UNIVERSITY OF NAIROBI

# INDICATIONS AND CHALLENGES OF IMPLANT REMOVAL FOLLOWING LONG BONE OSTEOSYNTHESIS IN FOUR URBAN HOSPITALS IN KENYA

**BY**

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A DISSERTATION SUBMITTED TO THE DEPARTMENT OF ORTHOPAEDIC SURGERY IN PARTIAL FULFILMENT OF THE REQUIREMENTS OF THE DEGREE OF MASTER OF MEDICINE IN ORTHOPAEDIC SURGERY IN THE SCHOOL OF MEDICINE, COLLEGE OF HEALTH SCIENCES, UNIVERSITY OF NAIROBI

## DECLARATION

This research was undertaken in partial fulfilment of the requirements of the Degree of Masters of Medicine in Orthopaedic Surgery. This research thesis is my original work and has not been undertaken or presented for a degree in any other university. Where other peoples' work has been used, this has been acknowledged and referenced in accordance with the University of Nairobi requirements.

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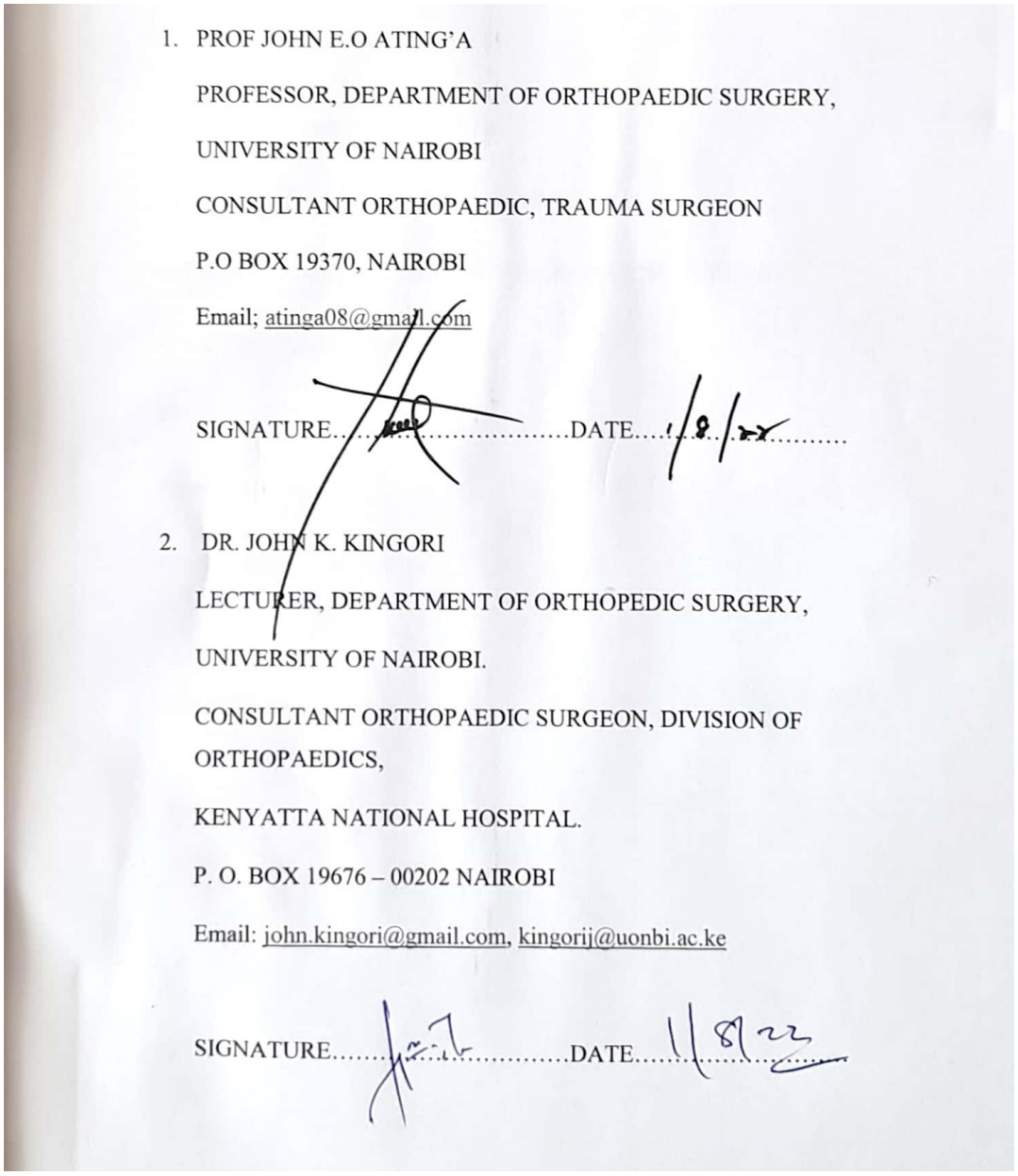

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# Contents

# DEDICATION

To my parents:

George Mutiiria Mbacha and Catherine Karimi Mutiiria

with profound gratitude, for their immense love, prayers, support and as my *de novo* teachers, for teaching me that;

"To Dare is to Do"

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# LIST OF ABBREVIATIONS

AO- (Arbeitsgemeinschaft für Osteosynthesefragen) or the Association of the Study of Internal Fixation

KNH – Kenyatta National Hospital

AKUH- Aga Khan University Hospital

KMTC- Kenya Medical Training Centre

## ABSTRACT

### Introduction

In orthopedic trauma, surgical stabilization is key and majorly involved. Fracture stabilization by the use of metals has been widely used since the Second World War. It is a widely accepted method, with almost all fractures managed with metallic implants in recent times. Osteosynthesis is the treatment of fractures in which bone fragments are joined with screws, plates, or nails. Following fracture healing, the question arises whether to remove the implant or leave it in situ.

While a great deal of research has been conducted in the area of osteosynthesis, scholars have not addressed the question on if and when the implant should be removed. This study aims to fill a knowledge gap by examining the various indications used in implant removal surgery as well as the challenges encountered during the actual implant removal surgery. This knowledge will guide surgeons when approaching the decision of removing or leaving the implant in situ and the challenges that can be encountered during the removal.

### Study Objective

To determine the indications and challenges of implant removal following long bone osteosynthesis in four urban hospitals in Kenya.

### Study Setting

This study was conducted in four urban hospitals in Kenya; Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital.

### Study Design

This is a quantitative research involving use of cross-sectional descriptive design. The use of this design is justified because it helps in estimating a population parameter, such as the prevalence of indications and challenges of implant removal after long-bone osteosynthesis, or

determining the average value of a quantitative variable in the study population. Convenience sampling was used to recruit participants.

**Study Population**

All patients presenting at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital for removal of implants following long-bone osteosynthesis.

**Methodology**

The main method of data collection was researcher-administered questionnaires and examination of medical records. Data collected through questionnaires from patients presenting for implant removal after long bone osteosynthesis, data on the challenges encountered during the surgical removal of implants and physical characteristics of broken implants was retrieved from the patient's medical records.

**Data Analysis**

Data collected through questionnaires and medical records was analysed through descriptive and inferential statistics with the help of Statistical Package for Social Sciences (SPSS) software, version 25. Where significant associations were established multivariate logistic regression was computed between the variables.

# Results

Data was collected using questionnaires from 204 patients at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital. Pain in the implant area was the most common reason for implant removal at the four hospitals.

46.1% of patients reported implant-related pain, and that the doctor was the one who suggested the implant be removed (43.6%). Furthermore, 36.3 % of patients reported that they had an infection in the implant area, 32.4% said they had a swelling in the implant area while 21.6% said they commonly had irritation/implant prominence.

The study found out that broken implants (19.6%), bone overgrowth (10.8%), and locked screws on plates (11.8%) were the main challenging aspects of implants encountered during surgical implant removal. On the category of broken implants removed 21.1% of the patients had mechanical failure and implants of 14.2% of the patients were damaged and broken while implants removed from 5.9% of the patients had brittle failure.

## Discussion

The study found that in the four urban hospitals, pain in the implant area, doctor's request, swelling in the implant area, and irritation/implant prominence were the most common indications for implant removal which is consistent with findings of other similar studies.

Broken implants, bone overgrowth and locked screws were major challenges encountered during implant removal among respondents in this study. In addition, bone growth over the implant, rounded screw head core, cold fusion, difficulty finding the implant, and inability to remove part of the implant were other notable challenges affecting implant removal.

Mechanical failure and breakage were common characteristics of broken implants removed from patients.

## Conclusion

The most common indication for implant removal in this study was implant related pain. The study concludes that there is a significant relationship between indications of implant removal, challenges of implant removal and characteristics of broken implants and the decision for implant removal at the four urban hospitals in Kenya. This finding is supported by multinomial regression analysis which determined that there was a significant relationship between independent and dependent variables (p-value, 0.000). Presence of indications of implant removal would hence result in consideration of removal of the said implant.

# CHAPTER ONE: INTRODUCTION

## Background

Fracture stabilization by the use of implants has widely been used since the Second World War. (1) These implants are mostly made of stainless steel and titanium alloys. (2) Osteosynthesis is the treatment of bone fractures in which bone fragments are joined with screws, plates or nails. Long bones are the bones in arms and legs apart from patella, bones of wrist and ankle. These bones are longer than wider and have a shaft and two ends. (3)

Following a fracture fixation, the surgeon is required to guide the patient on if and when the implant should be removed. Early removal of implants presents risks such as refracture. A delay in the removal might eventually make it difficult as a result of extensive bony integration and overgrowth.(4) In addition, there are many challenges associated with this procedure such as broken screws, cold wielded implants and bony overgrowths. These unexpected surgical inconvenience have great impact on the patients' surgical experience and outcome.(5) However, for patients who end up with internal fixation, one of the most common concerns is if and when the implant is going to be removed. (6)

Surgeons are divided on whether it is better to retain or remove an implant following osteosynthesis - the process by which bones are attached to the body. (2) Implants can be removed for various reasons such as surgical site infection, metal allergy, failure of osteosynthesis or failure of soft tissue surgery. (7) The removal of implant requires at least another surgical procedure. The burden of balancing on when to expose the patient to the risks for a removal of an implant lies on the surgeon. However, there is inadequate local and international evidence to guide decisions of surgeons on if or when to remove an implant. (5)

The most common indications for orthopaedic implant removal, according to the literature, are patient request, protruding implants, fracture, septic implant, surgeon decision, and pain at the implant area. However, there is no agreement standard that guides a surgeon's

decision on the likely indications of implant removal. This study sought to address this knowledge gap by bringing out the most common indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals in Kenya.

## Problem Statement

After fracture fixation, the need for removal is dictated by factors whose consensus is not well established. The surgery for removal of implants is a common procedure which in most cases can be straightforward. There are documented and assumed benefits of implant removal such as pain relief and improvement in function. However, some challenges can be encountered during the removal of these implants some of which may leave the patient worse off. There are general surgical complications including hemorrhage and infection as well as procedure-specific challenges such as refracture and neurovascular injuries.(8)

Several studies have been conducted in the field of osteosynthesis. Vos et al.,(9) assessed the opinions and practices of trauma and orthopaedic surgeons in the Netherlands regarding implant removal after fracture healing. The study discovered that infection of the implant or bone was one of the most common reasons for implant removal. The study also found that the most common postoperative complications were wound infection, unpleasant scarring, and postoperative haemorrhage. Mingo-Robinet &Aguila investigated osteosynthesis implant removal in Spain. The researcher specifically assessed surgeons' beliefs, indications, usual practice, and perceived complications. The most common intraoperative complications, according to the study, were bone growth over the implant, rounded screw head core, cold wielding, difficulty finding the implant, and inability to remove part of the implant.(10)

Nwosu, et al., sought to ascertain the prevalence, indications, and outcomes of orthopaedic implant removal in Nigeria, as well as to propose appropriate solutions. According to the study, plate and screws were the most commonly removed implants, and a patient request

was the most common reason for removal. Furthermore, the study found that retained hardware was the most common postoperative complication, while external fixation was mostly done as a separate procedure.(11)

Kuubiere et al., conducted a retrospective study in Ghana on the incidence and indications for orthopaedic implant removal. The key finding was that the incidence of implant removal was twice as high in males as in females and that the most common reason for implant removal in adults was a patient request, whereas surgeon request was the most common reason for orthopaedic implant removals in children.(12)

Von Kaeppler, et al., compared clinical and radiographic outcomes of infra-isthmic femoral shaft fractures treated with antegrade versus retrograde intramedullary nailing in Tanzania. The researchers discovered that antegrade nailing of infra-isthmic femur fractures resulted in a higher incidence of alignment loss but no pain, radiographic healing, or reoperation, whereas retrograde nailing resulted in increased knee pain and decreased knee range of motion at early time points.(13) Ahmed evaluated the outcome of the Surgical Implant Generation Network (SIGN) initiative in Ethiopia, locking intramedullary nailing that does not require fluoroscopy and fracture table. The study found that the union rate and rehabilitation were both very good, with a low infection rate, minimal malunion, and a short hospital stay.(14)

Soren researched the outcomes of the surgical implant generation network nail initiative in the treatment of long bone shaft fractures in Kenya. According to the study, the most common orthopaedic implant removal complications are superficial infection, deep infection, and screw loosening.(15) Oeba et al.., sought to describe the patients' characteristics and treatment of distal tibia fractures at Moi Teaching and Referral Hospital (MTRH) in Kenya, as well as compare the outcomes of the various treatments options. According to the study, patients who underwent fracture fixation with plating experienced complications such as wound infections, malunions, and chronic osteomyelitis.(16)

The empirical studies discussed above show that none of them have provided answers to the question of whether or not to remove the orthopaedic implant. The knowledge gap that this study seeks to fill is a lack of scientific evidence to guide surgeons' decisions on whether or not to remove an implant following long bone osteosynthesis.

Thus, there is a need to assess the benefits and risks of any surgical procedure more so of removal of an implant which is considered an elective procedure; and the commitment required by both the patient and the surgeon to achieve good outcomes during and following the surgery.

## Justification

Following fracture healing, the implants in the patient body remains as a foreign body having lost its initial purpose. The need to debate whether the implant should be removed or not, arises, and if the consensus is yes, then the procedure needs to be planned.

This study aims to bring out the most common indications of orthopaedic implant removal and the difficulties encountered during the actual removal of the implant. The knowledge acquired and shared from this study will be of great help in helping surgeons guide their patients on making the appropriate decision on removal of implants. The knowledge of anticipating complications during the surgery shall equip surgeons in planning for the surgery and the post-surgical care of the patients.

In many Orthopaedic practices across the world, removal of implants is generally accepted for patients with surgical site infection, metal allergies, soft tissue compromise or even failure of osteosynthesis. (7)

The concerns with retaining metal implants include deep late infection, metal allergy or toxicity, tumorigenicity, hardware migration, metal failure and secondary fracture at plate ends. On the one hand, issue of pain relief, local irritating symptoms, ease of management if re-fracture occurs, benefits to the residents in developing operative proficiency and surgical

skills favour implant removal procedures; however, on the other hand, potential complications associated with the removal such as neurovascular injuries, re-fracture, anaesthesia and surgery-related complications, economic burden to the patient, increased workload to the hospitals and ethical issues discourage this as a routine procedure. (4)

As noted by Hanson, there exists no standard reference or consensus on the indications of implant removal following long bone osteosynthesis. (2) The complications and difficult surgery that can be the removal of implants has also been acknowledged. A look at the local practice on implant removal and the likely complications that are associated with implant removal during and after the surgery is worthwhile to further build on local and global literature.

# Objectives of the Study

## General Objective

To determine the indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals in Kenya.

## Specific objectives

i. To determine the common indications of orthopaedic implant removal among patients undergoing implant removal following long bone osteosynthesis in four urban hospitals in Kenya

ii. To describe challenges encountered during the surgical removal of implants procedure among patients undergoing implant removal following long bone osteosynthesis in four urban hospitals in Kenya

iii. To analyze physical characteristics of broken implants removed from patients in four urban hospitals in Kenya.

# CHAPTER TWO: LITERATURE REVIEW

Hanson et al in 2008 conducted a study in which 730 attendees of the AO Principles and Masters Courses of Operative Fracture Treatment in Davos, Switzerland were asked of the preference and indications of Implant removal. 380 of the 655(58%) surgeons in attendance did not agree that routine implant removal was necessary and 48% felt that removal is riskier than leaving the implant in situ. The main attributing factor towards this response was the association with the many complications which can be occasioned by the procedure of the removal of implant or during the surgery. In a global conglomerate of surgeons such as this surveyed by Hanson, there was simply no consensus as to what are the indications of implant removal and when the implants should be removed.(2)

The need of clear guidelines on if and when orthopaedic implants should be removed has been brought out across the globe. In the study on the orthopaedic surgeons perceptions towards removal of implants, Vos described the various discrepancies in opinion on if and when the implants should be removed(5). The author noted that many surgeons did not refer to any clearly outlined institutional or regional guidance when it came to removal of implants. In addition, many of the surgeons in the study did not believe in benefits of implant removal. Based on the findings the author strongly argued for the need of clear guidelines on indications of implant removal.

Removal of implants is one of the most common procedures in bone and joint surgery. After the fracture has healed, the removal of orthopaedic implant has been a topic varying discussions and differing opinions. This is mostly because the indications and criteria of removal of these implants has not been well documented in most cases. The removal of implants used in fracture fixation in children is generally practiced following fracture union so as not to interfere with their growth. However, the indications for removal of implants are still

not documented since mostly this applies to those implants applied close to the growth plate. (18)(19)

Removal of implants as a surgical procedure is mostly viewed as a routine procedure with minimal if any complications expected. The patient is largely expected to resume day to day routine following the procedure. However, this is not the exact picture as reported by Reith et al in a study in which the authors sought to determine patient satisfaction following implant removal. In this retrospective study in a level 1 trauma centre in Germany, the authors determined that up to 96 % of patients who underwent removal would opt for the surgery again. However, the study also established that 66% of the patients also subjectively perceived post-operative complications, with 10% of them experiencing clinically established complications. The study which involved 332 respondents, established that impaired wound healing, infection, nerve damage and incomplete removal were the most common complications post removal of the implants. [6]

In a systematic literature review that identified 13 studies on implant removal, it was largely established that removal of implants should be principally based on patient to patient factors, such as age and physical activity. In addition, possible outcomes associated with removal or non-removal should also be put into consideration. These factors which are key in planning for the patient management include physical functioning, chronic pain, complications, reoperations, negative body sensations and spatial limitations. This review reiterated that benefits of removal of implants in asymptomatic patients are not sufficiently analysed. [14](10)

Is hardware removal necessary? Unno Veith et al argues in his 2009 study in which he concluded that implant removal should be carried out after weighing economic and medical implications. He discouraged against routine removal of implants since clear medical and surgical guidelines do not exist for most removal of implant procedures. (20)

Regionally surgeons rely on generally agreed upon approaches towards removal of implants such as fracture union, infected implants and allergies. According to I.I Onche et al in a study that was evaluating the indications, outcomes and economic consequences of implant removal in two year prospective comparative study in three hospitals in North Central Nigeria, the most common reason for implant removal was patient request, at 72.3% that is 34 of the 47 patients included in the study.(21)

In this study, the authors found that some of the post-operative complications included fractures, bleeding, nerve injuries and infection; hence the conclusion that implants removal as a procedure may be associated with substantial morbidity. The results from this study emphasize the need for clear policy and guidelines to guide the indications of and the procedure of orthopaedic implant removal(18)

In Kenya, the need for local policy and guidelines in the general use of orthopaedic implants has been alluded to by Ndeleva et al in their study regulation of orthopedic implants in Kenya. The authors noted the lack of clear guidelines on not only the use of which implants but also the need for patient follow up and eventual handling of the implants.(22)

**i) Indications of Implant Removal**

Majority of patients complain of pain, swelling and stiffness and relate these symptoms to the metal implant presence following fracture fixation. The lingering query then is if these symptoms are really due to the implant placed or as a result of the injury that was fixed. The removal of implants also brings about significant morbidity bearing in mind that the surgery is performed on already scarred tissue with some amount of difficulty. So when patients report of symptoms before and after implant removal it becomes difficult to ascertain the real cause of the reported symptoms, especially when the patients report worsening of the symptoms on removal of the implants. [2] [3]

In a prospective description of 83 patients who underwent implant removal in a government hospital in Kashmir India, Haseeb and colleagues established that the most common indication for removal of implant in the patients was pain followed by implant prominence. 39.75% of the patients had pain or discomfort. Other indications in order of frequency described in the study were infected hardware, implant failure, elective (patient's insistence) and other reasons.(17)

In review of 128 cases in a Nigerian tertiary hospital, admitted for removal of implants, D D Mue and colleagues found that the commonest indication was infected implants at 22.6 % followed by patients' demands at 17.2 %. In another study in Northern Nigeria, patient request was the main indication for removal of implants for patients who presented for removal of implants in this two year prospective study. In this study Onche eta al strongly argued on the need for guidelines for removal of implants to safeguard patients and hospital economically in the view that the removal of implants was not necessarily a routine procedure.(18) (21)

This global and regional variability in considering if and when to remove implants presents a challenge to surgeon on seeking guidance on how to tackle implant removal. This necessities this study which attempts to describe the common indications of implant removal among patients presenting for removal of implants.

**ii) Challenges Encountered During Removal of implants**

The challenges encountered during surgical removal of implants have been profoundly alluded to in a few of the studies conducted concerning removal of hardware. In describing technical challenges encountered in removal of broken implants in Germany, Barbilian et al recommended proper evaluation on the need for removal of implants and reiterated the need for guidance on the procedure. The author of this study concluded that implant removal should not be viewed as just a routine procedure mostly due to the challenges encountered intra

operatively. Some of the challenges described include broken nails, stripped or broken screws, cold wielded screws and plates. [3]

Titanium is a softer metal and hence associated with the unique phenomenon of cold wielded screws. This can be a frustrating encounter intraoperatively as much as it is not commonly reported. [10]. The use of locking plates has also brought about some difficulties while removing the implant. Some of the reported challenges include stripping of the recess of the screw head for the screw driver, cross threading between threads in the screw head and screw hole. (23)

Factors that do not favour routine removal of orthopaedic implants include bony overgrowth and stripping of screws in angular stable implants. This was observed by Callistus et al in their study which they sought to find out incidence and indications of implant removal at Tania Specialist Hospital in Ghana. The study determined that the most common indication of implant removal among adults was patient request and doctors' advice being the most common indication in the paediatric group. [12**]**

**iii) Characteristics of broken implants**

In carrying out internal fixation, the surgeon is in a race between implant fatigue and fracture healing. Mechanical failure of implants fall into 3 categories, plastic, brittle and fatigue failure. Plastic failure is one in which the device failed to maintain its original shape resulting in a clinical failure. Brittle failure, an unusual type of implant failure, is caused by defect in design or metallurgy. Fatigue failure occurs as a result of repetitive loading on a device. [14](24)

Orthopaedic implants are subjected to many biomechanical stresses while fixed in the human body as they play a role in force transmission through the bone. Manufacturing technology, design and material selection have all improved as decades turn. Despite this improvements, coupled with modern surgical technology, implant damage and breakages still

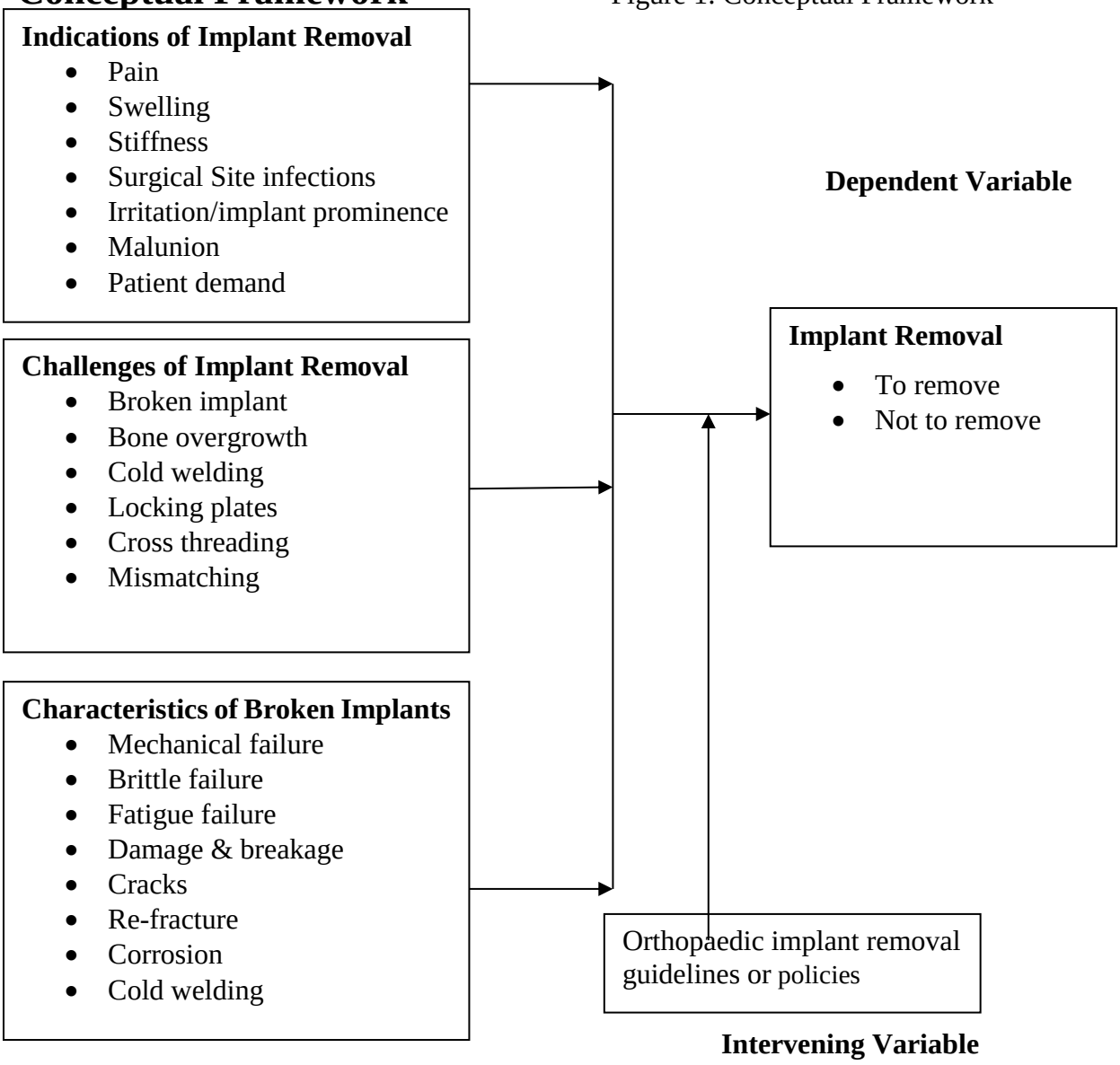
occur. When this occurs the patient might develop symptoms or not depending on the stage of healing and bone fixed.(25) In analyzing broken implants, Agota et al examined the metallography, fractography, and hardness testing of broken plates. The authors of this study concluded that for broken plates the cracks started from the screw surface and for the implants that were extracted from a refracture, the fractures did not start simultaneously. The authors established that the cracks from the screw surface which could have occurred during tightening or by a scratch by a piece of bone led to weakness of the implant and hence breakage and refracture. (26) In an experimental study of orthopaedic compression plates fatigue Saenoddin et al, determined that the cracks and the lines of weakness originated from the compression hole and spread form the lower to the upper surface. (27)

Cold wielding is a complication quite unique to titanium implants. It is occasioned by the overtightening or cross threading at the time of insertion. Extraction becomes a challenge once the screw head attaches firmly to the plate. This coupled with the fact that titanium is a softer metal make the removal a difficult encounter. The observable features after difficult extraction due to the cold wielding or cross threading have not been widely described to aid surgeons plan well on how to handle implants during fixation and removal. (28)

# CONCEPTUAL FRAMEWORK

## Conceptual Framework

Figure 1: Conceptual Framework




The interactions between the independent and dependent variable is illustrated in Figure 1. Implant indications such as pain, swelling, stiffness, surgical site infections, irritation/implant prominence, malunion, or patient demand can affect a surgeon's decision to remove or keep an implant. Broken implants, bone overgrowth, cold welding, locking plates, cross threading, and mismatching are all issues that can affect a surgeon's decision to remove or keep an implant. Broken implants which are characterized by metal failure (mechanical, brittle and fatigue), implant damage/breakage,

cracks, refracture and cold welding may also determine a surgeon's decision to remove or to retain an implant.

The clear lack of guidelines on when the implants should be removed presents a challenge to surgeons locally since they cannot really decide when to leave the implant in situ and when to get it out. There are cases of patients developing symptoms following implant removal. Was the removal of such implants necessary? This coupled with the actual difficulties encountered during the removal of implants suggest the need for guidelines and change of perception of the removal of implants as a routine procedure.

The author seeks to build evidence on the local practice of removal of implants and the challenges involved, with the aim of influencing the practice and contributing to the existing global debate on if and when implants should be removed.

# CHAPTER THREE: RESEARCH DESIGN AND METHODOLOGY

## Location of the study

The study was carried out at the Kenyatta National Hospital, Nairobi Hospital, Aga Khan University Hospital and Kikuyu Hospital. The Kenyatta National Hospital is one of the national referrals and teaching hospitals in the country. As a National Referral Centre, the hospital receives patients from all corners of the country from all strata of social status with 1800 bed capacity.

This places KNH at the centre of all disciplines countrywide and especially the practice of Orthopaedic Surgery. Due to the fact that the hospital is a national confluence of trauma and general orthopedic cases, served by faculty and residents in Orthopaedic Surgery, it provides a rich catchment of patients from all corners of the country and a sizeable number of surgeons to include in the study.

The Nairobi hospital is a private healthcare provider and neighbours the Kenyatta National Hospital. The facility is a specialized hospital with more than 350 beds, mostly run by admitting consultants. The facility is known to serve the well insured and clients who can afford the services. The hospital is served by a vibrant team of Orthopaedic surgeons with some of the longest serving surgeons practising in the institution.

Aga Khan University Hospital is a private hospital located in Nairobi's Parklands area. Established in 1958, the hospital has a 254-bed capacity and provides general medical services, specialist clinics and diagnostic services to the general public. Aga Khan Hospital is well known for providing high-quality health care, but it is also highly expensive, making it out of reach for most Kenyans. It is renowned, however, to serve well-insured clients and those who

can afford the services. The hospital is served by a vibrant team of orthopaedic surgeons and longest-serving surgeons.

Kikuyu Hospital is one of the oldest hospitals in Kenya. It is located in Kiambu County and was established in 1908 by missionaries. This research was carried out in the PCEA Kikuyu Orthopaedic and Rehabilitation centre (KORC). This is a fully equipped and dedicated Orthopaedic Unit with 37 beds, which provides orthopaedic, reconstructive surgery and rehabilitation for its clients. Annually about 5000 patients are seen and over 800 surgical procedures performed.

The author identified the four institutions as study sites for inclusive purposes since KNH and Kikuyu Hospital serves patients from all backgrounds, but with majority from disadvantaged backgrounds whereas the Nairobi Hospital and Aga Khan Hospital caters for mostly those that can afford who are majorly from well to do backgrounds and the insured.

## Design of the Study

This is a quantitative research involving use of cross-sectional descriptive design. The use of this design is justified because it helps in estimating a population parameter, such as the prevalence of indications and challenges of implant removal after long-bone osteosynthesis, or determining the average value of a quantitative variable in the study population. Convenience sampling was used to recruit participants.(30)

The author was interested in the collection of data on the indications of implant removal among patients undergoing the removal of implants following long bone osteosynthesis and challenges encountered during the procedure at Kenyatta National Hospital, Nairobi Hospital Aga Khan Hospital and PCEA Kikuyu Hospital.

# Research Methodology

The author conducted a quantitative descriptive cross-sectional study determining the most common indications and challenges in implant removal among patients undergoing the removal of implants in the four hospitals.

All patients presenting at the four institutions for removal of implants following long bone fixation were included in the study. The main methods of data collection were researcher-administered questionnaires and examination of medical records. Data collected through questionnaires from patients presenting for implant removal after long bone osteosynthesis included; demographic characteristics, type of bone with implant, indications for implant removal, and duration of implant before removal and type of implant removed. Data on the challenges encountered during the surgical removal of implants and physical characteristics of broken implants was retrieved from the patient's post-operative medical records.

The patients were selected by help of six assistants who are clinical officers (holders of Diploma in Clinical medicine and Surgery from KMTC). Each of the three Orthopaedic firms in KNH and Kikuyu hospital was assigned one assistant. The other three assistants were stationed in Nairobi Hospital and Aga Khan Emergency unit, clinics and wards respectively. They were trained on data collection from a small number of patients during the pilot study.

The principal researcher ensured completeness and accuracy of the questionnaire administered by research assistants. Patients were managed according to hospital protocol with no interference from the research team. The study team interacted with patients presenting for removal of implants at the clinic, accident and emergency and those already admitted in the wards for the procedure according to the code of conduct as prescribed by the respective hospitals. The study team reviewed daily admissions into the Orthopaedic Unit for the period of the study to recruit participants who fit the inclusion criteria. The study team reviewed the patient and the existing records, and determined if they met the inclusion criteria. The notes

within their files were reviewed according to the developed data collection questionnaire. The collected data was analysed for appropriateness and presented.

## Target Population

The target population for this study was patients presenting for implant removal at four urban hospitals including; Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and Kikuyu Hospital. The respondents in this study were patients presenting at the four hospitals for the implant removal following long bone osteosynthesis. The patients were encountered and recruited at the outpatient Orthopaedic clinics and the Orthopaedic wards. The study team kept contact with the patient to review the patient before and after the surgery. The four hospitals conduct an approximate of 432 implant removals annually. Thus the population size of this study was 432 as summarized below:

***Table 1: Target population***

| Hospital | Population |
|---|---|
| 1) Nairobi Hospital | 120 |
| 2) Aga Khan Hospital | 96 |
| 3) Kenyatta National Hospital | 108 |
| 4) Kikuyu Hospital | 108 |
| Total | 432 |

Source; Theatre records of Nairobi, Aga Khan, KNH & Kikuyu Hospitals (2021)

## Sampling Techniques and Sample Size

In targeting all patients presenting for removal of implants at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and Kikuyu Hospital, the study used the convenience sampling method in data collection.

The sample size to be included in the study was calculated using the Cochrane's formula:

$$n0 = \frac{Z^2 pq}{e^2}$$

Where n0 is the random sample, Z is the statistic corresponding to the level of confidence (1.96=standard deviation of 95$^{th}$ percentile, p is the expected prevalence, q is (1-p) and e is the confidence interval.

Formula $n_0 = \frac{1.96^2(0.5)(0.5)}{0.05^2}$

Random sample=385 patients

Sample size was determined as follows:

$$n = \frac{n0}{1+\frac{n0-1}{N}}$$

Where n is the sample size and N is the population size.

$$n = \frac{385}{1+\frac{385-1}{432}}$$

n= 204

Sample size = 204 patients

**Sample Size Distribution**

The sample size was distributed proportionally across the four hospitals based on the population size as summarized in Table 2 below:

*Table 2: Sample Size Distribution*

| Hospital | Population | Sample Size |
|---|---|---|
| 1) Nairobi Hospital | 120 | $\frac{120}{432} \times 204 = 57$ |
| 2) Aga Khan Hospital | 96 | $\frac{96}{432} \times 204 = 45$ |
| 3) Kenyatta National Hospital | 108 | $\frac{108}{432} \times 204 = 51$ |
| 4) Kikuyu Hospital | 108 | $\frac{108}{432} \times 204 = 51$ |
| Total | 432 | 204 |

## Sampling Frame and Data Collection

Ethical approval to carry out the study was sought from the Kenyatta National Hospital-University of Nairobi Ethics and Research Committee, The Agha Khan University Hospital Ethics and Research Committee, The Kikuyu Orthopaedic Hospital, The Nairobi Hospital and National Commission for Science and Innovation (NACOSTI).

The sampling frame for this research was the the patient registers of the Kenyatta National Hospital and Kikuyu Hospital accident and Emergency department, Orthopaedic Clinic and wards; and the Nairobi Hospital and Aga Khan Accident and Emergency Orthopaedic clinic and wards, of the patient presenting for removal of implants during the period of the study.

The study used consecutive sampling procedure where all patients meeting the inclusion criteria were selected until the sample size is attained. This method was key in controlling bias as the patients present without any preference of day or time, and unknown to the study team. This ensured that all patients had an equal chance of being involved in the study. The selected patients who consent were included in the study.

The study team coordinated with Orthopaedic residents and consultants in recruiting patients at each point. Once a patient presented for removal of implant, the study team offered

participant education, registered written consent and collected the data using a standard questionnaire.

Patient data was retrieved and the following data was recorded using a standardized form; demographic characteristics, type of bone with implant, indications for implant removal, duration of implant before removal, type of implant removed, characteristics and challenges during the actual procedure of removal

## Data Analysis and Presentation

In analyzing data collected from questionnaires and medical records, the researcher was be guided by research objectives. The Statistical Package for Social Sciences (SPSS) software, version 25, was used to analyze quantitative data. Specific statistical techniques were be used to analyze data for each of the three research objectives:

The first research objective is quantitative and was analyzed using simple univariate statistics. It focuses on common indications of orthopaedic implant removal among patients undergoing implant removal following long bone osteosynthesis in four urban hospitals in Kenya. The common indications were computed using means and percentages, and presented in the form of tables. Pearson correlation and multiple regression analyses was also be used to test relationships between common indications and implant removal decisions.

The second research objective, which focuses on the challenges encountered during the surgical removal of implants after long bone osteosynthesis in four urban hospitals in Kenya, was analyzed using descriptive statistics such as means and percentages. Furthermore, Pearson correlation analysis and multiple regression analysis was used to show the statistical differences between the challenges encountered during surgical implant removal and the decision to remove the implant.

The physical characteristics of broken implants removed from patients in four Kenyan urban hospitals were analysed using qualitative and quantitative methods in research objective

three. Document analysis methods and simple univariate analysis were used. Document analysis of medical records were used to identify the physical characteristics of broken implants, while regression analysis was used to test the relationship between the physical characteristics of broken implants and the decision to remove the implant.

## Quality Control

The principal researcher is an Orthopaedic Resident assisted by two holders of Diploma in Clinical Medicine from Kenya Medical Training College. The team was trained on how to recruit respondents and fill in questionnaires using the correct variables. The team engaged the residents and faculty on a continuous basis which ensured accurate data collection as well as continuous improvement on different aspects during the study period.

Data was cleaned for accuracy prior to entry to avoid errors and analysis shall be done with the help of a statistician.

## Ethical Considerations

Ethical approval to carry out the study was obtained from the Kenyatta National Hospital- University of Nairobi Ethics and Research Committee, The Agha Khan University Hospital Ethics and Research Committee, The Kikuyu Orthopaedic Hospital, The Nairobi Hospital and National Commission for Science and Innovation (NACOSTI).

Written consent was registered from all the patients participating in the study prior to involving them as respondents. These patients' records were treated with utmost confidentiality. The filled questionnaires were kept in a lockable briefcase and stored in a lockable file cabinet. While on transit the questionnaires were carried in a lockable briefcase and bag. The electronic data was uploaded and saved in coded numbers and password protected databases.

Patients who declined to be involved in the study were not be prejudiced, their decision was fully respected.

## Limitations and Delimitations

i. Patients who declined to be included in the study, declined consent.

## Conflict of Interest

None to declare.

# CHAPTER FOUR: RESULTS

## Characteristics of Respondents

The purpose of this study was to determine the indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals in Kenya. Data was collected using questionnaires from 204 patients at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital. The general characteristics of the respondents are shown in Table 3:

***Table 3: Characteristics of Respondents Stratified by Gender***

| | **Male** N=150 (73.5%) | **Female** N=54 (26.5%) | **Total** N=204 (100%) | **P-value** |
|---|---|---|---|---|
| **Age** | | | | .256 |
| 18-24 years | 49 (24.0%) | 16 (7.8%) | 65 (31.9%) | |
| 25- 34 years | 49 (24.0%) | 12 (5.9%) | 61 (29.9%) | |
| 35-64 years | 50 (24.5%) | 24 (11.8%) | 74 (36.3%) | |
| 65 and above years | 2 (1.0%) | 2 (1.0%) | 4 (2.0%) | |
| **Education Level** | | | | .008 |
| University | 14 (6.9%) | 4 (2.0%) | 18 (8.8%) | |
| Tertiary/Vocational | 30 (14.7%) | 11 (5.4%) | 41 (20.1%) | |
| Secondary | 60 (29.4%) | 11 (5.4%) | 71 (34.8%) | |
| Primary | 42 (20.6%) | 21 (10.3%) | 63 (30.9%) | |
| Informal | 4 (2.0%) | 7 (3.4%) | 11 (5.4%) | |
| **Occupation** | | | | .001 |
| Formal employment | 22 (10.8%) | 5 (2.5%) | 27 (13.2%) | |
| Casual labour | 45 (22.1%) | 4 (2.0%) | 49 (24.0%) | |
| Business | 48 (23.5%) | 20 (9.8%) | 68 (33.3%) | |
| Housewife | 2 (1.0%) | 1 (0.5%) | 3 (1.5%) | |
| Outside labour force | 3 (1.5%) | 0 (0.0%) | 3 (1.5%) | |
| Student | 17 (8.3%) | 9 (4.4%) | 26 (12.7%) | |
| Not employed | 13 (6.4%) | 15 (7.4%) | 28 (13.7%) | |
| **Average Daily Income** | | | | .009 |
| Less than Kshs 100 | 51 (25.0%) | 15 (7.4%) | 66 (32.4%) | |
| Kshs 101-200 | 40 (19.6%) | 10 (4.9%) | 50 (24.5%) | |
| Kshs 201-500 | 30 (14.7%) | 6 (2.9%) | 36 (17.6%) | |
| Kshs 501-800 | 11 (5.4%) | 6 (2.9%) | 17 (8.3%) | |
| Kshs 801-1,100 | 7 (3.4%) | 3 (1.5%) | 10 (4.9%) | |

| | | | | |
|---|---|---|---|---|
| Above Kshs 1,101 | 11 (5.4%) | 14 (6.9%) | 25 (12.3%) | |
| **Type of Bone with Implant** | | | | .119 |
| Tibia | 19 (9.3%) | 6 (2.9%) | 25 (12.3%) | |
| Tibia/Fibula | 26 (12.7%) | 12 (5.9%) | 38 (18.6%) | |
| Femur | 42 (20.6%) | 14 (6.9%) | 56 (27.5%) | |
| Humerus | 27 (13.2%) | 3 (1.5%) | 30 (14.7%) | |
| Radius | 19 (9.3%) | 14 (6.9%) | 33 (16.2%) | |
| Spine | 1 (0.5%) | 1 (0.5%) | 2 (1.0%) | |
| Hip | 16 (7.8%) | 4 (2.0%) | 20 (9.8%) | |
| **Duration of Implant** | | | | .006 |
| Less than a month | 4 (2.0%) | 2 (1.0%) | 6 (2.9%) | |
| 1-11 months | 123 (60.3%) | 31 (15.2%) | 154 (75.5%) | |
| 1-5 years | 8 (3.9%) | 10 (4.9%) | 18 (8.8%) | |
| 6-10 years | 13 (6.4%) | 9 (4.4%) | 22 (10.8%) | |
| 11-15 years | 2 (1.0%) | 2 (1.0%) | 4 (2.0%) | |
| **Pre-existing condition** | | | | .205 |
| Yes | 21 (10.3%) | 4 (2.0%) | 25 (12.3%) | |
| No | 129 (63.2%) | 50 (24.5%) | 179 (87.7%) | |

Table 2 shows that implant removal was three times more in males (73.5%, n=150) than females (26.5%, n=54). In both males (24.5%, n=50) and females (11.8%, n=24), incidence of implant removal was high among the age group of 35-64 years. Further, the results showed that majority (34.8%, n=71) of the patients presenting for implant removal at the four urban hospitals had secondary education. Besides, incidence of implant removal occurred more among patients who were engaged in business (33.3%, n=68) and casual labour (24.0%, n=49). Average daily income of most of the patients presenting for implant removal at the four urban hospitals was below Kshs 100, implying that they were living below poverty line.

The most implants were removed from the femur (27.5%, n=56) in both males and females, followed by the tibia/fibula (18.6%, n=38), radius (16.2%, n=33), humerus (14.7%, n=30), tibia (12.3%, n=25), and hip (7.8%, n=16). A small percentage of patients (2 %, n=1.0%) had their implants removed from the spine bone. Furthermore, the majority of the respondents reported that the implant was in place for a duration of 1-11 months before being removed. Only 12.3 % (n=25) of the 204 patients who presented for implant removal had pre-

existing problems. Asthma, diabetes, ischemic heart disease, epilepsy, HIV, hypertension, depressive disorder, and multiple myeloma were examples of pre-existing conditions among patients for implant removal.

## Common Indications

According to the findings, pain in the implant area was the most common reason for implant removal at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital, and PCEA Kikuyu Hospital as shown in Figure 2.

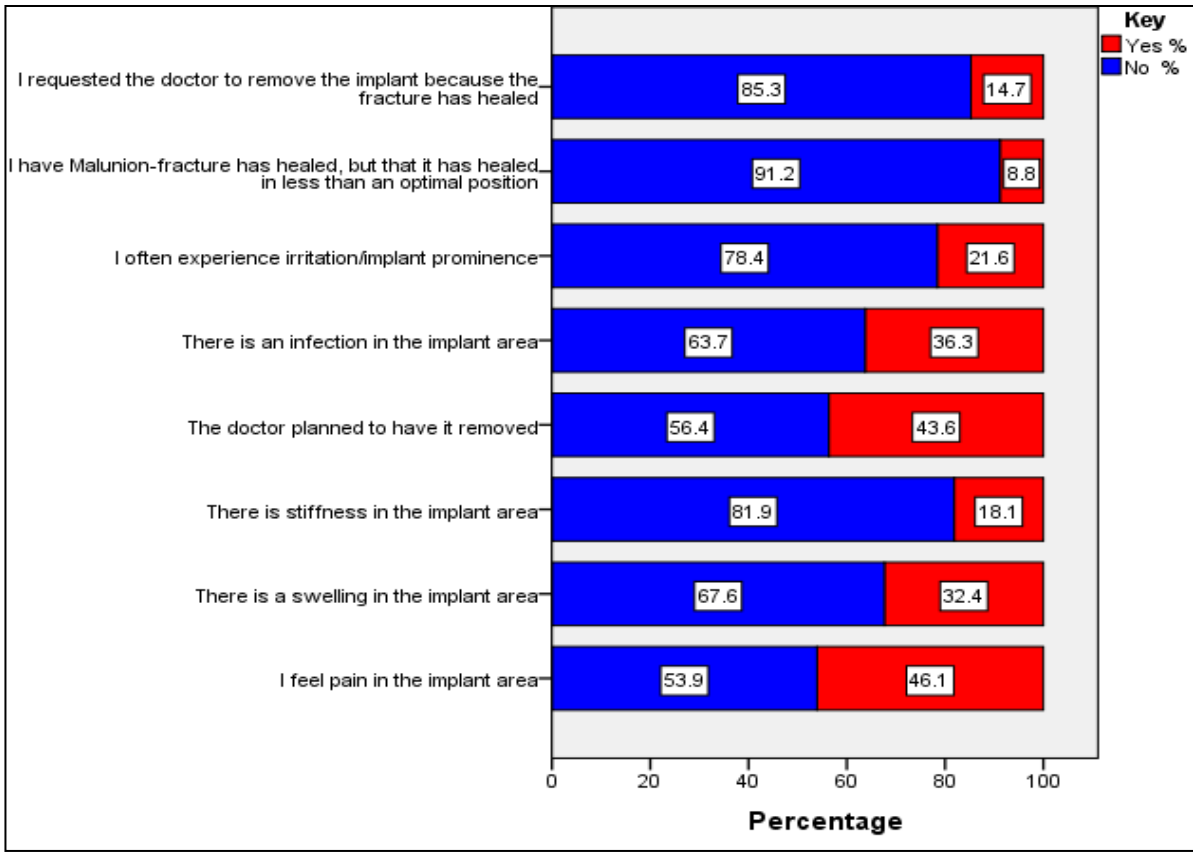



*Figure 2: Common Indications*

Figure 2 shows that 46.1% of patients reported implant-related pain, and that the doctor was the one who suggested the implant be removed (43.6%). Furthermore, 36.3 % of patients reported that they had an infection in the implant area, 32.4% said they had a swelling in the implant area while 21.6% said they commonly had irritation/implant prominence. This finding

show that discomfort caused by pain, swelling, or infection, either the doctor or the patient may request that the implant be removed.

## Challenges of Surgical Implant Removal

Broken intramedullary nails, bone overgrowth, and locked screws on plates were the major challenges affecting surgical implant removal as shown in Figure 3:

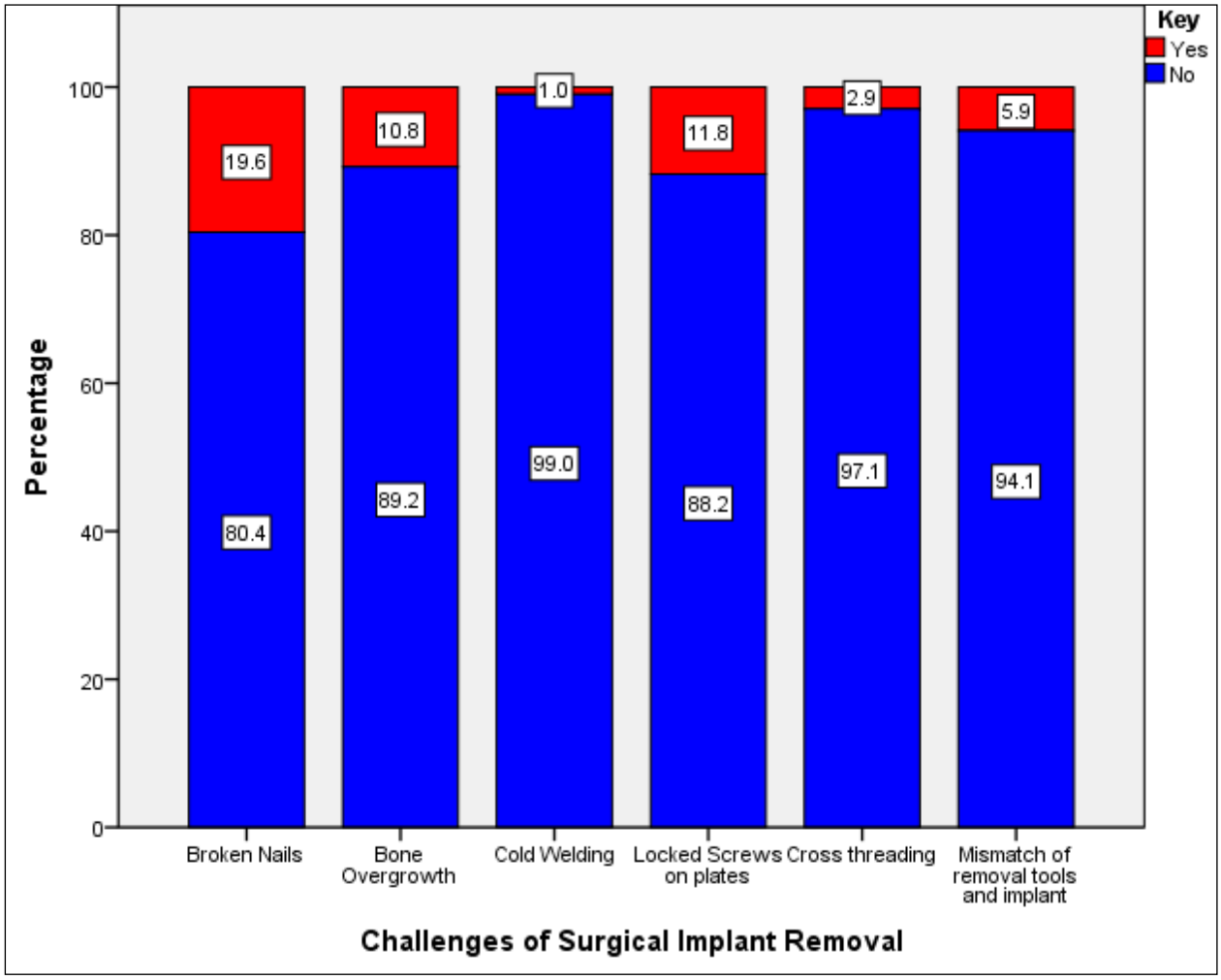
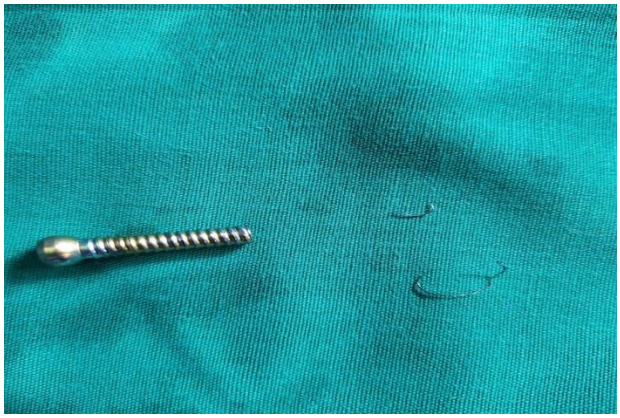


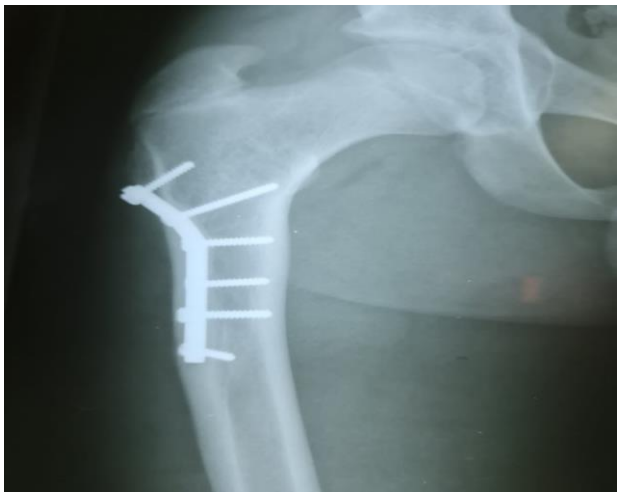

*Figure 3: Challenges of Surgical Implant Removal*

According to the findings, broken nails (19.6%), bone overgrowth (10.8%), and locked screws on plates (11.8%) were the main challenges affecting surgical implant removal. These challenges make it difficult for the surgeon and subsequently the patient. The following are some of the challenging aspects of implants encountered during removal.



*Broken screw*

*Broken Nails*



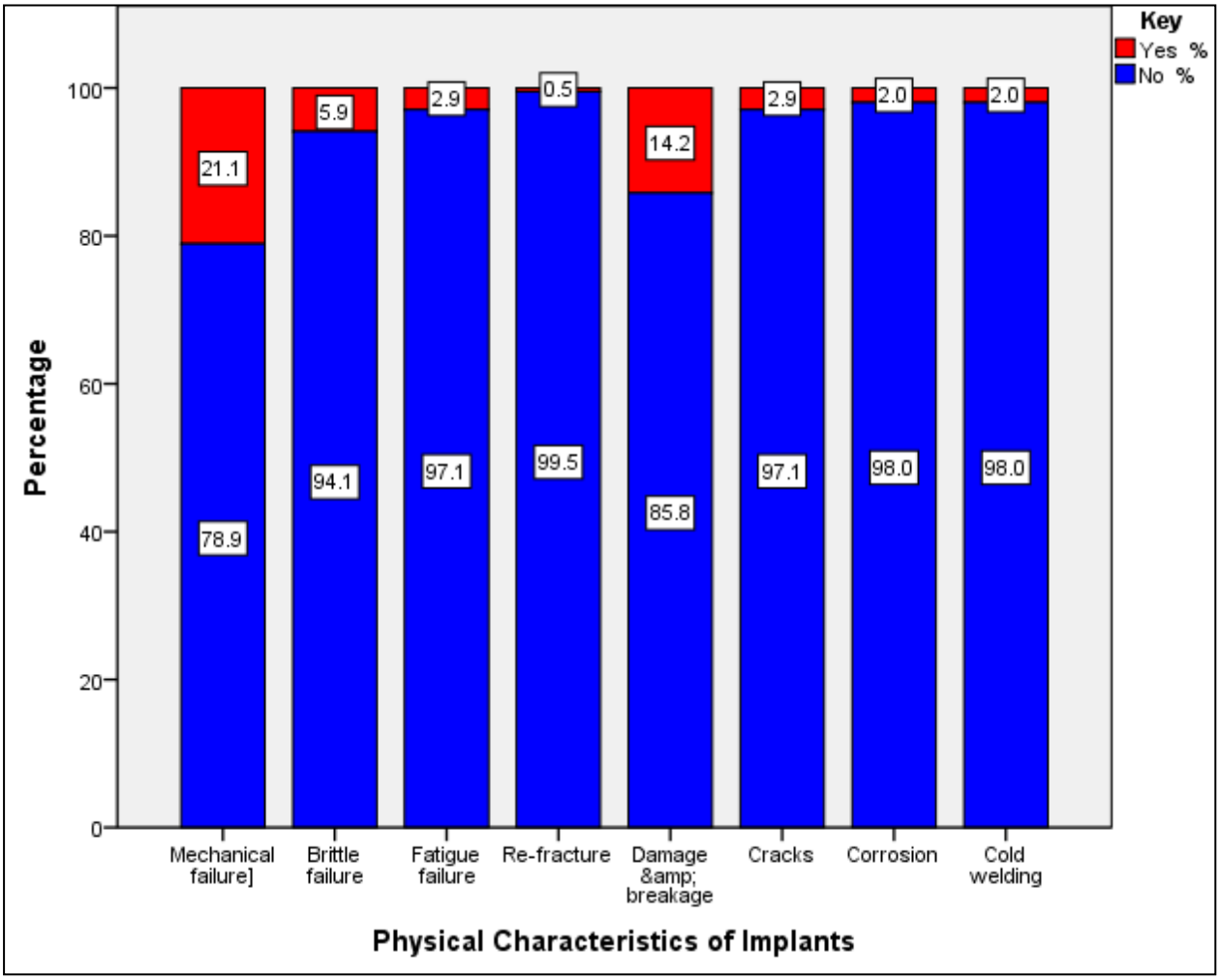
*Bone Overgrowth*

*Screw Thread Cuttings*

The images above demonstrate that while implants are strong, they can break depending on the type of metal used or size of the implant. In most cases, metal implants break because of fatigue due to persistent stress. This can lead to implant-related pain, swelling, prominence as well as delayed or lack of complete healing (non-union).

## Physical Characteristics of Removed Implants

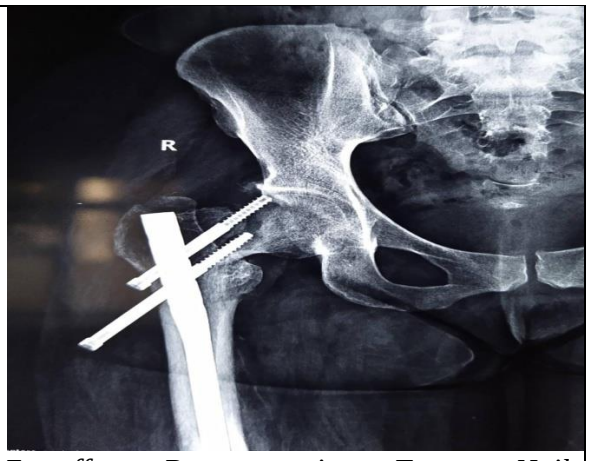
According to the results, mechanical failure breakage were common characteristics of implants removed from patients as shown in Figure 4:




According to presentation in Figure 4, implants of 21.1% of the patients had mechanical failure and implants of 14.2% of the patients were damaged and broken while implants removed from 5.9% of the patients had brittle failure. This can be interpreted to mean that incidence of mechanical failure, followed by damage & breakage and brittle failure was likely among patients presenting for implant fixation at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital. Such failures may occur due to deformation of the implant, fracture of the implant or loosening of the implant. There are circumstances where such failures may make the implant to cause pain, infection or toxicity thereby

prompting the decision to remove the implant. Some features of implants removed from patients are shown below:

*Corrosion*



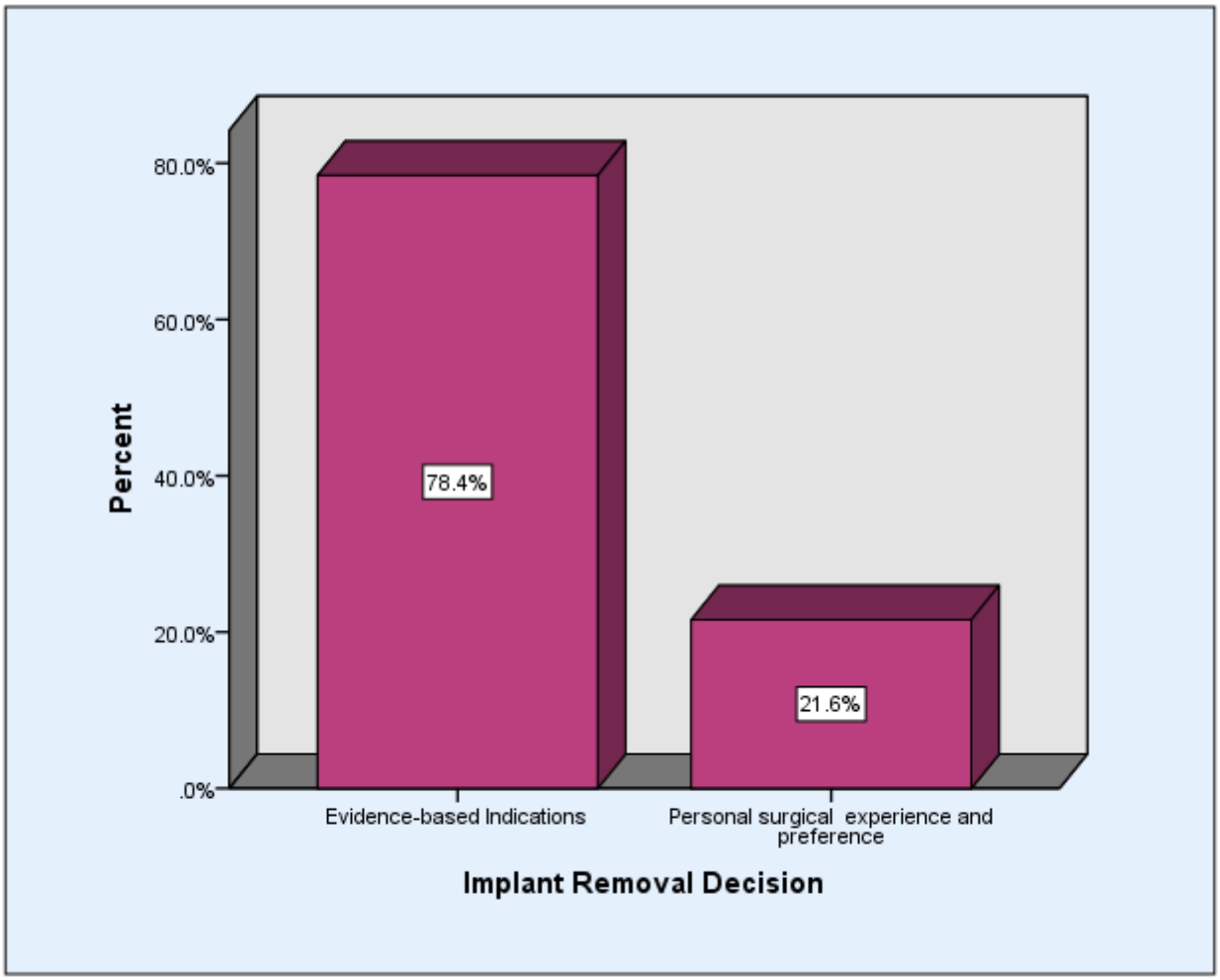

*Z effect Reconstruction Femur Nail Proximal screws*

*Cold welding*

*Bent, removal difficulties*

## Determinant of Implant Removal Decision

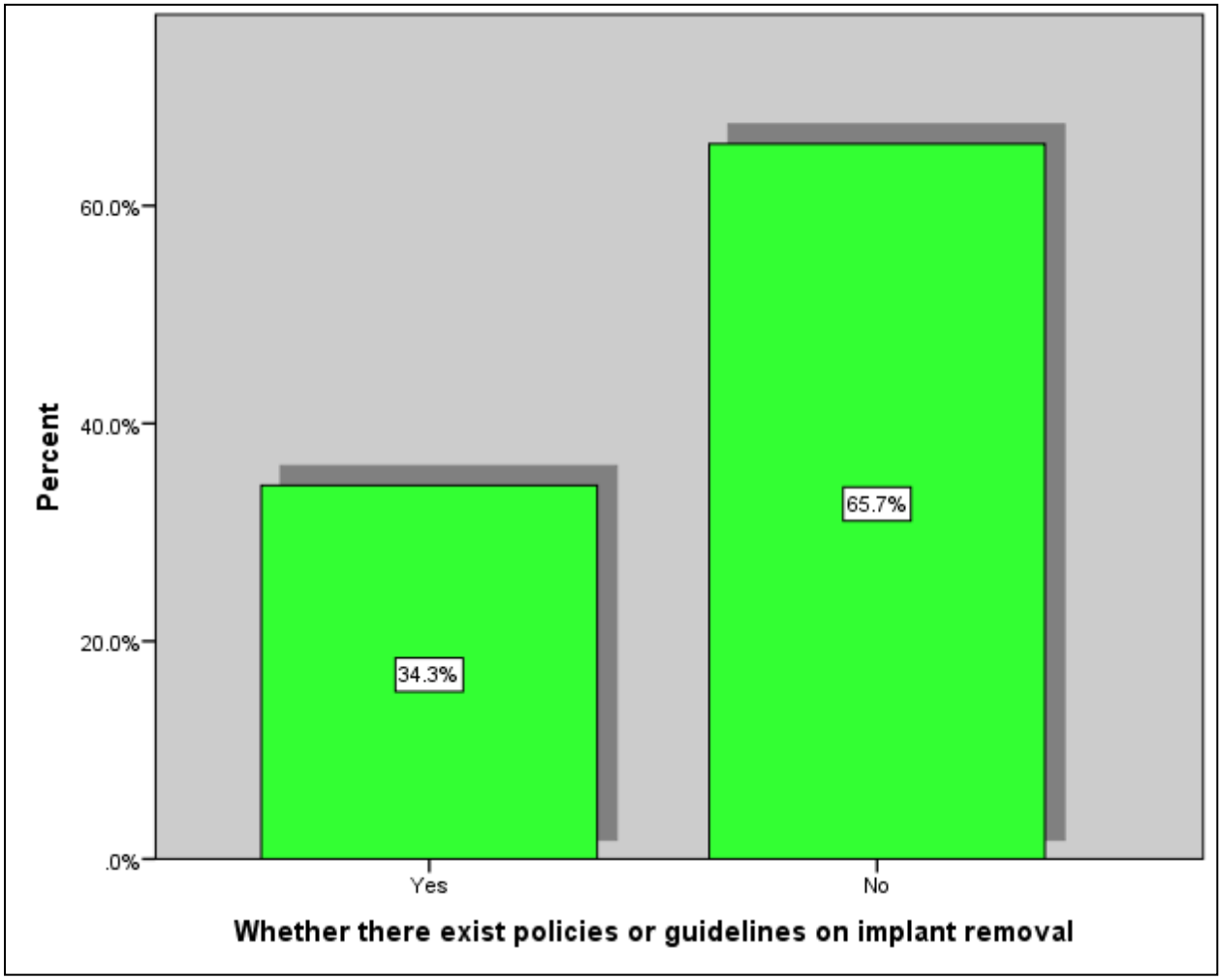
The respondents were asked to indicate what influenced the decision to remove the implant and the results are shown in below:




According to the findings, decisions to remove the implant was informed by evidence-based indications (78.4%) while 21.6% of the respondents reported that decision for implant removal was influence by personal surgical experience and preference. This finding is a clear demonstration that there is lack of a common understanding on the best criteria which should guide implant removal.

## Existence of Policies or Guidelines Governing Implant Removal

The respondents were asked to indicate whether the hospital had policies or guidelines governing implant removal and the results are shown as follows:




According to the presentation above, the study revealed that there were no policies and guidelines on implant removal (67.5%). This is despite the fact that implant removal is one of the most regularly performed elective orthopedic surgeries. Removal of orthopedic implants is often done to relieve symptoms but this procedure ought to be informed by clear policies and guidelines.

## Multinomial Logistic Regression

The study adopted multinomial regression to determine the cause-effect relationship between independent and dependent variables. Multinomial Logistic regression was considered for this study because dependent and dependent variables comprised of categorical variables. The findings are summarized in Table 4:

*Table 4: Model Fitting Information*

| Model | Model Fitting Criteria | Likelihood Ratio Tests | | |
|---|---|---|---|---|
| | -2 Log Likelihood | Chi-Square | df | Sig. |
| Intercept Only | 119.073 | | | |
| Final | 52.117 | 66.956 | 3 | .000 |

The presentation in Table 4 shows that the model was significant (p-value, 0.000). The likelihood ratio chi-square of 66.956 can be interpreted to mean that the model fits significantly well as opposed to a case where there is a model without predictors. This imply that there is a positive significant relationship between indications, challenges and characteristics of implants and implant removal decisions at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital in Kenya.

*Table 5: Pseudo R-Square*

| | |
|---|---|
| Cox and Snell | .280 |
| Nagelkerke | .432 |
| McFadden | .315 |

The *Pseudo R-Square* explains the variation of dependent variable due to the changes of independent variables. As shown in Table 5, the *Nahelkerke* value of 0.432 can be interpreted to mean that 43.2% variations of implant removal decision was due to changes in the

indications of implant removal, challenges of implant removal and characteristics of broken nails.

*Table 6: Likelihood Ratio Tests*

| Effect | Model Fitting Criteria | Likelihood Ratio Tests | | |
|---|---|---|---|---|
| | -2 Log Likelihood of Reduced Model | Chi-Square | df | Sig. |
| Intercept | 80.280 | 28.163 | 1 | .000 |
| Indications of implant removal | 88.354 | 36.237 | 1 | **.000** |
| Challenges of implant removal | 53.296 | 1.180 | 1 | .277 |
| Physical characteristics | 52.999 | .882 | 1 | .348 |

Likelihood Ratio Tests in Table 6 illustrates the impact of each independent variable on dependent variable. By taking all independent variables constant at zero, implant removal decision coefficient was 80.280. The findings equally show that when all other independent variables are at zero, a unit increase in indications of implant removal will lead to a 88.354 increase in implant removal decision, a unit increase in challenges of implant removal will lead to 53.296 increase in implant removal decision while a unit increase in physical characteristics of broken implants will lead to a 52.999 increase in implant removal decision among patients presenting for implant removal at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital in Kenya. Besides, results showed that out of the three independent variables, only indications of implant removal were significant in determining the decision for implant removal.

# CHAPTER FIVE: DISCUSSION

## Discussion

This study sought to determine the indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals in Kenya. Results showed that implant removal was three times more in males than females. This is higher than the incidence reported by Kuubiere and colleagues who their retrospective study in Ghana found that the incidence of implant removal was twice as high in males as in females.(12) The high incidence of male implant removal could be attributed to the fact that male have higher rate of fractures than females since they engaged in high-intensity physical activities or are involved in situations which put them at a higher risk of fractures in Kenya.

This study revealed that incidence of implant removal was high among patients aged 35-64 years as well as in patients with secondary education and those engaged in business and casual labour for a living. This finding corroborates with findings of Kuubiere and colleagues who found that implant removal was more among patients aged 40 years and above. This also compares closely with Mue, et al who established that the mean age in his study of Indications of Implant removal in Northern Nigerian Tertiary Hospital was 40 years. The fact that as people becomes older, their bone tissues changes, making the bone weaker and lead to an increase in the incidence of bone fractures.(12)(18)

In addition, the results showed that a third of patients who presented for implant removal were living below poverty line. These findings are consistent with the findings of Onche,. et at who evaluated the economic impact of Implant removal in Northern Nigeria, and established that removal of implants should be principally based on patient to patient factors, such as age, gender and physical activity. This was based on the finding that a great deal of

resources especially by the patients was spent in pursuing implant removal.(21) Poor socioeconomic conditions may result in lack of basic needs such as food, in extension good nutrition required for healthy bones, thereby increasing the risk of fractures.

Most implants were removed from the femur bone in the four urban hospitals, according to the study, and patients had stayed for a period of 1-11 months with the implant *in situ* before it was removed. This finding is comparable to that of Kuubiere et al., who discovered that the majority of implants were in the femur bone in their study. Shreestha and colleagues in their study to establish epidemiological and outcome analysis of Implant removal in Kathmandu, India, established that implants from the femur were the most removed by surgeons. The femur bone is one of the longest and strongest bone in the body, yet it is also susceptible to fractures caused by falls, gunshot injuries, or motor accidents. Asthma, diabetes, ischemic heart disease, epilepsy, HIV, hypertension, depressive disorder, and multiple myeloma were among the comorbidities that patients presenting for implant removal had.(8) (12) In addition, most other bony injuries in the body can be managed non operatively, unlike femur fractures whose definitive management is open reduction and internal fixation.

On indications of implant removal, the study found that in the four urban hospitals, pain in the implant area, doctor's request, swelling in the implant area, and irritation/implant prominence were the most common indications for implant removal. This is consistent with findings of Haseeb and colleagues, who established that the most common indication for removal of implant in India was pain followed by implant prominence as well as infected hardware, implant failure, elective (patient's insistence) and other reasons.(17). This is supported by a study by Vos et al.,(9) that found that infection of the implant or bone was one of the most common reasons for implant removal. The study also found that the most common postoperative complications were wound infection, unpleasant scarring, and postoperative haemorrhage. However, the finding of doctor's request as a common indication among the four

studies hospitals contradicts findings of a study by Callistus et al in Ghana who determined that the most common indication of implant removal among adults was patient request.(12)

On the challenges of surgical implant removal, the study found that broken intramedullary nails, bone overgrowth and locked screws were major impediments. Hak and colleagues noted that the use of locking plates can bring difficulties while removing the implant. Such difficulties include; stripping of the recess of the screw head for the screw driver, cross threading between threads in the screw head and screw hole.(23) In addition, the findings are consistent with Mingo-Robinet & Aguila who investigated osteosynthesis implant removal in Spain and revealed that bone growth over the implant, rounded screw head core, cold fusion, difficulty finding the implant, and inability to remove part of the implant were major challenges affecting implant removal.(10)

On the physical characteristics of broken implants, the study found that mechanical failure, and breakage were common characteristics of implants removed from patients. This finding is consistent with Agota and colleagues who examined the metallography, fractography, and hardness testing of broken plates. The authors of this study concluded that for broken plates the cracks started from the screw surface and for the implants that were extracted from a refracture, the fractures did not start simultaneously. The authors established that the cracks from the screw surface which could have occurred during tightening or by a scratch by a piece of bone led to weakness of the implant and hence breakage and refracture. (26) Similarly, an experimental study of orthopaedic compression plates fatigue by Saenoddin et al, determined that the cracks and the lines of weakness originated from the compression hole and spread form the lower to the upper surface. (27)

# CHAPTER SIX; CONCLUSION AND RECOMMENDATION

## Conclusion

This study investigated the indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals in Kenya. The study found that implant removal was three times more in males than females. Incidence of implant removal was high among patients aged 35-64 years as well as in patients with secondary education and those engaged in business and casual labour for a living. In addition, the results showed that a third of patients who presented for implant removal were living below poverty line.

Most implants were removed from the femur bone in the four urban hospitals and patients had stayed for a period of 1-11 months with the implant *in situ* before it was removed. The study found that in the four urban hospitals, pain in the implant area, doctor's request, swelling in the implant area, and irritation/implant prominence were the most common indications for implant removal. Besides, the study found that broken intramedullary nails, bone overgrowth and locked screws were major challenges affecting implant removal. Mechanical failure and breakage were common characteristics of implants removed from patients.

The study concludes that there is a significant relationship between indications of implant removal, challenges of implant removal and characteristics of broken implants and decision for implant removal at Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and PCEA Kikuyu Hospital in Kenya. This finding is supported by multinomial regression analysis which determined that there was a significant relationship between independent and dependent variables (p-value, 0.000). Further, Likelihood Ratio Tests found

that indications of implant removal were a significant predictor of implant removal decision among the four studied hospitals (p-value, 0.000). Thus,a unit increase in indications led to unit increase in removal of implants and as such the presence of indications would lead to the removal of implants following long bone osteosynthesis.

## Recommendations

Implant removal surgery accounts for a large percentage of elective orthopedic procedures, yet the study found no guidelines on whether or not to remove the implant. This study found decision for implant removal in the four urban hospitals was informed by indications. However, it is imperative that implant removal should be guided by scientific evidence and clear guidelines. Thus, this study recommends that implant removal should be avoided in asymptomatic patients. The procedure should not require any more extensive surgery than the implant fixation surgery.

Moreover, the study suggests that orthopaedic surgeons should examine implant indications before making implant removal decision. Hence, in undertaking informed consent with the patients, the benefits and risks of implant removal ought to be well understood. The study also suggests that Kenya's Ministry of Health, in partnership with other healthcare stakeholders in Orthopaedic surgery and beyond, should formulate guidelines or policies to guide decisions on implant removal.

## Study Timeline

| Task/Month | May-Oct 2021 | Oct-Nov 2021 | Nov-Dec 2021 | Jan-April 2022 | April 2022 | May 2022 | May 2022 |
|---|---|---|---|---|---|---|---|
| **Proposal Development** | | | | | | | |
| **Proposal Presentation** | | | | | | | |
| **Field Study Documents (License, Permit, Letters)** | | | | | | | |
| **Data Collection** | | | | | | | |
| **Data Analysis** | | | | | | | |
| **Defence** | | | | | | | |
| **Final Report and Submission** | | | | | | | |

## Working Budget

| Items | Costs (Kshs) |
|---|---|
| Stationery and printing | 20,000 |
| Logistics (Data Collection, licenses, transport) | 110,000 |
| Library fees | 5,000 |
| Research Assistants | 90,000 |
| Miscellaneous | 10,000 |
| Contingency | 15,000 |
| **Total** | **250,000** |

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# Appendix A: Consent Form

**Preliminary**

My name is Dr. Mutiria Flavio Mugendi. I would like to tell you about a study I am conducting on indications and challenges of implant removal following longbone osteosynthesis at four urban hospitals (Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and Kikuyu Hospital) in Kenya. This consent form will give you the information you will need to decide whether or not you should participate in the study. Feel free to ask any questions about the purpose of this research, what happens if you participate, the possible risks and benefits, your rights as a volunteer, and anything else related to the study.

**Study Background**

Osteosynthesis is the treatment of bone fractures in which bone fragments are joined with screws, plates or nails. Fracture stabilization by the use of metals has been widely used since the Second World War. Following fracture healing, the question arises whether to remove the implant or leave it in situ. It is in effort to address this gap that this study seeks to document the different indications used in removal of implants and the challenges encountered during the actual removal of implants surgery. This knowledge will guide surgeons when approaching the decision of removing or leaving the implant in situ. The knowledge will also equip surgeons with likely challenges that can be encountered during the removal.

**Broad Objective**

To describe the indications and challenges of orthopaedic implant removal among patients undergoing removal of implant surgery following long bone osteosynthesis in four urban hospitals (Kenyatta National Hospital, Nairobi Hospital, Aga Khan Hospital and Kikuyu Hospital) in Kenya.

**Study Procedures**

You will be requested to respond to an interviewer administered questionnaires as well

as some data will be retrieved from your records. This information will be written in a coded questionnaire without names or any of your personal identification. You might also be asked to take part in a discussion with research assistants to gather information on your general health and fracture fixation challenges. The entire process could take at least 1 hour. We however ask for your consent to participate in this study.

**Voluntariness of Participation**

Your agreement to participate in this study is entirely voluntary. You have the option to withdraw from the study at any time in case you do not feel comfortable answering questions in this study and you will not be victimized or denied any benefits or services you are entitled to in this hospital. Furthermore, you will be are allowed to ask any questions that will enable you to understand the nature of this study.

**Confidentiality**

Strict privacy and confidentiality will be ensured during the data collection process and after the study. The researcher will keep all the information about participants to the study alone; participants should not write their names on the questionnaires. The research findings will be communicated to you, if you wish, through your contacts.

**Benefits of Participation**

This study may not benefit you directly but will assist hospitals offering orthopaedic services to develop policies which will promote surgical implant removal and care. You may benefit from the study by receiving free health education and information on importance of nutritional requirements, where necessary we will refer you to a hospital for care and support.

**Risks of Participation**

This medical research study has a potential to introduce participants to psychological, emotional and physical risks. However, efforts will be put in place to minimise the risks. This include, observation of total confidentiality for every information that will be provided, data will only be accessible to the co-investigators. Your feelings and personal opinions will be respected. Guidance and counselling sessions will be provided for those in need of the sessions by the counselling department in the facility.

**Right of Withdraw**

Your participation in this study is entirely voluntary. You are free to leave the study at any moment without having to give a reason. Refusal or withdrawal from this study will have no impact on the services you are entitled to in this or any other facility.

**Compensation**

There shall be no compensation for taking part in the study.

**STATEMENT OF CONSENT**

**Participant's 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 the researcher. I have had my questions answered in a language that I understand. The risks and benefits have been explained to me. I understand that my participation in this study is voluntary and that I may choose to withdraw any time. I freely agree to participate in this research study. I understand that all efforts will be made to keep information regarding my personal identity confidential.

By signing this consent form, I have not given up any of the legal rights that I have as a participant in a research study.

a) I agree to participate in this research study: Yes ( ) No ( )
b) I agree to provide contact information for follow-up: Yes ( ) No ( )

**Participant Name: ……..**

**Participant Signature /Thumb Stamp:…… Date: …….**

**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 willingly and freely given his/her consent.

**Researcher's Name**: ……. **Date**:……..

**Signature: ……**

**Role in the study**: ……..*[i.e. study staff who explained informed consent form.]*

Witness Printed Name (*If witness is necessary, A witness is a person mutually acceptable to both the researcher and participant*)

**Name _____ Contact information _____**

**Signature/Thumb Stamp: _____ Date**: _____

**Contacts Information:**

In case you have questions or concerns about the content of this study or about your rights as a participant, please feel free to contact the following persons:

| | | | |
|---|---|---|---|
| Dr. Mutiria Flavio Mugendi M.Med Registrar, Tel; +254722 839 378 drmugendi@gmail.com | Prof. John E.O Ating'a Professor, Department of Orthopaedic Surgery, P.O Box 19370, Nairobi Email:atinga08@gmail.com | KNH-UON ERC secretary Tel no. 2726300, Ext; 44102, Email:uonknh_erc@uonbi.ac.ke. | AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136 |

# Appendix B: Questionnaire for Patients

Research Title: Indications and Challenges of Implant Removal following long bone osteosynthesis in four urban hospitals in Kenya

Respondent Code:

**PART I: DEMOGRAPHIC FACTORS**

This section contains questions about your demographic characteristics. Kindly respond to all questions either by ticking or complete in the spaces provided.

1. What is your sex?
   Male ( ) 1 Female ( ) 2 Bisexual ( ) 3
2. What is your age?
   18-24 years ( ) 1 25- 34 years ( ) 2 35-64 years ( ) 3 above 65 years ( ) 4
3. What is your marital status?
   Single ( ) 1 Married ( ) 2 Separated ( ) 3 Divorced ( ) 4
4. What is your highest education level?
   University ( ) 1 Tertiary/Vocational ( ) 2 Secondary ( ) 3 Primary ( ) 4 Informal ( ) 5
5. What is the nature of your occupation?
   Formal employment ( ) 1 Casual labour ( ) 2 Business ( ) 3 Housewife ( ) 4 Outside labour force ( ) 5 Student ( ) 6 Not employed ( ) 7
6. What is your average daily income?
   Less than Kshs 100 ( ) 1 Kshs 101-200 ( ) 2 Kshs 201-500 ( ) 3 Kshs 501-800 ( ) 4 Kshs 801-1,100 ( ) 5 Above Kshs 1,101 ( ) 6
7. Do you have any pre-existing condition?
   Yes 1 ( ) No 2 ( )
   If yes, specify.....
8. Location of the implant in the patient's body?
   .....
9. How long have you stayed with the orthopaedic implant?
   .....

## PART II: INDICATIONS OF ORTHOPAEDIC IMPLANT REMOVAL

10. This section contains questions about indications of orthopaedic implant removal following long bone osteosynthesis. Kindly respond to all questions either by ticking or completing in the spaces provided.

| **Item** | **Yes 1** | **No 2** |
|---|---|---|
| I feel pain in the implant area | | |
| There is a swelling in the implant area | | |
| There is stiffness in the implant area | | |
| The doctor planned to have it removed | | |
| There is an infection in the implant area | | |
| I often experience irritation/implant prominence | | |
| I have Malunion-fracture has healed, but that it has healed in less than an optimal position | | |
| I requested the doctor to remove the implant because the fracture has healed | | |

## PART III: CHALLENGES OF SURGICAL IMPLANT REMOVAL

11. This section contains questions on challenges of surgical implant removal. (*This information should be retrieved from the patient's records)*

| **Item** | **Yes 1** | **No 2** |
|---|---|---|
| Broken implant | | |
| Bone overgrowth | | |
| Cold welding | | |
| Locked Screws on plates | | |
| Cross threading | | |
| Mismatch of removal tools and implant | | |

## PART IV: PHYSICAL CHARACTERISTICS OF BROKEN IMPLANTS

12. This section contains questions on the physical characteristic of broken implants removed from patients. *(This information should be retrieved from the patient's records or through assessment of the physician)*

| **Item** | **Yes** 1 | **No** 2 |
|---|---|---|
| Mechanical failure | | |
| Brittle failure | | |
| Fatigue failure | | |
| Re-fracture | | |
| Damage & breakage | | |
| Cracks | | |
| Corrosion | | |
| Cold welding | | |

## PART V: DETERMINANT OF IMPLANT REMOVAL

13. What influenced the decision to remove the implant from the patient?

    a) Evidence based Indications of implant removal ( )1

    b) Personal surgical experience and preference ( )2

    c) Other factors (specify) 3.....

14. Does this hospital have policies or guidelines governing implant removal?

    Yes ( ) No ( )

    If yes, specify.....

15. What would you recommend is the best time for implant removal?

    .....

    .....

**END: THANK YOU**

## APPENDIX C: Fomu Ya Idhini (Swahili Consent Form)

**Awali**

Jina langu ni Dkt. Mutiria Flavio Mugendi. Ningependa kukuambia kuhusu utafiti ninaofanya kuhusu dalili na changamoto za kuondolewa kwa vipandikizi kufuatia osteosynthesis ya mifupa mirefu katika hospitali nne za mijini (Hospitali ya Kitaifa ya Kenyatta, Hospitali ya Nairobi, Hospitali ya Aga Khan na Hospitali ya Kikuyu) nchini Kenya. Fomu hii ya idhini itakupa taarifa utakayohitaji ili kuamua kama unapaswa kushiriki katika utafiti au la. Jisikie huru kuuliza maswali yoyote kuhusu madhumuni ya utafiti huu, nini kitatokea ukishiriki, hatari na manufaa yanayoweza kutokea, haki zako kama mtu aliyejitolea, na kitu kingine chochote kinachohusiana na utafiti.

**Usuli wa Utafiti**

Osteosynthesis ni matibabu ya mivunjiko ya mfupa ambapo vipande vya mfupa huunganishwa kwa skrubu, sahani au misumari. Uimarishaji wa fracture kwa matumizi ya metali umetumika sana tangu Vita vya Pili vya Dunia. Kufuatia uponyaji wa fracture, swali linatokea kama kuondoa implant au kuacha katika situ. Ni katika juhudi za kukabiliana na pengo hili ambapo utafiti huu unalenga kuandika dalili tofauti zinazotumika katika uondoaji wa vipandikizi na changamoto zilizojitokeza wakati wa kuondolewa kwa upasuaji wa vipandikizi. Ujuzi huu utawaongoza madaktari wa upasuaji wanapokaribia uamuzi wa kuondoa au kuacha implant katika situ. Ujuzi huo pia utawapa madaktari wa upasuaji na changamoto zinazowezekana ambazo zinaweza kupatikana wakati wa kuondolewa.

**Madhumuni Mapana**

Kuelezea dalili na changamoto za kuondolewa kwa vipandikizi vya mifupa miongoni mwa wagonjwa wanaofanyiwa upasuaji wa kupandikizwa kufuatia osteosynthesis ya mifupa mirefu katika hospitali nne za mijini (Hospitali ya Kitaifa ya Kenyatta, Hospitali ya Nairobi, Hospitali ya Aga Khan na Hospitali ya Kikuyu) nchini Kenya.

**Taratibu za Utafiti**

Utaombwa kujibu hojaji zinazosimamiwa na mhojaji na pia baadhi ya data itarejeshwa kutoka kwa rekodi zako. Habari hii itaandikwa katika dodoso la msimbo bila majina au kitambulisho chako chochote cha kibinafsi. Unaweza pia kuombwa kushiriki katika majadiliano na wasaidizi wa utafiti ili kukusanya taarifa kuhusu afya yako kwa ujumla na changamoto za kurekebisha mipasuko. Mchakato mzima unaweza kuchukua angalau saa moja. Hata hivyo tunaomba idhini yako ya kushiriki katika utafiti huu.

**Hiari ya Kushiriki**

Makubaliano yako ya kushiriki katika utafiti huu ni ya hiari kabisa. Una chaguo la kujiondoa kwenye utafiti wakati wowote iwapo hujisikii vizuri kujibu maswali katika utafiti huu na hutadhulumiwa au kunyimwa manufaa au huduma zozote unazostahili kupata katika hospitali hii. Zaidi ya hayo, utaruhusiwa kuuliza maswali yoyote yatakayokuwezesha kuelewa asili ya utafiti huu.

**Usiri**

Faragha na usiri mkali utahakikishwa wakati wa mchakato wa kukusanya data na baada ya utafiti. Mtafiti ataweka taarifa zote kuhusu washiriki kwenye utafiti peke yake; washiriki hawapaswi kuandika majina yao kwenye dodoso. Matokeo ya utafiti yatawasilishwa kwako, ikiwa unataka, kupitia anwani zako.

**Manufaa ya Kushiriki**

Utafiti huu unaweza usikufaidishe moja kwa moja lakini utasaidia hospitali zinazotoa huduma za mifupa kuunda sera ambazo zitakuza uondoaji na utunzaji wa vipandikizi kwa upasuaji. Unaweza kufaidika na utafiti kwa kupokea elimu ya afya bila malipo na taarifa kuhusu umuhimu wa mahitaji ya lishe, inapohitajika tutakuelekeza kwa hospitali kwa ajili ya uangalizi na usaidizi.

**Hatari za Kushiriki**

Utafiti huu wa utafiti wa kimatibabu una uwezo wa kuwajulisha washiriki hatari za kisaikolojia, kihisia na kimwili. Walakini, juhudi zitawekwa ili kupunguza hatari. Hii ni pamoja na, uchunguzi wa usiri kamili kwa kila taarifa itakayotolewa, data itapatikana kwa wachunguzi-shirikishi pekee. Hisia zako na maoni yako ya kibinafsi yataheshimiwa. Vikao vya mwongozo na ushauri vitatolewa kwa wale wanaohitaji vikao na idara ya ushauri katika kituo.

**Haki ya Kujitoa Kwa Utafiti**

Kushiriki kwako katika utafiti huu ni kwa hiari kabisa. Uko huru kuondoka kwenye utafiti wakati wowote bila kulazimika kutoa sababu. Kukataa au kujiondoa katika utafiti huu hakutakuwa na athari kwa huduma unazostahili kupata katika kituo hiki au kingine chochote.

**Fidia**

Hakutakuwa na fidia kwa kushiriki katika utafiti.

**TAARIFA YA RIDHAA**

**Taarifa ya mshiriki**

Nimesoma fomu hii ya idhini au nimesomewa maelezo. Nimepata nafasi ya kujadili utafiti huu na mtafiti. Nimejibiwa maswali yangu kwa lugha ninayoielewa. Hatari na faida zimeelezewa kwangu. Ninaelewa kuwa ushiriki wangu katika utafiti huu ni wa hiari na kwamba ninaweza kuchagua kujiondoa wakati wowote. Ninakubali kwa uhuru kushiriki katika utafiti huu. Ninaelewa kuwa juhudi zote zitafanywa ili kuweka taarifa kuhusu utambulisho wangu wa kibinafsi kuwa siri.

Kwa kutia saini fomu hii ya idhini, sijaacha haki zozote za kisheria nilizo nazo kama mshiriki katika utafiti wa utafiti.

a) Ninakubali kushiriki katika utafiti huu: Ndiyo ( ) Hapana ( )

b) Ninakubali kutoa maelezo ya mawasiliano kwa ufuatiliaji: Ndiyo ( ) Hapana ( )

Jina lililochapishwa la mshiriki

Sahihi ya mshiriki / mhuri ya kidole gumba _____Tarehe _____

**Taarifa ya mtafiti**

Mimi, niliyetia saini hapa chini, nimeeleza kikamilifu maelezo muhimu ya utafiti huu kwa mshiriki aliyetajwa hapo juu na ninaamini kuwa mshiriki ameelewa na ametoa ridhaa yake kwa hiari na kwa uhuru.

Jina la Mtafiti _____ Tarehe _____

Saini_____

Dhima katika utafiti _____ [i.e. wafanyakazi wa utafiti walioeleza fomu ya idhini iliyo na taarifa.]

Kwa maelezo zaidi wasiliana na _____ kwa _____

kutoka _____ hadi _____

Jina Lililochapishwa na Shahidi (Ikiwa shahidi ni muhimu, Shahidi ni mtu anayekubalika kwa pande zote mbili kwa mtafiti na mshiriki)

Jina _____ Maelezo ya mawasiliano

Saini/Muhuri wa kidole gumba_____Tarehe;_____

**Kwa maelezo zaidi kuhusu utafiti huu, wasiliana na mmojawapo wa wafuatao;**

| | | | |
|---|---|---|---|
| Dr. Mutiria Flavio Mugendi<br>M.Med<br>Registrar,<br>Tel; +254722 839 378<br>drmugendi@gmail.com | Prof. John E.O Ating'a<br>Professor,<br>Department of Orthopaedic Surgery,<br>P.O Box 19370, Nairobi<br>Email:atinga08@gmail.com | KNH-UON ERC secretary<br>Tel no. 2726300, Ext; 44102,<br>Email:uonknh_erc@uonbi.ac.ke. | AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136 |

## APPENDIX D: Swahili Questionnaire

**DODOSO KWA WAGONJWA**

Kichwa cha Utafiti: Dalili na Changamoto za Kuondolewa kwa Kipandikizi cha Mifupa Mirefu Baada Ya Kupandikiza Mfupa Katika Hospitali Nne za Mjini Nchini Kenya

Nambari ya Wajibu ……

**SEHEMU YA KWANZA: MAMBO YA DEMOGRAFI**

Sehemu hii ina maswali kuhusu demografi yako. Tafadhali jibu maswali yote kwa kuweka tiki au kamilisha katika nafasi zilizoachwa.

1. Jinsia yako ni nini?

Mwanaume ( ) 1 Mwanamke ( ) 2 Mwenye jinsia mbili ( ) 3

2. Una umri gani?

Miaka 18-24 ( ) 1 Miaka 24- 34 ( ) 2 Miaka 35-64 ( ) 3 Zaidi ya miaka 65 ( )4

3. Hali yako ya ndoa ikoje?

Sija ( ) 1 Ndoa ( ) 2 Umetengana ( ) 3 Umetalikiana ( ) 4

4. Kiwango chako cha juu zaidi cha elimu ni kipi?

Chuo Kikuu ( ) 1 Elimu ya Juu/Ufundi ( ) 2 Sekondari ( ) 3 Msingi ( ) 4 Isiyo rasmi ( ) 5

5. Ni aina gani ya kazi yako?

Ajira rasmi ( ) 1 Kazi ya kawaida ( ) 2 Biashara ( ) 3 Mama wa nyumbani ( ) 4 Nguvu kazi ya nje ( ) 5 Mwanafunzi ( ) 6 Hajaajiriwa ( ) 7

6. Mapato yako ya kila siku ni yapi?

Chini ya Kshs 100 ( ) 1 Kshs 101-200 ( ) 2 Kshs 201-500 ( ) 3 Kshs 501-800 ( ) 4 Kshs 801-1,100 ( ) 5 Zaidi ya Kshs 1,101 ( )

7. Je, una hali yoyote iliyokuwepo hapo awali?

Ndiyo 1 ( ) Hapana 2 ( ) Kama ndiyo, taja..... .....

8. Mahali pa kupandikiza katika mwili wa mgonjwa?

..... .....

9. Umekaa kwa muda gani na upandikizaji wa mifupa?

..... .....

**SEHEMU YA PILI: VIASHIRIA VYA KUONDOA KIPANDE CHA MIFUPA**

10. Sehemu hii ina maswali kuhusu dalili za kuondolewa kwa implant ya mifupa. Tafadhali jibu maswali yote kwa kuweka tiki au kukamilisha katika nafasi zilizotolewa.

| Kipengee | Ndiyo 1 | Hapana 2 |
|---|---|---|
| Ninahisi maumivu katika sehemu ya kupandikiza | | |
| Kuna uvimbe kwenye sehemu ya kupandikiza | | |
| Kuna ugumu wa sehemu ya kupandikiza | | |
| Kuna maambukizi katika sehemu ya kupandikiza | | |
| Mara nyingi mimi hupata mwasho/ kupandikiza umaarufu | | |
| Nimepandikizwa Malunion-fracture imepona, lakini imepona katika hali isiyofaa | | |
| Nilimwomba daktari aondoe kipandikizi kwa sababu kinaumiza | | |

**SEHEMU YA TATU: CHANGAMOTO ZA KUONDOA KIPANDE CHA UPASUAJI**

11. Sehemu hii ina maswali kuhusu changamoto za kuondolewa kwa vipandikizi kwa upasuaji.

(Maelezo haya yanapaswa kurejeshwa kutoka kwa rekodi za mgonjwa)

| Kipengee | Ndiyo 1 | Hapana 2 |
|---|---|---|
| Kipandikizi kilichovunjika | | |
| Kukua zaidi kwa mifupa | | |
| Kuchomelea kwa baridi | | |
| Sahani za kufunga | | |

| | | |
|---|---|---|
| Kuunganisha nyuzi | | |
| Kutolingana | | |

**SEHEMU YA NNE: SIFA ZA VIPANDISHI VILIVYOVUNJIKA**

12. Sehemu hii ina maswali juu ya sifa ya vipandikizi vilivyovunjika vilivyoondolewa kutoka kwa wagonjwa. (Maelezo haya yanapaswa kurejeshwa kutoka kwa rekodi za mgonjwa au kupitia tathmini ya daktari)

| **Kipengee** | **Ndiyo 1** | **Hapana 2** |
|---|---|---|
| Kushindwa kwa mitambo | | |
| Kushindwa kwa mitambo | | |
| Kushindwa kwa uchovu | | |
| Kuvunjika tena | | |
| Kuvunjika kwa uharibifu | | |
| Nyufa | | |
| Kutu | | |
| Kuchomelea kwa baridi | | |

**SEHEMU YA TANO: AZIMIO LA KUONDOA KIPANDE**

13. Ni nini kilichangia uamuzi wa kuondoa kipandikizi kutoka kwa mgonjwa?

a) Dalili za kuondolewa kwa vipandikizi ( )$_1$

b) Changamoto za kuondolewa kwa vipandikizi ( )$_2$

c) Mambo mengine (taja)$_3$..... .....

14. Je, hospitali hii ina sera au miongozo inayosimamia uondoaji wa vipandikizi?

Ndiyo ( ) Hapana ( ) Kama ndiyo, taja..... .....

15. Je, ungependekeza ni wakati gani mzuri wa kuondolewa kwa implant?

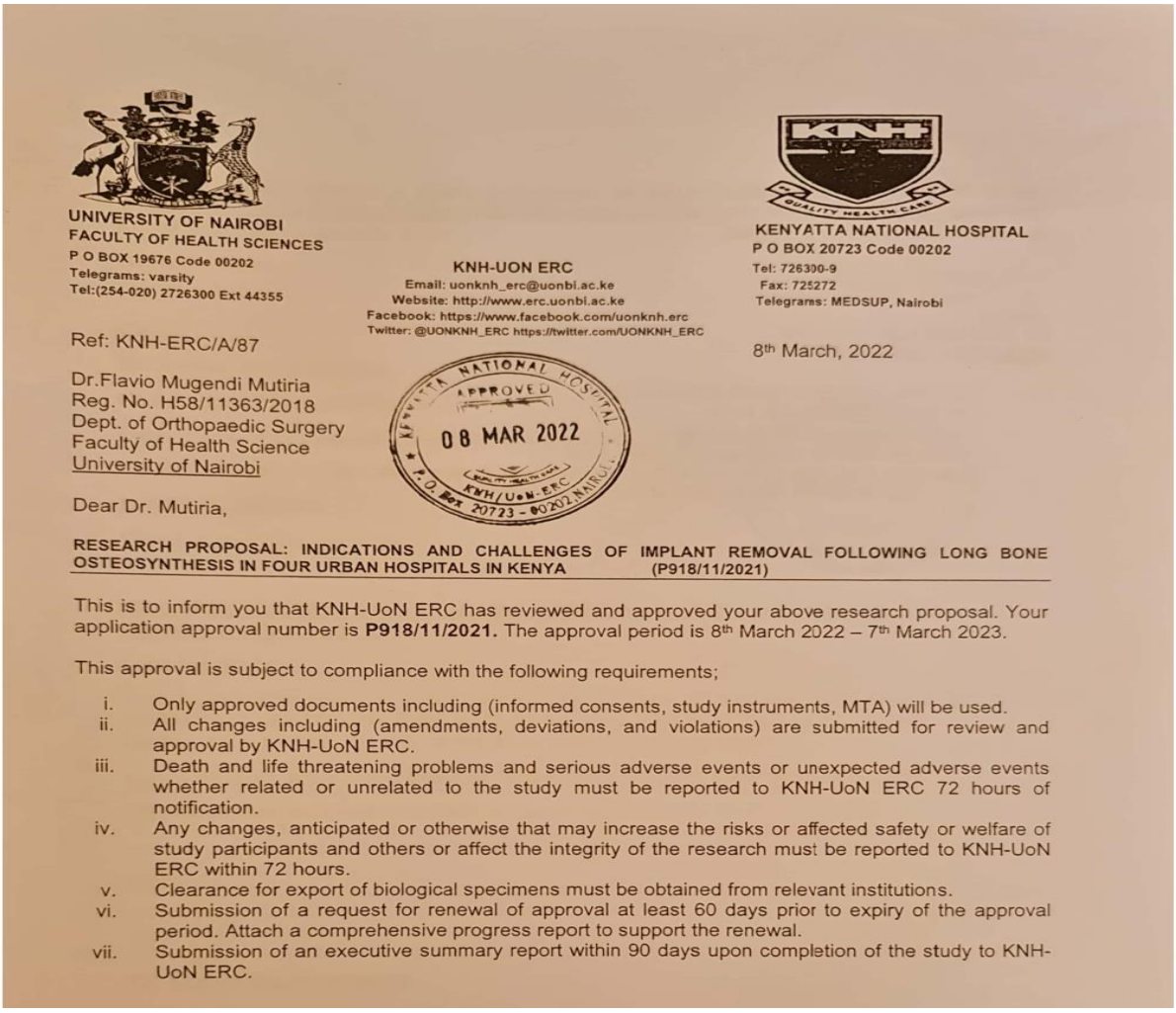
.....

..... .....

**MWISHO: ASANTE**

# APPENDIX E; Ethics and Research Committee approvals

## UON-KNH ETHICS APPROVAL



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KNH-UON ERC
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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/87

8th March, 2022

Dr.Flavio Mugendi Mutiria
Reg. No. H58/11363/2018
Dept. of Orthopaedic Surgery
Faculty of Health Science
University of Nairobi

KENYATTA NATIONAL HOSPITAL APPROVED 08 MAR 2022 KNH/UoN-ERC P.O. Box 20723 - 00202 NAIROBI

Dear Dr. Mutiria,

**RESEARCH PROPOSAL: INDICATIONS AND CHALLENGES OF IMPLANT REMOVAL FOLLOWING LONG BONE OSTEOSYNTHESIS IN FOUR URBAN HOSPITALS IN KENYA (P918/11/2021)**

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P918/11/2021.** The approval period is 8th March 2022 – 7th March 2023.

This approval is subject to compliance with the following requirements;

i. Only approved documents including (informed consents, study instruments, MTA) will be used.
ii. All changes including (amendments, deviations, and violations) are submitted for review and approval by KNH-UoN ERC.
iii. 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

## National Commission for Science, Technology and Innovation Licence

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: **985338**

Date of Issue: **02/April/2022**

### RESEARCH LICENSE

**This is to Certify that Dr.. FLAVIO MUTIRIA of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: INDICATIONS AND CHALLENGES OF IMPLANT REMOVAL FOLLOWING LONG BONE OSTEOSYNTHESIS IN FOUR URBAN HOSPITALS IN KENYA for the period ending : 02/April/2023.**

License No: **NACOSTI/P/22/16656**

**985338**

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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# The Aga Khan University Hospital ISERC Approval

THE AGA KHAN UNIVERSITY

Faculty of Health Sciences
*Medical College*

Ref: 2022/ISERC_41(v2)
April 27, 2022

Mordicai Ating'a –AKU Supervisor
Flavio Mugendi – MMed. Orthopedic Surgery
Department of Orthopedic Surgery
University of Nairobi
P.O. Box 30197-00100,
Nairobi, Kenya

Dear Dr. Mordicai Ating'a, Dr. Flavio Mugendi and team

**RE: INDICATIONS AND CHALLENGES OF IMPLANT REMOVAL FOLLOWING LONG BONE OSTEOSYNTHESIS IN FOUR URBAN HOSPITALS IN KENYA**

The Aga Khan University, Nairobi Institutional Scientific and Ethics Review Committee (ISERC), is in receipt of your protocol resubmitted to the Research Office (RO) on 21st April, 2022. The ISERC has reviewed and approved this project *{as per attached official stamped protocol and attachments - version Ref: 2022/ISERC_41(v2)*. You are authorized to conduct this study from **April 27, 2022**. This approval is valid until **April 26, 2023** and is subject to compliance with the following requirements;

1. The conduct of the study shall be governed at all times by all applicable national and international laws, rules and regulations. ISERC guidelines and Aga Khan University Hospital policies shall also apply, and you should notify the committee of any changes that may affect your research project (amendments, deviations and violations)
2. Researchers desiring to initiate research activities during COVID-19 pandemic must comply with the COVID-19 SOPs for Research as well as submit to the Research Office a Request Form to Initiate, Reinstate or Continue Research During COVID-19 Pandemic.
3. **Prior** to human subjects enrolment you must obtain a research license from the National Commission for Science, Technology and Innovation (NACOSTI), *where applicable*, site approvals from the targeted external site(s) and file the copies with the RO.
4. *As applicable*, **prior** to export of biological specimens/data, ensure a Material Transfer Agreement (MTA)/Data Transfer Agreement (DTA), is in place as well as seek shipment authority/permit from the relevant government ministry. Copies of these approvals, should be submitted to the RO for records purpose.
5. All Serious Adverse Events and the interventions undertaken must be reported to the ISERC as soon as they occur but not later than 48 hours. The SAE shall also be reported through the AKUHN quality monitoring mechanism(s) at Client Relations Department of the Chief of Staff's Office.
6. All consent forms must be filed in the study binder and where applicable, patient hospital record.
7. Further, you must provide an interim Progress Report Form **60 days before expiration** of the validity of this approval and request extension if additional time is required for study completion; as well as submit the completed Self-Assessment Tool -Monitoring Ethical Compliance in Research. You must advise the ISERC when this study is complete or discontinued and a final report submitted to the Research Office for record purposes.
8. The Aga Khan University Hospital management should be notified of manuscripts emanating from this work.

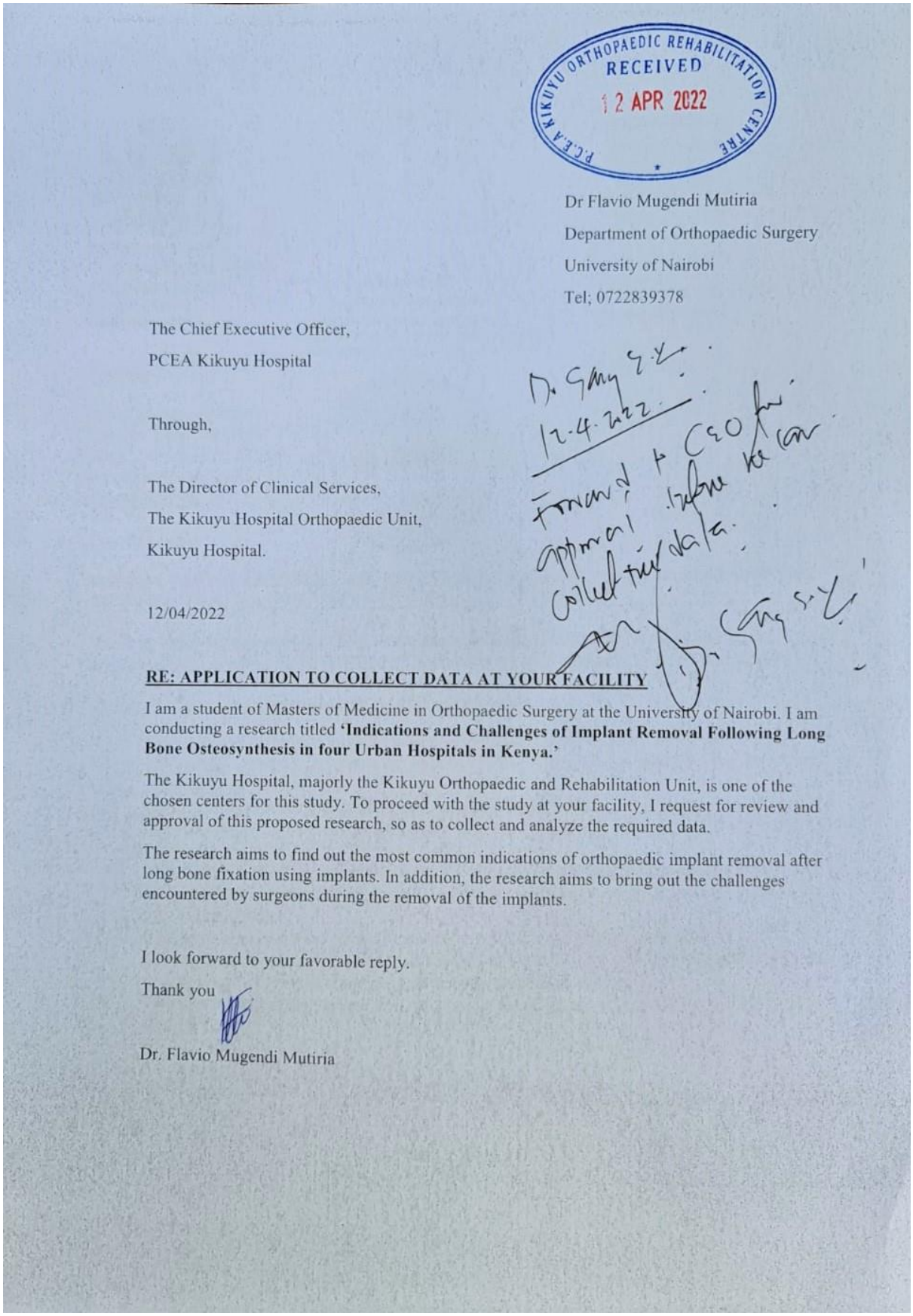
If you have any questions, please contact Research Office at AKUKenya.ResearchOffice@aku.edu or 020-366 2148/1136.

With best wishes,

Dr. Christopher Opio,
Chair – Institutional Scientific and Ethics Review Committee (ISERC)
**Aga Khan University, (Kenya)**

*3rd Parklands Avenue, off Limuru Road, P. O. Box 30270, GPO 00100, Nairobi, Kenya*
*Telephone: +254 20 366 2107/2109; Fax: +254 20 374 4035*

**APPENDIX C; The Kikuyu Hospital Ethics Approval**



P.C.E.A KIKUYU ORTHOPAEDIC REHABILITATION CENTRE
RECEIVED
12 APR 2022

Dr Flavio Mugendi Mutiria
Department of Orthopaedic Surgery
University of Nairobi
Tel; 0722839378

The Chief Executive Officer,
PCEA Kikuyu Hospital

Through,

The Director of Clinical Services,
The Kikuyu Hospital Orthopaedic Unit,
Kikuyu Hospital.

12/04/2022

Dr. Gmy S.Y.
12.4.2022
Forward to CEO for approval to collect the data.
Dr. Gmy S.Y.

**RE: APPLICATION TO COLLECT DATA AT YOUR FACILITY**

I am a student of Masters of Medicine in Orthopaedic Surgery at the University of Nairobi. I am conducting a research titled **'Indications and Challenges of Implant Removal Following Long Bone Osteosynthesis in four Urban Hospitals in Kenya.'**

The Kikuyu Hospital, majorly the Kikuyu Orthopaedic and Rehabilitation Unit, is one of the chosen centers for this study. To proceed with the study at your facility, I request for review and approval of this proposed research, so as to collect and analyze the required data.

The research aims to find out the most common indications of orthopaedic implant removal after long bone fixation using implants. In addition, the research aims to bring out the challenges encountered by surgeons during the removal of the implants.

I look forward to your favorable reply.

Thank you

Dr. Flavio Mugendi Mutiria

# INDICATIONS AND CHALLENGES OF IMPLANT REMOVAL FOLLOWING LONG BONE OSTEOSYNTHESIS IN FOUR URBAN HOSPITALS IN KENYA

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DR V.M. MUTISO
24/08/2022