UNIVERSITY OF NAIROBI

HEALTH-RELATED QUALITY OF LIFE IN ADULT PATIENTS WITH EXTERNAL FIXATION DEVICES SEEN AT KENYATTA NATIONAL HOSPITAL AND AIC KIJABE HOSPITAL

BY

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A dissertation to be submitted in partial fulfilment of the requirements for the award of the degree of Master of Medicine (M. Med) in Orthopaedic Surgery at the University of Nairobi.

DECLARATION

This dissertation is my original work. It has not been presented in any other university in partial fulfilment of requirements for the award of a degree.

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DEDICATION

To my family and friends for your prayer and support.

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LIST OF ABBREVIATIONS

ADLs – activities of daily living

ANOVA – Analysis of variance

EQ-5D - European Quality of Life 5-Dimension

EuroQoL - European Quality of Life

EXOFIX – External fixator

HRQOL – Health-related quality of life

KH IERC - AIC Kijabe Hospital Institutional Ethics Review Committee

KNH – Kenyatta National Hospital

KNH-UON ERC- Kenyatta National Hospital – University of Nairobi Ethics and Research Committee

LRS – Limb Reconstruction System

QOL – Quality of life

QWB-SA - Quality of Well Being Questionnaire

SF-36 Short Form – 36 tool

SF-12 - Short Form – 12 tool

SPSS - Statistical Package for Social Sciences

TSF – Taylor Spatial Frame

WHO-QOL BREF - World Health Organization Quality of Life

WHO – World Health Organization

UON – University of Nairobi

OPERATIONAL DEFINITIONS

External fixation – This is a surgical procedure that involves the percutaneous placement of metal pins or wires into the bone, they are then attached to a rigid external frame to keep them in place.

Health-related quality of life (HRQOL) - The aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment'.

Quality of life (QOL) - An individual's perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns.

ABSTRACT

BACKGROUND; External fixation of bone involves placement of pins or wires inserted percutaneously through small skin incisions into bone then held externally with a framework of clamps and metal rods or rings. External fixators have been in use over the last 2 centuries. They have shown excellent outcomes in the management of fractures, bone deformities and bone loss.

By contrast, these devices can potentially interfere with a patient's daily life and ability to accomplish activities of daily living (ADLs). This can lead to a significant impact on the patient's health-related quality of life (HRQOL). This may be due to their placement externally and prolonged treatment duration in indications such as deformity correction, bone loss management, and definitive fracture treatment.

STUDY OBJECTIVES; To determine the perceived health-related quality of life (HRQOL) in patients with external fixation devices.

METHODOLOGY; This was a descriptive cross-sectional study carried out at Kenyatta National Hospital (KNH) and AIC Kijabe Hospital. 78 patients were consecutively recruited. Data on patient demographics as well as HRQOL was collected using a structured questionnaire and the World Health Organization Quality of Life BREF (WHOQOL BREF) validated tool. Analysis was done using Statistical Package for Social Sciences (SPSS) Version 22.

RESULTS; 78 patients were recruited. The mean age of the patients was 33.1±9.6. The majority of them were male (76.9%) with about half being unemployed. Their area of residence was equally distributed between rural and urban. 92% of the patients had the uniplanar external fixator with hybrid and circular external fixators being 4% each. About 1/3 of the patients had the external fixation device for <6 weeks with a further 1/3 having the device for between 6 and 12 weeks. The remaining 1/3 of patients had the device for >12 weeks.

More than half of the patients rated their overall quality of life as poor or very poor with about 2/3 being dissatisfied with their overall health. All the WHOQOL BREF domain scores were low, corresponding to a low HRQOL (physical 24.5±11.9, psychological 48.2±14.2, social relationships 41.6±17.2 and environmental 36.7±11.4). There was no statistically significant

association between HRQOL domain scores and the type as well as the duration of external fixation. (p-value >0.05 in all domains)

CONCLUSION; Patients on management with external fixation devices have a low health-related quality of life. This study found no association between HRQOL and the type as well as the duration of external fixation.

Due to the HRQOL impact of these devices, a multidisciplinary team approach should be employed in the management of these patients. Efforts should be made to avoid prolonging the duration of treatment with these devices and alternative forms of management should be considered where possible.

CHAPTER 1: INTRODUCTION

1.1. BACKGROUND

Management of bone fractures and deformities has evolved remarkably over the years. Around 400BC, Hippocrates held the opinion that immobilization should follow fracture alignment to allow for healing. (1) He achieved this by use of Egyptian leather straps with interconnecting rods made of English dogwood. (2)

As the field of orthopaedics advanced, new fracture management techniques were invented including external fixation techniques.

External fixation involves the management of fractures and other bone deformities by the placement of pins or wires inserted percutaneously into bone. They are then held externally with a framework of clamps and metal rods or rings.

External fixators have been in use since the 19th century. Malgaigne (1843) invented the first external fixation device. (1) This underwent changes over the years and in the 1950s, Ilizarov invented a ring external fixator. (3)

External fixators play a crucial role in bone deformity and fracture management today. They are used in temporary fracture fixation and definitive fracture management. They are excellent devices in damage control. Their use minimizes surgical trauma hence preventing "2nd hit" in acute trauma as well as allowing soft tissue swelling to subside. (4) Numerous studies have described their excellent outcomes in indications such as limb lengthening, management of bone loss and infection control in bone. (5–8)

By contrast, because of their placement externally and for a potentially prolonged duration in specific indications, (8) external fixation devices can interfere with the activities of daily living. Moreover, they are cumbersome, uncomfortable and call for attention in public spaces. This can potentially lead to depression and anxiety. (9) Increased responsibility of the caregiver for the care of these patients can result in stress within the family. (10)

Lower health-related quality of life (HRQOL) has been demonstrated in these patients. This has been done by use of HRQOL measurement instruments that look at the self-perceived status of

health and its constituents. This includes social, physical and psychological functioning as well as the presence of pain. (11–14)

Harris A. et al showed that outcome assessment by the surgeon in orthopaedic trauma did not correlate with patients' satisfaction. This is because the surgeon's assessment focused on objective data. This was different from the patient's own assessment. (15) Therefore, assessment of a patient's status during treatment is important. This enables matching of the surgeon's and the patient's assessment of outcome after treatment.

This study focused on the assessment of the health-related quality of life (HRQOL) in patients with external fixation devices. The study set up was within a developing country and the patient population within the study sites were mainly from the lower and middle socioeconomic class. They were likely to encounter unique challenges in their daily lives while on management with these devices. No studies had been conducted in a setup similar to ours.

1.2 STATEMENT OF RESEARCH PROBLEM

External fixation devices are commonly used in our setup for the management of fractures, bone loss and other bone deformities. Treatment in these patients is primarily focused on the outcome of the patients in terms of bone union and deformity correction. Little attention is given to these devices' physical, psychological, and social impact. Often, there is a mismatch between surgeon driven assessment and the patient's own assessment of the treatment process and outcome. (15)

1.3 STUDY QUESTION

What is the perceived health-related quality of life (HRQOL) in patients with external fixation devices seen at Kenyatta National Hospital and AIC Kijabe Hospital?

1.4 STUDY OBJECTIVES

1.4.1 BROAD OBJECTIVE

To determine the perceived health-related quality of life (HRQOL) in patients with external fixation devices.

1.4.2 SPECIFIC OBJECTIVES

1. To determine the perceived HRQOL in patients with external fixation devices
2. To establish the association between HRQOL and duration of external fixation.
3. To establish the association between the type of external fixator used and the perceived HRQOL.

1.5 STUDY JUSTIFICATION

External fixation has resulted in remarkable improvement in the management of open fractures as well as limb deformities and bone loss. These devices are used for prolonged periods in specific indications. This can potentially have a negative impact on the patient's physical, psychological and social well-being.

Establishing the health-related quality of life (HRQOL) in patients with external fixation devices will assist the orthopaedic surgeon in recognizing their physical, psychological and social impact.

This should encourage a multidiscipline team approach in these patients before, during and after treatment to maximize the treatment benefit and limit morbidity.

1.6 CONCEPTUAL FRAMEWORK

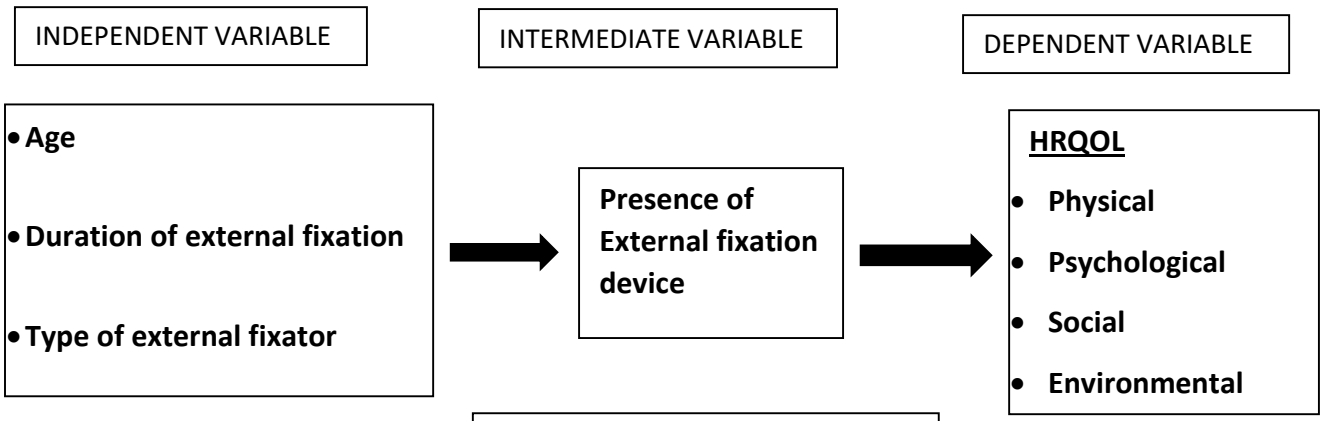

Figure 1: Conceptual Framework

CHAPTER 2: LITERATURE REVIEW

2.1 HISTORY OF EXTERNAL FIXATOR DEVICES

The first use of external fixators has been traditionally attributed to Malgaigne (1843). He invented a device consisting of two hooks attached to an external screw. This was used in the management of transverse patella fractures. However, Lambotte in 1902 devised a fixator considered by many to be the first 'real fixator'.(1) He used two pins fixed to the cortex on either side of the fracture clamped together by two longitudinal plates. Hoffman in 1938 devised a technique of closed reduction and percutaneous pin placement based on a fixator designed with adjustable knobs. (1) Gavril Ilizarov in the 1950s invented a multi-planar ring fixator used in the management of fractures, deformities and bone defects. (3) The Taylor spatial frame (TSF) is a modern ring fixator with hexapod struts. It has the ability to correct deformities in six-axis simultaneously. It was created by the Taylor brothers in 1994. (16)

2.2 TYPES OF EXTERNAL FIXATORS

There are three types of external fixators; uniplanar external fixators, ring external fixators and hybrid external fixators. (17)

2.2.1 UNIPLANAR EXTERNAL FIXATOR

Uniplanar external fixators are composed of Schanz pins fixed in a bi-cortical manner above and below the fracture site. The pins are then connected to a rod (stainless steel or carbon fibre) via clamps. This setup is in a single plane. Uniplanar fixators are applied in diaphyseal fractures of long bones. (17)

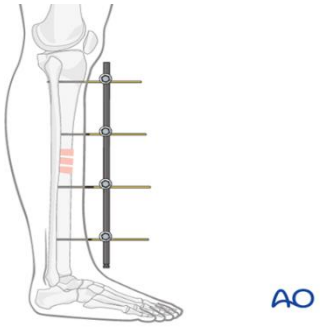

Figure 2. Uniplanar external fixator. Adapted from AO surgical reference

Frame constructs

The uniplanar external fixator can be applied in different configurations for varied indications. These include;

a) Joint spanning external fixator

   This is applied when fixation is required across a joint.

b) Modular external fixator

   This allows for fracture reduction in all planes. Schanz pins are inserted into each fragment and connected by a rod to make a partial frame. It is composed of 2 partial frames in each fragment interconnected by a rod.

c) Lengthening frames

   These frames apply the principle of distraction osteosynthesis. (18) Slow lengthening can be done with uniplanar fixators. Their limitation is the inability to correct angular deformities as well as malrotation simultaneously. Lengthening can be performed with an intramedullary nail in situ to overcome this disadvantage. (17)

d) Hinged external fixators

   This external fixator construct is used in spanning joints to maintain reduction in dislocations or fracture-dislocations. They allow calibrated motion across the joint. Early joint motion prevents stiffness. The elbow joint is a common site for hinged external fixators. (17)

2.2.2 RING EXTERNAL FIXATORS

The ring external fixator is composed of Kirshner wires or olive wires passing through bone under tension applied to circular or semicircular frames. The frames can also be attached to the bone via half pins. The circular frames are then interconnected by rods.

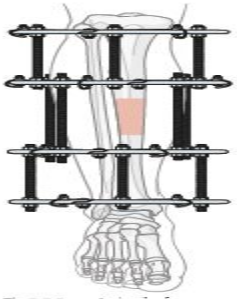

Figure 3. A circular external fixator on the tibia. Adapted from AO surgical reference

The ring fixator was first used by Gavril Ilizarov in the 1950s. (3)

It provides a stable fixation that allows for early weight-bearing. This allows for compressive loading and micro-motion at the fracture site that provides an optimum mechanical environment for healing. (19)

Using Ilizarov's principles, newer types of ring fixators have been developed. A variant developed by Dr. Charles Taylor and others (the Taylor Spatial Frame - TSF) is composed of rings attached to the bone with half pins. These rings are interconnected with six struts that can be adjusted and allow for computer-assisted correction of a deformity. (16) The Ortho-SUV frame; another variant of the original circular frame; is a novel computer-aided hexapod fixator. It has a customizable construction that can be easily adapted to a limb. (20)

2.2.3 HYBRID EXTERNAL FIXATOR

This fixator has a circular frame combined with a uniplanar set-up. It is applied in peri-articular fractures where the k-wires under tension holding the fragments are applied onto a ring. The ring is then attached to a uniplanar fixator along the diaphysis. (17)

Figure 4. A hybrid external fixator on the tibia. Adapted from AO surgical reference

2.3 INDICATIONS OF EXTERNAL FIXATORS

Clinicians have been using external fixators for the management of bone pathology for more than two centuries. It was first described by Hippocrates as a tool for fracture immobilization with soft tissue preservation. While the designs and biomechanics have improved over time, the principles remain unchanged. (4) The indications are as follows;

2.3.1 DAMAGE CONTROL ORTHOPAEDICS

The use of external fixators immediately after injury in polytrauma patients prevents the “second hit” phenomenon. Their application is quick, percutaneous and has little blood loss. This allows time for soft tissue swelling to decrease as well as management of other systemic life-threatening injuries. (4)

The external fixator is thereafter converted to internal fixation or used definitively for fracture management.

2.3.2 OPEN FRACTURE MANAGEMENT

The introduction of external fixators has resulted in marked improvement in the management of open fractures. Open fractures are classified as described by Gustillo and Anderson. (21) The goals of open fracture treatment are infection prevention, fracture stabilization and soft tissue coverage. Debate continues about the optimum method of fracture stabilization in Gustillo Anderson I and II fractures. (22) External fixators are particularly useful in Gustillo Anderson III fractures. (17)

External fixators have been used successfully in the definitive treatment of open fractures particularly in limited-resource areas. O Bach et al while using external fixation in open fracture management in a hospital in Malawi found that 80% of patients retained a functional extremity. These results were not significantly different from those seen in settings with adequate resources. (23) Abduljabbar Alhammoud et al during the Syrian war used external fixators for definitive management of long bone fractures. He found this to be reliable in times of wars, conflicts and in limited-resource settings. They had up to 70% union rate of tibia fractures. (24) External fixators continue to be used in our low resource set-up for definitive management of open fractures despite the challenges faced.

2.3.3 LIMB DEFORMITY CORRECTION, LENGTHENING AND BONE LOSS MANAGEMENT

Limb lengthening can be achieved by the application of distraction osteosynthesis principles studied by Ilizarov. (3) The principles continue to be used in bone reconstruction and treatment of fractures.

These principles are also employed in the management of bone loss. Abdel-Aal et al demonstrated use of the Ilizarov frame in management of bone loss ranging from 7cm to 22cm. (6)

The Taylor spatial frame (TSF) is used in the multiaxial correction of deformity. (16)

2.3.4 COMMINUTED PERI-ARTICULAR FRACTURES

The goal of external fixation in peri-articular fractures is length restoration, bone fragments reduction by ligamentotaxis and temporary stabilization to allow for a reduction in soft tissue swelling.

External fixation is used in the treatment of these fractures. Hybrid external fixators have been used successfully in the definitive management of tibial plateau fractures. (25)

2.3.5 ARTHRODESIS

Joint arthrodesis in a functional position can provide an option for joint salvage in extensive peri-articular bone loss and joint deformities. Bony union has been achieved in joints affected by active chronic infection by the use of external fixation. The Ilizarov frame has been shown to be an effective technique in achieving joint fusion. (26)

2.3.6 SOFT TISSUE DISTRACTION IN JOINT STIFFNESS

External fixators were originally applied in bone stabilization. Over time, their application has been extended to provide an alternative method of management for soft tissue problems. This is through the application of the principles of distraction histogenesis. (27) Hinged external fixators have been successfully used in the arthrolysis of stiff joints. (28,29)

2.3.7 BONE INFECTION

In chronic osteomyelitis, external fixation devices can be used to stabilize bone following extensive debridement of dead bone. (8) In cases of osteomyelitis with the presence of hardware,

hardware removal is often done. This is then followed by the placement of an external fixator to restore mechanical stability across the infected non-union. (30) (31)

2.4 COMPLICATIONS OF EXTERNAL FIXATORS

Common complications include; pin loosening, pin tract infection, iatrogenic soft tissue injury, nonunion, delayed union, iatrogenic fractures and poor tolerance by patients.

Some of the complications are discussed below.

2.4.1 PIN TRACT INFECTION

Infection along the pin tract is the commonest complication of external fixators. Abdullahi et al (2017) found pin tract infection rates to be high as 87.7% in patients admitted to KNH. (32) Studies in other settings are comparable.

2.4.2 PIN LOOSENING

Pin and wire loosening interferes with bone stabilization. It can occur in association with pin tract infection. Self-drilling pins have been shown to have 25% less purchase and are more likely to loosen. Predrilling the cortex to avoid thermos-necrosis is one strategy that can be employed to avoid early loosening. Other techniques for improving pin–bone interphase include using larger diameter pins as well as the use of hydroxyapatite-coated pins. (33)

2.4.3 IATROGENIC NEUROVASCULAR INJURY AND TENDON TRANSFIXATION

Neurovascular injury and tendon transfixation can occur as a result of poor pin positioning. This can be avoided by a good knowledge of anatomy and the use of safe corridors. (34)

2.4.4 POOR TOLERANCE BY PATIENTS

Fracture management and deformity correction by external fixation is usually a lengthy process. The impact of these devices on the physical, social and psychological well-being of patients is often overlooked. The focus of this study was on the impact of these devices on the perceived HRQOL in patients as discussed below.

2.5 HEALTH-RELATED QUALITY OF LIFE (HRQOL) CONCEPT

2.5.1 DEFINITIONS

The WHO in the 1947 constitution defined health as '*a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity'*. Enjoyment of the highest attainable health is a right of every human. (35)

Health therefore includes physical, mental and social domains. (35) As medical advances are being made in the treatment of disease, it is logical to measure treatment outcomes not only by physical health but also in terms of improvement of quality of life.

Quality of life (QOL) was defined by WHO as *'an 'individuals' perception of their position in life in the context of the culture and value systems in which they live and in relation to their goals, expectations, standards and concerns'*. (36)

Health-related quality of life (HRQOL) is defined as *'those aspects of self-perceived well-being that are related to or affected by the presence of disease or treatment'.* (37) Understanding this concept is important in the management of a patient, assessing the prognosis of a disease and outlining the overall impact of the disease.

HRQOL measurement instruments look at the self-perceived status of health and its constituents such as social, physical and psychological functioning as well as pain.

2.5.2 HRQOL IN PATIENTS WITH EXTERNAL FIXATION DEVICES

The use of external fixation devices in the management of fractures and deformities has been shown to affect patients' QOL. In the assessment of outcomes of treatment in orthopaedic trauma, surgeons' satisfaction is often driven by objective data which does not correlate with patients' satisfaction. Patients' satisfaction is majorly driven by their perception of the treatment process as well as how the disease is affecting their QOL. (15) This shows the importance of looking at patients' status during the course of treatment.

Modin et al looked at twenty patients undergoing primary treatment of proximal/distal tibia fractures with Ilizarov external fixators. They assessed the post-operative impact of this treatment on the daily life of the patients. They found that the patients experienced major limitations in their

health-related life situation during the first month post-operatively. This was related to the accomplishment of activities of daily living and personal hygiene. (11)

Hrutkay et al looked at lower extremity lengthening and associated psychological aspects. They found that 14 out 22 children experienced psychological problems. They recommended that preoperative psychological preparation of the patient and family along with continued support during the treatment process be a routine protocol. These findings are similar to an integrative research review by Patterson et al that found that all studies reviewed reported psychological and behavioural changes in adolescents treated with external fixation devices. It was found that the preoperative preparation of patients was crucial in determining psychological health after treatment with external fixation devices. (38)

In an assessment of the quality of life and complications in different stages of bone transport using the short-form health survey score (SF – 36), Hu wang et al found that patients had reduced physical and mental wellbeing during treatment and that the mental component scores were still lower than the normal population at final follow up after treatment. They concluded that it was essential to explain to patients and their relatives the demanding nature of this treatment prior to the start of treatment to increase their compliance with the emotionally draining treatment. (13)

In Turkey, a study done on male patients with lower extremity external fixators found 93% of them to have sexual dysfunction after assessment with the Brief Sexual Function Inventory Tool (BSFI). This had an overall negative impact on their QOL. (39)

The importance of adaptive coping mechanisms in patients with external fixation devices was highlighted by Sandi et al. Maladaptive coping strategies such as denial and substance abuse were shown to lead to poorer QOL as well as depression and anxiety. (14)

The type of external fixation device was also found to correlate with the psychological impact of the treatment. Alimujiang et al compared the psychological impact of the orthofix limb reconstruction system (LRS) to the Ilizarov frame in the treatment of patients with bone defects and found that the orthofix LRS appeared to have a less negative psychological impact. They believed that the smaller size allowed for more normal activities, including sleep. (40)

Despite challenges associated with HRQOL faced by patients during treatment with external fixators, Ugaji et al found that the post-treatment mental component score (of the SF – 36) was

similar to the general population. This suggested that the treatment had enhanced overall health despite being based on external fixation. Better pain control, shortening of external fixation duration as well as mental health support were discussed as some of the factors that may improve treatment satisfaction. (41)

2.5.3 HRQOL ASSESSMENT TOOLS.

Several tools are available for measuring HRQOL. These include generic as well as disease-specific tools.

Examples of tools include the WHOQoL-100 (World Health Organization Quality of Life 100) WHOQoL BREF tool (World Health Organization Quality of Life BREF), SF-36 (Short Form - 36) tool, SF-12 (Short Form – 12) tool, QWB-SA (Quality of Well Being Questionnaire) EuroQoL (European Quality of Life) and EQ-5D (EuroQoL 5-Dimension).

2.5.3.1 THE WHOQOL BREF

The WHOQoL-100 is a quality of life assessment tool developed by the WHOQOL group. The WHOQoL BREF is an abbreviated version of the WHOQoL-100.

It contains 26 items. The first part of the tool has questions on self-rating of patients' own quality of life and health. The next part has questions used to calculate four domain scores which denote an individual's perception of QOL in each particular domain. The four domains are; physical, psychological, social and environment. Responses to questions within each domain use a 5-point scale. (36)

Scores for each domain are computed and converted to a 0 – 100 scale based on the WHOQOL manual. (36) A higher score indicates a better quality of life.

Table 1: WHOQOL BREF domains. Adapted from 'The World Health Organization Quality of Life group'

DOMAIN	FACET INCORPORATED WITHIN THE DOMAIN	
Physical Health	• Activities of daily living • Dependence on medicinal substances and medical aids • Energy and fatigue	• Mobility • Pain and discomfort • Sleep and rest • Work capacity
Psychological	• Body image and appearance • Negative feelings • Positive feelings • Self-esteem	• Spirituality/ religion/personal belief • Thinking, learning, memory and concentration
Social relationships	• Personal relationships • Social support	• Sexual activity
Environmental	• Financial resources • Freedom, physical safety and security • Health and social care; accessibility and quality • Home environment • Opportunity for acquiring new	• information and skill • Participation in and opportunities for recreation/leisure activities • Physical environment (Pollution/Noise/traffic/climate) • Transport •

The WHOQoL BREF development was a multi-national project. It was tested in 14 countries during its development phase. This includes Sub-Saharan African countries (Nigeria and Zimbabwe). It was based on a cross-culturally sensitive concept. The WHOQoL BREF is used in the assessment of a patient's overall satisfaction with their QOL and health as well as physical, psychological, social and environmental wellbeing. It has excellent psychometric properties such as validity and reliability. It has been translated into many languages and is available in Kiswahili. It therefore can be easily applied to our patient population.

This tool has been previously used in our setup in the assessment of HRQOL among patients with epilepsy (42) as well as in patients with diabetes. (43).

The WHOQoL BREF tool was therefore been chosen for the assessment of HRQOL in this study.

CHAPTER 3: METHODOLOGY

3.1 STUDY DESIGN

This was a descriptive cross-sectional study.

3.2 STUDY SETTING

This study was conducted in the orthopaedic clinics at Kenyatta National Hospital and AIC Kijabe hospital.

KNH is a level 6 referral hospital in Nairobi Kenya. It offers emergency and elective orthopaedic services. The orthopaedic clinic (clinic 5) runs five days a week. It is run by orthopaedic consultants as well are registrars within the orthopaedic department. The clinic attends to all orthopaedic patients on follow up as well as non-emergency orthopaedic patients presenting to KNH for the first time.

AIC Kijabe Hospital is a faith-based, tertiary teaching and referral hospital located in Kijabe off the Nairobi-Nakuru highway. It offers emergency as well as specialized elective orthopaedic surgery including limb reconstruction procedures. The orthopaedic clinic is run by orthopaedic consultants and orthopaedic registrars training in the facility. It runs 3 days a week (Monday, Wednesday and Friday) and reviews all orthopaedic patients on follow up and non-emergency first-time patients.

3.3 STUDY POPULATION

The study population comprised patients attending the orthopaedic clinic within the study facilities.

3.4 INCLUSION AND EXCLUSION CRITERIA

3.4.1 INCLUSION CRITERIA

- Participants over 18 years of age.
- Participants who give consent.
- Participants with a lower extremity external fixation device in-situ.

3.4.2 EXCLUSION CRITERIA

- Participants with cognitive inability to consent/respond to questions
- Participants with external fixation devices in other sites apart from the lower extremity.

- Participants with concurrent bone fractures on conservative management by other methods other than external fixation.

3.5 SAMPLE SIZE DETERMINATION

Sample size calculation was done using the Cochran's formula,

Where;

$$n = \frac{Z^2\sigma^2}{E^2}$$

Z= critical value for 95% confidence interval that is 1.96

σ = 22.5. This is the psychological domain standard deviation in a previous study. (14)

(This study utilized the WHOQOL BREF tool in the assessment of HRQOL in Patients with external fixation devices)

E= margin of error = 5, expected margin error of mean estimated from the psychological domain in previous studies (13,14,41)

$$n = \frac{1.96^2 X 22.5^2}{5^2}$$

n=78

3.6 SAMPLING PROCEDURE

Participants meeting the inclusion criteria were consecutively sampled until the sample size was achieved.

3.7 STUDY PROCEDURE

Eligible study participants were recruited from the clinics and A/E departments of the study sites. Informed consent (appendix 1-4) was sought from the participants meeting the inclusion criteria.

Data was collected using the structured data collection tool. (appendix 5-6)

Information on participants' demographics as well as the duration of external fixation was obtained from the participant. Information on the type of external fixation device was obtained by examination of the patient's external fixation device.

The WHOQOL BREF questionnaire was administered by the principal researcher and/or 2 trained research assistants.

3.8 DATA COLLECTION TOOL

The data collection tools were a structured questionnaire and the WHOQOL BREF form. (appendix 5 - 6)

The structured questionnaire collected information on participants' demographics as well as the type and duration of external fixation.

The validated WHOQOL BREF form collected information on participants' perceived HRQOL in four domains; physical, psychological, social and environmental; through a set of 26 questions. Responses used a five-point Likert scale enquiring 'how much', 'how satisfied', 'how completely' the participant was feeling in relation to the domain being investigated.

3.9 DEFINITION OF VARIABLES

Independent variables;

- Type of external fixation device
  This was categorized as; uniplanar, circular and hybrid
- Duration of external fixation
  This was categorized as; < 6weeks, 6 – 12 weeks, 12 – 24 weeks and > 24 weeks

Dependent variable

- The four HRQOL domain scores
  - Physical domain score
  - Psychological domain score
  - Social domain score
  - Environmental domain score

3.10 DATA ANALYSIS

Analysis was done using the IBM SPSS® version 26.

Analysis of HRQOL was done by transforming the domain scores of the WHOQOL BREF form into a linear scale (0-100) following the transformation guidelines. (Appendix 7) A higher score corresponds to a better QOL while a lower score corresponds to a poor QOL.

Categorical data was analyzed and presented as frequencies and percentages. Continuous data was presented as means and standard deviations.

Association between HRQOL and type as well as the duration of external fixation was established using the ANOVA test.

3.11 ETHICAL CONSIDERATIONS

Approval for this study was sought from the Kenyatta National Hospital – University of Nairobi Ethics and Research Committee (KNH-UON ERC) as well as the AIC Kijabe Hospital Institutional Ethics Review Committee (KH IERC). A copy of the approval has been attached in the appendices.

Written informed consent from the participants was obtained after an explanation of the objectives of the study.

Information collected about the participants was strictly confidential. Participants' information was coded and participants' names were not used. All physical information was under lock and key. All the information stored in soft copy was kept secured using a password.

3.12 STUDY RESULTS DISSEMINATION PLAN

Dissertation results shall be disseminated through the University of Nairobi (UON), Orthopaedic Surgery Unit library as well as the UON online repository. It shall thereafter be published in a peer-reviewed journal.

3.13 STUDY LIMITATIONS

Some limitations of the study included;

Illiterate participants may have had challenges giving consent and answering the WHOQoL BREF questionnaire.

3.14 DELIMITATION MEASURES

The principal researcher and the research assistants assisted in interpreting some of the items on the questionnaire.

The questionnaire was availed in Kiswahili language.

3.15 CONFLICT OF INTEREST

The investigators have no conflict of interest to declare.

CHAPTER 4: RESULTS

4.1 INTRODUCTION

A total of 78 patients with external fixation devices were recruited for the study.

4.2 DEMOGRAPHIC CHARACTERISTICS

The mean age of the patients was 33.1 (SD 9.6) years, where the minimum age was 18.0 years, and the maximum was 62.0 years. The median age was 32.0 (IQR 26.0 – 39.0) years.

The majority of the patients were male (76.9%) with females being only 23.1%.

About half of the patients recruited into the study were unemployed. 34.6% were self-employed with only 16.7% being employed. All patients had some level of education with 44.9% having attended secondary school. Only 16.7% of the patients had tertiary education.

The area of residence was almost equally distributed between rural and urban areas. (47.4% vs 52.6%)

Table 2: Demographic characteristics

	Frequency	**Percentage**
Age		
≤30	34	43.6
31 – 40	29	37.2
41 – 50	11	14.1
>50	4	5.1
Gender		
Male	60	76.9
Female	18	23.1
Employment		
Employed	13	16.7
Self-employed	27	34.6
Unemployed	38	48.7
Education		
Primary	30	38.5
Secondary	35	44.9
Tertiary	13	16.7
Residence		
Urban	41	52.6
Rural	37	47.4
Marital status		
Single	32	41.0
Married	43	55.1
Separated	3	3.8

4.2 TYPE OF EXTERNAL FIXATION DEVICE

The majority of the patients recruited into the study had uniplanar external fixators with only 8% having other types of external fixators (4% Hybrid and 4% Circular)

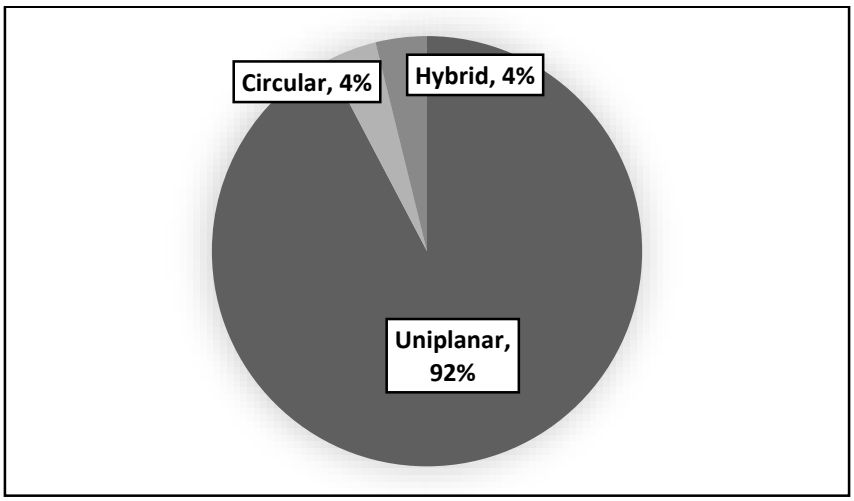

Figure 5: Type of external fixation device

4.3 DURATION OF EXTERNAL FIXATION

About 1/3 of the patients had the external fixation device for less than 6 weeks with a further 1/3 having the device for between 6 and 12 weeks. The remaining 1/3 of patients had the device for 13-24 weeks (19%) and >24 weeks (15%)

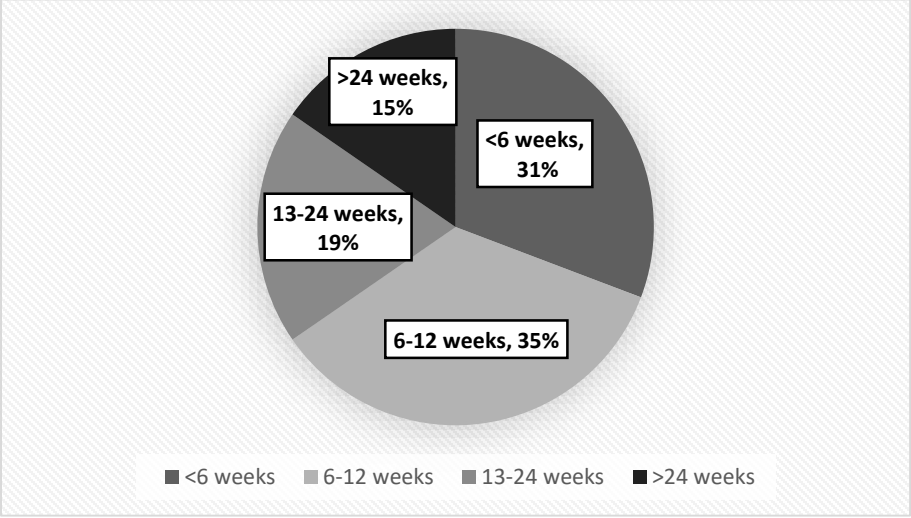

Figure 6: Duration of external fixation

4.4 HEALTH-RELATED QUALITY OF LIFE

4.4.1: OVERALL QUALITY OF LIFE

The patients were asked to rate their overall quality of life, and the responses in a 5 point Likert scale are shown in figure 7. More than half of the patients rated their overall QOL as poor or very poor with only 1.3% (n=1) rating their overall QOL as very good. About a third of the patients rated their QOL as neither poor nor good.

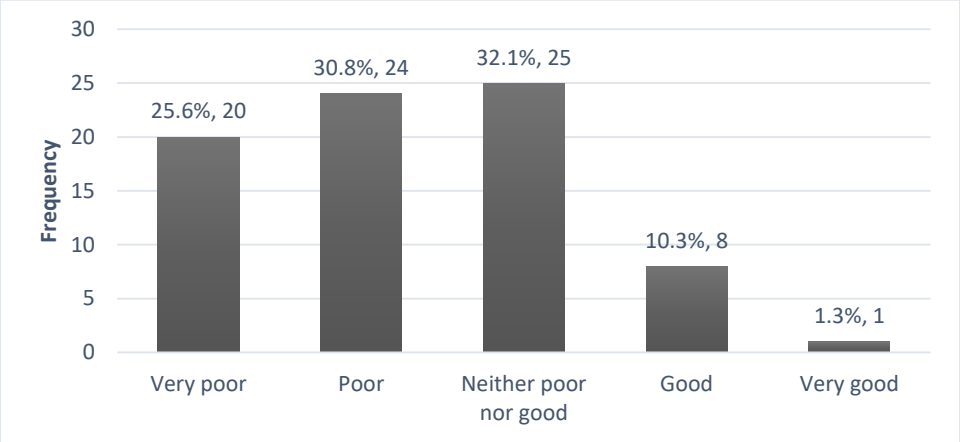

Figure 7: Overall quality of life

When asked to rate their level of satisfaction with their overall health, the majority of the patients were dissatisfied (37.2% n=29). About a quarter of the patients were very dissatisfied while 12.8% (n=10) were satisfied.

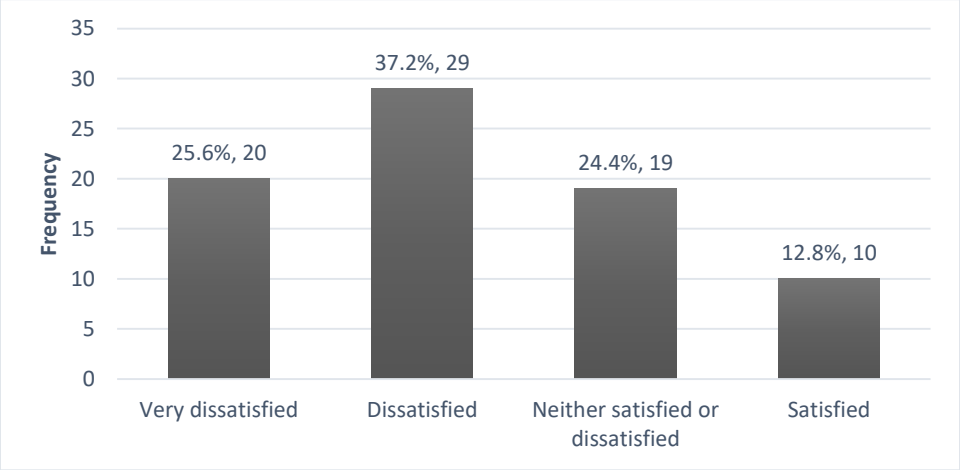

Figure 8; Overall satisfaction with health

4.4.2 WHOQOL BREF DOMAIN SCORES

Table 3: Selected facet responses for different WHOQOL BREF domains

	Frequency	Percentage
Physical capacity		
Pain and discomfort		
Not at all	1	1.3
A little	7	9.0
A moderate amount	9	11.5
Very much	41	52.6
An extreme amount	20	25.6
Psychological		
Self-esteem		
Very dissatisfied	7	9.0
Dissatisfied	17	21.8
Neither satisfied nor dissatisfied	31	39.7
Satisfied	18	23.1
Very satisfied	5	6.4
Bodily image and appearance		
Not at all	3	3.8
A little	19	24.4
A moderate amount	15	19.2
Very much	38	48.7
An extreme amount	3	3.8
Level of independence		
Mobility		
Very poor	22	28.2
Poor	27	34.6
Neither poor nor good	17	21.8
Good	12	15.4
Activities of daily living		
Very dissatisfied	40	51.3
Dissatisfied	31	39.7
Neither satisfied nor dissatisfied	6	7.7
Satisfied	1	1.3
Social relationships		
Sexual activity		
Very dissatisfied	25	32.1
Dissatisfied	36	46.2
Neither satisfied nor dissatisfied	13	16.7
Satisfied	3	3.8
Very satisfied	1	1.3
Environment		
Transport		
Very dissatisfied	8	10.3
Dissatisfied	27	34.6
Neither satisfied nor dissatisfied	33	42.3
Satisfied	9	11.5
Very satisfied	1	1.3

Table 4: WHOQOL BREF domain scores

	Mean±SD	Median (IQR)	Minimum	Maximum
Physical health	24.5±11.9	25.0 (14.3 – 32.1)	3.6	71.4
Psychological	48.2±14.2	52.1 (37.5 – 58.3)	8.3	70.8
Social relationship	41.6±17.2	41.7 (33.3 – 50.0)	0.0	91.7
Environment	36.7±11.4	35.9 (28.1 – 43.8)	6.3	62.5

4.5: ASSOCIATION BETWEEN HRQOL AND DURATION OF EXTERNAL FIXATION

Analysis of Variance (ANOVA) test was used to determine if there was an association between HRQOL and duration of external fixation. The p-value for all the 4 WHOQOL BREF domains was >0.05. Therefore, there is no statistical association between any of the HRQOL domains and the duration of external fixation.

Table 5: Association between HRQOL and duration of external fixation

	N	Physical health	Psychological	Social relationship	Environment
<6 weeks	24	24.9±10.8	51.0±14.8	39.9±23.0	38.2±13.9
6-12 weeks	27	21.8±10.5	45.7±13.8	42.3±17.0	37.2±10.3
13-24 weeks	15	25.5±11.4	49.7±11.8	46.1±7.6	36.9±10.0
>24 weeks	12	28.6±16.8	46.2±16.9	37.5±12.6	32.8±10.1
p-value		0.413	0.535	0.586	0.617

4.6: ASSOCIATION BETWEEN HRQOL AND THE TYPE OF EXTERNAL FIXATION DEVICE

Analysis of Variance (ANOVA) test was used to determine if there was an association between the perceived HRQOL and the type of external fixation device used in the patient. The results indicate there is no statistical association between any WHOQOL BREF domain and type of external fixation.

Table 6: Association between perceived HRQOL and type of external fixation device.

	N	Physical health	Psychological	Social relationship	Environment
Uniplanar	72	24.4±11.6	48.2±13.9	41.6±17.5	36.5±11.5
Circular	3	15.5±14.9	36.1±21.4	33.3±16.7	31.3±6.3
Hybrid	3	36.9±6.4	59.7±6.4	50.0±8.3	47.9±7.2
p-value		0.080	0.126	0.501	0.166

CHAPTER 5; DISCUSSION

5.1 INTRODUCTION

The external fixator has been in use for the last two centuries. Today, it is an important device in the management of fractures and bone deformities. (4–8) The negative impact of these devices on the HRQOL has been described in the literature. (9–14) Recognition of this impact in our setup may assist the orthopaedic surgeon in the adjustment of treatment strategies and goals to minimize the negative burden of these devices.

This study thus assessed the perceived HRQOL in 78 patients and sought to establish its association with the type and duration of external fixation.

5.2 DEMOGRAPHIC CHARACTERISTICS

The age findings in our study are similar to those reported in the literature. Majority of the patients in our study were 18 – 40 years (80.8% n=63) with a mean age of 33.1 ±9.6. Buyukyilmaz et al (9) had a study population mean of 32.62±13.1 while 68% of Dheensa et al (14) study population was in the 18 – 45 years age group. This may be due to the higher likelihood of this group's involvement in traffic accidents with the subsequent need for external fixation. (44)

The gender distribution was 76.9% male and 23.1% female. The distribution is almost similar to what Abdullahi et al (32) found while studying a population of patients with external fixators in the same study setting. His population comprised 68% males and 32% females.

Majority of our patients had uniplanar external fixator (92%). Abdullahi et al (32) in their study found that the main indication for external fixation in our setup was open fractures of the tibia. This is the likely reason why majority of the patients had a uniplanar lower limb construct.

5.3 OVERALL HRQOL

When asked to rate their overall QOL, 56.4% of patients felt that their QOL was poor or very poor. 32.1% felt their QOL is neither good nor poor. The majority of patients (63%) were very dissatisfied or dissatisfied with their current state of health. This was further seen in the assessment of the different WHOQOL BREF domain scores.

5.4 PHYSICAL HEALTH

Our study population had low mean scores in the physical health domain of QOL assessment (24±11.9). This corresponds to poor physical quality of life. These findings were comparable to a

study by Hu Wang et al (13) who found reduced physical component scores in their population. Modin et al (11) also found that the majority of their study population experienced significant difficulty in accomplishing activities of daily living. This is similar to the patient population in this study where 90% of them were dissatisfied or very dissatisfied with their ability to accomplish activities of daily living.

Pain was a major factor in the poor physical health score. 89% of the patients experienced moderate to extreme amounts of pain. Hu Wang et al (13) in their study found that all patients experienced pain in the course of treatment. They found an average visual analogue scale (VAS) pain score of 6.

5.5 PSYCHOLOGICAL DOMAIN

The psychological domain average score was 48.2±14.2 corresponding with poor psychological health. Dheensa et al (14) found a psychological domain mean score of 57.13. This was lower than the population norms. Hu Wang et al also found a low mental component score (SF-36) in their study population corresponding to poor psychological health. 14 out of 22 patients in a study by Hrutkay et al (12) experienced psychological issues. Low self-esteem and poor body image and perception issues contributed to the low psychological domain scores. 71% of patients in this study were dissatisfied with their appearance due to presence of the external fixation device.

5.6 SOCIAL RELATIONSHIPS

The social relation domain also had a low score of 41.6±17.2 corresponding to a poor HRQOL. This poor score was contributed by low scores on social support and sex life. 78% of our population was dissatisfied or very dissatisfied with their sex life with the exofix in situ. Only 5% of patients were satisfied or very satisfied with their sex life. Adas M. et al (39) in their study on effects of external fixators on the sexual life of male patients found that 89% of patients had sexual dysfunction after assessment with the Brief Sexual Function Inventory Tool (BSFI). This had an overall negative impact on their QOL.

5.7 ASSOCIATION BETWEEN HRQOL AND THE TYPE OF EXTERNAL FIXATION DEVICE

When looking at the association between the type of external fixation device and HRQOL domain scores, it was noted that patients with circular external fixation devices had lower HRQOL scores in all domains compared to uniplanar and hybrid external fixator patients. However, this difference

was not found to be statistically significant. This is in contrast to Abulaiti et al (40) who found a positive correlation between the type of external fixator and the HRQOL. In their study, they found the Ilizarov frame to have a more negative impact compared to the orthofix LRS. They believed that the smaller size of the LRS allowed for more normal ADLs.

5.8 ASSOCIATION BETWEEN HRQOL AND THE DURATION OF EXTERNAL FIXATION

This study found lower psychological, social and environmental domain scores in patients who had stayed with the external fixator for > 24 weeks. Physical health scores were noted lower in patients who had external fixation devices for <12 weeks compared to those who had them for longer. However, this association between the duration of external fixation and HRQOL domain score was not statistically significant. Modin et al (11) in their study found that the patients experienced major limitations in their physical health domain during the early post-operatively duration. They experienced difficulty in accomplishment of ADLs. This may be related to higher pain scores in the earlier post-operative period.

CHAPTER 6; CONCLUSION

6.1 CONCLUSION

Patients with external fixation devices have a low health related quality of life. This is due to the presence of pain, bodily image and self-esteem issues as well as difficulty in accomplishment of activities of daily living.

This study found that the duration of external fixation as well as the type of external fixation device did not have any association with the HRQOL domain scores of the patients.

6.2 RECOMMENDATIONS

Due to the physical and psychological impact of eternal fixators on patients on management with these devices, a multidisciplinary team approach should be employed. Provision of psychological support to these patients and their caregivers before, during and after treatment should be considered.

Measures should be taken to shorten the duration of external fixation. Conversion to other modes of management should be considered where possible.

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APPENDIX 1; PATIENT INFORMATION

TITLE; HEALTH-RELATED QUALITY OF LIFE IN ADULT PATIENTS WITH EXTERNAL FIXATION DEVICES AT KENYATTA NATIONAL HOSPITAL AND AIC KIJABE HOSPITAL

Principal investigator; Dr. Patrick Gicheru

Supervisor; Dr. V. Mutiso, Dr. E. Gakuya

INVESTIGATOR'S NOTE

This form gives you information about the study. It will help you decide if you want to take part in this study or not. Appropriate interpretation will be carried out to enable you to understand the information.

STUDY DESCRIPTION

External fixation devices are commonly used in the management of patients with open fractures and bone deformities. Their use has been shown to have an impact on the physical, psychological and social health of the patients. This study aims to assess the perceived health-related quality of life in patients with external fixation devices seen at KNH and AIC Kijabe Hospital.

PROCEDURE

If you agree to this study, information on your demographics as well as how having an external fixation device is affecting your daily life will be collected.

BENEFITS AND RISKS

The findings of this study will assist in coming up with policies and protocols to improve the lives of patients with external fixation devices. Enlisting in this study will not expose you to any risks.

COSTS AND COMPENSATION

There will be no cost incurred by participation in this study. There will be no monetary compensation offered.

CONFIDENTIALITY

All information provided by you will be held in strict confidentiality and only be used in this study.

REASSURANCE

Your participation in this study is voluntary. You may refuse to answer any question you are uncomfortable with. You can withdraw from the study at any point during the interview if you so wish. This research proposal has been reviewed by the UON-KNH Ethics committee as well as AIC Kijabe Hospital IERC to ensure participants in this research are protected from harm.

WHO TO CONTACT

If you wish to ask any questions regarding this study later, you may contact the principal investigator;
Dr. Patrick Gicheru Nguku, Registrar, Orthopaedic Surgery Unit, University of Nairobi
ngukupatrick@gmail.com, **TEL 0723069332**

AIC Kijabe Hospital IERC - Tel: **0709728200-637** Email: researchcoord@kijabehospital.org

UON-KNH Ethics committee - Email: uonknh_erc@uonbi.ac.ke

APPENDIX 2; PATIENT INFORMATION; SWAHILI

UTAFITI; HALI YA MAISHA YA WAGONJWA WALIO NA CHUMA CHA NJE CHA KUSHIKILIA MFUPA KATIKA HOSPITALI YA RUFAA YA KENYATTA NA HOSPITALI YA AIC KIJABE

Mtafiti Mkuu; Dr. Patrick Gicheru

Wasmamizi; Dr. V. Mutiso, Dr. E. Gakuya

UJUMBE KUTOKA KWA MTAFITI

Fomu hii itakupa maelezo kuhusu utafiti huu na itakusaidia kuamua kama utahusisika katika utafiti wenyewe. Maelezo zaidi yatatolewa iwapo hauta elewa jambo lolote.

KUHUSU UTAFITI

Chuma za nje za kushikilia mfupa hutumika katika matibabu ya mifupa iliyovunjika ama yenye ulemavu. Utafiti uliofanywa kwa wagonjwa walio na chuma hizi umeonyesha kuwa chuma hizi zinawathiri katikamaisha yao ya kila siku na pia kisaikologia. Utafiti huu unanuia kuangalia hali ya maisha ya wagonjwa walio na chuma za nje za kushikilia mfupa katika Hospitali ya Rufaa ya Kenyatta hospitali ya AIC Kijabe

JINSI UTAFITI UTAFANYWA

Iwapo utakubali kujiunga na utafiti huu, ujumbe kukuhusu na kuhusu jinsi kuwa na chuma ya nje ya mfupa unaadhiri maisha yako utanakiliwa.

FAIDA NA HATARI

Ujumbe wa utafiti huu utasaidia katika kuboresha matibabu ya wagonjwa wa mifupa na wale wlio na chumaza nje za mifupa. Hakuna hatari yeyote ya kujiunga na utafiti huu.

MALIPO

Hakuna malipo yatakayo tolewa kwa watuwatakao jiunga na utafiti huu.

SIRI

Ujumbe utakao toa utahifadhiwa kwa siri

KUSHIRIKI KWA UTAFITI

Unahakikishiwa kuwa kushiriki kwa utafitihuu sii lazima. Unafaa kutoa ruhusa bila ya kulazimishwa. Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu. Utapewa nafasi ya kuuliza maswali na yote yatajibiwa vilivyo. Unaweza jitoa katika utafiti huu wakati wowote iwapo hutaki kuendelea.

Utafiti huu umengaliwa na bodi za hospitali (UON-KNH Ethics committee na AIC Kijabe Hospital IERC) na kubainiwa kuwa hauna madhara kwa binadamu.

UJUMBE ZAIDI

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UON-KNH Ethics committee – Barua Pepe: uonknh_erc@uonbi.ac.ke

APPENDIX 3; CERTIFICATE OF CONSENT

I have read/ been explained to and understood the above information. All my queries in regards to this study have been addressed satisfactorily.

I voluntarily agree and consent to participate in this study.

Name of Participant_____

Signature of Participant_____

Date_____

STATEMENT BY RESEARCHER

The participant has read/I have read to and explained to the participant the information about this study.

The participant has understood the following;

The decision to participate in the study is voluntary

Withdrawal/refusal to participate in the study will not affect their treatment in any way.

All information given will be handled with the utmost confidentiality.

I confirm that the participant has been given an opportunity to ask questions about the study and the question have been answered satisfactorily.

I confirm that the participant has not been coerced into giving consent.

A copy of the consent form has been provided to the participant.

Name of researcher/person taking consent _____

Signature of researcher/person taking consent_____

Date_____

APPENDIX 4: CERTIFICATE OF CONSENT; KISWAHILI VERSION

Fomu Ya Makubaliano Ya Kujiunga Na Utafiti

Nimeelezewa utafiti huu kwa kina. NakubaIi kushiriki utafiti huu kwa hiari yangu. Nimepata wakati wa kuuliza maswali na nimeelewa kuwa iwapo nina maswali zaidi, ninaweza kumwuliza mtafiti mkuu au watafiti waliotajwa hapa juu.

Jina la mshiriki_____

Sahihi ya mshiriki _____

Tarehe_____

Ujumbe kutoka kwa mtafiti

Nimemsomea mshiriki ujumbe kiwango ninavyoweza na kuhakikisha kuwa mshiriki amefahamu yafuatayo:

Kutoshiriki au kujitoa kwenye utafiti huu hautadhuru kupata kwake kwa matibabu.

Ujumbe atakao toa utahifadhiwa kwa siri.

Ninathibitisha kuwa mshiriki alipewa nafasi ya kuuliza maswali na yote yakajibiwa vilivyo.

Ninahakikisha kuwa mshiriki alitoa ruhusa bila ya kulazimishwa.

Mshiriki amepewa nakala ya hii fomu ya makubaliano.

Jina la mtafiti _____

Sahihi ya mtafiti _____

Tarehe_____

APPENDIX 5; STUDY QUESTIONNAIRE

PATIENT DEMOGRAPHICS

PATIENT ID;
GENDER; MALE ☐ FEMALE ☐
MARITAL STATUS; SINGLE
MARRIED

DATE OF BIRTH; ____/____/_____
OCCUPATION_____

EDUCATION LEVEL; NO FORMAL EDUCATION ☐ PRIMARY ☐ SECONDARY ☐ TERTIARY ☐

RESIDENCE; RURAL ☐ URBAN ☐

MARITAL STATUS; SINGLE ☐ MARRIED ☐ WIDOW/WIDOWER ☐ SEPARATED ☐

EXTERNAL FIXATOR DETAILS

Type of external fixator

UNIPLANAR ☐	CIRCULAR ☐	HYBRID ☐

Duration of external fixation

< 6weeks ☐

6 – 12 weeks ☐

12 – 24 weeks ☐

> 24 weeks ☐

WHOQOL BREF QUESTIONNAIRE

This assessment asks how you feel about your quality of life, health, or other areas of your life. **Please answer all the questions**. If you are unsure about which response to give to a question, **please choose the one** that appears most appropriate. This can often be your first response.

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life **in the last two weeks**.

1. How would you rate your quality of life?

Please circle the number				
Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
1	**2**	**3**	**4**	**5**

2. How satisfied are you with your health?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

The following questions ask about **how much** you have experienced certain things in the last two weeks.

3. To what extent do you feel that physical pain prevents you from doing what you need to do?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

4. How much do you need any medical treatment to function in your daily life?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

5. How much do you enjoy life?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

6. To what extent do you feel your life to be meaningful?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

7. How well are you able to concentrate?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

8. How safe do you feel in your daily life?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

9. How healthy is your physical environment?

Please circle the number				
Not at all	**A little**	**A moderate amount**	**Very much**	**An extreme amount**
1	**2**	**3**	**4**	**5**

The following questions ask about **how completely** you experience or were able to do certain things in the last two weeks.

10. Do you have enough energy for everyday life?

Please circle the number				
Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
1	**2**	**3**	**4**	**5**

11. Are you able to accept your bodily appearance?

Please circle the number				
Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
1	**2**	**3**	**4**	**5**

12. Have you enough money to meet your needs?

Please circle the number				
Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
1	**2**	**3**	**4**	**5**

13. How available to you is the information that you need in your day-to-day life?

Please circle the number				
Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
1	**2**	**3**	**4**	**5**

14. To what extent do you have the opportunity for leisure activities?

Please circle the number				
Not at all	**A little**	**Moderately**	**Mostly**	**Completely**
1	**2**	**3**	**4**	**5**

15. How well are you able to get around?

Please circle the number				
Very poor	**Poor**	**Neither poor nor good**	**Good**	**Very good**
1	**2**	**3**	**4**	**5**

The following questions ask you to say how **good or satisfied** you have felt about various aspects of your life over the last two weeks.

16. How satisfied are you with your sleep?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

17. How satisfied are you with your ability to perform your daily living activities?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

18. How satisfied are you with your capacity for work?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

19. How satisfied are you with yourself?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

20. How satisfied are you with your personal relationships?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

21. How satisfied are you with your sex life?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

22. How satisfied are you with the support you get from your friends?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

23. How satisfied are you with the conditions of your living place?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

24. How satisfied are you with your access to health services?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

25. How satisfied are you with your transport?

Please circle the number				
Very dissatisfied	**Dissatisfied**	**Neither satisfied nor dissatisfied**	**Satisfied**	**Very satisfied**
1	**2**	**3**	**4**	**5**

The following question refers to **how often** you have felt or experienced certain things in the last two weeks.

26. How often do you have negative feelings such as blue mood, despair, anxiety, depression?

Please circle the number				
Never	**Seldom**	**Quite often**	**Very often**	**Always**
1	**2**	**3**	**4**	**5**

THANK YOU FOR YOUR TIME

APPENDIX 6; STUDY QUESTIONNAIRE; KISWAHILI VERSION

KUHUSU MGONJWA

NAMBARI; _____ TAREHE YA KUZALIWA; ____/____/_____
MWANAMME ☐ MWANAMKE ☐ KAZI; _____

MASOMO; SINA MASOMO YA SHULE ☐ MSINGI ☐ UPILI ☐ CHUO KIKUU ☐

MAKAAZI; KIJIJINI ☐ MJINI ☐

KUOLEWA; NIMEOLEWA ☐ SIJAOLEWA ☐ MJANE ☐ NIMETENGANA NA MME/MKE WANGU ☐

MAELEZO KUHUSU CHUMA CHA NJE CHA MFUPA

AINA

UNIPLANAR ☐	CIRCULAR ☐	HYBRID ☐

KIMEKAA KWA MUDA GANI

<wiki 6 ☐

wiki 6 – 12 ☐

wiki 12 – 24 ☐

> wiki 24 ☐

WHOQOL –BREF KISWAHILI VERSION

The following questions ask how you feel about your quality of life, health, or other areas of your life. I will read out each question to you, along with the response options. Please choose the answer that appears most appropriate. If you are unsure about which response to give to a question, the first response you think of is often the best one.

'Maswali yafuatayo yanajaribu kuchunguza jinsi wewe unavyohisi hali yako ya afya na maisha yako kwa jumla. Nitakusomea maswali na vile vile hiari za majibu ambazo unazo. Tafahdahli chagua jibu ambayo inalingana na maoni yako au ni karibu na jibu lako'

Please keep in mind your standards, hopes, pleasures and concerns. We ask that you think about your life in the last two weeks.

'Ukijibu maswali tafadhali jaribu ukumbuke kanuni, ridhaa, na shaka zako. Vile vile tungeuliza ukijibu wasali ukumbuke vitu ambazo zimefanyika maishani mwako kuanzia sasa na kurudi nyuma wiki mbili vilizo pita'

1. How would you rate your quality of life?
Je, ukikaripia hali ya maisha yako, je waweza kusemaje?

Very poor **(Mbaya sana)**	Poor (**Mbaya)**	Neither poor nor good **(Sio mbaya wala sio mzuri**	Good **(Nzuri)**	Very good **(Nzuri sana)**
1	2	3	4	5

2. How satisfied are you with your health?

Je, unaridhiswa na hali yako ya afya?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

The following questions ask about how much you have experienced certain things in the last two weeks.
'Maswali yafuatayo yana jaribu kupima maarifa zako kuhusu vitu mbali mbali katika wiki mbili zilizo pita'

3. To what extent do you feel that physical pain prevents you from doing what you need to do?
Ni kwa kiasi gani ambayo unaona kwamba maumivu ya mwili imekuzuiya kufanya vitu ambazo ungependa kuyafanya?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

4. How much do you need any medical treatment to function in your daily life?
Ni kwa kiasi gani ambayo unahitaji matibabu katika maisha yako ya kila siku?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

5. How much do you enjoy life?
Ni kwa kadiri/kiasi gani ambayo wewe unafurahia maisha?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

6. To what extent do you feel your life to be meaningful?
Ni kwa kiasi gani ambayo wewe unaona kwamba maisha yako ina muhimu?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

7. How well are you able to concentrate?
Ni kwa kiasi gani ambayo wewe unaweza kukaza fikira ju ya jambo?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

8. How safe do you feel in your daily life?
Ni kwa kiasi gani ambayo wewe unahisi usalama wako katika shughli zako za kila siku?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

9. How healthy is your physical environment?

Je, sifa za mazingira yako unayaonaje?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

The following questions ask about how completely you experience or were able to do certain things in the last 2weeks.

Maswali yanayofuata yanauliza uwezo wako wakupima maarifa yako au kufanya vitu fulani kwa wiki mbili zilizopita.

10. Do you have enough energy for everyday life?

Je, una nguvu ya kutosha kufanya shughli za kawaida za kila siku?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

11. Are you able to accept your bodily appearance?

Je, una ridhika na umbo lako au hali yako ya kimwili?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

12. Have you enough money to meet your needs?

Je, una pesa za kutosha kutimiza mahitaji yako?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

13. How available to you is the information that you need in your day-to-day life?

Je, maelezo ambazo unazotaka katika maisha yako ya kila siku unayapata?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

14. To what extent do you have the opportunity for leisure activities?

Je, ni kwa kiasi gani ambayo unapata nafasi ya kupumzika na kufaragha?

Not at all (**Hakuna hata kidogo)**	A little (**Kidodgo)**	A moderate amount **(Kadiri)**	Very much (**Sana)**	An extreme amount **(Kabisa)**
1	2	3	4	5

15. How well are you able to get around?

Je, ni kwa kiasi gani ambayo unaweza kuwasiliana/kutembea?

Very poor **(Mbaya sana)**	Poor (**Mbaya)**	Neither poor nor good **(Sio mbaya wala sio mzuri**	Good **(Nzuri)**	Very good **(Nzuri sana)**
1	2	3	4	5

16. How satisfied are you with your sleep?

Je, ni kwa kiasi gani ambayo unaridhishwa na uwezo wako wa kulala?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

17. How satisfied are you with your ability to perform your daily living activities?

Je, ni kwa kiasi gani ambayo wewe unaridhishwa na uwezo wako wa kjiendelza katika maisha yako ya kila siku?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

18. How satisfied are you with your capacity for work?

Je, ni kwa kiasi gani ambayo wewe unaridhiswa na uwezo wako wa kufanya kazi?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

19. How satisfied are you with yourself?

Je, ni kwa kiasi gani ambayo unaridhishwa na maisha yako?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

20. How satisfied are you with your personal relationships?

Je, ni kwa kiasi gani ambayo unridhishwa na uhusiano yako na watu wengine?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

21. How satisfied are you with your sex life?

Je, ni kwa kiasi gani ambayo unridhishwa na maisha yako ya kimapenzi?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

22. How satisfied are you with the support you get from your friends?

Je, ni kwa kiasi gani ambayo unridhishwa na usaidizi ambayo unpata kutoka marafiki zako?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

23. How satisfied are you with the conditions of your living place?

Je, ni kwa kiasi gani ambayo unridhishwa na hali ya makao ambayo unaishi?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

24. How satisfied are you with your access to health services?
Je, ni kwa kiasi gani ambayo unridhishwa na uwezo wa kupata huduma za matibabu?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

25. How satisfied are you with your transport?
Je, ni kwa kiasi gani ambayo unridhishwa na huduma za usafirishaji?

Very dissatisfied (**Hai ridhishi sana)**	Dissatisfied (**Hai ridhishi)**	Neither satisfied nor dissatisfied (**Hai ridhishi wala haipendezi)**	Satisfied (**Inaridhisha)**	Very satisfied (**Inaridhisha sana)**
1	2	3	4	5

The following question refers to how often you have felt or experienced certain things in the last 2 weeks.
'Swali linalofuata linahusu mara ngapi wewe umehisi au kuarifu vitu mbali mbali katika wiki mbili zilizo pita'
26. How often do you have negative feelings such as blue mood, despair, anxiety, and depression?
Je, kuhisi ya kuwa na hali ya moyo mzito, taruki au wasi wasi huja kwako mara ngapi?

Never (**Hakuna hata kidogo)**	Seldom (**Kidogo)**	Quite often (**Mara kwa mara)**	Very often (**Sana)**	Always (**Kila mara)**
1	2	3	4	5

Do you have any comments about the assessment?
Je, una maoni yeyote kuhusu maswala ambayo yameulizwa?

The World Health Organization Quality of Life (WHOQOL)-BREF

APPENDIX 7; SCORE COMPUTATION AND CONVERSION

DOMAIN	EQUATION FOR SCORE COMPUTING	RAW SCORE	TRANSFORMED SCORE	
			4-20	0-100
DOMAIN 1	(6-Q3) + (6-Q4) + Q10 + Q15 + Q17 + Q18			
DOMAIN 2	Q5 + Q6 + Q7 + Q11 + Q19 + (6-Q26)			
DOMAIN 3	Q20 + Q21 + Q22			
DOMAIN 4	Q8 + Q9 + Q12 + Q13 + Q14 + Q23 + Q24 + Q25			

Table 2; WHOQOL BREF score computation table

DOMAIN 1		
raw score	transformed score	
	4-20	0-100
7	4	0
8	5	6
9	5	6
10	6	13
11	6	13
12	7	19
13	7	19
14	8	25
15	9	31
16	9	31
17	10	38
18	10	38
19	11	44
20	11	44
21	12	50
22	13	56
23	13	56
24	14	63
25	14	63
26	15	69
27	15	69
28	16	75
29	17	81
30	17	81
31	18	88
32	18	88
33	19	94
34	19	94
35	20	100

DOMAIN 2		
raw score	transformed score	
	4-20	0-100
6	4	0
7	5	6
8	5	6
9	6	13
10	7	19
11	7	19
12	8	25
13	9	31
14	9	31
15	10	38
16	11	44
17	11	44
18	12	50
19	13	56
20	13	56
21	14	63
22	15	69
23	15	69
24	16	75
25	17	81
26	17	81
27	18	88
28	19	94
29	19	94
30	20	100

DOMAIN 3		
raw score	transformed score	
	4-20	0-100
3	4	0
4	5	6
5	7	19
6	8	25
7	9	31
8	11	44
9	12	50
10	13	56
11	15	69
12	16	75
13	17	81
14	19	94
15	20	100

DOMAIN 4		
raw score	transformed score	
	4-20	0-100
8	4	0
9	5	6
10	5	6
11	6	13
12	6	13
13	7	19
14	7	19
15	8	25
16	8	25
17	9	31
18	9	31
19	10	38
20	10	38
21	11	44
22	11	44
23	12	50
24	12	50
25	13	56
26	13	56
27	14	63
28	14	63
29	15	69
30	15	69
31	16	75
32	16	75
33	17	81
34	17	81
35	18	88
36	18	88
37	19	94
38	19	94
39	20	100
40	20	100

Table 3; WHOQOL BREF score conversion tables

Adapted from; *'WHOQOL-BREF. INTRODUCTION, ADMINISTRATION, SCORING. AND GENERIC VERSION OF THE ASSESSMENT. Field Trial Version*

APPENDIX 8; KNH-UON ERC APPROVAL

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

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

Ref: KNH-ERC/A/173

10th May, 2022

Dr. Patrick Gicheru Nguku
Reg. No H58/7153/2017
Dept. of Orthopaedic Surgery
Faculty of Health Sciences
University of Nairobi

Dear Dr. Nguku,

RESEARCH PROPOSAL: HEALTH RELATED QUALITY OF LIFE IN ADULT PATIENTS WITH EXTERNAL FIXATION DEVICES SEEN AT KENYATTA NATIONAL HOSPITAL AND AIC KIJABE HOSPITAL (P65/02/2022)

This is to inform you that KNH-UoN ERC has reviewed and approved your above research proposal. Your application approval number is **P65/02/2022.** The approval period is 10th May 2022– 9th May 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

c.c. The Dean, Faculty of Health Sciences, UoN
The Senior Director, CS, KNH
The Chairperson, KNH- UoN ERC
The Assistant Director, Health Information, KNH
The Chair, Dept. of Orthopaedic Surgery, UoN.
Supervisors: Dr. Vincent Muoki Mutiso, Dept. of Orthopaedic Surgery, UoN
Dr. Edward Gakuya, Dept. of Orthopaedic Surgery, UoN
Dr. Morris Kitua, Consultant Orthopaedic Surgeon, AIC Kijabe Hospital

APPENDIX 9; KH IERC APPROVAL

KIJABE HOSPITAL INSTITUTIONAL ETHICS AND RESEARCH REVIEW COMMITTEE
PO Box 20 Kijabe 00220, Kenya
Tel: 0709728200/637
E-mail:researchcoord@kijabehospital.org
Website: www.kijabehospital.org

Reference : KH/IERC/0012/2022
Formal Approval Number: KH/ IERC/02718/0120/2022
Date: 28/02/2022

Dear Patrick Gicheru,

RE: HEALTH RELATED QUALITY OF LIFE IN PATIENTS WITH EXTERNAL FIXATION DEVICES SEEN AT KENYATTA NATIONAL HOSPITAL AND AIC KIJABE HOSPITAL.

The Institutional Ethics and Research review Committee having carefully reviewed your above title proposal grants you approval to conduct this study at Kijabe hospital as of 28th February 2022 to 28th February 2023.

The draft of any manuscript resulting from the study should be submitted to the IERC for review before it is submitted for publication.

This approval is subject to compliance with the following requirements:
a. Only approved documents (informed consents, study instruments, advertising materials etc.) will be used.
b. All changes (amendments, deviations, violations etc.) are submitted for review and approval by KH IERC before implementation.
c. Death and life threatening problems and severe adverse events (SAEs) or unexpected adverse events whether related or unrelated to the study must be reported to the KH IERC immediately.

d. Any changes, anticipated or otherwise that may increase the risks or affect safety or welfare of study participants and others or affect the integrity of the research must be reported to KH IERC immediately.
e. For studies lasting more than one year an annual report must be submitted for ongoing approval to be valid.
f. Submission of a request for renewal of approval at least 60 days prior to expiry of the approval period (attach a comprehensive progress report to support the renewal).
g. Clearance for export of biological specimen or any form of data must be obtained from KH IERC, NACOSTI and Ministry of Health for each batch of shipment /export.
h. Submission of an executive summary report within 90 days upon completion of the study. This information will form part of the database that will be consulted in future when processing related research studies so as to minimize chances of study duplication and/ or plagiarism.
Please do not hesitate to contact the AIC Kijabe Hospital IERC Coordinator (researchcoord@kijabehospital.org) for any clarification or query.
We wish you all the best in the study.
Thank you.

Yours Sincerely,

Peter Halestrap
BMBCh, MRCGP, DCH, DRCOG,MA (OXON)

Chair, AIC Kijabe Hospital IERC

APPENDIX 10; NACOSTI RESEARCH LICENSE

REPUBLIC OF KENYA

NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Ref No: 445825

Date of Issue: 19/May/2022

RESEARCH LICENSE

This is to Certify that Dr.. Patrick Nguku of University of Nairobi, has been licensed to conduct research in Nairobi on the topic: HEALTH-RELATED QUALITY OF LIFE IN ADULT PATIENTS WITH EXTERNAL FIXATION DEVICES SEEN AT KENYATTA NATIONAL HOSPITAL AND AIC KIJABE HOSPITAL for the period ending : 19/May/2023.

License No: NACOSTI/P/22/17586

445825

Applicant Identification Number

Director General
NATIONAL COMMISSION FOR SCIENCE,TECHNOLOGY & INNOVATION

Verification QR Code

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