikaelongas@gmail.com

Department of Surgery,

Faculty of Health Sciences,

University of Nairobi **Supervisors:**

Dr. Joseph Kimani Wanjeri,

Phone: 0722708051

Email: joseph.wanjeri@uonbi.ac.ke

Dr. Ferdinand Nangole

Phone: 0714342214

Email: nangole2212@gmail.com

Or The Secretary,

UON/KNH-ERC,

P.O. Box 20723- 00202, KNH, Nairobi.

Tel: 020-726300-9 EXT 44355

Email: uonknh_erc@uonbi.ac.ke

Appendix VI: Parental Consent Form (English Version)

Title of Study: HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA

Principal Investigator \ and institutional affiliation: Dr. Michael Ongas, University of Nairobi

Co-Investigators and institutional affiliation: Drs. Ferdinand Wanjala Nang'ole and Joseph Kimani Wanjeri, University of Nairobi Introduction:

I would like to tell you about a study being conducted by the above listed researchers. The purpose of this consent form is to give you the information you will need to help you decide whether or not your child should participate in the study. Feel free to ask any questions about the purpose of the research, what happens if your child participates in the study, the possible risks and benefits, the rights of your child as a volunteer, and anything else about the research or this form that is not clear. When we have answered all your questions to your satisfaction, you may decide if you want your child to be in the study or not. This process is called 'informed consent'. Once you understand and agree for your child to be in the study, I will request you to sign your name on this form. You should understand the general principles which apply to all participants in medical research: i) Your child decision to participate is entirely voluntary ii) You child may withdraw from the study at any time without necessarily giving a reason for his/her withdrawal iii) Refusal to participate in the research will not affect the services your child is entitled to in this health facility or other facilities.

May I continue? YES / NO

For children below 18 years of age we give information about the study to parents or guardians. We will go over this information with you and you need to give permission in order for your child to participate in this study. We will give you a copy of this form for your records. If the child is at an age that he/she can appreciate what is being done then he/she will also be required to agree to participate in the study after being fully informed.

What Is the Purpose of the Study?

The researchers listed above are interviewing individuals who are cleft lip or cleft palate patients and have undergone surgical repair for that condition. The purpose of the interview is to find out their associated health-related quality of life. Participants in this research study will be asked questions about their general wellness and in other specific areas on their quality of life. There will be approximately 114 participants in this study randomly chosen. We are asking for your consent to consider your child to participate in this study.

What Will Happen If You Decide You Want Your Child to Be In This Research Study?

If you agree for your child to participate in this study, the following things will happen: You (you and your child) will be interviewed by a trained interviewer in a private area where you feel comfortable answering questions. The interview will last approximately 15 to 30 minutes. The interview will cover topics such as the psychological functioning, social functioning and speech distress of your child.

We will ask for a telephone number where we can contact you if necessary. If you agree to provide your contact information, it will be used only by people working for this study and will never be shared with others. The reasons why we may need to contact you include to clarify on your responses within the questionnaire

Are There Any Risks, Harms, Discomforts Associated with This Study

Medical research has the potential to introduce psychological, social, emotional and physical risks. Effort should always be put in place to minimize the risks. One potential risk of being in the study is loss of privacy. We will keep everything you tell us as confidential as possible. We will use a code number to identify your child in a password-protected computer database and will keep all of our paper records in a locked file cabinet. However, no system of protecting confidentiality can be absolutely secure so it is still possible that someone could find out your child was in this study and could find out information about your child.

Also, answering questions in the interview may be uncomfortable for you. If there are any questions you do not want to answer, you can skip them. You have the right to refuse the interview or any questions asked during the interview.

It may be embarrassing for you to have to give vulnerable and private information on your child's health. We will do everything we can to ensure that this is done in private. Furthermore, all study staff and interviewers are professionals with special training in these examinations/interviews.

Are There Any Benefits Being in This Study?

You may benefit by receiving free health information. We will also refer your child to a hospital for care and support if necessary. Also, the information you provide will help us better understand health-related quality of life benefits after cleft repair surgery. This information is a major contribution to science and will help drive cleft patient advocacy.

Will Being in This Study Cost You Anything?

You might be asked to be physically present to fill in the questionnaires. This might cost you transportation fees.

Is There Reimbursement for Participating in This Study?

You will be reimbursed any personal costs you incur to participate in the study in full.

What If You Have Questions in Future?

If you have further questions or concerns about your child participating in this study, please call or send a text message to the study staff at the number provided at the bottom of this page. For more information about your child's rights as a research participant you may contact the Secretary/Chairperson, Kenyatta National Hospital-University of Nairobi Ethics and Research Committee Telephone No. 2726300 Ext. 44102 email uonknh_erc@uonbi.ac.ke.

The study staff will pay you back for your charges to these numbers if the call is for studyrelated communication.

What Are Your Other Choices?

Your decision to have your child participate in this research is voluntary. You are free to decline or withdraw participation of your child in the study at any time without injustice or loss of benefits.

Just inform the study staff and the participation of your child in the study will be stopped. You do not have to give reasons for withdrawing your child if you do not wish to do so. Withdrawal of your child from the study will not affect the services your child is otherwise entitled to in this health facility or other health facilities.

Consent Form (Statement of Consent)

The person being considered for this study is unable to consent for him/herself because he or she is a minor (a person less than 18 years of age). You are being asked to give your permission to include your child in this study.

Parent/Guardian Statement

I have read this consent form or had the information read to me. I have had the chance to discuss this research study with a study counselor. I have had my questions answered by him or her in a language that I understand. The risks and benefits have been explained to me. I understand that I will be given a copy of this consent form after signing it. I understand that my participation and that of my child in this study is voluntary and that I may choose to withdraw it any time.I understand that all efforts will be made to keep information regarding me and my child's personal identity confidential.

By signing this consent form, I have not given up my child's legal rights as a participant in this research study.

I voluntarily agree to my child's participation in this research study: Yes No

I agree to have my child undergo_____testing: Yes No

I agree to have (**define specimen**) preserved for later study: Yes No

I agree to provide contact information for follow-up: Yes No

Parent/Guardian signature /Thumb stamp:_____ Date _____

Parent/Guardian printed name: _____ Researcher's statement

I, the undersigned, have fully explained the relevant details of this research study to the participant named above and believe that the participant has understood and has knowingly given his/her consent.

Printed Name:_____

Signature:_____***Date:***_____

Role in the study:_____

Appendix VII: Parental Consent Form (Kiswahili Version)

Fomu ya Ridhaa Ya Mzazi

Kichwa: <u>UBORA WA MAISHA UNAOHUSIANA NA AFYA KATIKA WAGONJWA WA MIDOMO NA PALATE MABAYA NCHINI KENYA.</u>

Mpelelezi Mkuu \ na uhusiano wa kitaasisi: Dkt Michael Ongas , Chuo Kikuu cha Nairobi

Wachunguzi-wenza na taasisi uhusiano: Dkt Ferdinand Wanjala Nang'ole na Dkt Joseph Kimani Wanjeri , Chuo Kikuu cha Nairobi Utangulizi:

Ningependa kukueleza kuhusu utafiti huu. Madhumuni ya fomu hii ya idhini ni kukupa taarifa utakayohitaji ili kukusaidia kuamua kama mtoto wako atashiriki au la. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti, nini kitatokea ikiwa mtoto wako atashiriki katika utafiti, hatari na manufaa yanayoweza kutokea, haki za mtoto wako kama mtu wa kujitolea, na jambo lingine lolote kuhusu utafiti au fomu hii ambayo si wazi. Wakati tumejibu maswali yako yote kwa kuridhika kwako, unaweza kuamua kama ungependa mtoto wako awe kwenye utafiti au la. Utaratibu huu unaitwa 'kibali cha taarifa'. Ukishaelewa na kukubali mtoto wako awe kwenye utafiti, nitakuomba utie sahihi pamoja na jina lako kwenye fomu hii. Unapaswa kuelewa kanuni za jumla zinazotumika kwa washiriki wote katika utafiti wa matibabu:

i) Uamuzi wa mtoto wako kushiriki ni wa hiari kabisa ii) Mtoto wako anaweza kujiondoa kwenye utafiti wakati wowote bila ya kueleza sababu ya kujiondoa

iii) Kukataa. kushiriki katika utafiti hakutaathiri huduma anazostahiki mtoto wako katika kituo hiki cha afya au vituo vingine.

Naweza kuendelea? Ndiyo / Hapana

Kwa watoto walio chini ya umri wa miaka 18 tunatoa taarifa kuhusu utafiti kwa wazazi au walezi. Tutapitia maelezo haya nawe na unahitaji kutoa ruhusa ili mtoto wako ashiriki katika utafiti huu. Tutakupa nakala ya fomu hii kwa rekodi zako. Iwapo mtoto yuko katika umri ambao anaweza kufahamu kinachofanyika basi atahitajika pia kukubali kushiriki katika utafiti baada ya kufahamishwa kikamilifu.

Ni Nini Kusudi la Utafiti?

Mtafiti atwahoji watu ambao ni wagonjwa wa midomo iliyopasuka au kaakaa iliyopasuka na wamefanyiwa ukarabati wa upasuaji wa hali hiyo. Madhumuni ya mahojiano ni kujua ubora wa maisha yao yanayohusiana na afya. Washiriki katika utafiti huu wataulizwa maswali kuhusu afya zao kwa ujumla na katika maeneo mengine mahususi kuhusu ubora wa maisha yao. Kutakuwa na takriban washiriki 114 katika utafiti huu waliochaguliwa bila mpangilio.

Tunaomba idhini yako ya kuzingatia mtoto wako kushiriki katika utafiti huu.

Nini Kitatokea Ukiamua Unataka Mtoto Wako Awe Katika Utafiti Huu?

Ukikubali mtoto wako kushiriki katika utafiti huu, mambo yafuatayo yatafanyika:

Wewe (wewe na mtoto wako) mtahojiwa na mhojiwa aliyefunzwa katika eneo la faragha ambapo unahisi vizuri kujibu maswali. Mahojiano yatachukua takriban dakika 15 hadi 30. Mahojiano yatashughulikia mada kama vile utendaji kazi wa kisaikolojia, utendakazi wa kijamii na dhiki ya usemi ya mtoto wako. Tutaomba nambari ya simu ambapo tunaweza kuwasiliana nawe ikibidi. Ukikubali kutoa maelezo yako ya mawasiliano, yatatumiwa na watu wanaofanya kazi katika utafiti huu pekee na kamwe hayatashirikiwa na wengine. Sababu ambazo tunaweza kuhitaji kuwasiliana nawe ni pamoja na kufafanua juu ya majibu yako ndani ya dodoso

Je, Kuna Hatari, Madhara, Masumbuko Yoyote Yanayohusishwa na Utafiti Huu ?

Utafiti wa kimatibabu una uwezo wa kuanzisha hatari za kisaikolojia, kijamii, kihisia na kimwili. Jitihada zinapaswa kuwekwa kila wakati ili kupunguza hatari. Hatari moja inayoweza kutokea ya kuwa katika utafiti ni kupoteza faragha. Tutaweka kila kitu unachotuambia kama siri iwezekanavyo. Tutatumia nambari ya msimbo kumtambua mtoto wako katika hifadhidata ya kompyuta iliyolindwa na nenosiri na tutaweka rekodi zetu zote za karatasi kwenye kabati ya faili iliyofungwa. Hata hivyo, hakuna mfumo wa kulinda usiri unaoweza kuwa salama kabisa kwa hivyo bado kuna uwezekano kwamba mtu anaweza kujua mtoto wako alikuwa katika utafiti huu na kupata taarifa kuhusu mtoto wako.Pia, kujibu maswali katika mahojiano kunaweza kuwa na wasiwasi kwako. Ikiwa kuna maswali yoyote ambayo hutaki kujibu, unaweza kuyaruka. Una haki ya kukataa mahojiano au maswali yoyote yaliyoulizwa wakati wa mahojiano.Inaweza kuwa aibu kwako kutoa habari hatari na ya faragha juu ya afya ya mtoto wako. Tutafanya kila tuwezalo kuhakikisha kuwa hili linafanyika kwa faragha. Zaidi ya hayo, wafanyakazi wote wa utafiti na wahojaji ni wataalamu walio na mafunzo maalum katika mitihani/mahojiano haya.

Je, Kuna Manufaa Yoyote Kuwa Katika Utafiti Huu?

Unaweza kufaidika kwa kupokea maelezo ya afya bila malipo. Pia tutaelekeza mtoto wako hospitalini kwa matunzo na usaidizi ikihitajika. Pia, maelezo utakayotoa yatatusaidia kuelewa vyema manufaa ya maisha yanayohusiana na afya baada ya upasuaji wa kurekebisha nyufa. Habari hii ni mchango mkubwa kwa sayansi na itasaidia kuendesha utetezi wa wagonjwa wenye mipasuko.

Je, Kuwa Katika Somo Hili Kutakugharimu Chochote?

Unaweza kuulizwa ujiwasilishe ili kujaza dodoso. Hii inaweza kukugharimu ada za usafiri.

Je, Kuna Fidia kwa Kushiriki katika Utafiti Huu?

Utafidiwa gharama zozote za kibinafsi utakazotumia kushiriki katika utafiti huu kikamilifu.

Ukiwa na Maswali Baadaye/Wakati Ujao?

Ikiwa una maswali zaidi au wasiwasi kuhusu mtoto wako kushiriki katika utafiti huu, tafadhali piga simu au tuma ujumbe mfupi wa maandishi kwa wafanyikazi wa utafiti kupitia nambari iliyotolewa chini ya ukurasa huu. Kwa maelezo zaidi kuhusu haki za mtoto wako kama mshiriki wa utafiti unaweza kuwasiliana na Katibu/Mwenyekiti, Hospitali ya Kitaifa ya KenyattaKamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi Nambari 2726300 Ext. 44102 barua pepe uonknh_erc@uonbi.ac.ke. Wafanyikazi wa utafiti watagharamia malipo yako kwa nambari hizi ikiwa simu ni ya mawasiliano yanayohusiana na masomo.

Je! Umechagua Nini Nyingine?

Uamuzi wako wa kumfanya mtoto wako ashiriki katika utafiti huu ni wa hiari. Uko huru kukataa au kuondoa ushiriki wa mtoto wako katika utafiti wakati wowote bila dhuluma au hasara ya faida.Wajulishe tu wafanyakazi wa utafiti na ushiriki wa mtoto wako katika utafiti utasitishwa. Sio lazima utoe sababu za kumwondoa mtoto wako ikiwa hutaki kufanya hivyo. Kuondolewa kwa mtoto wako kutoka kwa utafiti hakutaathiri huduma ambazo mtoto wako anastahili kupata katika kituo hiki cha afya au vituo vingine vya afya.

Fomu ya Idhini (Taarifa ya Idhini)

Mtu anayezingatiwa kwa utafiti huu hana uwezo wa kujikubali kwa sababu yeye ni mtoto mdogo (mtu aliye chini ya miaka 18). Unaombwa kutoa idhini yako ya kujumuisha mtoto wako katika utafiti huu.

Taarifa ya Mzazi/Mlezi

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili utafiti huu na mshauri wa utafiti. Nimejibu maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa nitapewa nakala ya fomu hii ya idhini baada ya kuitia saini. Ninaelewa kuwa ushiriki wangu na ule wa mtoto wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kuuondoa wakati wowote. Ninaelewa kuwa jitihada zote zitafanywa ili kuweka taarifa kunihusu na ya mtoto wangu kuwa siri.

Ninakubali kwa hiari ushiriki wa mtoto wangu katika utafiti huu	**Ndiyo**	**La**
Ninakubali mtoto wangu afanyiwe uchunguzi:	**Ndiyo**	**La**
Ninakubali (sampuli) kuhifadhiwa kwa ajili ya utafiti wa baadaye	**Ndiyo**	**La**
Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji	**Ndiyo**	**La**

Mzazi/Mlezi Sahihi /Kidole gumba muhuri: _____

Tarehe _____

Jina la Mzazi/Mlezi lilochapishwa : _____

Kauli ya Mtafiti

Mimi, nilliyetia sahihi hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake akijua.

Jina Lililochapishwa: _____

Sahihi:

_____Tarehe:_____

Jukumu katika utafiti: _____

Appendix VIII: Child Assent Form (English Version)

Project Title: **HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA**

Investigator(s): **Michael Ongas, Ferdinand Wanjala Nang'ole, Joseph Kimani Wanjeri** We are doing a research study to determine the quality of your life after you come out of an operation to repair your cleft lip or palate using a questionnaire.

Permission has been granted to undertake this study by the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee (KNH-UoN ERC Protocol No._) This research study is a way to learn more about people. At least 114 children will be participating in this research study with you.

If you decide that you want to be part of this study, you will be asked to fill in a questionnaire that will take you about 15 to 30 minutes to complete**.**

There are some things about this study you should know. These are that there is always a risk that your personal data is compromised or misused. We will however try our best to protect your data.

Not everyone who takes part in this study will benefit. A benefit means that something good happens to you. We think these benefits might be a better understanding of the benefits of cleft repair surgery to aid in advocacy of the procedure and its quality improvement for patients like you.

When we are finished with this study we will write a report about what was learned. This report will not include your name or that you were in the study.

You do not have to be in this study if you do not want to be. If you decide to stop after we begin, that's okay too. Your parents know about the study too.

If you decide you want to be in this study, please sign your name.

I,_____, want to be in this research study.

_____ _____

(Signature/Thumb stamp) (Date)

Appendix IX: Child Assent Form (Kiswahili Version)

Kichwa cha Mradi:: UBORA WA MAISHA UNAOHUSIANA NA AFYA KATIKA WAGONJWA WA MIDOMO NA PALATE MABAYA NCHINI KENYA.

Wapelelezi: Michael Ongas, Ferdinand Wanjala Nang'ole, Joseph Kimani Wanjeri

Tunafanya utafiti ili kubaini ubora wa maisha yako baada ya kutoka kwa upasuaji wa kurekebisha mdomo au kaakaa lako lililopasuka kwa kutumia dodoso. Ruhusa imetolewa kufanya utafiti huu na Hospitali ya Kitaifa ya Kenyatta-Kamati ya Maadili na Utafiti ya Chuo Kikuu cha Nairobi (KNH-UoN ERC Protocol No.)

Utafiti huu ni njia ya kujifunza zaidi kuhusu watu. Angalau watoto 114 watashiriki nawe katika utafiti huu.Ukiamua kuwa ungependa kuwa sehemu ya utafiti huu, utaombwa kujaza dodoso ambalo litakuchukua kama dakika 15 hadi 30 kukamilisha.Kuna baadhi ya mambo kuhusu utafiti huu unapaswa kujua. Haya ni kwamba daima kuna hatari kwamba data yako ya kibinafsi inaathiriwa au kutumiwa vibaya. Hata hivyo tutajaribu tuwezavyo kulinda data yako. Sio kila mtu atakayeshiriki katika utafiti huu atafaidika. Faida inamaanisha kuwa kitu kizuri kinatokea kwako. Tunafikiri manufaa haya yanaweza kuwa ufahamu bora wa manufaa ya upasuaji wa kurekebisha nyufa ili kusaidia katika utetezi wa utaratibu na uboreshaji wake wa ubora kwa wagonjwa kama wewe.Tukimaliza na somo hili tutaandika ripoti kuhusu kile tulichojifunza. Ripoti hii haitajumuisha jina lako au kwamba ulikuwa kwenye utafiti.Si lazima uwe katika utafiti huu ikiwa hutaki kuwa. Ukiamua kuacha baada ya sisi kuanza, hiyo ni sawa pia. Wazazi wako wanajua kuhusu utafiti pia. Ukiamua ungependa kuwa katika utafiti huu, tafadhali tia Saini na jina lako.

Mimi, nataka kuwa katika utafiti huu.

_____ _____

(Sahihi/Bomba muhuri) (Tarehe)

Appendix X: NACOSTI Study Permit

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **924490**

Date of Issue: **11/May/2023**

RESEARCH LICENSE

This is to Certify that Dr.. Michael Ongas of University of Nairobi, has been licensed to conduct research as per the provision of the Science, Technology and Innovation Act, 2013 (Rev.2014) in Garissa, Kakamega, Kisumu, Machakos, Meru, Mombasa, Nairobi, Nakuru on the topic: HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA for the period ending : 11/May/2024.

License No: **NACOSTI/P/23/25795**

924490

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

NOTE: This is a computer generated License. To verify the authenticity of this document, Scan the QR Code using QR scanner application.

See overleaf for conditions

Appendix XI: KNH/UoN-ERC Letter of Approval

UNIVERSITY OF NAIROBI
FACULTY OF HEALTH SCIENCES
P O BOX 19676 Code 00202
Telegrams: varsity
Tel:(254-020) 2726300 Ext 44355

KNH-UON ERC
Email: uonknh_erc@uonbi.ac.ke
Website: http://www.erc.uonbi.ac.ke
Facebook: https://www.facebook.com/uonknh.erc
Twitter: @UONKNH_ERC https://twitter.com/UONKNH_ERC

KENYATTA NATIONAL HOSPITAL
P O BOX 20723 Code 00202
Tel: 726300-9
Fax: 725272
Telegrams: MEDSUP, Nairobi

Ref: KNH-ERC/A/62

8th February, 2023

Dr. Michael Ongas
Reg. No. H58/11538/2018
Dept. of Surgery
Faculty of Health Sciences
University of Nairobi

APPROVED
08 FEB 2023

Dear Dr. Ongas,

RESEARCH PROPOSAL: HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA (P760/10/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P760/10/2022**. The approval period is 8th February 2023 – 7th February 2024.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
i. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
ii. Death and life threatening problems and serious adverse events or unexpected adverse events whether related or unrelated to the study must be reported to KNH-UoN ERC 72 hours of notification.
iv. Any changes, anticipated or otherwise that may increase the risks or affected 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.
v. Clearance for export of biological specimens must be obtained from relevant institutions.
vi. 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.
vii. Submission of an executive summary report within 90 days upon completion of the study to KNH-UoN ERC.

Prior to commencing your study, you will be expected to obtain a research license from National Commission for Science, Technology and Innovation (NACOSTI) https://research-portal.nacosti.go.ke and also obtain other clearances needed.

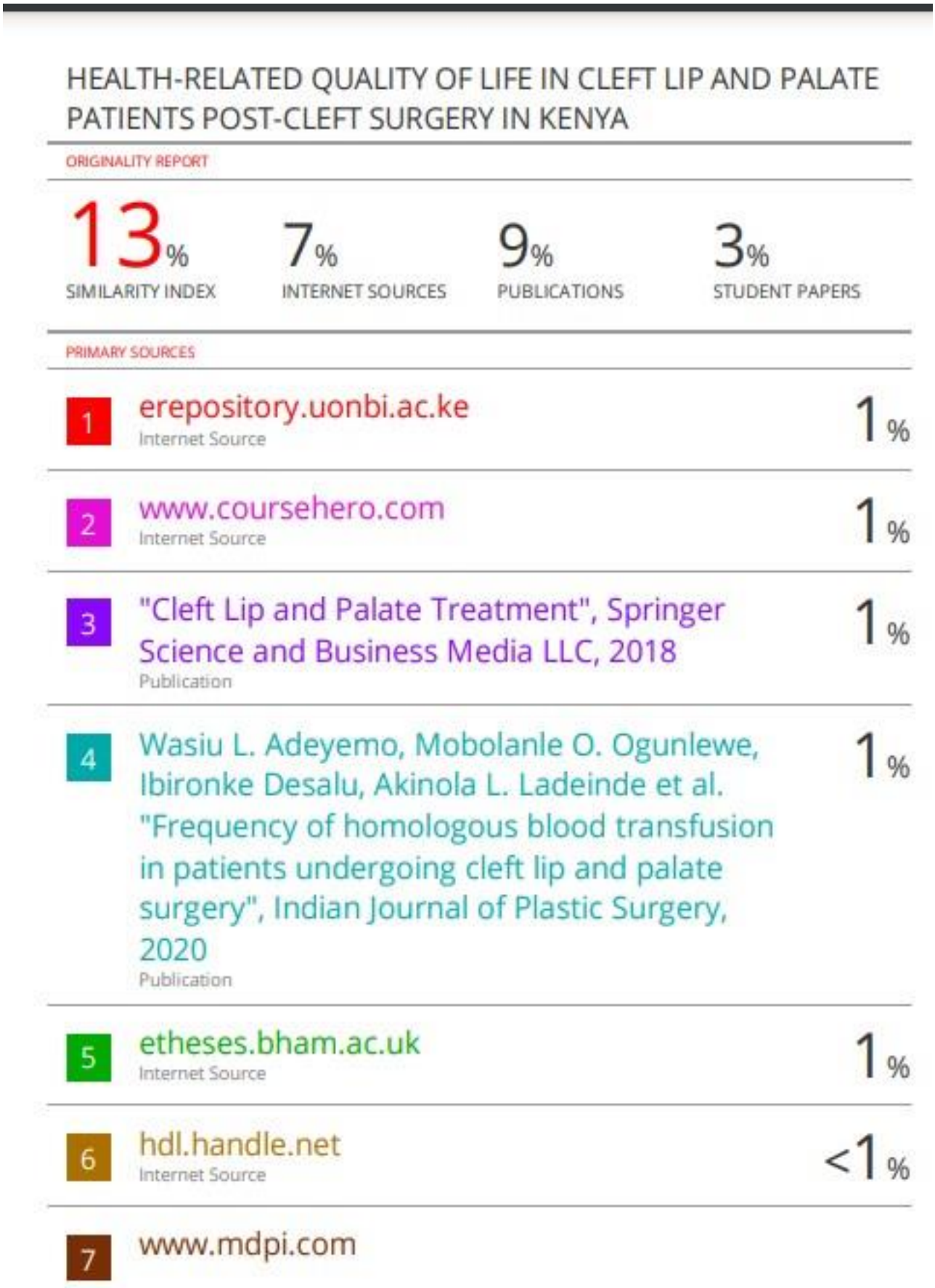
Yours sincerely,

DR. BEATRICE K.M. AMUGUNE
SECRETARY, KNH-UoN ERC

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Assistant Director, Health Information Dept., KNH
The Chairperson, KNH- UoN ERC
The Chair, Dept. of Surgery, UoN
Supervisors: Dr. Ferdinand Wanjala Nang'ole, Dept. of Surgery, UoN
Dr. Joseph Kimani Wanjeri, Dept. of Surgery, UoN

Protect to discover

Appendix XII: Certificate of Plagiarism



HEALTH-RELATED QUALITY OF LIFE IN CLEFT LIP AND PALATE PATIENTS POST-CLEFT SURGERY IN KENYA

ORIGINALITY REPORT

13%	7%	9%	3%
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3	"Cleft Lip and Palate Treatment", Springer Science and Business Media LLC, 2018 Publication	1%
4	Wasiu L. Adeyemo, Mobolanle O. Ogunlewe, Ibironke Desalu, Akinola L. Ladeinde et al. "Frequency of homologous blood transfusion in patients undergoing cleft lip and palate surgery", Indian Journal of Plastic Surgery, 2020 Publication	1%
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