OUTCOMES OF OPEN LONG BONE FRACTURES IN PATIENTS TREATED WITH EXTERNAL FIXATORS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET, KENYA

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THESIS SUBMITTED IN PARTIAL FULFILMENT OF THE REQUIREMENT FOR THE AWARD OF DEGREE OF MASTERS OF MEDICINE IN ORTHOPAEDIC SURGERY, SCHOOL OF MEDICINE, MOI UNIVERSITY.

DECLARATION

Declaration by candidate

This thesis is the original work and has not been presented to any other institution. Where other views have been expressed their references have been cited.

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DISCLOSURE

The candidate did not receive any grants or outside funding in support for this study. Neither he nor a member of his immediate family received payments or other benefits or commitment or agreement to provide such benefits from a commercial entity.

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DEDICATION

This thesis is dedicated to the patients who had major complications resulting from management with external fixators.

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To you all, thank you.

LIST OF ABBREVIATIONS AND ACRONYMS

AO	(Arbeitsgemeinschaft für Osteosynthesefragen) Association of Osteosynthesis
DCO	Damage Control Orthopaedics
IREC	Institutional Research & Ethics Committee
K.N.B.S	Kenya National Bureau of Statistics
KNH	Kenyatta National Hospital
MESS	Mangled Extremity Severity Score
MSK	Musculoskeletal
MTRH	Moi Teaching and Referral Hospital
ORIF	Open Reduction and Internal Fixation
POP	Plaster of Paris
PROM	Patient Report Outcome Measure
RTA	Road Traffic Accident
SPSS	Statistical Package for the Social Sciences
TSF	Taylor Spatial frame

OPERATIONAL DEFINITIONS OF VARIABLES AND KEY CONCEPTS

External fixator: It is a system which utilizes an external frame to connect screws or schanz pins to transfix the main bone fragments of a fracture.

Intramedulllary nail: It is a metal rod inserted into the medullary cavity of long bones.

Long bone: It is characterized by having a diaphysis, with an epiphysis at both ends covered by hyaline cartilage. It is made up of an outer layer (periosteum), a cortex then a deeper (cancellous bone) which contains the bone marrow and interiorly there is the medullary cavity. The long bones include the femur, tibia, fibula, radius and ulna.

Open fracture: a fracture that has a break in the soft tissues and communicates with the external environment..

Outcomes: Temporary and definitive options of external fixators including conversion to other methods of treatment, radiological and clinical outcomes including complication rates.

ABSTRACT

Background: Open fractures result from high energy trauma with the long bones being most commonly affected. Because they are minimally invasive, available and allow for concomitant management of soft tissue injuries, external fixators are the treatment modality of choice for these injuries. Once the scope concerning usage of temporary external fixators, clinical and radiological outcomes including complication rates is achieved, it will benefit the patients, clinicians and Moi Teaching and Referral Hospital (MTRH) as an institution.

Objective: To describe the outcomes of open long bone fractures treated using external fixators at MTRH, Eldoret, Kenya.

Methods: This was a prospective descriptive census study conducted among adult and paediatric patients with open long bone fractures treated using external fixators at MTRH between November 2015 and October 2016. An interviewer-administered questionnaire was used for data collection. Data on characteristics and aetiology of open fractures, temporary use of external fixators, pain scores, union, non-union and pin-site infection rates were recorded. Categorical variables were summarised using frequencies and percentages. Continuous variables were summarized using mean and standard deviations. Data was analysed using R statistical package (R Core team 2017). Mann Whitney U, Fisher's exact, post-hoc and Chi-square tests were used to assess the associations.

Results: A total of 95 patients were recruited in the study. Mean age of the patients was 37.3 years (SD: 15.2). Male patients were 78 (82.1%). Gustilo-Anderson type III fractures were seen in 58 patients (61.1%). Only modular type of external fixators was used. Forty (42.1%) patients had temporary external fixators converted to mostly intramedullary nailing 24 (60%) and plating 12 (30.0%). There was a statistical difference in mean pain score between all review periods ($p < 0.001$). Those who had delayed union were significantly older ($p= 0.033$). There was a statistically significant association between non-union and severity of open fractures ($p= 0.003$). Major early complications included superficial infections affecting 22 (23.1%) patients and 7 (7.3%) had peripheral nerve injuries. Major Late complications included non-union seen in 23 (44.2%) of patients and 15 (28.9%) delayed union. Pin-site infection rate was 67 (70.5 %). Five (9.6%) patients had complete union.

There was a statistical difference between severity of fractures and outcomes ($p= 0.0028$).

Conclusions: All patients were treated with modular external fixators. Major clinical and radiological outcomes included pin-site infections, non-union and delayed union. Low union rate was seen at 6 months.

Recommendations: Modular external fixator is optimal for temporary use, thus are not suitable for definitive management. More research to be carried out in areas such as pin-site infection and non-union post external fixation in order to improve patient care.

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CHAPTER ONE

1.0 Introduction

This chapter will introduce one to back ground, problem statement, justifications and objectives.

1.1 Background

1.1.1 Definition of open fractures and long bones

Open fracture is described as a fracture with an overlying wound. There are various classifications that have been proposed to grade open fractures according to the extent of the injury in order to help in deciding on optimal management. The most widely used is the Gustilo-Anderson classification which grades the injuries based on the size of the open wound, degree of contamination and extent of soft-tissue damage. Due to a broad classification type-III, Gustilo et al reclassified it into 3 subgroups, based on the extent of bone exposure, adequacy of soft tissue cover and the need of neurovascular repair (Kim & Leopold, 2012)

- Type I: wound less than 1cm with minimal contamination and of low energy.
- Type II: the laceration is between 1cm and 10cm long and is associated with minimal contamination. There is moderate soft tissue damage and usually high energy is involved.
- Type III: Wound is more than 10cm and is contaminated massively. there is extensive tissue damage.

  Type IIIA: Extensive soft tissue damage but with adequate soft tissue to cover the bone.

  Type IIIB: Extensive soft tissue damage and loss associated with periosteal stripping and requires a flap advancement.

Type IIIC: Open fractures with neurovascular injury that require repair.

The following fractures are considered as special categories and fall into Type III

- ❖ All Gunshot wounds
- ❖ Open fractures that are severely contaminated such us those that have happened in the farmyard, contamination from sewers
- ❖ Fractures that occur in wars or natural disasters
- ❖ Fractures due to high energy trauma

1.1.2 Long bones

They are characterized by having a diaphysis, with an epiphysis at both ends covered by hyaline cartilage. It is made up of an outer layer (periosteum), a cortex then a deeper (cancellous bone) layer which contains the bone marrow and interiorly there is the medullary cavity. The long bones include the femur, tibia, fibula, radius and ulna.

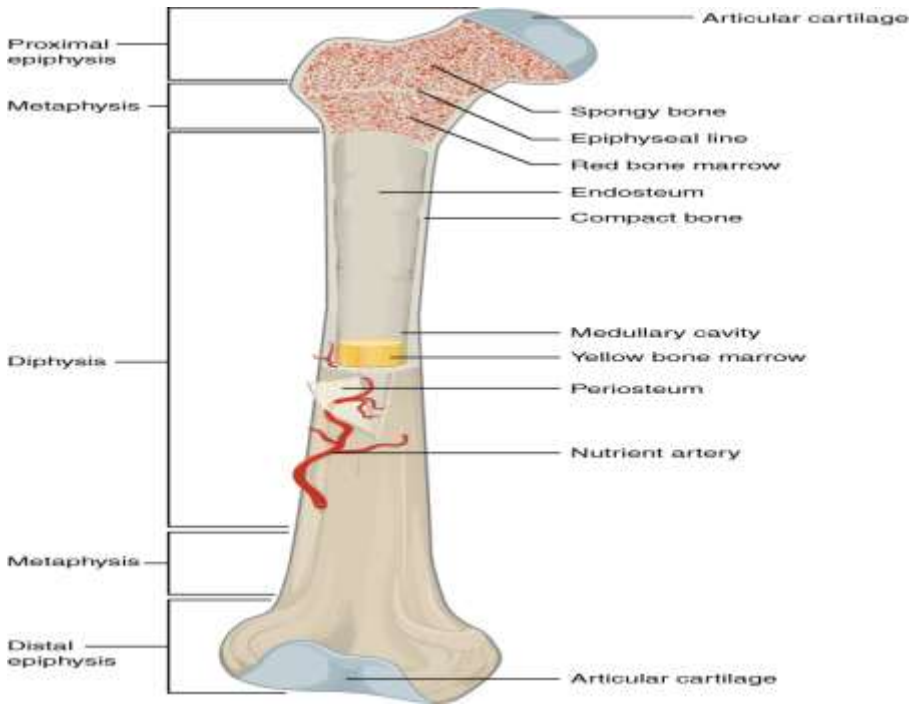


Figure 1: Long bones *Adapted from (Illustration of Anatomy & Physiology, 2013)*

1.1.3 External fixators

This is a system of fixation which utilizes an external frame to connect screws or pins transfixing the main bone fragments. There are different sizes and shapes of the external frames with a varying diameter of the pins too. There are various types of external fixators that are used depending on the fracture site and severity of the injury. Types include; Modular/standard AO which include poly-planar (pins applied in different planes), uni-planar (pins applied in one plane), unilateral (one frame) bilateral (two frames) hybrid etc. Modern types include the circular, Ilizarov and Taylor spatial frames.

External fixators have been used in orthopaedic surgery, dating back to 2400 years ago where Hippocrates described a device consisting of leather rings connected to four wooden rods. In 1840, Jean Francois Malgaigne used a claw like device to hold fragments of a fractured patella. Clayton Parkhill and Albine Lambotte in 1894 to 1902 used threaded pins and they invented the modern concept of unilateral external fixation. Many mechanical and biological principles were not fully understood and these led to many devastating complications encountered, until Raoul Hoffman in 1938 and Gavriil Ilizarov in 1950s built on the work of others and had major improvements (Paul et al., 2003).

Certain biomechanics have to be implemented for better outcome such as larger number of pins and spacing them as far as possible on each fragment, pin should not traverse the fracture line and a small distance should be maintained between the bone and frame of external fixators. The biomechanics will depend on the function the external fixator is being used for. During fracture healing, the external fixators help

in, stabilizing the skeleton, holding the limb in correct alignment, providing a suitable mechanical environment for fracture healing and enhancing of soft tissue healing.

1.1.4 Outcomes of external fixators

Trauma is one of the leading causes of death in the society. With an upsurge of Road Traffic Accidents burdening the society in terms of resources used for treating and rehabilitation of injured persons, this has been a major concern. Other high-energy trauma aetiologies are also on the rise such as falls, assaults, firearm injuries, sports and industrial accidents and most of them are associated with fractures (Chalya et al., 2013). The annual worldwide incidence of open fractures of long bones is estimated to be around 11.5 per 100,000 persons, with 40% occurring in the lower limb, mostly at the tibial diaphysis (C. Court-Brown, S. Rimmer, U. Prakash, & M. McQueen, 1998).

Various protocols and advancements have been made in fracture care despite this, open fractures still remain a major surgical problem. Other factors determining the outcome of management include availability of resources, equipment, expertise, finances etc.

External fixation is an essential component of trauma and limb reconstruction surgery. It is used widely owing to its minimally invasive nature compared to the other different internal fixation techniques which are often burdened by relatively high complication rates. When treating fractures, the goal is to achieve normal alignment and reduce articular displacement of a joint that is involved thus regain a stable, mobile and painless limb, while avoiding infections and wound complications (Rockwood, Green, Bucholz, Heckman, & Court-Brown, 2006). Poor outcome has

been shown to significantly affect limb function. Treatment of fractures with external fixators is usually challenging as it is often difficult to assess the potential risks of surgical complications due to variations in clinical findings.

Indications for external fixators include, stabilization of severe open fractures, stabilization of infected non-unions, correction of extremity mal-alignments and length discrepancies, initial stabilization of soft tissue and bony disruption in poly trauma patients through DCO , treatment of closed fractures with associated severe soft tissue injuries, treatment of severely comminuted diaphyseal and periarticular lesions, temporary trans-articular stabilization of severe soft tissue and ligamentous injuries, treatment of pelvic ring disruptions and stabilization of osteotomies.

In injuries associated with soft tissue compromise, external fixation has been shown to reduce the incidence of deep infections (Kataria, Sharma, & Kanojia, 2007). A study done on external fixation versus internal fixation for unstable distal radius fractures found that in surgical fixation of unstable distal radius fractures, open reduction and internal fixation yields significantly better functional outcomes, forearm supination, and restoration of anatomic volar tilt. However, external fixation results in better grip strength, wrist flexion, and remains a viable surgical alternative for managing the above fractures. Fractures of the distal humerus in the elderly are usually treated with ring fixators due to difficulty in achieving fixation while using open reduction and internal fixation (ORIF) as the bones are usually fragile (Wei, Poolman, Bhandari, Wolfe, & Rosenwasser, 2012).

This treatment modality is however associated with its own complications. Parameswaran, Roberts, Seligson and Voor, (2003) found that use of mono-lateral

hybrid fixators showed higher incidences of pin-site sepsis than ring fixators. Studies have also shown that use of standard, uncoated pins lead to deterioration of bone-pin interface strength. Many institutions have abandoned the standard pins and are using hydroxyapatite-coated pins which show improved fixation strength with lower rates of pin-site sepsis.

Non-union of fractures is a major complication and difficult problem to treat. Using various forms of fixation including intramedullary nailing, various plating methods and external fixation have rates from 0-6%(Ali & Saleh, 2000). There is no universally accepted definition of non-union, but most studies give 6 months without healing.

According to a meta-analysis of several papers, incidence of delayed union was at 24% for 392 open tibial fractures treated with external fixators. The rate of mal-union was up to 20% in 458 fractures. Sixty eight percent of the above fractures required at least one further operation before union was achieved. Union had occurred in 94% at a mean time of 37 weeks. The incidence of deep infection was at 16.2% with 4.2% developing chronic osteomyelitis and pin track infection rate going up to 32.2% (Giannoudis, Papakostidis, & Roberts, 2006).

A retrospective study done on 198 open tibial fractures, found a 9.1% incidence of compartment syndrome having a close association with severity of the injury. Eighty three percent of the fractures which developed compartment syndrome were type III, and 94% were moderately to highly comminuted. Therefore monitoring of intercompartmental pressures especially in unconscious patients is mandatory (Blick, Brumback, Poka, Burgess, & Ebraheim, 1986).

The radiological and clinical outcomes explained above have been seen frequently in Orthopaedic and Radiological Department at MTRH with their exact scope not fully known.

1.2 Problem statement

Ideally external fixators are mostly used as temporizing implants before conversion to either intramedullary nails or plating. They are used in management of open fractures and mostly damage control orthopaedics in patients involved in high energy injuries. Unfortunately, some of the patients stay longer with the constructs due to severity of the injury, financial restraint to convert to other implants and lack of proper follow up thus ending up with unfavourable outcomes. There are significant cases of pin site infections, non-union, mal-union, delayed union and chronic osteomyelitis seen in local orthopaedic clinics as the patients come for reviews. An average of 142 open fractures were treated at Moi Teaching and Referral Hospital (MTRH) using external fixators in year 2012 to 2013, of which 20 cases were taken back to theatre for revision and readjustment due to various complications in 2013.

1.3 Justification

Moi Teaching and Referral Hospital has a catchment area of almost 17 million people and has a high demand for trauma care. External fixator use is common in the institution due to its minimally invasive nature and affordability even though it is associated with complications thus leading to injury burden at MTRH which needs to be quantified. Open long bone fractures are a public health concern due to their far reaching socioeconomic impact in terms of their management at an individual up to the national level, hence knowing the characteristics of patients treated with external fixators will be of great importance in prevention purposes. Knowing the conversion

rates of temporary external fixators to other definitive options would be key in future planning. Locally, studies related to both radiological and clinical outcomes of open long bone fractures treated with external fixators have not been done. Due to the paucity of data on the subject, this study will be used to highlight the aetiological mechanisms of injury which will help plan for areas needing primary intervention. It will build on the existing literature of this subject and also improve patient care at MTRH. Once the scope concerning outcomes of external fixation is achieved it will benefit the patients, clinicians and MTRH as an institution as it will allow evidence based planning, resource allocation for better healthcare delivery.

1.4 Research question

- What are the outcomes of open long bone fractures in patients treated using external fixators at MTRH?

1.5 Objectives

1.5.1 Broad objective

- To describe the outcomes of open long bone fractures in patients treated using external fixators at MTRH.

1.5.2 Specific objectives

1. To describe characteristics of patients with open long bone fractures treated using external fixators at MTRH.
2. To describe the use of external fixators as a temporary implant and its conversion to other definitive implants.
3. To describe the clinical and radiological outcomes in patients with open long bone fractures treated by using external fixators at MTRH.
4. To determine the association between severity of open fractures and outcomes using Gustilo-Anderson classification.

CHAPTER TWO:

2.0 LITERATURE REVIEW

2.1 Introduction

This chapter will cover a detailed literature review as per stated objectives, hence answering the research questions.

In an accident or incident leading to trauma, long bones are more likely to be injured. Tibia fractures occur more than any other long bone fractures with Gustilo-Anderson grade III being the most frequent (Court-Brown, Rimmer, Prakash & McQueen, 1998 Sept). These fractures are not only common, but they are challenging to treat. The subcutaneous location of the anteromedial surface of the tibia, with little soft tissue cover, means that severe bone and soft tissue injury or loss are common. External fixators are widely used in management of open long bone fractures.

External fixation is a system which utilizes an external frame to connect screws or pins transfixing the main bone fragments. There are different sizes and shapes of the external frames with a varying diameter of pins. There are various types of external fixators that are used depending on the fracture site and severity of the injury. Types include, Circular, poly-planar (pins applied in different planes), uni-planar (pins applied in one plane), unilateral (one frame) bilateral (two frames) hybrid etc.

2.2 Characteristics of patients with open long bone fractures

2.2.1 Social demographic profile

According to (Giannoudis et al., 2006) the annual incidence of open fractures for long bones was 11.5 per 100,000 persons with 40% occurring in the lower limb, mostly at the tibia diaphysis. A prospective study done in Nigeria found that out of 63 patients, 42 were males, with a ratio of 2:1. The youngest patient was 4 years of age and the oldest 78 years. Mean age was at (32+ 15.7) years (Ikem, Oginni, & Bamgboye, 2001). According to Moola et al., (2014) who did a study reviewing open fractures, 68% were men and 32% were women. Average age was 42 (range 16-94).

In a local study conducted at MTRH involving 196 patients with post- traumatic open fractures, males were more affected (M: F = 5.76:1) and the mean age was 32.51years (SD=13.26). All Patients had exposed bones due to open fractures (97%) and degloving injuries (3%) in association with polytrauma (36.8%). The tibia was the most affected bone. Road traffic accidents were responsible in 49.5% of the patients (Ayumba, Lelei, Emarah & Langat, 2012).

2.2.2 Aetiologies of open long bone fractures

A non-experimental, observational-analytical retrospective study was done on 67 patients with open tibial fractures who were treated with external fixators in Vryheid Hospital, Kwazulu Natal, South Africa. It found that the common aetiologies were Road Traffic Accidents and gunshot wounds (R Oriyes-perez et al., 2007). A study done in Uganda showed that motorcycles contributed to73% of trauma patients (Kigera et al., 2010). Another study done in Rwanda reported motorcycle involvement at 30% (Twagirayezu et al., 2008).

High-velocity trauma accounts for most of the injuries at 77.1% with 24.5% resulting from motor vehicle crashes, followed by motor vehicle-pedestrians collisions at 21.4%, these two are the commonest. Low-velocity accidents account for the remaining 22.9% which include fall from a height as one of the commonest mechanism of injury especially in the elderly (Moola et al., 2014).

Other high-energy trauma aetiologies are also on the rise such as falls, assaults, firearm injuries, sports and industrial accidents and most of them are associated with fractures (Chalya et al., 2013). Another study found that road traffic accident was the most common aetiology, followed by blast injury, firearm injury, fall from trees and direct forceful blow by iron rods 68.3%, 10%, 10%, 8.3% and 3.3% respectively by (Wani, Baba, Kangoo and Mir, 2011).

2.2.3 Patterns of open long bone fractures

Open fractures of the lower limb tend to be more severe than that of the arm due to the degree of frequency of associated musculoskeletal injuries and the degree of soft-tissue damage. Open fractures of the femur are associated with high energy trauma therefore tend to be found in patients with multiple injuries. Hence their management should follow guidelines of the Advanced Trauma Life Support System.

Studies have shown that tibial open fractures are the commonest injuries among the long bones (Cosco, Risi, Pompili, & Boriani, 2001). Annual incidence of open tibial fractures in the United States was at 5.6 per 100, 000 persons according to a study done on epidemiology of open long bone fractures (Court-Brown, S. Rimmer, U. Prakash, & M. M. McQueen, 1998). Tibial fractures form the commonest site for open fractures of long bones. Unfortunately, they have reduced soft tissue cover at the

shaft and reduced blood supply making these fractures vulnerable to non-union and infections (Wani, et al., 2011).

Long bone fractures are mostly graded according to AO classification (Muller,Koch, P., Nazarian & Schatzker,J, 1990).

A retrospective study conducted at Panzi Missionary Hospital in Democratic Republic of Congo was reviewing the outcome of external fixators in the management of open limb's fractures secondary to Gunshot. The study took a period of 4 years. Out of 220 patients who were enrolled in the study 62 had open wound fractures and out of these the commonest site involved was tibia with 42 patients (Kaguku, Reinekainnen, Luhiriri, & Baldan, 2007). A study done in Niger also found out that lower limbs were commonly affected and the most affected location was the tibial shaft (Kortor, Yinusa, & Ugbeye, 2010). Moola et al., (2014) conducted a study whereby they reviewed 297 open fractures treated at a single Level 1 trauma centre, and out of these, Gustilo-Anderson Type III open injuries accounted for 24 %, Type I had 51.2% and Type II for 24.6 %.

2.2.4 Time frame from injury to debridement and external fixation.

There has been a controversy with regards to timing from injury to surgery with some studies suggesting that early intervention leads to less rates of infections (Kindsfater and Jonassen, 1995; Kreder and Armstrong, 1995). Data gathered indicates that there was no statistical significance of timing in terms of surgery hence the 6-hour rule has lacked support. A study done on treatment of open fracture tibia had an infection rate of 11.6% (12 out of 103 cases). Seven were taken in for surgery within 6 hours and 5 after 6 hours (Kamat, 2011). A study done on relationship between timeframe to surgery and infections found that time frame between injury and operative

debridement is not a significant independent factor for predicting risk of infection, though timely admission had significant beneficial influence on reducing infections after open high-energy lower extremity trauma (Pollak et al., 2010). Also time frame from injury to treatment was a major factor as for the injuries which were intervened earlier showed reduced complications(Kaguku, Reinekainnen, Luhiriri, & Baldan, 2007).

2.2.5 Antibiotic use in open fractures

As most open fractures are contaminated with micro-organisms, antibiotics are used not for prophylaxis but treatment. In order to prevent clinical infections, immediate antibiotic administration, surgical debridement, soft tissue coverage and fracture stabilization are necessary. Tetanus prophylaxis is necessary depending on the patient's immunization status (Zalavras, Marcus, Levin, & Patzakis, 2007).

Antibiotics administered should cover both gram-positive and gram-negative organisms. Culture of wound specimen prior to surgical debridement is no longer recommended due to their poor predictive value but post-debridement culture and sensitivity results may help in choosing subsequent treatment of an early infection (Patzakis et al.,2000; Fischer, Gustilo, & Varecka, 1991).

Common regimen used include, first or second generation of cephalosporins which is active against gram-positive, combined with an aminoglycoside which is covering gram-negative (cefazolin and gentamicin). Substitutes for aminoglycosides include quinolones, third-generation cephalosporins and other antibiotics which have gram-negative coverage. Ampicillin or penicillin is usually added to farmyard injuries to prevent Clostridial myonecrosis (gas gangrene) (Patzakis et al., 2000).

Antibiotic use according to Gustilo-Anderson Type

- Gustilo Type I and II
    - 1st generation cephalosporin.
    - Clindamycin or vancomycin can also be used if allergies exist.
- Gustilo Type III
    - 1st generation cephalosporin and aminoglycoside.
- Farm injuries or possible bowel contamination
    - Add penicillin for anaerobic coverage (clostridium).
- Duration
    - Initiate as soon as possible.
        - Studies show increased infection rate when antibiotics are delayed for more than 3 hours from time of injury.
    - Continue for 24 hours after initial injury if wound is able to be closed primarily.
    - continue until 24 hours after final closure if wound is not closed during initial surgical debridement (Kent, 2012).

2.3 Use of external fixators

2.3.1 Introduction

The treatment of open long bone fractures is always a challenging dilemma for orthopaedic surgeons because it requires special caution and thorough individual assessment in each case. Different treatment modalities are used at MTRH which include use of plates, intramedullary nails and external fixators. The treatment of high-energy injuries aims to preserve life, limb and function.

In traumatology it has become a standard practice to use external fixation as a temporary means of treatment of severely injured patients who cannot tolerate extensive surgeries and may also serve as a stop gap procedure for heavily contaminated open long bone fractures.

It is always possible to manage the patients with an immediate one stage procedure. Reduction is usually less invasive, with minimally soft tissue exposure and blood loss. Other advantages include adjustment of alignment if need be, allows compression and distraction both during and after surgery and patients can be allowed early weight-bearing (Fleming, Paley, Kristiansen, & Pope, 1989).

Paediatric long bone fractures are also well managed by external fixators. Both circular and mono-lateral fixators have been successful. Despite mono-lateral fixators being used more due to their easy application, they are usually associated with increased loss of reduction leading to development of mal-union. Circular fixators minimise angulation and one is able to perform corrections to obtain acceptable reduction and alignment(Tafazal et al., 2014).

An interventional study comparing external fixation and intramedullary interlocking nail conducted in the Orthopaedic and Trauma Department of a tertiary health institution in south west, Nigeria found that deep wound infections were 35 %(external fixation) and 11.1% (interlocking nailing). Mean duration to union was 14.8 weeks in external fixation group and 14.4 weeks in interlocking nailing groups respectively. Difference in mean was not statistically significant, ($t=0.133$, $p=0.895$). However, they concluded that the risk of infection was higher in external fixation (Esan, Ikem, Oginni and Esan, 2014).

A study done on incidence and analysis of open fractures of the mid-shaft and distal femur showed that using external fixation in acute fracture treatment was safe. Various treatment modalities including external fixation, intramedullary nailing, plating and screw fixations were used. A suggestion that the use of external fixator in acute fracture treatment was found to be superior to other modalities was made (Kovar, Jaindl, Schuster, Endler, & Platzer, 2013). `

Another conclusion made was that in a war zone environment or during war, external fixation is the treatment of choice for lower extremity injuries by virtue of patient, environment, equipment and mission factors (Eichinger, McKenzie, & Devine, 2012).

2.3.2 Outcomes of treatment using temporary external fixators

External fixation is usually used as a temporizing modality in stabilization of open fractures affecting lower extremities. It allows recovery of traumatized skin, prevents further soft tissue damage, permits wound management and does not negatively impact systemic complications in a poly-trauma patient. Commonly used in damage control orthopaedics to provide temporary stability while stabilizing the patient. This allows for elective definitive management mostly through use of plates and intramedullary nails later. Open fractures are associated with soft tissue compromise especially in high energy injuries resulting from road traffic accidents, hence external fixator is an ideal device because it allows stabilization of the fracture without further soft tissue insult.

In developed countries, external fixators are kept on an average of about 7 days with a range of 1-49 days. Once the soft tissues have healed depending on the severity of the fractures and energy involved, conversion to definitive management ensues. This time

frame may be as long as 6 weeks but is usually at least 2 weeks in duration, however there is no consensus on the optimal conversion point that exists (Carroll, E.A, & Andrew Koman, L. 2011).

2.3.3 Outcomes of treatment using definitive external fixators

External fixators are usually used as a temporizing construct to stabilize fractures then converted to definitive implants. Mostly the modular/standard mono-lateral constructs are used. In the developing countries due to financial constraints and poor follow-up patients end up using these constructs as definitive management which has been shown to be associated with unfavourable outcomes (Carroll, E.A, & Andrew Koman, L. 2011).

A study done on monolateral frame external fixators in the definitive management of open limb fractures in North-western Nigeria found that; although there is a fledging health insurance scheme, it is limited to civil servants and does not cover major orthopaedic procedures. Due to limited resources, poor patient financial capacity, definitive fracture fixation using external fixators from the time of admission ensues (Lawal et al., 2016) There are complex modernized external fixators which are used for definitive management and do not need further surgeries or conversion to other implants. They have been shown to have better outcomes even though they are expensive. Most common examples include, Ilizarov, circular ring constructs and Taylor spatial frames. A study done on TSF fixation on long bone fractures showed that its advantages included continuity of device until union, reduced risk of infection, early mobilization and restoration of primary defects (Sala, Elbatrawy, Thabet, Zayed, & Capitani, 2013).

A study done on paediatric femoral fractures treated with external fixators and intramedullary nails, found both ways were effective and the mean time for union rates were not statistically different (Aslani, Tabrizi, Sadighi, & Mirbolook, 2013). In a study, which compared two modalities for treating open diaphyseal tibial fractures; bi-planar external fixation or reamed locked intramedullary nailing found that consolidation occurred in 90.3% of patients who were treated with bi-planar external fixation, and 84.6% of patients who underwent reamed intramedullary nailing. Both treatment choices had statistically similar results (Rodrigues et al., 2014).

Circular external fixators have been used in the treatment of fractures. The outcomes were good, complete union was found in all cases. The mean healing time for open fractures treated by circular external fixators was 17 weeks compared to 12.8 weeks for Taylor spatial frames.(Tafazal et al., 2014).

2.4 Clinical and radiological outcomes of external fixation

2.4.1 Introduction

Clinical outcomes are broadly agreed measurable changes in health or life that results from a specific care administered. Can be subjective (patient related) or objective (doctors related). Constant review of clinical outcomes of patients and measuring change using clinical outcome measures is one of the way used to measure clinical impact. Measurable outcomes may include infection and pain rates. Radiological outcomes are also measurable changes seen in radiographs or scans serially taken to determine bone healing. Outcomes consist of complete union, mal-union, delayed unions or non-union rates. These are usually measured for the patients who have external fixators as a definitive treatment. Associated complications do arise and can be classified as immediate post-operative complications and late complications.

2.4.2 Subjective outcome measures

Subjective follow up evaluation is directed on what the patients perceive in regard to physical status, psychological status and also social well-being. Validated self-administered questionnaires can be used for assessment where by a low score indicates minimal problems while a high score indicates greater perception of problems. Other functions that can be assessed include self-care, sleep and rest, pain leisure, emotional adjustment and many more (Goldfarb, Ricci, Tull, Ray, & Borrelli, 2005).

Many studies done have reported on clinical and radiological functional outcomes without emphasis on patient-based functional outcomes. This is important because it will create a better understanding for outcomes after treatment of open fractures and also may facilitate better patient care and counselling regarding post-operative expectations (MacKay, Montero, Paksima, & Egol, 2013). Various types of valid scores are used widely to quantify patients' outcome based on their perception mostly in terms of pain and also disability.

There are various interpretations of pain and this has led to the development of tools that address different components of pain. Many tools were formed but Visual Analogue Scale (VAS) was found to be simple, easy to administer and methodologically sound. A standard visual analogue scale is usually used to analyse pain in most studies post-operatively (VAS; 0 no pain while VAS; 10 stands for severe pain) (Coll, Ameen, & Mead, 2004). Other scales for evaluating pain include the Numeric Rating Scale for Pain (NRS Pain), McGill Pain Questionnaire (MPQ), Chronic Pain Grade Scale (CPGS), Faces rating scale (FRS) and many other scales

(Hawker, Mian, Kendzerska, & French, 2011). In this study WONG Baker Face Scale for scoring pain was used as per appendix 7. (Wong, D.L., & Baker, C. M. 1998).

For fractures of the upper limbs, patients can rate their ability to perform common physical activities such as turning doorknobs, opening jars and similar activities. A low score indicates reduced to 'no disability' while 100 indicates severe 'disability'. DASH score has been used widely and stands for disabilities of the arm shoulder and hand score (Goldfarb et al., 2005). Example is the Keele musculoskeletal patient report outcome measures which monitors the health status of a patient suffering from a musculoskeletal disorder (Hill, Thomas, Hill, Foster, & van der Windt, 2015). This tool will be used in this study to help evaluate or assess the subjective measures. It has 6 categories as seen in appendix 9. PROMs provide additional "patient-centred" data which captures the patient's own opinion on the impact of their disorder, and its treatment, on their life. The use of PROMs has some advantages over the traditional research-based outcome measures, as they may directly influence behavioural changes for patients, clinicians and policy makers.

2.4.3 Objective outcome measures

This is what the doctor considers as good in terms of functional joint movements, range of movement e.g. supination and pronation, inversion and eversion, radiological healing, painless ambulation, objective pain scoring, general quality of life. Various tools are also used to score depending on the fracture site. Here one can use the radiological outcome measures such as Radiologic union score for hip (RUSH) and Radiologic union score for tibia (RUST). These scoring systems have been accepted by many surgeons and radiologists in assessing fracture repair and healing. Assessment is based on the number of the 4 cortices bridged by callus formation. It

may also be applicable to humerus, ulna, radius and femur. It is valid and reliable (Cekic et al., 2014). However, endosteal bone formation and the disappearance of fracture line may vary according to type of surgery and technique (Bhandari et al., 2013 ; Kooistra et al., 2010).

Health care providers from various countries are changing their focus from clinical processes to outcomes. More concentration and emphasis is put on quality rather than quantity of health; therefore, reliable outcome measures are essential in various fields. PROMs are increasingly used by clinicians in guiding routine patient care. Learning about patient's perspective towards a certain procedure is instrumental as it will help both the surgeon and patient to assess their surgical outcome (Auerbach,2009 ; Suk et al.,2013). More than 300 tools are used worldwide and each has its advantages and disadvantages some are specific to the site of injury while some are generalised.

Musculoskeletal Functional Assessment questionnaire are also used widely which has 101 items. A short Musculoskeletal Function Assessment questionnaire (SMFA) has 34 items for dysfunction index and 12 items for the bother index. It was designed for use in managing patients with musculoskeletal disease. It was evaluated for reliability, validity and responsiveness and it demonstrated good results (Swiontkowski, Engelberg, Martin, & Agel, 1999).

2.4.4 Early post-operative complications

- **Infections:** Infections occurs within 30 days after operation. Associated with at least one of the following; purulent discharge with or without laboratory confirmation, organisms isolated from cultures and clinical signs which include: pain, redness and localised swelling. Infection is one of the commonest

complications in open fractures due to contamination and exposure of bone tissue to environment. In addition, due to severe haemorrhage there may be systemic shock reducing blood supply to bone and soft tissue. This usually results in poor tissue oxygenation and devitalization of the surrounding tissue providing a medium for infection and multiplication of bacteria. Most acute infections are hospital acquired. Tibial fractures form the commonest site for open fractures of long bones. Unfortunately, they have reduced soft tissue cover at the shaft and reduced blood supply making these fractures vulnerable to non-union and infections (Wani et al., 2011).

According to a study done on isolated type 1 distal radial fractures, it was found that timing of debridement is not related to incidence of post-operative infections in Gustilo-Anderson type 1open fractures (Kurylo, Axelrad, Tornetta, & Jawa, 2011 ; Yang & Eisler, 2003). A randomized study on prophylactic antibiotic use in Gustilo-Anderson type II open tibia fractures in Kenyatta national hospital found had infection rates at 23% (9/40) (Ondari, Masika, Ombachi, & Ating'a, 2016).

Risk of infection is related to the severity of injury. Type-I Gustilo having a risk of infection at (0-2%), Type-II Gustilo (2-10%) and Type-III Gustilo ranging from 10% to 50% (Zalavras et al., 2007). The rate of infection is also associated with fracture characteristics, antibiotic therapy and patient parameters. Also location of fracture is important, with infection rate for open tibial fractures being twice that of other locations (Bowen & Widmaier, 2005).

- **Peripheral vascular injuries:** May result from penetrating or blunt trauma to the extremities. Peripheral injuries account for 80% of all cases of vascular trauma in the United States. Lower extremities are involved in two thirds of all patients

with vascular diseases. A study done in USA found that more than half of high energy tibial fractures, significant abnormalities were identified by CT angiogram (LeBus & Collinge, 2008). Another study done on vascular injuries and how it affected the outcome of open tibial had an incidence of 3% and concluded that vascular injury independently influenced long-term limb function (Chummun et al., 2013).

- **Peripheral nerve injuries** may result in loss of motor function, sensory function, or both. Such injuries may occur as a result of trauma (penetrating or blunt) or acute compression. Peripheral nerve injury may result in demyelination and axonal degeneration leading to sensory motor disruption. Graded into 3 categories according to Seddon classification, neurapraxia (nerve contusion), axonotmesis (axon and myelin is disrupted) and lastly neurotmesis (complete nerve division). A study done on entrapped posteromedial structures in distal tibia fractures found 12% of neurological deficit (Eastman, Firoozabadi, Benirschke, Barei, & Dunbar, 2014).

- **Compartmental syndrome** is defined by increased pressure in an enclosed osteofascial space leading to inhibition of capillary perfusion necessary for tissue viability. The main causes include intracompartmental haemorrhage from fracture, constricting cast or garment. Clinical signs include ("5 Ps"): pain, paresthesia, pulselessness, pallor and paralysis. Once diagnosed it is an emergent indication for fasciotomy (Skinner & Fitzpatrick, 2007). A study done in Austria on acute compartment syndrome following fractures of the lower leg, incidence was at 1.3%, injuries were high energy and 45% were caused by motorcycle accidents (Ferlic, Singer, Kraus, & Eberl, 2012).

2.4.5 Late complications

- **Non –union**: It is an arrest in the fracture repair process, an incomplete fracture healing or absence of healing seen at 6 months following an injury, along with lack of both clinical and radiological progressive signs of healing requiring a secondary surgical intervention for recovery. There is no standard criteria that exists for diagnosing fracture non-union and assessment of fracture healing varies among orthopaedic surgeons (Bishop, Palanca, Bellino, & Lowenberg, 2012). Delayed bone healing and non-union occur in approximately 10% of long bone fractures (Panteli, Pountos, Jones, & Giannoudis, 2015). Another study where Non-union rates of 20.3% for patients having open tibial fractures treated by external fixators were reported also (Papaioannou et al., 2001). Non-union resulting from humeral fractures is usually common if the fracture lines involve the upper one-third and middle one-third due to poor blood supply of the area (Singh et al., 2014).

- **Mal-union** may be defined as healing of a fracture in an abnormal position or alignment. A varus or valgus malalignment of 5° or more, anterior posterior angulation of 10° or more, shortening of 1cm or more and rotational malalignment of 10° or more. Can occur by having the bones improperly aligned when immobilized. The rate of mal-union was up to 20% in 458 fractures according to a meta-analysis of several papers (Giannoudis, Papakostidis, & Roberts, 2006).
- **Delayed union** is present when an adequate time frame has elapsed since the initial injury without achieving bone union. Healing past 6 months and does not need secondary surgical interventions to acquire union (Newton & Nunamaker, 1985). According to a meta-analysis of several papers, incidence of delayed union

was at 24% for 392 open tibial fractures treated with external fixators (Giannoudis, Papakostidis, & Roberts, 2006).

- **Re-fracture:** breaking of a bone that has united after a given stipulated management. Under external fixation the incidences are rare. An analysis of the outcomes and complications of 17 paediatric long bone fractures managed with external fixators was conducted in Afghanistan. Treatment used consisted of Uni-planar external fixation for 12 femoral shaft fractures (11 closed), 4 tibial shafts (open fractures) and 1 closed subtrochanteric fracture. All fractures united without incidences of refracture (Aslani, Tabrizi, Sadighi, & Mirbolook, 2013).

  Other late complications include chronic osteomyelitis, joint stiffness, etc.

- **Pin-site infection;** A common type of complication that can occur in the early stages post external fixators or even later on for those with definitive constructs. May also recur quite often. Pin itself as a foreign body acts as a focus of infection. Infection begins superficially before spreading to the deep soft tissues and eventually bone if left untreated. Pins are a critical element in the external fixation construct because it transmits forces from the injured bone to the bar and have the potential to loosen over time and may become infected. Pin-site sepsis is often noted as a major complication with reported incidence ranging from 11.3 to 100% (Ferreira & L. C. Marais, 2012). A study done by Kovar, Jaindl, Schuster, Endler, and Platzer,(2013) found out pin-site infection rate at 6.8%. Pin-site sepsis is usually the first symptom of a vicious cycle involving pin loosening and sustained pin-site infection. There is a misconception that pin-site sepsis leads to pin loosening; studies have shown that pin loosening is more often the inciting event that leads to pin-site infection (Piza, Caja, Gonzalez-Viejo, & Navarro, 2004). A

study done in Nigeria showed 35% of infections in patients treated with external fixators (Esan, Ikem, Oginni, & Esan, 2014). A study on use of external fixation on complex femoral shaft fractures and found that pin tract infections were not major problems despite their common occurrence as mostly would be treated by wound care and antibiotics: The common problem was decreased range of motion of the knee especially when external fixator is applied across the knee joint or fractures around the knee (Zlowodzki *et al.,* 2007). Pin site infections is graded according to Checketts-Otterburn Classification into 6 grades depending on the severity, see appendix 6. (Ferreira *et al.*, 2012).

Use of external fixators in Gustilo Type IIIB tibial fractures had incidences of non-union, wound infection, and osteomyelitis (17%, 6%, 11%, respectively) (Rohde et al., 2007). A different study reviewed external fixators use on tibial fractures and found that most frequent complications were non-union, infections followed up by delayed union with rates of 46%, 38% and 19% respectively (Madadi, Eajazi, Daftari Besheli, Sadeghian, & Nasri Lari, 2011). An up-to-date meta-analysis on internal versus external fixatures for unstable radius fractures had results showing rates of pin tract infections at 8.3% and malunion at 11.44% (Cui, Pan, Yu, Zhang, & Xiong, 2011).

2.4.6 Union rates

Normal healing was defined as union within 6 months both radiologically and clinically. No secondary surgeries were needed. A retrospective study was done on evaluation of Taylor special frame fixation in patients with multiple traumatic injuries of long bones where 52 patients who had 57 fractures were seen (25 involved the femur while 35 the tibia). Out of the 57 fractures 49 were open. An injury severity

score used was ≥ 16 for all patients. Clinical and radiological outcomes were analysed and 91% of the patients had complete union at an average of 29 weeks. There were 4 non-unions and one delayed union. Hence a conclusion of effectiveness in using the Taylor special frame fixation was made due to its reduced risk of infection, early immobilization, easy and accurate application and improved union rates. Better results according to bone and functional outcomes were also achieved after applying the Ilizarov criteria score (Sala, Elbatrawy, Thabet, Zayed, & Capitani, 2013). Although external fixation is not the preferred method of choice for definitive treatment of long bone fractures, it is still widely used and yields reasonable results. The union rates for a study done on external fixation of complex femoral shaft fractures were 91.5% (Zlowodzki, Prakash, & Aggarwal, 2007). There are reported union rates for external fixation of femoral shafts fracture ranging between70% to 100% (Murphy et al., 1998; Rooser, Bengston, Herrlin, & Onnerfalt, 1990; Titius, Krawehl-Nakath, & Klammer, 1989). However, in some various studies which showed high rates of union up to 90% without additional surgeries were not using the standard mono-lateral but advanced external fixators for example circular, ilizarov and taylor spatial frames (Kara et al., 2016; O'Neill, Fox, Molloy, O'HEireamhoin, & Moore, 2016).

2.5 Association between severity of open fractures and outcomes

The most widely used classification for open fractures is the Gustilo-Anderson which grades the injuries based on the size of the open wound, degree of contamination and extent of soft-tissue damage. Type III is reclassified it into 3 subgroups, based on the extent of bone exposure, adequacy of soft tissue cover and the need of neurovascular repair. Kim and Leopold described many limitations of the classification with a particular emphasis on the limited inter-observer reliability with as little as 60%

concordance between observers, However the classification still shows some value as a prognostic indicator and a useful guide towards treatment (Kim & Leopold, 2012).

A study done in Malaysia on factors associated with the outcome of open open tibial fractures found that there were high rates of infection and non-union, particularly in severe open fractures. Type I had 0% non-union and 0% infection, Type IIIA had 40% non-union and 41.2% infection while Type IIIB had 30% non-union and 41.2% infection (Yusof et al., 2013).

The infection rates for Type IIIB open fractures has been reported to be between 8.5% and 52% (Gustilo et al., 2013; Templeman et al., 1998). A study done on Gustilo-Anderson classification system as a predictor of non-union and infections in open tibia fractures found that 13% had infection and 12% had non-union. Type III had much higher rates of complications than Type I and Type II fractures. A conclusion of Gustilo-Anderson grading being by far the greatest predictor of non-union and infection was made (Thakore et al., 2017).

Type III Gustilo-Anderson was associated with high likelihood of non-union, malunion and infections unlike Type 1 which was likely to have union with less complications as probable outcomes (Giannoudis et al., 2006).

A study done in Nigeria on Determinants of management outcome in open tibia fractures showed that the higher the Gustilo-Anderson grading of the open fractures, the more severe the wound and bone infection occurred. There was a statistically significant correlation between Gustilo-Anderson and Infection ($p<0.001$), Osteomyelitis ($p<0.001$), Delayed union ($p<0.017$) and Union ($p<0.001$). Commonest complication observed were infection 39.3% and delayed union at 33.1%. Gustilo-Anderson classification was also encouraged as it provided the ability in statistical comparison and in determining the prognosis of open fractures (Ikem et al., 2006).

CHAPTER THREE

3.0 Methodology

Chapter three covers methodology used to conduct this study, including research design, study site, target population, study procedures and ethical considerations.

3.1 Study setting

The study was carried out in Orthopaedic wards, Clinics and Radiological Department at Moi Teaching and Referral Hospital which is the second largest hospital in Kenya after Kenyatta National Hospital (KNH). The hospital is located along Nandi Road in Eldoret town (about 310 kilometres Northwest of Nairobi the capital city of Kenya), Uasin Gishu County, in the North Rift region of Western Kenya. According to Kenya National Bureau of Statistics (KNBS, 2010) the hospital has a catchment area of about 22 million.

According to the central statistics of the hospital, MTRH has an average outpatient of 1500-2000 per day, with the accidents and emergency department receiving over 10,000 outpatients per year. It also has over 1200 inpatients per day. MTRH was therefore appropriate for this study.

3.2 Study design

This study was a descriptive prospective census study.

3. 3 Study population

All the patients who had open long bone fractures treated with external fixators at MTRH and who met the inclusion criteria and consented for the study between November 2015 to October 2016.

3.3.1 Sample size determination

Census study was preferred as all participants who underwent external fixation in MTRH from November 2015 to May 2016 were recruited and followed up for another 6 months. Previously in 2012 and 2013, an average of 142 patients were treated annually with external fixators secondary to open long bone fractures.

3.4 Eligibility

3.4.1 Inclusion criteria

- All Patients with open fractures of long bones managed using external fixators at MTRH.
- All patients who consented to be enrolled in the study.

3.4.2 Exclusion criteria

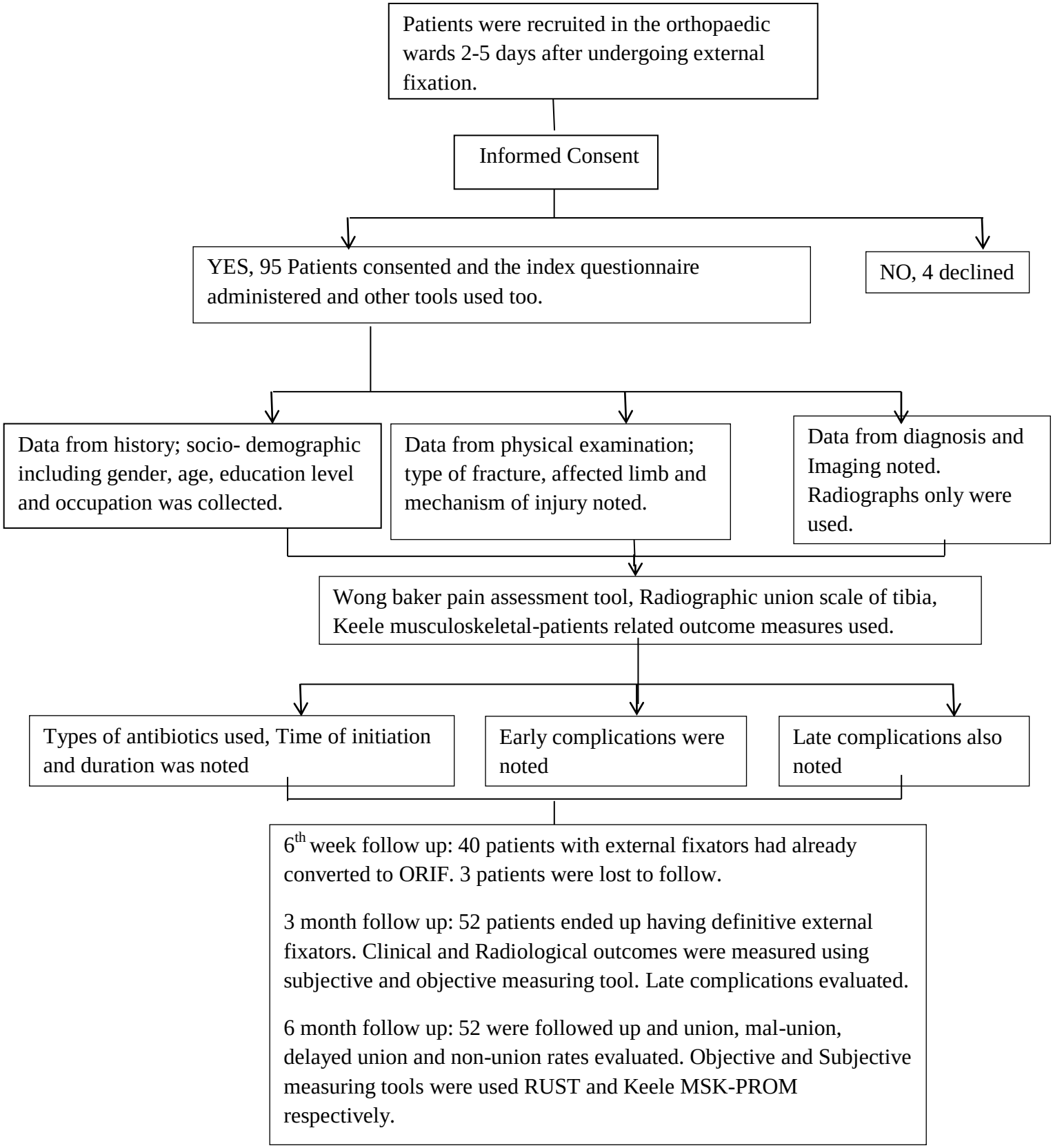
- Patients with external fixators inserted from other institutions.
- Patients who had previous history of surgery on the affected limb.

3.5 Study procedures

Upon admission patients were evaluated, stabilized and submitted to protocols as stipulated where wound exploration and debridement was performed followed by fracture stabilization with external fixators. Clinical assessments took place at the time of the first encounter with the patient, which was between 2 to 5 days' post external fixation. 95 patients consented and were included in the study. Follow up was then done at two weeks, six weeks, three months and 6 months after surgery. At each follow up, patient's status was ascertained (adverse events/ complications), and verification of information within medical records was also done. All fractures were classified according to the Gustilo and Anderson and AO classification. Time frame

to both surgical debridement and application of external fixators was recorded. Intra-operative management details were retrieved from the files. The index questionnaire and pain assessment tools were issued in order to have a baseline. The patients were followed up postoperatively and any complication arising was noted and intervened. Follow up visits were four as stated above. During these visits both subjective and objective outcome measuring tools were used.

Recruitment algorithm



3.6 Quality control

In regards to quality control the modified questionnaire was developed and pilot study done on 7 patients who were not included in the final study. Reviews were done to rectify the unclear parts, clearing of data and counter checks on data entry was done. Clinical and radiological assessment was made subsequently to determine the precise outcome. A radiologist who was blinded from the study reviewed the challenging radiographs to determine, mal-union and non-union.

3.7 Data collection and management

3.7.1Data collection

Collection of data and recording was done once patients had obtained an informed consent. A data collection tool was used in the wards and orthopaedic clinics. Patients' hospital medical records were also used to obtain data. Collection of data was carried out by the principal researcher with the aid of trained research assistants over a period of 12 months.

Data in the questionnaires were coded and transferred into an electronic format using the double entry approach. The database with the data was encrypted with password system and accessible to one person to ensure confidentiality. The data was de-identified (ripped off the identifying information) before entry. Back-up copies of the database were created and ensured that all were encrypted. The questionnaires with the data were kept also in safe filing cabinets under lock with only one key and accessible to only one person.

3.7.2 Data Analysis

Data analysis was done using R: A language and environment for statistical computing (R Core team 2017). Categorical variables such as gender were summarized using frequencies and the corresponding percentages. Continuous variables such as age were summarized using mean and the corresponding standard deviation whenever the Gaussian assumptions were assessed using histograms and normal probability plots such as QQ- plots. Results were presented using tables and graphs.

3.8 Study Variables

Were divide into Independent variables which included sociodemographic details, aetiology and fracture patterns while Dependent variables include the outcome measures such as non-union, pin-site and union rates.

3.8.1 Socio-demographic details-age, gender, occupation, level of education

3.8.2 Aetiology

This categorised as falls, assault, firearm injuries, sports injuries, industrial injuries and road traffic accidents

3.8.3 Fracture patterns

This constituted the affected limb, fractured bone, classification according to Gustilo & Anderson classification, AO classification

3.8.4 Treatment of patients using external fixators

-Time frame from injury to debridement and external fixation

-Type of external fixator used

-Type of antibiotics used

-Time of antibiotics initiation

-Duration of antibiotics used

3.8.5 Outcomes of external fixators

-Temporary external fixators and conversion rates to other treatment options

-Pain scale severity score.

-Keele MSK-PROM measure score.

-Immediate complications; infections, compartment syndrome, peripheral nerve injuries and vascular injuries.

-Late complications; pin-site infections, re-fracture, mal-union, delayed union and non-union.

-Union rates.

3.9 Ethical considerations

IREC approval was sought prior to commencement of the study. Formal approval number: IREC 1453 (Appendix 12).

Permission from Moi Teaching and Referral Hospital was granted (Appendix 13). Patients who fulfilled the inclusion criteria received a well informed consent in a language that they fully understood. All patients who met the inclusion criteria were included 2 to 5 days after surgery in order to have optimum time to consider their participation. Informed assent from children (> 7 years) was also obtained.

Parents or Guardians were disclosed to and made to understand the purpose of the study. Their permission was obtained first after being given an optimum time frame to consider whether or not their child should participate in the study. Reassurance that all information received from them or the patient would be handled with care and utmost confidentiality. This was a voluntary participation and no patient was denied

treatment whether he or she consented or not. Patients were not coerced and had a right to withdraw from the study. Once the thesis is ready, an oral presentation would be conducted and be published in peer review journals.

3.10 Study limitations

Collection of data was done in a period of one year which was limited compared to other studies in which data was averagely collected for over 3 years. It was difficult to include Functional outcome assessment as it needed more time until the patient gained full recovery. This had a huge impact as part of the outcome was not studied. Keele MSK-PROM subjective measuring tool was used to evaluate the patient's perceptions on how they related to the external fixation post-operatively and also how they were adjusting to their daily activities.

This being a prospective study, loss to follow-up was anticipated, this was mitigated by recording patients and relative contacts and reminding the patients of their scheduled clinic visits.

CHAPTER FOUR

4.0 RESULTS

Chapter four covers the documentation of research results/ findings as per the stated objectives.

A total of 95 patients with 98 fractures treated by external fixators between 2015 and 2016 were studied. The age range was between 5.0 and 78.0 years with mean age (± SD) of (37.3 ± 15.2). The sample comprised 11.6% patients aged < 20 years, 78 (82.1%) male patients. Forty patients had temporizing external fixators converted to mostly ORIF while 52 had definitive external fixators who were followed up completely to 6 months and their outcomes analysed. 3 patients were lost to follow up at 6 weeks.

4.1 Characteristics of Patients Treated with External Fixators

Table 1: Socio-demographic characteristics

Variable	N 95	n (%) or Mean (SD)
Age (Years)		37.3 (15.2)
Range (Min., Max.)		5.0 – 78.0
Male		78 (82.1%)
Occupation		
Casual labourer		14 (14.7%)
Farmer		27 (28.4%)
Housewife		9 (9.5%)
Student/Pupil		11 (11.6%)
Motorcyclist		18 (18.9%)
Employed		5 (5.3%)
Self-employed		3 (3.2%)
Driver		6 (6.3%)
Police officer/security guard		2 (2.1%)
Education		
None		4 (4.2%)
Primary		47 (49.5%)
Secondary		35 (36.8%)
Tertiary		9 (9.5%)

Up to 18.9% of the patients were motorcyclists, 14.7% casual labourers, 27 (28.4%) farmers, 9.5% housewives, and 11.6% students or pupils.

Half of the patients had primary level of education, and 36.8% had a secondary, and 9.5% tertiary level of education.

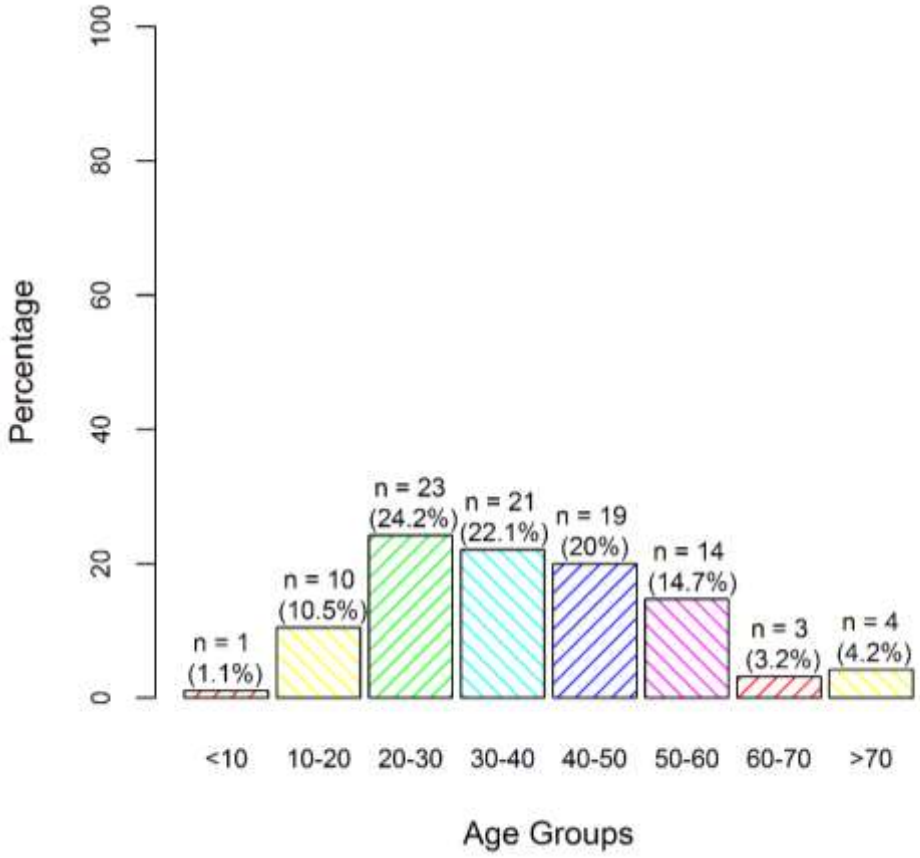


Figure 2: Distribution of patients by age

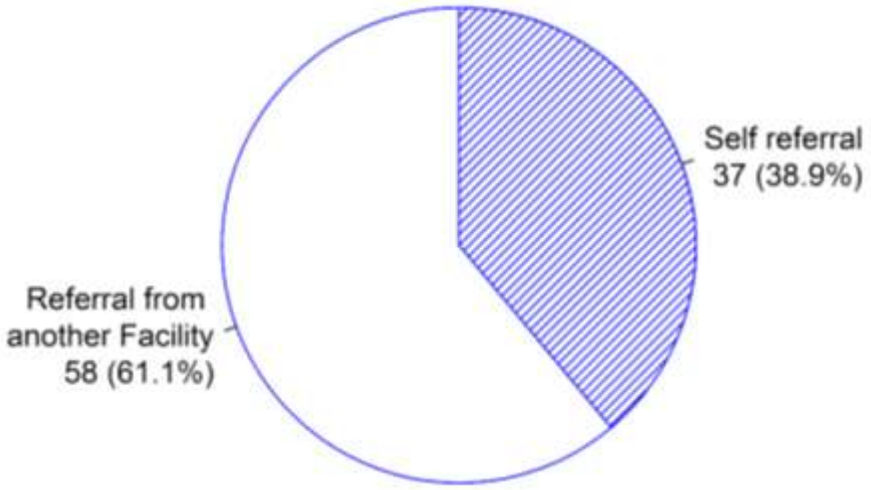


Figure 3: Referral to the MTRH facility

Up to 61.1% of the patients were referred from other facilities.

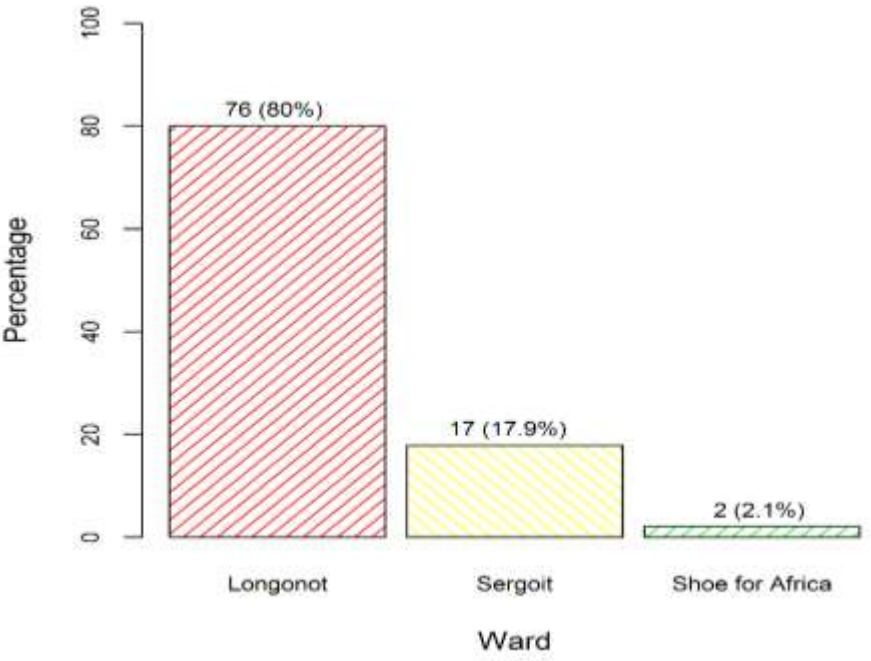


Figure 4: Distribution of patients by the ward they were admitted to

Eighty percent of the patients were under treatment in the Longonot ward, and 2.1% were from the Shoe for Africa ward. Longonot represented male ward, Sergoit female ward and Shoe for Africa paediatric ward

Table 2: Type of bone fractured

Variable	N 95	n (%)
Fractured bone		
Tibia fibula		65 (68.4%)
Femur		17 (17.9%)
Tibia		8 (8.4%)
Distal femur and proximal tibia		3 (3.2%)
Humerus		1 (1.1%)
Distal radius		1 (1.1%)

Up to two thirds (68.4%) of the patients had a fracture of tibia fibula, 17.9% had a fracture of the femur, and 8.4% had a fracture of the tibia. The rest of the fractures were as shown in Table 2.

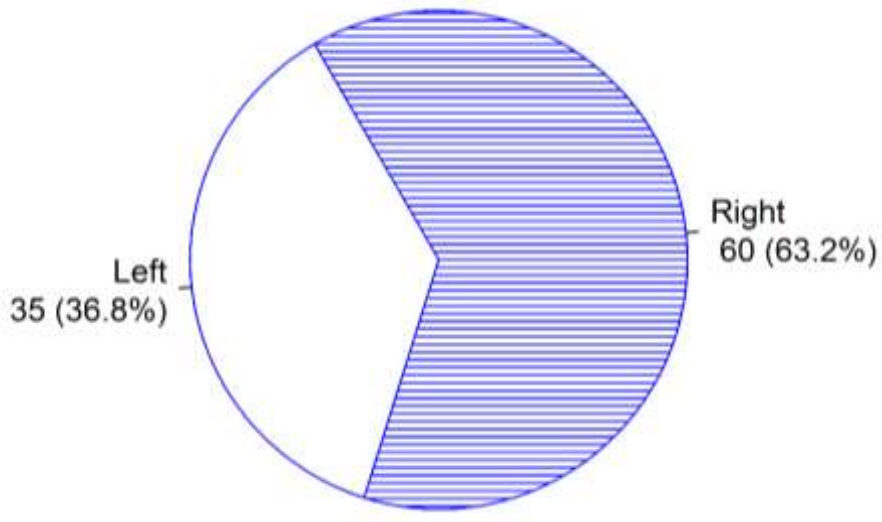


Figure 5: Limb affected
Of the 95 patients, 60 (63.2%) had a fracture of the right limb.

Table 3: Aetiology

Variable	N 95	n (%)
Aetiology		
Road traffic accidents		77 (81.1%)
Falls		10 (10.5%)
Assault		5 (5.3%)
Fire arm injuries		2 (2.1%)
Industry injuries		1 (1.1%)

Road traffic accidents contributed 77 (81.1%) of the fractures, followed by falls that accounted for 10 (10.5%) of the total injuries.

The industry injury was caused by chaff cutter.

The cause of the road traffic accidents as shown in Figure 6.

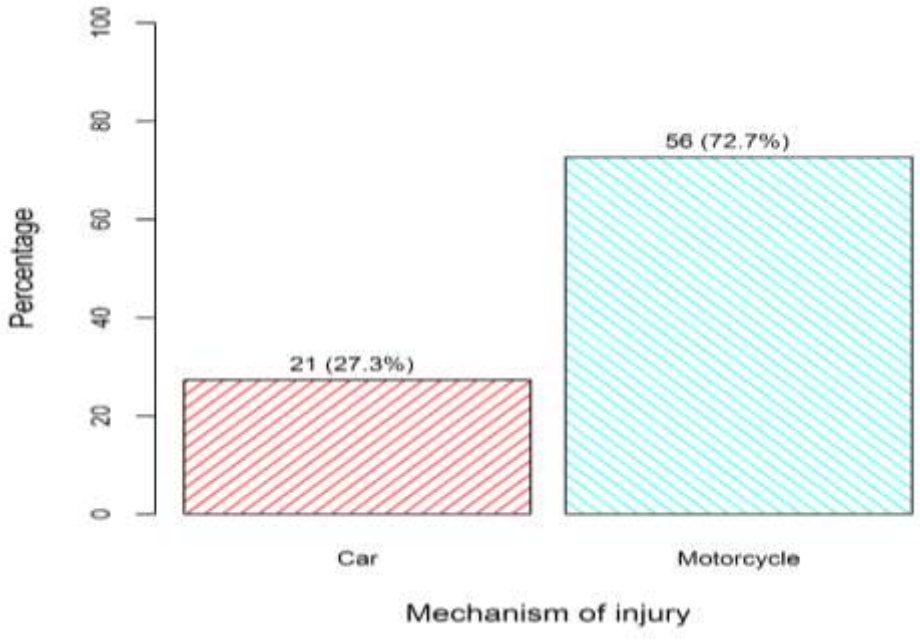


Figure 6: Causes of the road traffic accidents

Of the fractures due to road traffic accidents, car accidents accounted for 27.3%, and motorcycle accidents accounted for 72.7%.

Table 4: Classification of fractures

Variable	N 95	n (%)
Gustilo-Anderson classification		
Type I		6 (6.3%)
Type II		31 (32.6%)
Type IIIA		29 (30.5%)
Type IIIB		26 (27.4%)
Type IIIC		3 (3.2%)

Based on Gustilo-Anderson classification, 31 (32.6%) of the patients had Type II fractures, 29(30.5%) had Type IIIA, 26 (27.4%) had Type IIIB fractures, and 3 (3.2%) had Type IIIC fractures.

Table 5: Muller AO classification of fractures

Variable	**N 95**	**n (%)**
Segment		
Diaphyseal		50 (52.6%)
Distal		32 (33.7%)
Proximal		13 (13.7%)

The segments were diaphyseal for 50 (52.6%), and proximal for 13 (13.7%). One third had distal fractures.

Table 6: Initial management of patients treated with external fixators

Variable	**N 95**	**n (%)**
Time from injury to debridement		
≤ 24 hours		83 (87.4%)
24 – 72 hours		6 (6.3%)
> 72 hours		6 (6.3%)
Time of initiation of antibiotics		
≤ 24 hours		87 (91.6%)
24 – 72 hours		6 (6.3%)
> 72 hours		2 (2.1%)
Duration of antibiotics used		
2 weeks		8 (8.4%)
2 – 4 weeks		28 (29.5%)
> 4 weeks		59 (62.1%)

Up to 87.4% of the patients took at most 24 hours before debridement. Twelve (12.6%) patients took more than 24 hours before they had debridement.

Treatment with antibiotics was started within 24 hours for 87 (91.6%) of the participants. This lasted for more than four weeks for 59 (62.1%) of the patients.

4.2 Outcome of temporary external fixators to other treatment options

Table 7: Temporary external fixators

Variable	**N 40**	**n (%)**
Conversion to ORIF/POP/Removal		
Description		
Changed to nailing		24 (60.0%)
Changed to plating		12 (30.0%)
Conversion to POP		1(2.5%)
Removal and amputations		
Below knee amputations		2 (5.0%)
Above knee amputation		1 (2.5%)

Forty patients had temporary external fixators which were converted to either ORIF or POP. Of these, two thirds were changed to nailing, and one third to plating.

Conversion to POP was done to one of the patients who had temporary external fixators. Three other patients had to undergo removal of external fixators then amputations done due to early vascular complications.

4.3 Radiological and Clinical Outcomes of Patients Using External Fixators

Subjective outcomes;

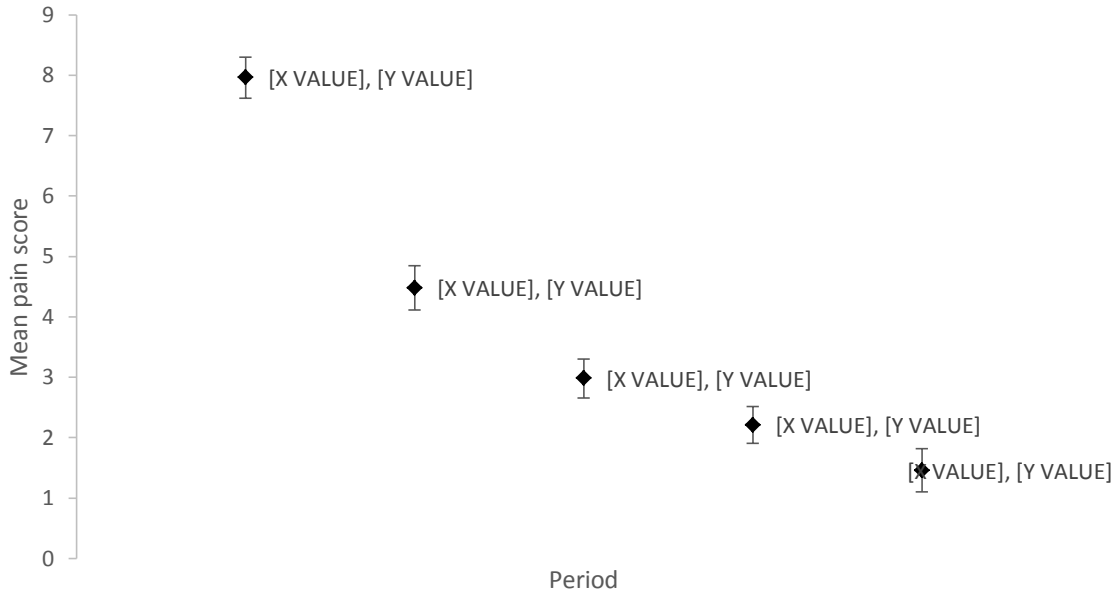


Figure 7: Distribution of mean pain score

Wong Baker face scale was used for scoring pain. There was significant difference in mean pain score between all review periods ($p<0.001$). However, the level of pain scores at any given review period was not dependent on the severity of open fracture (Gustilo-Anderson classification) ($p>0.05$).

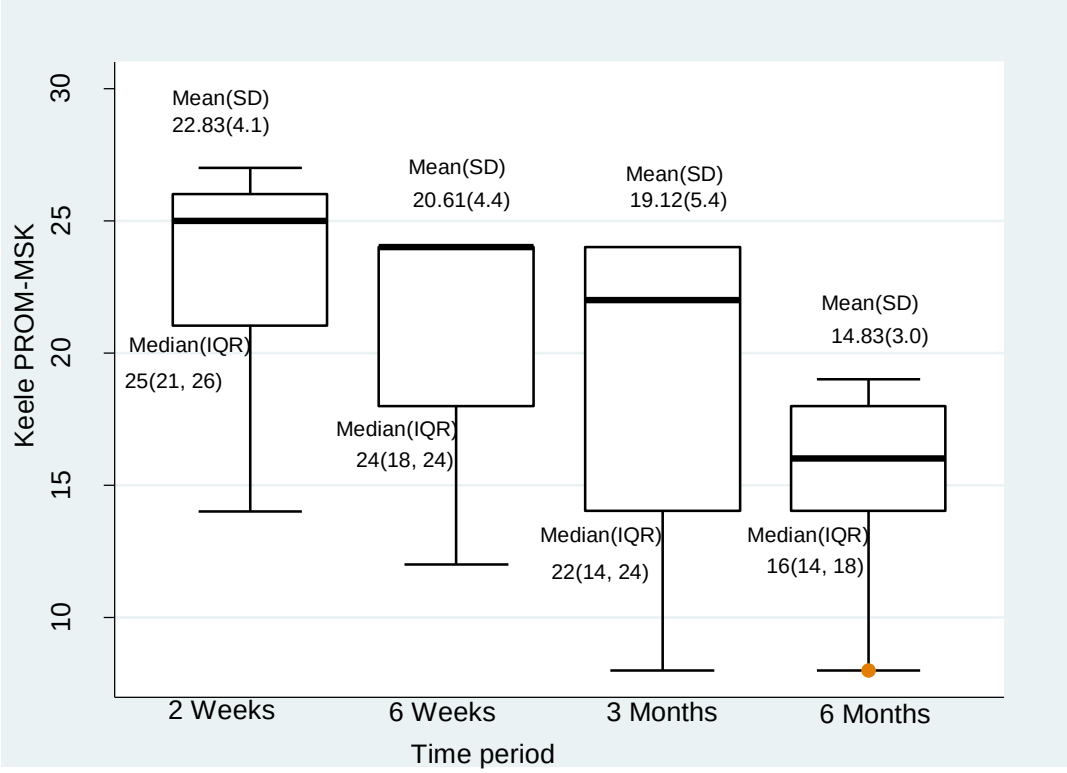


Figure 8: Keele PROM-MSK distribution over the period

In all the box plots above the Keele PROM-MSK distributions were slightly skewed to the left. There was a constant moderate reduction on the average Keele PROM-MSK from week 2 to 3 months, however the reduction seems to be pronounced at 6 months. Significant difference in average keele was realized between week 2 and 3 months ($p<0.001$), and 6month against all other review periods ($p<0.001$). Fitted regression models to associated between severity of open fracture and keele PROM-MSK were not fit (that is, severity of open fracture cannot be used a predictor of keele PROM-MSK).

Table 8: Immediate post-operative complications

Variable	N 95	n (%)
Infections		22 (23.1%)
Compartment syndrome		2(2.1%)
Peripheral nerve injuries		7 (7.3%)
Vascular injuries		4 (4.2%)

Twenty two patients (23.1%) presented with infections, compartment syndrome seen in 2 (2.1%), 7 (7.3%) had peripheral nerve injuries, and 4 (4.2%) had vascular injuries.

Figure 9: External fixator applied on the tibia associated with superficial infections.

Table 9: Late complications

Variable	N 95	n (%)
Pin-site infections		67 (70.5%)
Pin-site Grade		
Grade 1		4 (6.0%)
Grade 2		19(28.3%)
Grade 3		39 (58.2%)
Grade 4		5 (7.5%)
Radiological outcomes/complications		
Mal-union	52	9 (17.3%)
Delayed union	52	15 (28.9%)
Non-union	52	23 (44.2%)

Pin-site infections were reported for 67 (70.5%) of the patients at different stages of the treatment. Of this, 6.0% were in Grade 1, 28.3% in Grade 2, 58.2% In Grade 3, and 7.5% in Grade 4.

Mal-union was observed in 9(17.3%), delayed union in another 15 (28.9%), and non-union in 23 (44.2%).

Other complications included chronic osteomyelitis that was seen in 13 patients. Stiffness of ankle and knee joints was also a common complication.

Table 10: Delayed union against other factors

		Delayed union		
Variable	**Category**	**No**	**Yes**	**p-value**
Age	Median (IQR)	30(20, 45)	38(30, 53)	0.033†
Gender	Female	7	1	0.412[c]
	Male	30	14	
Gustilo classification	I+II	9	5	0.918[c]
	IIIA	20	7	
	IIIB	8	3	
Bone segment	D	6	4	0.564[c]
	M	27	9	
	P	4	2	
Surgical intervention	No	27	14	0.145[c]
	Yes	10	1	

† Mann Whitney u test, [c] Fisher's Exact test

Those who had delayed union were significantly (p=0.033) older (median=38; IQR 30, 53) compared to those who did not have delayed union (median=30; IQR 20, 45)

Table 11: Nonunion against other factors

		Nonunion		
Variable	**Category**	**No**	**Yes**	**p-value**
Age	Median (IQR)	37(29, 46)	30(20, 38)	0.132†
Gender	Female	4	4	>0.999[c]
	Male	25	19	
Gustilo classification	I+II	13	1	0.003[c]
	IIIA	11	16	
	IIIB	5	6	
Bone segment	D	7	3	0.521[c]
	M	18	18	
	P	4	2	
Surgical intervention	No	25	16	0.182[c]
	Yes	4	7	
† Mann Whitney u test, [c] Fisher's Exact test				

There was a significant association between severity of open fracture and nonunion (p=0.003) where only 7.1% among those classified as having Gustilo Type I and II had nonunion but among IIIB 54.5% had nonunion and 59.3% among those classified as IIIA had nonunion. .

Table 12: Malunion against other factors

		Malunion		
Variable	**Category**	**No**	**Yes**	**p-value**
Age	Median (IQR)	35(28, 46)	27(16, 37)	0.107†
Gender	Female	6(75.0)	2(25.0)	>0.615[c]
	Male	37(84.1)	7(15.9)	
Gustilo classification	I+II	11(78.6)	3(21.4)	0.890[c]
	IIIA	23(85.2)	4(14.8)	
	IIIB	9(81.8)	2(18.2)	
Bone segment	D	9(90.0)	1(10.0)	0.857[c]
	M	29(80.6)	7(19.4)	
	P	5(83.3)	1(16.7)	
Surgical intervention	No	35(85.4)	6(14.6)	0.378[c]
	Yes	8(72.7)	3(27.3)	
† Mann Whitney u test, [c] Fisher's Exact test				

Those classified as IIIA had the lowest (14.8%) proportion of patients with malunion compared to those classified as I&II (21.4%) and those classified as IIIB (18.2%).

Table 13: Pin site infections against other factors

Variable	Category	Pin site infections		p-value
		No	Yes	
Age	Median (IQR)	55(53, 61)	31.5(22, 40)	0.008†
Gender	Female	1	7	>0.999[c]
	Male	5	39	
Gustilo classification	I+II	5	9	-
	IIIA	1	26	
	IIIB	0	11	
Bone segment	D	3	7	0.071[c]
	M	2	34	
	P	1	5	
Surgical intervention	No	6	35	-
	Yes	0	11	

† Mann Whitney u test, [c] Fisher's Exact test

There were only 6 patients who did not develop pin site infection and majority (83.3%) of them were those classified as having gustilo I&II. All (100%) of those classified as IIIB had pin site infections. Those who developed pin site infection were significantly (p=0.008) younger 31.5(IQR 22, 40) years compared to those who did not develop 55(IQR 53, 61) years.

Table 14: Chronic osteomyelitis against other factors

Variable	Category	Chronic osteomyelitis		p-value
		No	Yes	
Age	Median (IQR)	35(27, 46)	31(17, 40)	0.505†
Gender	Female	5(62.5)	3(37.5)	>0.396[c]
	Male	34(77.3)	10(22.7)	
Gustilo classification	I+II	11(78.6)	3(21.4)	0.270[c]
	IIIA	22(81.5)	5(18.5)	
	IIIB	6(54.5)	5(45.5)	
Bone segment	D	10(100)	0(0.0)	-
	M	25(69.4)	11(30.6)	
	P	4(66.7)	2(33.3)	
Surgical intervention	No	32(78.0)	9(22.0)	0.435[c]
	Yes	7(63.6)	4(36.4)	

† Mann Whitney u test, [c] Fisher's Exact test

About 45% of those classified as IIIB had chronic osteomyelitis, class IIIA had the lowest (18.5%) proportion of patient with chronic osteomyelitis.

Figure 10: Grade II pin-site infection (appendix 6)

Figure 11: A radiograph depicting mal-union; The patient was scheduled later for another surgery.

Figure 12: Images showing high energy open fractures managed by external fixators, bone transport as secondary surgeries done due to bone loss leading to non-union.

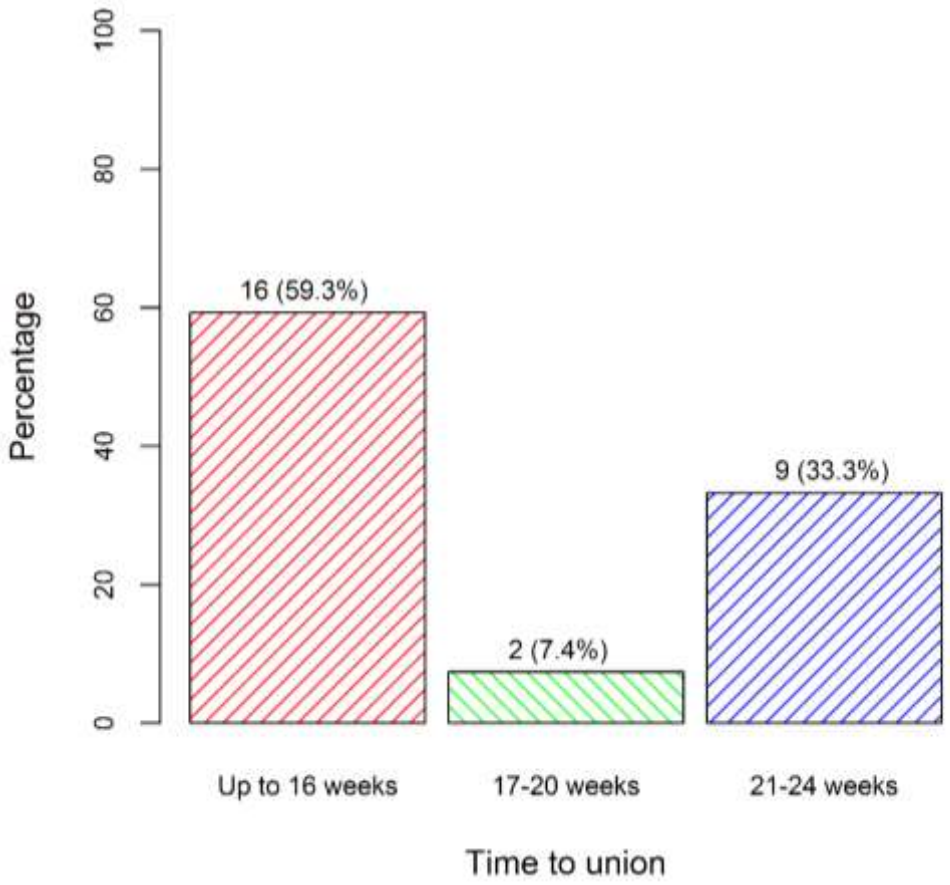


Figure 13: Time to union of the fracture

Close to 60% of the 27 patients had started having union by 16 weeks. Most of these patients had delayed unions and mal-unions.

4.4 Radiographic union scale for tibial fractures.

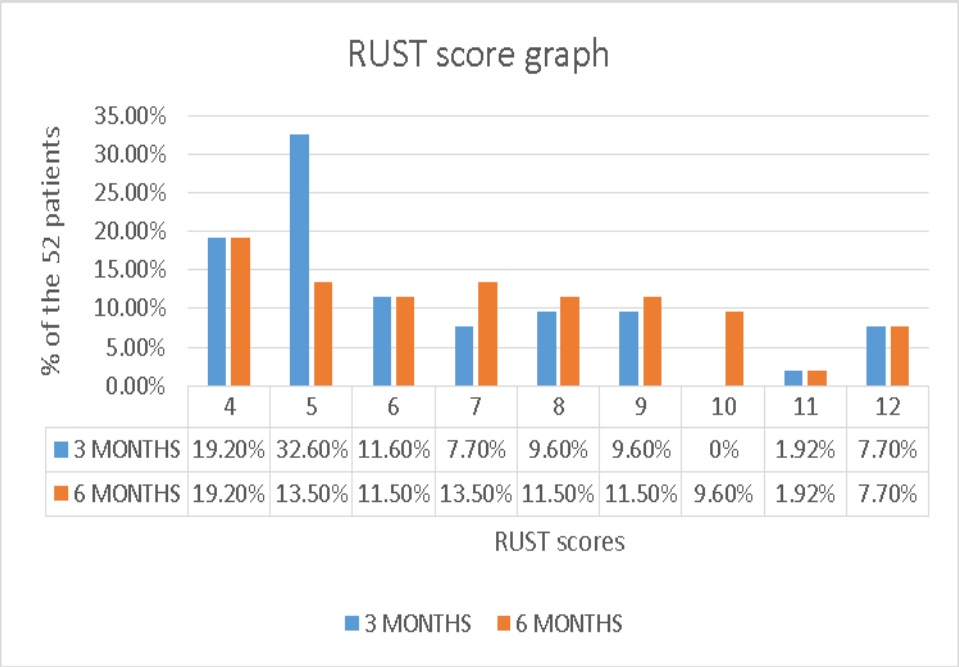


Figure 14: RUST scores graph at 3 months and 6 months for 52 Patients

The graph depicts that there were significant number of patients 19.2 % who had non-unions and scored 4 in both 3 and 6 months. There was a reduction from the number of patients who still had non-union and scored 5 from 32.6% at 3 months to 13.5% at 6 months. 7.7% of patients had a RUST score of 12 and 1.92% scored 11 at both 3 and 6 months. This shows that there were no changes in the patients who had complete union at 3months and 6 months respectively.

It shows that most patients still had non-union and scored 21.3% and 14.5% at RUST scores 4 and 5, as complete union was 9.62%.

4.5 Union rates.

In this study 5 patients who had external fixators had complete union and did not need further surgical intervention for their recovery.

Table 15: Union against other factors

Variable	Category	Union		p-value
		No	Yes	
Age	Median (IQR)	32(22, 45)	46(32, 54)	0.186†
Gender	Female	7	1	<0.999[c]
	Male	40	4	
Gustilo classification	I+II	9	5	-
	IIIA	27	0	
	IIIB	11	0	
Bone segment	D	8	2	0.204[c]
	M	34	2	
	P	5	1	
Surgical intervention	No	36	5	-
	Yes	11	0	

† Mann Whitney u test, [c] Fisher's Exact test

All (100%) those who had union were classified as Gustilo I and II. They also did not need other surgical interventions. 12.5% of females had union compared to 9.1% of males.

4.6 Association between Gustilo & Anderson classification with major outcomes.

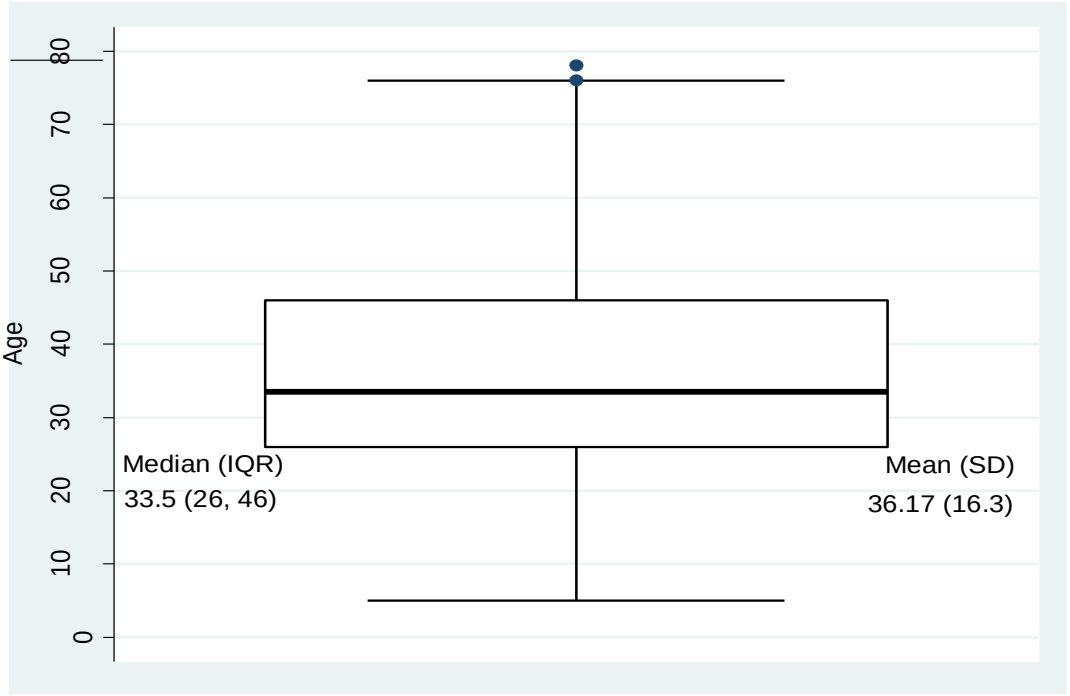


Figure 15: Age distribution

The age of the patients was slightly skewed to the right having a mean of 36.17(SD 16.3) years and Median of 33.5 (IQR 26, 46) years.

Only 8 (15.4%) patients were females. On average females significantly (p=0.003) older (M=51.5, IQR=41.5, 60.5) years compared to males (Median=30.5; IQR=22, 39) years. However, there was no significant association between sex and severity of open fracture (p=0.234).

There was a significant (p=0.025) difference in average age of patients in different gustilo categories. A post hoc analysis showed the significance difference in average age to be between gustilo I and II (median=43; IQR=29, 56) and gustilo IIIA (median=29; IQR 20, 38).

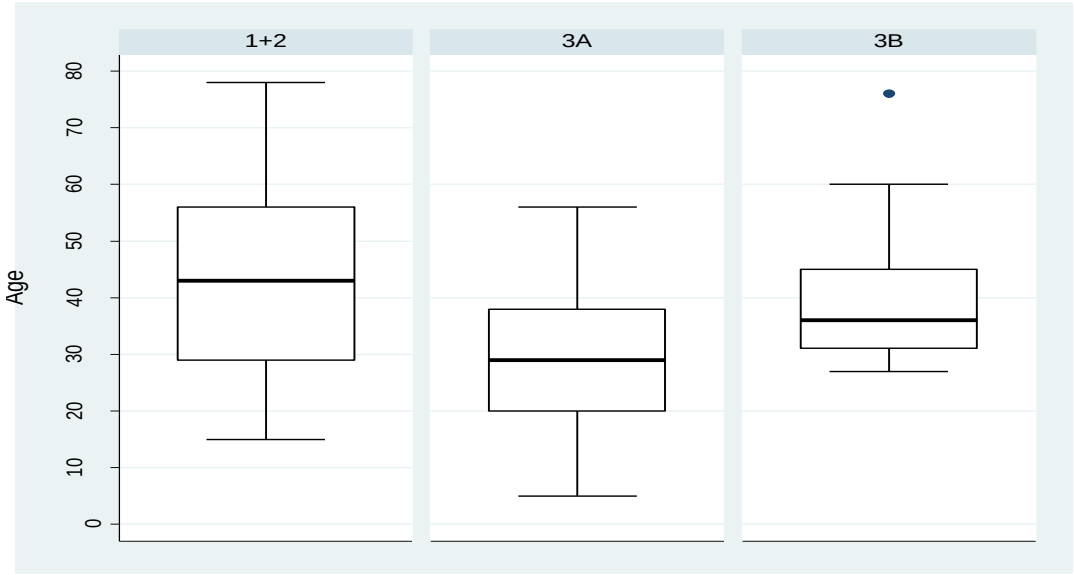


Figure 16: Age distribution by Gustilo classification

Statistic	DF	Value	Prob
Chi-Square	20	24.0000	0.2424
Likelihood Ratio Chi-Square	20	18.7285	0.5395
Mantel-Haenszel Chi-Square	1	0.1929	0.6605
Phi Coefficient		2.0000	
Contingency Coefficient		0.8944	
Cramer's V		1.0000	

Fisher's Exact Test	
Table Probability (P)	0.0028
Pr <= P	1.0000

An analysis was conducted to determine whether outcomes (union, malunion e.t.c) are independent of the kind of fractures reported according to fractures pattern classified by Gustilo-Anderson. A Chis square test of independence was conducted on aggregated data to ascertain this. The null hypothesis for this was that the outcomes observed are independently distributed to the type of Gustilo-Anderson fracture

reported. The relation between these variables was statistically significant, χ^2 (5, N = 95) = 24.00, p <.05.

Fisher's exact statistics was used to make inference, since the aggregated data had cells with expected frequencies less than 5. The p value was at 0.0028.

Type III Gustilo was associated with high likelihood of non-union, malunion, chronic osteomyelitis unlike Type I which was likely to have union with less complications as probable outcomes.

CHAPTER FIVE

5.0 Discussion

Chapter five covers the discussion of the research results and findings as per the objectives.

5.1 Characteristic of patients with open long bone fractures.

In this study males were approximately four times likely to sustain long bone open fractures than females with a ratio of 4.6:1. Majority were relatively young adults. Their mean age (+ SD) was (37.3 + 15.2) with a range 5-78 years. This concurred with studies done in Nigeria by Ikem, Oginni and Bamgboye (2001) which had similar results of mean age being 32 years (range: 5-78 years). According to Moola et al., 2014 who did a study reviewing open fractures, 68% were men and 32% were women with a range of 16-94 years.

Male predominance may be explained by the fact that they are more active outside their homes thus more likely to be involved in RTA. Also males undertaking risky activities such as over speeding, reckless motorcycle use without abiding by the safety road traffic rules and lastly driving under the influence of alcohol.

Concerning the educational level 9.5% had tertiary level of education. In regards to economic status, the study revealed a lower percentage at 5% for those who were in formal employment. This may have been as a result of them using other means of transport other than motorcycles or having better medical services enabling them to seek medical services in private facilities.

In this study the lower limbs were mostly affected with tibia being the most affected bone constituting 80%. Tibial fractures are associated with reduced soft tissue cover at the shaft and reduced blood supply making them vulnerable to non-union and infections (Wani, et al., 2011). A retrospective study conducted at Panzi Missionary

Hospital in Democratic Republic of Congo foundt that out of 62 patients with open fractures, 42 involved the tibia (Kaguku, Reinekainnen, Luhiriri, & Baldan, 2007). The right limb was also mostly affected at 63.2%. This result is in agreement with a study done in Niger where fractures affecting lower limbs represented 73.4% (Kortor et al., 2010).

Road traffic accident was the most common aetiology of open long bone fractures and out of this motorcycle related injuries were at 72.3%. This finding is in agreement with that in a study by Kigera and Naddumba (2010) where motorcycles contributed to 73% of trauma patients. However, a study done in Rwanda reported motorcycle involvement at 30% (Twagirayezu et al, 2008). This exposes people to the dependence on motorcycles as a form of transport in Uasin Gishu County and its environs.

The use of motorcycles as a means of transport without proper regulation and the upsurge of communal strife have increased the prevalence of extremity injuries requiring external fixation. Majority of the riders are prone to injuries due to increased recklessness, over speeding, lack of wearing helmets and other protective gears and carrying more than one passenger. The leg being most involved as it dangles precariously as the motorcycle meanders through heavy traffic.

Under the morphology of fractures, Gustilo-Anderson Type II was found in 32.6% of patients and Type III at 61.1%; Most of the fractures affected the shaft. According to Moola et al., (2014) who studied 297 open fractures and out of these Type III open injuries accounted for 24 %, Type I 51.2% and Type II 24.6 %. This can be explained by the dominance of motorcycles in the local society as discussed above leading to high energy injuries.

About 87.4% of the patients underwent debridement within 24 hours. Also 91.6% of patients were started on antibiotics within 24 hrs and 1st generation of cephalosporins were mostly used. These could be attributed to easy access to the hospital, therefore early referral and also good triage and effective medical team.

5.2 Temporary external fixators and their conversion to other definitive options.

All patients used the standard/modular external fixators in this study. No multi-planar and complex external fixators were used for example, Orthofix, Hoffmans, circular ring fixators and Taylor spatial frames which have lower incidences of complications as documented by Sala, Elbatrawy, Thabet, Zayed and Capitani 2013. External fixators were placed variably from the first debridement to several others depending on type of fractures as per Gustilo-Anderson classification and most importantly availability of funds to purchase the implants. Mean duration from injury to external fixation was at 7.3 days.

Forty (42.1%) patients had temporary external fixators, of these, 24 (60.0%) converted to intramedullary nailing, 12 (30.0%) changed to plating, 1 converted to POP and the remaining three had amputations due to vascular injuries. Two patients below knee amputations and one patient underwent above knee amputation. Most patients who converted to ORIF had Gustilo-Anderson Type I, Type II and IIIA where there was no excessive soft tissue damage or bone loss. This time frame may be as long as 6 weeks but is usually at least 2 weeks in duration, however there is no consensus on the optimal conversion point that exists. This is in agreement with a study done by Carroll, and Andrew., 2011. This may be explained by the fact that external fixators are usually used as a temporizing implant to ensure soft tissue healing then converted to ORIF depending on the severity and pattern of the fractures.

Having an optimal time frame from conversion of external fixators to ORIF is difficult because, various factors are involved such as soft tissue impairment, presence of infections, severity of the fracture pattern, associated injuries (poly-trauma patients) and finances.

Due to limited resources, poor financial capacity coupled with severe open fracture patterns, option of definitive fracture fixation using external fixators from time of admission ensued. Reasons for long period of external application in the local set up may be attributed to dearth of reconstructive expertise, for example use of computerised taylor spatial frames and other modern external fixators, and on the other side financial difficulties.

5.3. Clinical and radiological outcomes

Subjective outcomes:

5.3.1 Pain outcome measure

Pain score trend declined from a baseline mean of 7.96 to 1.46 at six months using the Wong Baker face scale for scoring pain. This was due to healing process and also use of analgesics, however, some participants still complained of pain at 6 months due to complications such as non-union, chronic osteomyelitis.

In reference to pain it reduced drastically from recruitment to month 6, this was attributed mostly to patient's recovery, the ones who had delayed union and non-union were complaining of moderate pain and had to be on analgesics on a daily routine.

5.3.2 Keele MSK-PROM outcome measure.

Health care providers from various countries are changing their focus from clinical processes to outcomes. More concentration and emphasis is put on quality rather than quantity of health; therefore, reliable outcome measures are essential in various fields. Learning about patient's perspective towards a certain procedure is instrumental as it will help both the surgeon and patient to assess their surgical outcome (Auerbach,2009; Suk et al.,2013).

The mean (+ SD) distribution for Keele MSK-PROM at first follow-up (2weeks) was 22.83(N=52, SD=+ 4.124). Making inference on the tools scale, this score implies the severity of the injuries is still critical. Comparing this distribution at follow up, after 6 months for the distribution showed a marginal decline in the mean to 14.83. These scores were high despite them declining in the routine follow ups and this indicated that the patients still had greater perception of problems. Fitted regression models to association between severity of open fracture and keele PROM-MSK were not fit (that is, severity of open fracture cannot be used solely as a predictor of keele PROM-MSK).

A study on PROMs also was in agreement with this study (Goldfarb, Ricci, Tull, Ray, & Borrelli, 2005). According to this it has been shown that a significant number of patients were treated with external fixators. Ideally it was supposed to be a temporizing implant then converted to plating or nailing, but 56% were followed up to 6 months. These patients were associated with complications as mentioned above. Also disease burden, in terms of depending on others, doing their daily house chores with difficulty, unable to resume work and other social interferences.

5.3.3 Early post-operative complications

In this study, 22(23.1%) had infections. This was in agreement with a study done on treatment of open fracture tibia by Kamat, (2011), which had an infection rate of 11.6% (12 out of 103 cases) A randomized study on prophylactic antibiotic use in Gustilo-Anderson type II open tibia fractures in Kenyatta national hospital documented infection rates at 23% (9/40) (Ondari, Masika, Ombachi, & Ating'a, 2016). This may be explained by the fact that most of the fractures were of high energy and highly contaminated. Severe haemorrhage leading to a decrease in blood supply to soft tissues, hence leading to low oxygen tension creating a media for infection and multiplication of bacteria. Most of the patients had to go in for several debridement procedures to help reduce the level of infection.

In this study, 2 (2.1%) of the patients had compartment syndrome. They underwent fasciotomy and external fixator at the same sitting. A study done in Austria on acute compartment syndrome following fractures of the lower limbs by Ferlic, Singer, Kraus and Eberl, (2012), found that the incidence was at 1.3%. The low incidence may be attributed to early management of fractures and when doing debridement there is extension of the wound and its soft tissues hence reduced compartmental pressures.

About 7.3% of the patients had peripheral nerve injuries. Three patients had total loss of sensory-motor (neurotmesis) involving common peroneal nerve supply area secondary to the high energy injuries. The other 4 had partial interruption (neuropraxia) involving both posterior tibial and common peroneal nerves which resolved later. A study done on entrapped posteromedial structures in distal tibia fractures found 12% had neurological deficit (Eastman, Firoozabadi, Benirschke, Barei, & Dunbar, 2014). There was no readjustment of the external fixators in fear of

iatrogenic nerve injury that was seen; this may be attributed to use of standard mono-lateral fixators compared to circular ring fixators and Taylor spatial frames which stand a higher chance of piercing the nerves.

Four (4.2%) of the patients had vascular injuries mostly involving the anterior and posterior tibial arteries according to the CT angiogram results. Three patients had amputations done; 1 above knee and the other 2 below knee. The other one was managed conservatively. A study done in USA found that more than half of high energy tibial fractures, significant abnormalities were identified by CT angiogram (LeBus & Collinge, 2008). Another study done in UK also found the same as documented by Chummun et al., 2013. This may be attributed to the high energy injuries that are experienced in our society. Also most of Gustilo-Anderson IIIB and IIIC would have already been subjected to MESS scoring system and amputation done before

5.3.4 Late complications

In this study, mal-union was observed in 9 (17.3%), delayed union in another 15 (28.9%) and non-union in 23 (44.2%). There was a statistical significance between severity of open fractures and non-union ($p = 0.003$). Delayed union was seen significantly in the older patients ($p = 0.033$). This was in agreement with a meta-analysis of several papers done on open tibial fractures treated with external fixators which reported an incidence of delayed union at 24% and mal-union was up to 20% (Giannoudis et al., 2006). A different study which reviewed external fixators use on tibial fractures found that most frequent complications were non-union, infections followed by delayed union with rates of 46%, 38% and 19% respectively (Madadi et al., 2011). Despite use of mono-lateral fixators often due to their easy application, they are usually associated with increased loss of reduction leading to development of

mal-union. Circular fixators minimise angulation problems and one is able to perform various corrections to obtain acceptable reduction and alignment as documented by Tafazal et al., 2014. In this study, high rates of non-unions and delayed unions were observed due to the high energy injuries associated with soft tissue impairment and even bone loss. Other factors may be smoking, immunosuppression and other comorbidities affecting the patients. Lack of finances were major causes for secondary surgery delays in management of the non-unions thus up to 6 months most of the patients still had external fixators in situ.

5.3. 5 Pin-site infection

In this study pin-site infection was reported in 70.5% of patients and most were in Type III at 58.2%. Patients treated definitively and followed up to 6 months also showed a high rate of pin site infection up to 88.4%. This was attributed to the longer stay with the construct and inefficient cleaning and dressing of the pin-site. Those who developed pin-site infection were significantly younger ($p = 0.008$). This was also noted as a major complication in another study which reported incidence ranging from 11.3 to 100% (Ferreira N., & Marais, L.C., 2012). A study done in Nigeria showed 35% of infections in patients treated with external fixators (Esan, Ikem, Oginni, & Esan, 2014); pin track infection rate has also been documented showing up to 32.2% (Giannoudis et al., 2006), However a study done by Kovar, Jaindl, Schuster, Endler, and Platzer, (2013) found pin-site infection rate at 6.8%. This can be explained by the fact that at MTRH orthopaedic surgeons are using standard stainless steel pins which have been abandoned by other institutions that have instead shifted to using hydroxyapatite-coated pins which show lower rates of pin-site infection and improved fixation strength. Standard uncoated pins lead to decreased bone-pin

interface strength resulting in loosening then pin-site infection as documented by Parameswaran et al.,2003.

Most of the patient with pin site infection underwent pin-site cleaning and dressing, some put on oral antibiotics. Majority of patients had reoccurrences at least once or twice. Five patients with grade 4 pin-site infection were taken back to theatre for external fixator removal.

High pin-site infection rate infection rate may be attributed to handing over the responsibility of cleaning the schanz screws to patients without close monitoring. Another reason was due to long stay of external fixators encouraging colonization of the schanz screw site.

5.3.6 Union rates

In this study 5 patients who had external fixators had complete union and did not need further surgeries for their recovery. All 100% of those who had union were classified as Gustilo-Anderson Type I and II. However in some various studies which showed high rates of union up to 90% without additional surgeries were not using the standard mono-lateral but advanced external fixators, for example; Circular, Ilizarov and Taylor spatial frames according to Kara et al., 2016; O'Neill, Fox, Molloy, O'HEireamhoin and Moore, 2016.

5.4 Association between Gustilo & Anderson classification of open long bones fractures and outcomes.

A Chi square test of independence was conducted on aggregated data to ascertain this. The null hypothesis for this was that the outcomes observed were independently distributed to the type of Gustilo-Anderson fracture reported. The relation between these variables was significant, χ^2 (5, N = 95) = 24.00, p <.05.

Fisher's exact statistics was used to make inference, since the aggregated data had cells with expected frequencies less than 5. The p value was at 0.0028.

Type III Gustilo-Anderson was associated with high likelihood of non-union, malunion, chronic osteomyelitis unlike Type I which was likely to have union with less complications as probable outcomes. This is in agreement with study done by Giannoudis et al., 2006. This was attributed to the fact that Type III fracture pattern had severe soft tissue injury and mostly comminuted fracture pattern and bone loss. Also RTA was the common aetiology as most patients had motorbike accident involvement.

CHAPTER SIX

6.0 Conclusions and Recommendations

This chapter cover the conclusions and recommendation of the study based on the stated objective

6.1 Conclusions

1. Majority of the patients were male and relatively young, road traffic accident especially involving motorcycles injuries was the major aetiology and tibia was the most affected bone.
2. Only standard/modular fixators were used in this study and conversion of temporary fixators was to mostly intramedullary nailing and plating as definitive options.
3. Major complications observed were pin-site infections, non-unions, delayed unions and mal-unions. Low union rates were recorded at 9.6 % (5 patients).
4. There was a significant association between severity of open fractures and major outcomes (p= 0.0028).

6.2 Recommendations

1. Control and preventive measures needed against the aetiological factors. Emphasis on educating the society especially young males on road safety rules should be enhanced.
2. Modular external fixators is optimal for temporary use but should be discouraged for definitive use.
3. Use of modern external fixators and hydroxyapatite coated pins to reduce complications should be emphasised
4. Gustilo-Anderson Type III should be managed with more emphasis especially when one is anticipating nonunion and pin-site infections.

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APPENDICES

The following documents are attached below as appendices to this research proposal:

- Appendix 1: Introductory letter.
- Appendix 2: Consent and assent form.
- Appendix 3: Data collection sheet (Questionnaire).
- Appendix 4: Gustilo -Anderson classification.
- Appendix 5: AO classification.
- Appendix 6: Checketts-Otterbun pinsite infection grading tool.
- Appendix 7: Wong Baker Face Scale for scoring pain tool.
- Appendix 8: RUST scoring tool.
- Appendix 9: The Keel MSK-PROM for monitoring musculoskeletal Health.
- Appendix 10: The Budget.
- Appendix 11: Work plan.
- Appendix 12: IREC approval.
- Appendix 13: MTRH approval.

Appendix 1: Introductory Letter

INTRODUCTORY LETTER

Dr. Ibrahim Rioba Nyamosi

P.O BOX 4606

ELDORET, KENYA

TEL: 0727784774

Dear respondent.

I hereby want to inform you that I am currently conducting a study on outcome of long bone open fractures treated with external fixators at MTRH, Eldoret, Kenya.

Once the study has been completed, the results will be used to provide more information on the rates of complications and union rates hence may help in provision of better management of patients in the future.

Yours faithfully

Dr. Ibrahim Rioba

Appendix 2: Consent Form

STUDY TITLE: OUTCOME OF LONG BONE OPEN FRACTURES IN PATIENTS TREATED WITH EXTERNAL FIXATORS AT MOI TEACHING AND REFFERAL HOSPITAL.

Introduction

My name is Dr. Ibrahim Rioba. I am a post-graduate student in the department of Orthopaedic surgery at Moi University. I am required to carry out a research projected as part of my post-graduate studies. My study is aimed at establishing the outcome of external fixation used on long bone open fractures at MTRH.

Study procedure

If you or your dependant agrees to participate in this study, questions will be asked surrounding your mechanism of injury, surgery and antibiotics used. Questionnaire will be used at first time of contact and then more measuring tools will be used on subsequent visits. Routine clinical follow up will progress as usual without interference.

Benefits of the study

There is no direct benefit to the participants but the study will contribute in informing policy makers on the strengths and weaknesses in the management of open fractures using external fixators.

Harm of the study

There may be discomfort in discussing private information.

Confidentiality

All information obtained from you or your dependant will be strictly kept confidential and used only for research purposes. Your name will not appear on the data collection tools. All papers and computer records will be kept strictly under lock and key using security codes.

Rights to refuse or withdraw from the study

Participation in this study is entirely voluntary. You or your dependant is free to withdraw from the study at any point.

In case of any questions regarding the study, you can contact Dr. Ibrahim Rioba on mobile phone 0727-784774

Having read and been explained to the above:

I Mr. / Mrs. / Miss _____

(Patient/ Guardian) to (name of dependant) _____

With knowledge that this study is voluntary, do hereby give my consent/ consent for my dependant to participate in the study.

I understand that I or my dependant can withdraw from the study without any penalty or harm.

Patient's signature _____ Date _____

Guardian/ Parent signature_____ Date _____

Principal investigator's signature _____ Date _____

b) Assent for patients below 18 years of age

I have been adequately informed that I am being recruited into a study on outcome of open long bone fractures in patients treated with external fixators at MTRH. The investigator has also informed me that my participation in this study is voluntary and even if I was to opt out, my confidentiality will be respected.

Patient's name_____

Patient's signature_____ Date_____

Kiambatisho 1: FOMU IDHINI

Kichwa cha Utafiti

Matokeo ya mifupa iliyovunjika baada ya kutibiwa na External fixators katika hospitali kuu ya Moi mjini Eldoret, (MTRH).

Utangulizi

Jina langu ni Daktari Ibrahim Rioba. Mimi ni mwanafunzi katika chuo kikuu cha Moi. Nahitimu katika idara ya upasuaji. Mimi ninahitajika kufanya utafiti vile inatarajiwa kama sehemu ya masomo yangu baada ya kuhitimu. Utafiti wangu una lengo la kubainisha matokeo ya mifupa iliyovunjika baada ya kutibiwa na External Fixators katika hospitali ya MTRH.

Utaratibu wa utafiti

Iwapo wewe au mtegemezi wako atakubali kushiriki katika utafiti huu, maswali utaulizwa kuhusu jinsi ulivyoumia, upasuaji na madawa unayoyatumia.. Dodoso zitatumika kwa wakati wa kwanza wa mawasiliano na kupima zana. basi zaidi zitatumika kwenye ziara za baadae. Mara kwa mara kliniki kufuatilia itakuwa maendeleo kama kawaida bila kuingiliwa.

Faida za utafiti

Hakuna faida ya moja kwa moja kwa washiriki lakini utafiti utachangia katika kuwaarifu watunga sera juu ya uwezo na udhaifu katika matibabu ya mifupa iliyovunjika.

Madhara ya kushiriki

Kunaweza kuwa na usumbufu katika kujadili habari binafsi.

Usiri

Taarifa zote zilizopatikana kutoka kwenu, au tegemezi wako itakuwa madhubuti siri na kutumika tu kwa madhumuni ya utafiti. Jina yako haitonekana kwenye zana ukusanyaji wa takwimu. Karatasi zote na kumbukumbu ya kompyuta yatawekwa madhubuti chini ya kufuli na ufunguo. Tarakilishi itatumika kuimarisha usalama.

Haki ya kukataa au kuondoka kutoka utafiti

Kushiriki katika utafiti huu ni hiari kabisa. Wewe au tegemezi wako yuko huru kuondoka kutoka utafiti katika hatua yoyote.

Katika kesi ya maswali yoyote kuhusu utafiti huu, unaweza kuwasiliana na Daktari Ibrahim Rioba kwanamabari ya simu za mkononi 0727-784774

Baada ya kusoma na kuelezwa kwa kina mambo yanayohusiana na utafiti huu;

Mimi Bwana / Bi _____

(Mshiriki / Mlezi wa mshiriki) wa (jina la mtegemezi)

_____

Nina maarifa kwamba utafiti huu ni wa hiari, ninafanya kutoa idhini yangu / ridhaa kwa ajili ya mtegemezi wangu ya kushiriki katika utafiti.

Naelewa kwamba mimi au mtegemezi wangu anaweza kuondoka kutoka utafiti bila adhabu yoyote au madhara.

Sahihi ya Mshiriki _____ Tarehe _____

Sahihi ya Mlezi / Mzazi _____ Tarehe _____

Sahihi ya Mkuu wa uchunguzi _____ Tarehe _____

b) Idhini ya mwanariadha aliye chini ya miaka 18

Nimeelezwa ipasavyo kwamba ninashirikishwa katika uchunguzi huu wa Matokeo ya mifupa iliyovunjika baada ya kutibiwa na External fixators katika hospitali kuu ya Moi mjini Eldoret, (MTRH).

Mchunguzi amenieleza pia kuwa ushiriki wangu ni kwa hiari na iwapo ninge pendelea kujiondoa katika uchunguzi huu, maelezo yangu yatahifadhiwa vyema.

Jina_____

Sahihi_____ Tarehe_____

APPENDIX 3: PART A DATA COLLECTION SHEET (QUESTIONNAIRE)

QUESTIONNAIRE: A STUDY ON OUTCOMES OF LONG BONE OPEN FRACTURES TREATED WITH EXTERNAL FIXATORS AT MTRH, ELDORET, KENYA

MTRH Ward/clinic: _____Date: _____

Participant's

Name_____

IP NO._____

Address_____ Phone no._____

Type of referral: Self ☐ another facility ☐

specify_____

D.O.B_____ Gender: Male ☐ Female ☐

Age_____ years

Occupation_____

Education Level: Primary ☐ Secondary ☐ Tertiary ☐ None ☐

Fractured bone: _____

Affected limb: Right ☐ left ☐

Aetiology: _____

Type of fracture according to Gustilo-Anderson classification:

Type 1 ☐ Type II ☐ Type IIIA ☐ Type IIIB ☐ Type IIIC ☐

(see attached appendix 4).

AO classification _____(see attached appendix 5).

Time frame from injury to debridement and external fixation:

Within 24 hrs ☐ 24-72 hrs ☐ more than 72 hrs ☐

Type of external fixator used _____

Type of antibiotics used_____

Time of initiation of antibiotics:

Within 24hrs ☐ 24-72 hrs ☐ more than 72hrs ☐

Duration of antibiotics used:

1 week ☐ 2weeks ☐ 2-4 weeks ☐ more than 4 weeks ☐

Pain scale severity score ☐ /10 (see attached tool for scoring pain: appendix 6).

Immediate complications: infections ☐ compartment syndrome ☐

Peripheral nerve injuries ☐ vascular injuries ☐

Others_____

PART B: DATA COLLECTING SHEET AND OUTCOME MEASURING TOOLS FOR FOLLOW UP

Late complications: Pin-site infections ☐ (See attached appendix 7)

Refracture ☐ mal-union ☐ delayed union ☐ non-union ☐

Others _____

Time of union:

Up to 16 weeks ☐ 17-20 weeks ☐ 21-24 weeks ☐

Temporary external fixators:

Conversion to ORIF/ intramedullary nailing ☐

Conversion to POP ☐

Objective outcome measuring using radiological assessment: (See appendix 8).

Subjective outcome measuring tool: (see appendix 9).

INVESTIGATOR:

Dr Ibrahim Rioba

P.O. BOX, 4606-30100

Eldoret, Kenya

Tel. 0727-784774

Appendix: 4 Gustilo-Anderson Classification of Open Fractures.

- Type I:wound less than 1cm with minimal contamination and of low energy.
- Type II: the laceration is between 1cm and 10cm long and is associated with minimal contamination. There is moderate soft tissue damage and usually high energy is involved.
- Type III: Wound is more than 10cm and is contaminated massively. There is extensive tissue damage.

Type IIIA: Extensive soft tissue damage but with adequate soft tissue to cover the bone.

Type IIIB: Extensive soft tissue damage and loss associated with periosteal stripping and require flap advancement.

Type IIIC: Open fractures with neurovascular injury that require repair.

The following fractures are considered as special categories and fall into Type III.

- ❖ All Gunshot wounds.
- ❖ Open fractures that are severely contaminated such us those that have happened in the farmyard, contamination from sewers.
- ❖ Fractures that occur in wars or natural disasters.
- ❖ Fractures due to high energy trauma.

(Kim & Leopold, 2012).

Appendix: 5 Müller AO Classification of Fractures

	1	**2**	**3**	**4**
Bone	Humerus	Radius and Ulna	Femur	Tibia and Fibula
Segment	Proximal	Diaphyseal	Distal	Malleolar

Segment	**A**	**B**	**C**
1	Extra-articular	Partial articular	Complete articular
2	Simple	Wedge	Complex
3	Extra-articular	Partial articular	Complete articular

Type	1	2	3
A-simple	Spiral	Oblique	Transverse
B-wedge	Spiral	Bending	Fragmented
C-complex	Spiral	Segmental	Comminuted

Adapted and modified from Müller, Koch, Nazarian and Schatzker, 1990

Appendix: 6 Checketts-Otterburn Classification of Pin Tract Infection

GRADE	APPEARANCE	TREATMENT
1	Slight redness, little discharge	Improved pin site care
2	Redness of skin, discharge, pain and tenderness in the soft tissues	Improved pin site care, oral antibiotics
3	Redness of skin, discharge, pain and tenderness in the soft tissues and not improved with antibiotics	Affected pin or pins resided and external fixation can be continued
4	Severe soft tissue infection involving severe pins, sometimes with associated loosening of the pin	External fixation must be abandoned
5	Severe soft tissue infection involving severe pins, sometimes with associated loosening of the pin but also involvement of the bone. Also visible on radiographs	External fixation must be abandoned
6	This infection occurs after fixator removal. The pin track heals initially but will break down and discharge in intervals. Radiograph shows new bone formation and sometimes sequestra	Curettage of the pin track

Adapted and modified from Nando Ferreira and Leonard Charles Marais, 2012.

Appendix 7: WONG Baker Face Scale for Scoring Pain

Instructions

Ask the patient to choose one of the faces that best describes how they feel. The far left face which is 0 indicates 'No hurt' and the far right face which has number 10 below indicates 'Hurts worst'. Documentation should be done on the number below the face (Wong & Baker, 1988).

Appendix 8: Radiographic Union Scale for Tibial Fractures

Cortex	**Fracture line visible, No callus. Score =1**	**Visible fracture line and callus. Score = 2**	**No fracture line visible callus. Score = 3**	**Total score** **Minimum:4** **Maximum: 12**
Anterior				
Posterior				
Lateral				
Medial				

Adapted and modified from Cekic, Alici and Yesil, 2014.

Appendix 9: Musculoskeletal outcome Measure. Adapted from Hill et al., 2015.

The Keele MSK-PROM for Monitoring Musculoskeletal Health

This questionnaire is about the health problem for which you are seeking treatment from this service.
Place a **tick** in **one** box for each question below to indicate which statement best describes **your view today**
Each **column** records a different treatment visit.

Q1. Needing help		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
How often do you need help from others because of your symptoms?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

Q2. Work/daily routine		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
How often have your symptoms interfered with your normal work/daily routine (including jobs around the house)?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

Q3. Activities and roles		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
How often are you prevented from doing activities and roles that matter to you?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

Q4. Severity of worst problem (e.g. sleep, fatigue, driving)		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Think about the one thing you have the most difficulty with. How often are you finding this difficult?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

Q5. Understanding how to deal with symptoms		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
How often do you feel unsure about how to deal with your symptoms?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

Q6. Overall impact		Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6
Overall, how often do your symptoms bother you?							
Never	1						
Rarely	2						
Sometimes	3						
Frequently	4						
All the time	5						

The tool is scored by summing all 6 items together.

Appendix 10: Budget

Items	**Quantity**	**Unit Price (K.shs)**	**Total (K.shs)**
Stationery & Equipment			
Printing Papers	6 reams	600.00	3,600.00
CD-roms	2	50.00	100.00
Writing Pens	1 packet	500.00	500.00
Flash Discs	1	2,000.00	2,000.00
Box Files	2	200.00	400.00
Document Wallets	3	50.00	150.00
Sub total			**6,750.00**
Research Proposal Development			
Typing, printing drafts & final proposal	6 copies	900.00	5,400.00
Photocopies of final proposal	6 copies	200.00	1200.00
Binding of copies of Proposal	6 copies	250.00	900.00
Sub total			**7,500.00**
Personnel			
Biostatician	1	15,000.00	15,000.00
Research assistants	2	10,000.00	20,000.00
Sub total			**35,000.00**
Communication			**20,000.00**
Thesis Development			
Typing, printing of drafts and final thesis	6 copies	1200.00	7,200.00
Photocopy of final thesis	6 copies	400.00	2400.00
Binding of thesis	6 copies	500.00	3000.00
Sub total			**12,600.00**
IREC approval fees			**1,000.00**
X-ray costs			**50,000.00**
Total			**132,850.00**
Miscellaneous Expenditure (10% of Total)			13,285.00
Grand Total			**146,135.00**

Appendix 11: Work Plan

	January 2015 to June 2017	Jan 2015 to April 2015	May 2015	June 2015	July 2015 to August	November 2015 to October 2016	November 2016 to January 2017	April 2019	July 2019
Developing a Proposal		■							
Proposal presentation			■						
Submission of the proposal to IREC for review				■					
Making corrections if any from IREC					■				
Data collection						■			
Data entry, coding, cleaning and Analysis							■		
Thesis submission								■	
Thesis defence									■

Appendix 12: IREC Approval

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke

P. O. Box 3
ELDORET

Ref: ELD/MTRH/R.6/VOL.II/2008

11th August, 2015

Dr. Ibrahim Rioba Nyamosi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

RE: APPROVAL TO CONDUCT RESEARCH AT MTRH

Upon obtaining approval from the Institutional Research and Ethics Committee (IREC) to conduct your research proposal titled:

"Outcomes of Long Bone Open Fractures Treated with External Fixators at Moi Teaching and Referral Hospital."

You are hereby permitted to commence your investigation at Moi Teaching and Referral Hospital.

DR.JOHN KIBOSIA

DIRECTOR
MOI TEACHING AND REFERRAL HOSPITAL

CC - Deputy Director (CS)
- Chief Nurse
- HOD,HRISM

Appendix I3: MTRH Approval

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
ELDORET
Tel: 33471/2/3

MOI UNIVERSITY
SCHOOL OF MEDICINE
P.O. BOX 4606
ELDORET

Reference: IREC/2015/131.
Approval Number: 0001453.

5th August, 2015

Dr. Ibrahim Rioba Nyamosi,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
05 AUG 2015
APPROVED
P.O. Box 4606-30100 ELDORET

Dear. Dr. Nyamosi,

RE: FORMAL APPROVAL

The Institutional Research and Ethics Committee has reviewed your research proposal titled:-

"Outcomes of Long Bone Open Fractures Treated with External Fixators at Moi Teaching and Referral Hospital."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1453*** on 5th August, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 4th August, 2016. If it is necessary to continue with this research beyond the expiry date, a request for continuation should be made in writing to IREC Secretariat two months prior to the expiry date.

You are required to submit progress report(s) regularly as dictated by your proposal. Furthermore, you must notify the Committee of any proposal change (s) or amendment (s), serious or unexpected outcomes related to the conduct of the study, or study termination for any reason. The Committee expects to receive a final report at the end of the study.

Sincerely,

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

cc Director - MTRH Dean - SOP Dean - SOM
Principal - CHS Dean - SON Dean - SOD