CHARACTERISTICS AND TREATMENT OUTCOMES OF DISTAL TIBIA FRACTURES AMONG ADULT PATIENTS AT MOI TEACHING AND REFERRAL HOSPITAL, ELDORET KENYA

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A thesis submitted in partial fulfillment of the requirements for the award of a Master of Medicine degree in Orthopaedic Surgery of Moi University

DECLARATION

DECLARATION BY THE CANDIDATE

This thesis is my original work and has not been presented for academic purposes in any other institution of higher learning. No part of this thesis may be reproduced without prior written permission of the author and/or Moi University.

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DECLARATION BY SUPERVISORS

This thesis has been presented for examination with our approval as Moi University supervisors.

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DEDICATION

I dedicate this thesis work to my family. I express a special feeling of gratitude to my loving parents; Krisanto and Marisera Oeba for encouraging and supporting me to study medicine.

I also dedicate this work and give special thanks to my wife Brenda, my son Adrian and my wonderful daughter Audrey for being there for me throughout my Masters program.

ABSTRACT

Background: The treatment of distal tibia fractures remains challenging since they are prone to higher rates of complications. Treatment options are expanding and although their indications, advantages and disadvantages have been discussed in literature, controversy still exists over the clinical efficacy and cost-effectiveness of each option. This has led to different orthopaedic surgeons employing different operative treatment options based on their experience, preference and patient characteristics.

Objective: This study sought to describe the characteristics and treatment of distal tibia fractures at MTRH and compare the outcome results of the various treatment options.

Methods: A prospective observational study design was used. Adult patients with distal tibia fractures admitted during the study period were included through consecutive sampling. A total of 76 patients were followed up. Data including injury aetiology, fracture types and classification, treatment and complications were collected. Functional outcome was assessed using Olerud and Molander Ankle Score (OMAS) at 6 months after treatment. Data was collected between October 2015 and March 2017 using a structured questionnaire and analyzed using STATA version 13 at 95% confidence level. Chi square test was used to determine the significance of associations between categorical variables.

Results: The median age was 40.0(30.0, 52.0) years, with a male-to-female ratio of 1.7:1. Most common causes of injury were RTA in 37 patients and falls in 29 patients. There were 48 closed and 28 open injuries. According to AO/OTA classification, there were 40(52.6%) type A, 28(36.8%) type B and 8(10.6%) type C fractures. Twenty-five (32.9%) patients were treated non-operatively, 28(36.8%) patients underwent internal fixation with plating and 23(30.3%) patients were treated using external fixation method. Non-operative treatment was mostly used for closed injuries (80%) whereas majority of open fractures (82%) were treated operatively (P=0.033). Complications occurred in 48(57.8%) patients, including 30(62.5%) wound infections, 21(43.7%) malunions and 3(6%) chronic osteomyelitis. Infections were significantly higher among external fixation treated patients (P=0.002). At final follow up the functional outcome using OMAS was excellent in 11(14.5%) patients, good in 28(36.8%), fair in 17(22.4%) and poor in 20(26.3%) patients. OMAS scores were significantly high in patients treated with plating and low in patients with comminuted fractures, complications and open injuries (P<0.001).

Conclusion: Distal tibia fractures mostly occurred in young males. Road traffic accidents and falls were the commonest causes. Treatment by plate fixation resulted in significantly higher functional outcome scores and lower rate of complications compared to non-operative treatment.

Recommendation: Distal tibia fractures should be treated operatively by plate fixation to improve treatment outcomes.

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ABBREVIATIONS AND ACRONYMS

A&E	Accident and Emergency
AO	Arbeitsgemeinschaftfür Osteosynthesefragen
	(German for “association for the study of internal fixation”)
FAOS	Foot and Ankle Outcome Score
GSRF	Global Self Rating Function
IM	Intramedullary
IQR	Inter-quartile range
MIPO	Minimally Invasive Plate Osteosynthesis
MTRH	Moi Teaching and Referral Hospital
OMAS	Olerud and Molander Ankle Score
ORIF	Open Reduction and Internal Fixation
OTA	Orthopaedic Trauma Association
RCT	Randomized Controlled Trial
RTA	Road Traffic Accident
SIGN®	Surgical Implant Generation Network

DEFINITION OF KEY TERMS

Adult- A human being of 18 years of age and above.

Characteristics of injury- Refer to the causes and mechanism of injury, types and classification of fractures. Distal tibia fractures were classified using the Arbeitsgemeinschaftfür Osteosynthesefragen (AO) classification system. Closed fractures were classified using the Tscherne grading system and open fractures according to the Gustilo-Anderson classification.

Distal tibia- The terminal end of the tibia which lies within two Muller squares of the ankle as defined by AO. This encompasses the distal metaphysis, the posterior malleolus and the tibial plafond.

Fracture- This is a break in the long continuity of a bone. A fracture is said to be closed when the overlying skin is intact or open when there is a wound that makes communication between the fractured bone and the outside environment. In a displaced fracture the fragments move from their natural position.

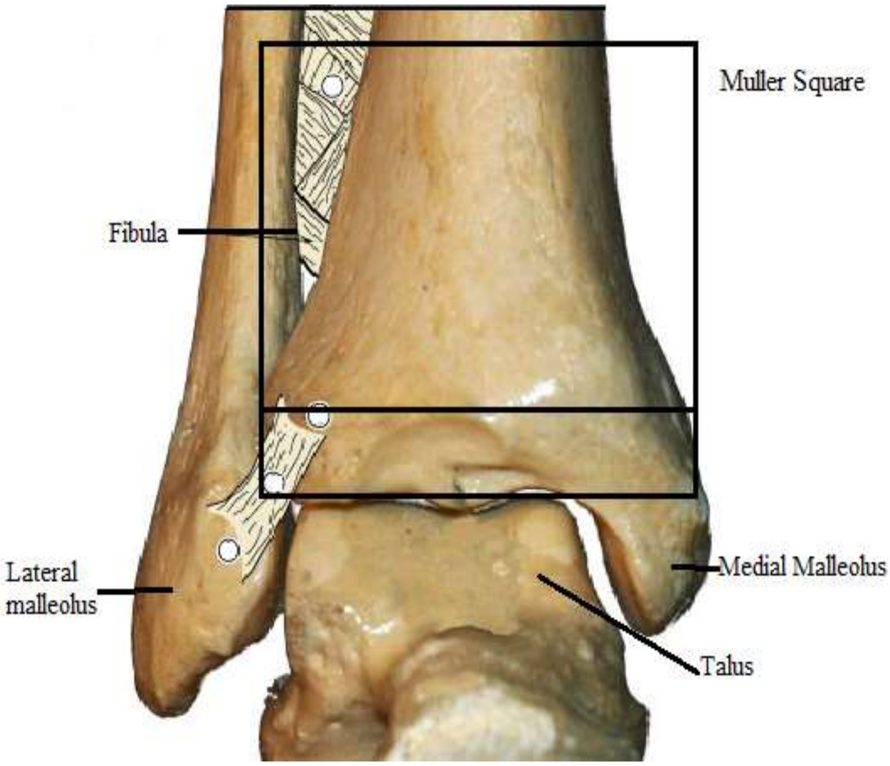
Outcomes- Refer to the consequences of distal tibia fractures and/or its treatment. They include the clinician observed results and patients reported effects of the injury and/or the treatment. Malunion is the deviation of a bone or part of it from its natural continuity and position including rotation, overlapping, shifting, and angulation. Functional outcome will be assessed using OMAS(Olerud & Molander, 1984).

Treatment- Refers to the operative and non-operative remedies given to a patient with distal tibia fracture. Basic methods of non-operative treatment include reduction by traction and manipulation followed by immobilization with plaster casts, splints, braces or other technique. Surgical treatment involves cutting/incising of the patients' tissues or closure of a previously sustained wound and reduction and fixation

CHAPTER ONE: INTRODUCTION

1.1 Background

Distal tibia refers to the terminal end of the tibia encompassing the distal metaphysis, medial malleolus, posterior malleolus and the tibial plafond. The Arbeitsgemeinschaft für Osteosynthesefragen and Orthopaedic Trauma Association (AO/OTA) define distal tibia fractures as those contained within two Muller squares of the distal tibia. Muller square of the distal metaphysis is the square of the portion of bone whose sides are the same in length as the widest part of the metaphysis. Tibial plafond refer to the weight bearing surface of the distal tibia (Marsh et al., 2007). Figure 1.1.1 below is an illustration of the Muller's square of the distal tibia.



Adapted from www.eORIF.com

Figure 1.1.1: Anatomy of distal tibia.

The cross-sectional shape of the tibia transitions from that of a triangle with an anterior apex to quadri-angular in shape shape moving distally from the diaphysis to the metaphysis. Compared to the diaphysis, the distal metaphysis is characterized by a thinner cortical bone and a wider medullary cavity that is filled with cancellous bone (Browner, Jupiter, Levine, Trafton, & Krettek, 2009).

The fibula articulates distally with the lateral surface of the distal tibial metaphysis through the lateral syndesmotic ligaments and the distal interosseous membrane and is the reason why the fibula is mostly injured in higher-energy fracture characteristics. In addition the inferior tibiofibular ligamentous complex is critical in maintaining the stability of the ankle joint. Therefore an intact fibula maintains tibial alignment during fracture healing (Bonnevialle et al., 2010; Joveniaux et al., 2010).

Blood supply to the distal tibia is derived from two sources. Perfusion to the outer one- third of the tibial cortex is extra-osseous and arises from a network of periosteal vessels which arise from the anterior and posterior tibial arteries. The inner two-thirds of the distal tibia are supplied by intra-osseous nutrient arteries, which are branches of the posterior tibial artery. Fractures can obliterate both intra-osseous and extra-osseous blood supply. The distal leg has a thin soft tissue cover. Therefore significant soft tissue injury or periosteal stripping during fixation destroys the remaining blood supply causing avascular necrosis of the bone and subsequently impairing bone healing resulting in nonunion (Richard, Kubiak, & Horwitz, 2014; Standring, Borley, & Gray, 2008).

Distal tibia fractures have a high complication rate pre-operatively as well as post-operatively. Because they are high-energy injuries, majority tend to be either open fractures or have associated extensive soft tissue damage (Mioc et al., 2018). In addition distal tibia fractures cause significant morbidity and result in prolonged periods away from work and social activities (Joveniaux et al., 2010). Limb loss can occur as a result of severe soft-tissue trauma, neurovascular compromise, compartment syndrome, or infection such as gangrene (Richard et al., 2014).

Several methods of treatment have been described including; non-operative treatment by use of plaster casts and braces, operative treatment by use of intramedullary nail, open plate fixation, minimally invasive plating, and various constructs of external fixation. Each of these options has its merits and demerits (Zelle, Bhandari, Espiritu, Koval, & Zlowodzki, 2006).

Although the indications, advantages and disadvantages of each of these operative treatment options have been discussed in the literature, controversy still exists over the clinical efficacy and cost-effectiveness of each option. This has led to different orthopaedic surgeons employing different operative treatment options based on their experience, preference and patient factors (Hattarki Ravindra, 2016).

There is an increasing need for orthopaedic practitioners to measure and collect patient-reported outcomes data. Most tools measure the success of the intervention applied by assessing if the patient is able to resume work and other activities (Hunt & Hurwit, 2013). The Olerud and Molander Ankle Score (OMAS) is a self-administered questionnaire. The score is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and work/activities of daily living. OMAS is well known and has been used in many studies for several years (Mioc et al., 2018).

Various studies have reported varying outcome results with different modalities of treatment. Treatment with open reduction and internal fixation (ORIF) has shown superior results in the setting of good soft tissue quality or low energy trauma

(Piątkowski, Piekarczyk, Kwiatkowski, Przybycień, & Chwedczuk, 2015). However, bad outcome as measured using OMAS has been reported with ORIF when performed on patients with associated nerve or vascular injury, wound complications and infections (Barcak & Collinge, 2016). Factors such as timing of treatment, method of stabilization, techniques of operative care, and postoperative rehabilitation, affect clinical and functional outcomes and have been subjects of debate among traumatologists (Liporace & Yoon, 2012).

MTRH serves as the main trauma care centre in the western region of Kenya. At MTRH fractures are managed by a team of clinicians with varied experience and qualifications but definitive management and further follow up after treatment is performed by orthopaedic registrars and orthopedic surgeons in consultation with other specialists (Kilonzo, Mwangi, Lelei, Nyabera, & Ayumba, 2014). The local epidemiological patterns and outcomes of the treatment modalities for distal tibia fractures at MTRH have not been documented before. This study therefore sought to describe the patients' characteristics and the treatment of distal tibia fractures at MTRH and compare the outcome results of the various treatment options.

1.2 Problem statement

The treatment of distal tibia fractures remains challenging since they are prone to higher rates of complications both preoperatively as well as post-operatively. Treatment options are expanding and although their indications, advantages and disadvantages have been discussed in literature, controversy still exists over the clinical efficacy and cost-effectiveness of each option. This has led to different orthopaedic surgeons employing different operative treatment options based on their experience, preference and patient characteristics. Results on outcome of various treatment options from different treatment centers are conflicting with no consensus on the most suitable treatment modality. MTRH is the main trauma center in the western region of Kenya and distal tibia fractures form a significant proportion of trauma patients. In 2015 the researcher came across 12 patients who were on follow up for various complications from distal tibia fracture. Data on the characteristics and mechanisms of injury, treatment outcomes of distal tibia fractures at MTRH has not been documented before.

1.3 Justification

At the orthopaedic unit of MTRH, there have been no studies done to assess the treatment and outcome of distal tibia fractures. This study was expected to generate information pertaining to the patients' and injury characteristics and treatment of distal tibia fractures at MTRH and compare the outcome results of the various treatment options. The measurement of patients' reported outcome scores using OMAS would help clinicians better meet the needs and expectations of patients before and after treatment as well as offer appropriate counseling on the anticipated prognosis. This will lead to increased clinicians' understanding of these fractures and their treatment and factors affecting outcomes. It is anticipated that this will result in appropriate treatment of distal tibia fractures thereby reducing morbidity and complications resulting in faster functional rehabilitation of the limb as a step towards improving patient care at MTRH.

1.4 Research question

How are the characteristics and treatment outcomes of distal tibia fractures in adult patients at MTRH?

1.5 Objectives

1.5.1 Broad objective

To describe the characteristics and treatment outcomes of distal tibia fractures in adult patients at MTRH

1.5.2 Specific objectives

i. To describe the characteristics of distal tibia fractures in adult patients at MTRH.
ii. To describe the treatment of distal tibia fractures in adult patients at MTRH.
iii. To assess the ankle function following treatment of distal tibia fractures in adult patients using OMAS at MTRH.
iv. To determine association between OMAS and the injury characteristics, fracture severity and mode of treatment in adult patients with distal tibia fractures at MTRH.

CHAPTER TWO: LITERATURE REVIEW

2.1 Epidemiology of distal tibia fractures

Few data exist on the epidemiology of distal tibia fractures of the metaphysis. Distal tibia fractures account for 7% of all non-fatal injuries. Pilon fractures account for 10% of all tibia fractures. The incidence rates of distal tibia fractures vary with age and gender. A study done in Sweden by Wennergren et al., (2018) to describe the epidemiology and incidence of fractures in the whole of the tibia classified according to the AO/OTA system reported an incidence of 9.1 per 100,000 per year for distal tibia fractures. The authors also found that distal tibia fractures account for 18% of all tibia fractures, occur more common in males, with an average age of 48.7 years and majority of the fractures (88.5%) being closed.

In another study by Stephens et al., (2015) to evaluate the use of the SIGN® intramedullary (IM) nail in distal metaphyseal tibia fractures in three developing countries including Kenya, Ethiopia and Pakistan, it was found that distal tibia fractures were four times more common in males than in females.

The mean age of patients with distal tibia fracture ranges 36-45 years with a male preponderance of between 60 to 75% (Bhairi, Mahesh, Qureshi, Kumar, & Kumar, 2017; Shah, Somshekar, Patel, & Chawda, 2019).

Distal tibia fractures are commonly caused by high energy trauma. In young patients and males of all ages, Road traffic Accidents (RTA), falls from height, direct trauma from assault, industrial accidents and sports related injuries are commonly listed as causative of distal tibia fractures. Simple fall is the most common cause for distal tibia fractures among postmenopausal women. Studies by Wennergren et al., (2018) and Stephens et al., (2015) report that road traffic accidents (RTA) and falls are the most common causes of distal tibia fractures. In a review of the hospital charts of all the patients presented to emergency and accident department in a tertiary hospital, by Meena et al., (2013), found that even though high energy trauma from RTA and fall from a height were the most common causes of distal tibia fractures across all age groups, there was an increase of distal tibia fractures caused by simple falls in women after the 5th decade of life.

2.2 Clinical and fracture characteristics

Because distal tibia fractures result from high energy trauma and the distal leg has thin soft tissue envelope, patients usually have significant soft tissue injury and associated fibula fracture. Studies have reported a range of spectrum of soft tissue injury from bruises and oedema to severe contusion and lacerations with degloving injuries. Stephen et al., (2015) in their study found that 60% of distal tibia fractures were of open type, majority of them being Gustillo-Anderson type II while about 93% of the fractures were associated with fibula fractures. Joveniaux et al., (2010) in a study done in France found the rate of ipsilateral fibular fracture to be 46% while Bonnevialle et al., (2010) found a higher rate of 93% of ipsilateral fibular fracture.

Most studies describe the distal tibia fractures using the OA/OTA classification system and have reported varied rate of occurrence of each fracture types, A, B and C. Wennergren et al., (2018) reported that within the distal tibia fractures, there was a fairly equal distribution between A, B and C fractures. However in most studies, Type A (metaphyseal extra-articular) is reported as the most common and Type C (intra-articular) is the least common (Richard et al., 2014; Richards et al., 2012).

2.3 Classification of distal tibia fractures

Several classification systems have been developed to describe distal tibia fractures. Soft tissue injury can be evaluated with the Gustilo-Anderson or Tscherne-Oestern classification systems for open or closed fractures, respectively (Gustilo, Mendoza, & Williams, 1984; Tscherne & Oestern, 1982).

Table 2.3.1: Tscherne Classification for closed fractures
(Tscherne & Oestern, 1982).

Grade 0	No appreciable soft tissue injury
Grade 1	Abrasion or contusion to skin or subcutaneous tissue
Grade 2	Deep abrasion or contusion to the muscle
Grade 3	Crush, avulsion, and severe muscle damage, compartment syndrome

Table 2.3.2: Abridged version of Gustillo-Anderson classification for open fractures
(Gustilo et al., 1984).

Type I	Wound ≤1 cm, minimal contamination or muscle damage.
Type II	Wound 1-10 cm, moderate soft tissue injury.
Type IIIA	Wound usually >10 cm, high energy, extensive soft-tissue damage, contaminated. Adequate tissue for flap coverage. Farm injuries are automatically at least Gustillo III
Type IIIB	Extensive periosteal stripping, wound requires soft tissue coverage
Type IIIC	Vascular injury requiring vascular repair, regardless of degree of soft tissue injury.

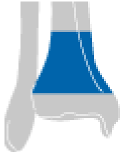
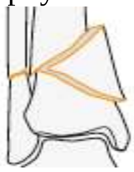
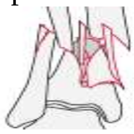
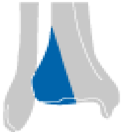
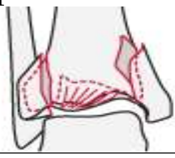
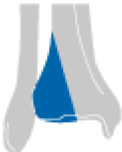
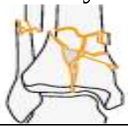
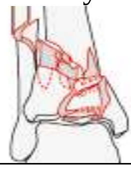
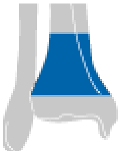
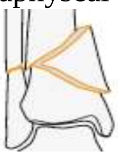
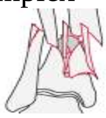
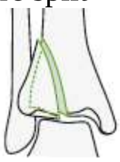
Robinson et al., (1995) developed a classification system after studying distal tibia metaphyseal fractures treated with IM nailing (IMN). Two distinct injuries were noted: type I fractures resulted from a direct bending force producing a transverse fracture pattern, and type II fractures resulted from a torsional force producing a spiral/helical fracture pattern of the tibia with an associated oblique fibular fracture at the same or different level.

Rüedi and Allgower, (1978) proposed a classification for intra-articular distal tibia fractures based on the size and displacement of articular fragments: type I represents non-displaced intra-articular fractures without loss of articular congruency; type II represents displaced fractures with loss of articular congruency; and type III represents those severely comminuted fractures with impaction of the distal tibia.

The Arbeitsgemeinschaft für Osteosynthesefragen and Orthopaedic Trauma Association (OA/OTA) system was developed primarily for use in research but it has gained popularity in clinical use currently. The AO classification describes all fractures in the body in the form of an alphanumeric code. Distal tibial fractures are 43 (4=tibia, 3=distal metaphysis). Based on intra-articular involvement, fractures are further sub-grouped into A (extra-articular), B (Partial articular) and C (complete articular). The final numbers in this classification represent the subgroups of each type and refer to the degree of comminution of the articular component and the metaphysis. Fractures of types 43 B3 and C1-C3 are the severest fracture characteristics of the distal tibia with involvement of the distal tibial articular surface (Marsh et al., 2007).

Table 2.3.3 on the next page is summary of the AO/ASIF classification of distal tibia fractures.

Table 2.3.2: AO/OTA classification of distal tibia fractures
(OTA Committee, Coding, & Classification, 1996)

Extra-articular 	**43-A1** Metaphyseal simple 	**43-A2** Metaphyseal wedge 	**43-A3** Metaphyseal complex 
Partial Articular 	**43-B1** Pure split 	**43-B2** Split-depression 	**43-B3** Multi-fragmentary depression 
Complete articular 	**43-C1** Articular simple 	**43-C2** Articular simple, metaphyseal multi-fragmentary 	**43-C3** Articular multi-fragmentary 
Extra-articular 	**43-A1** Metaphyseal simple 	**43-A2** Metaphyseal wedge 	**43-A3** Metaphyseal complex 
Partial Articular 	**43-B1** Pure split 	**43-B2** Split-depression 	**43-B3** Multi-fragmentary depression 
Complete articular 	**43-C1** Articular simple 	**43-C2** Articular simple, metaphyseal multi-fragmentary 	**43-C3** Articular multi-fragmentary 

2.4 Initial management of patients with distal tibia fractures

Distal tibia fractures are commonly caused by high-energy trauma and are often associated with life-threatening injuries. Therefore their management should be initiated according to Advanced Trauma and Life Support (ATLS) principles. At clinical examination the typical signs of fracture and concomitant soft tissue injuries will be present. Oedema, pain, deformity and functional impairment are the classic clinical signs of most fractures (Huebner, Iblher, Kubosch, Suedkamp, & Strohm, 2014; Richard et al., 2014).

A thorough medical history is obtained with the aim of identifying patient factors associated with the risk of soft tissue complications, poor fracture healing, and fixation failure. Factors such as pre-existing peripheral vascular disease, smoking, diabetes mellitus and associated neuropathy, alcoholism, malnutrition, and osteoporosis have been associated with increased risk of infection and nonunion and may affect the choice of definitive treatment option (Kline et al., 2009; Ristiniemi et al., 2007).

A complete physical examination should be performed, and it is critical to evaluate the neurovascular structures of the lower extremity, and check for imminent compartment syndrome since the distal tibia has thin soft tissue cover and is therefore vulnerable to injury because the muscle compartments at the lower leg lie in close proximity (Richard et al., 2014).

Early recognition of impending skin compromise and urgent fracture reduction reduces the risk of conversion to an open fracture and a compromised surgical approach. Signs such as oedema, ecchymosis, fracture blisters, and open fracture wounds should be looked for and documented (Strohm et al., 2010).

It is generally recommended that prompt administration of antibiotics, tetanus vaccination, and urgent debridement and irrigation should be performed during initial management of open distal tibia fractures. The limb should always be splinted pending definitive management (Tarkin, Clare, Marcantonio, & Pape, 2008).

The standard radiographic examination includes anteroposterior, mortise and lateral projections and must include the entire tibia and fibula and the foot. Special views of the entire lower leg with imaging of the adjacent joints are done to ensure that additional injuries and fractures are not missed.

Computed tomography (CT) scan is recommended to determine the fracture geometry and that of the articular surface, both of which are important in pre-operative surgical planning. CT scan has been shown to add information in 82% of patients and change the surgical plan in 64% of patients (Crist, Khazzam, Murtha, & Della Rocca, 2011; Topliss, Jackson, & Atkins, 2005).

In addition to clinical examination and diagnostic imaging, additional tests such as Doppler sonography or CT-angiography may be necessary if vascular injury is suspected (Hahn & Thies, 2004).

2.5 Definitive treatment of distal tibia fractures and their outcome

Several methods of treatment have been described in literature for distal tibia fractures including; non-operative treatment, operative treatment by use of intramedullary nail, open plate fixation, minimally invasive plating, and various constructs of external fixation. Each of these options has its merits and demerits and the best modality of treatment of distal tibial fractures remains controversial and challenging.

Non-operative treatment

Non-operative treatment of distal tibia fractures involves the use of casting and functional bracing with partial weight bearing on crutches, a walking frame or immobilization in a wheelchair with thrombosis prophylaxis and constant evaluation of soft tissue conditions. Full weight bearing is generally possible after 6–8 weeks. Non-operative treatment is reserved only for non-displaced fractures, patients who have surgical contraindications because of medical co-morbidities, patients with low demand such as those who are non-ambulatory and in patients with complex intra-articular injuries in whom secondary ankle arthrodesis is planned (Muller & Nerlich, 2010).

There are few published studies examining non-operative treatment of distal tibia fractures. Böstman, Vainionpää and Saikku, (1984) reviewed 103 patients managed initially with a long leg cast and subsequent intramedullary (IM) nailing if there was loss of reduction. A malunion rate of 26.4% was observed in the non-operatively managed group. The time to union was faster in those who underwent subsequent IM nailing than those who were managed by functional bracing alone. Sarmiento and Latta, (2004) reviewed 450 cases of closed fractures of the distal tibia. Non-operative treatment was chosen for fractures that were closed and within acceptable ranges of alignment in all planes after manipulation. A long leg cast was then applied for these fractures, patients were allowed to bear weight as tolerated and mobilize using walking aids. The authors reported a longer healing time, with an average time to union of 16.6 weeks and malunion of 13.1%. Huebner et al., (2014) performed a review of the management of distal tibia fractures. They found that the long period of immobilization in non-operative treatment is associated with increased risks of thrombosis, contractures and poor limb function. In addition there is increased risk of secondary reduction loss leading to fracture malunion and nonunion.

Although non-operative treatment avoids risks of surgery and post-operative complications, studies have shown that it is prone to complications including non-union, malunion, ankle joint stiffness and deformity. Joint stiffness following non-operative treatment has been reported to be as high as 40% of the patients. Long period of immobilization of an extremity is associated with increased risk of thrombosis, embolism, reflex dystrophy and contractures with subsequent persistent symptoms and impaired limb function. Inadequate immobilization of complex distal tibial fractures, can lead to secondary reduction loss and malunion with approximately 33% of patients healing with a deformity (Huebner et al, 2014, Joveniaux et al, 2010).

As a result of these high rates of complications, non-operative treatment should only be used in a select few patients with relatively stable fractures and opportunity for close monitoring (Richard et al., 2014).

Operative treatment

Most distal tibia fractures require operative treatment to avoid complications associated with non-operative means. The goals of operative treatment include soft tissue management, anatomical reconstitution of the articular surface, reduction of the metaphyseal component of the fracture to the diaphysis and restoration of normal axial alignment (length, angulation and rotation) and attainment of a stable fixation for early motion and functional rehabilitation of the limb (Ramos, Karlsson, Eriksson, & Nistor, 2013).

The type of operative treatment procedure should be tailored in accordance with the associated soft tissue injuries and the fracture characteristics specifically comminution and number of fragments. For open fractures, evidence does support debridement and early administration of intravenous broad spectrum antibiotics (Newman, Mauffrey & Krikler, 2011).

Helfet et al., (1994) first proposed a two-stage protocol for this distal tibia fractures, and subsequently several authors in recent years have highlighted the decision algorithms for the treatment of these fractures. Proponents of a staged protocol argue that most patients with distal tibia fractures have significant swelling, and severe soft tissue injuries. Surgery adds to soft-tissue injury and skeletal instability increases the soft-tissue insult. Therefore, it is advisable to proceed in two or more stages beginning with closed reduction and ankle-spanning external fixation, fibular fixation when indicated and finally definitive reconstruction (Kline et al., 2009).

A primary one-stage procedure with definitive fracture fixation and single-shot antibiotics may be done for fractures that present within 6–8 hours of trauma provided the soft tissues can tolerate several hours of surgery. Recent evidence has shown that early open surgery less than a week of injury results in a significantly higher rate of complications compared to delayed surgery usually 10-15 days or longer (Liporace & Yoon, 2012; Newman et al., 2011).

Most authors recommend the stabilization of concomitant fibular fractures with a plate during initial joint-spanning external fixation as a primary intervention. Fibular fractures can also be stabilized with an IM implant, such as a rush rod, flexible nail, or guide wire. Fixation of the fibula adds stability to the ankle joint and improves reduction and union of the distal tibia fracture. It is specifically indicated in the presence of injury to the inferior tibiofibular syndesmosis and when medial plating of the distal tibia is performed, to avoid valgus deformity. It has been demonstrated that fibular fixation can be done in the setting of tibia plating and external fixation to reduce malunion and improve the stiffness of the fixation construct (Strauss et al., 2007).

However fibular fixation is not without complications. It has been reported that fibular plating is associated with increased potential for delayed healing, and nonunion of fractures. Vallier et al., (2008) studied 113 distal tibia fractures located 4 to 11 cm from the plafond, and found a higher rate of nonunion in fractures treated with tibial and fibular fixation (14%) than tibial fixation alone (2.6%). The authors recommend the use of a flexible implant for fibular fixation to allow adjustments during reduction of distal tibia fracture.

The definitive operative treatment options for distal tibia fractures are expanding with a recent emphasis on minimally invasive techniques including locked intramedullary nailing, plate fixation and external fixation systems including the Ilizarov frame and hybrid fixators (Mioc et al., 2018).

External fixation

External fixation can be used either as temporary stabilization or definitive fixation of distal tibia fractures. Ankle spanning external fixation can be used for temporary fixation of open fractures and extensively comminuted fractures with significant soft tissue injury. Other indications for external fixators are open fractures involving bone loss, compartment syndrome after fasciotomy, and as adjunct to internal fixation.

External fixation constructs described in the literature include simple ankle-spanning frames, ankle-articulating devices, and hybrid or circular frames which are used mostly in conjunction with limited internal fixation (Jacob et al., 2015). Papadokostakis et al., (2008) reviewed the merits of ankle-spanning versus non-spanning frames and found that the overall deep infection rate with non-spanning frames was 2.7 %. The deep infection rate in the spanning group was 3.9 %. The authors concluded that there were no statistically significant differences with either technique with respect to infection, non-union or time to union. However, there was a higher rate of malunion in the spanning group.

External fixation is associated with less damage to blood supply of bone, minimal interference with soft-tissue cover; it is useful for stabilizing open fractures and achieves rigidity of fixation adjustable without surgery. External fixators are also good option in situations of active infection as they reduce risk of implant infection, and allow greater flexibility in the treatment of soft tissue defects. Procedures for external fixation require less experience and surgical skills than standard open reduction and internal fixation (Barcak et al., 2016).

Hybrid external fixators can be used alone as definitive treatment of distal tibia fractures with satisfactory results. Babis et al., (2010) studied 48 patients with distal tibia fracture treated definitively using hybrid external fixators and found a higher union rate of 83% within 6 months. When compared to previously reported series, with conventional open reduction and internal fixation, hybrid external fixation was associated with satisfactory clinical and radiographic results and limited complications. Other studies have reported similar results when using external fixation compared with conventional open reduction and fixation with plating. Wang et al., (2015) performed a meta-analysis of complications associated with ORIF versus with external fixation. They included nine studies with 498 fractures. They found no significant differences in bone healing complications, non-union, malunion or delayed union, superficial and deep infections, arthritis symptoms or chronic osteomyelitis between the two groups.

Watson et al., (2000) reviewed 107 intra-articular distal tibia fractures treated according to a staged protocol which included initial stabilisation with calcaneal traction. Forty-one patients with Tscherne grade 0 and I injuries underwent open reduction and internal fixation and sixty-four patients with Tscherne grade II and III injuries, underwent external fixation as definitive management. There was a significantly higher rate of complications including non-union, malunion and wound complications in the external fixation group.

The disadvantage external fixation is the increased risk of complications, predominantly pin tract infection, ankle stiffness, loosening, and delayed union. Hybrid external fixation is associated with malunion (range 5%–25%), nonunion (range 2.0%–17.6%), and pin tract infection (range 10%–100%). Pin tract infection and secondary loosening can result in osteomyelitis and septic arthritis. Due to their sizes, external fixators are cumbersome and not always well tolerated (Moss & Tejwani, 2007).

Intramedullary (IM) nailing

Historically, intramedullary (IM) nailing was reserved for fractures greater than 5 cm proximal to the ankle joint, but this limitation no longer exists because of newer nail designs which allow extreme nail fixation. The nail design determines the number, location, and orientation of distal interlocking screws. There must be enough screws in the short distal segment to provide sufficient stability (Kuo, Chi, & Chuang, 2015; Marcus et al., 2013).

Tibial nails such as Phoenix®, Expert®, Biomet®, Warsaw®, and SIGN® are currently available in the market and have been successfully used for treatment of distal tibia fractures. Stephens et al., (2015) reviewed 162 distal tibia fractures treated with the SIGN® intramedullary (IM) nail in 3 developing countries including Kenya, Ethiopia and Pakistan and showed excellent results comparable with studies from more developed nations regarding union rates, rates of malalignment, incidence of infection, and need for revision surgery. Im and Tae, (2005) found shorter operative times with improved function in the nailing group compared with plate fixation.

The operative technique involves first reducing the distal tibia fracture correctly before the nail is inserted. The undisplaced fracture lines must first be fixed with lag screws. A standard tibial nail with distal locking capability then inserted. Locking screws can be placed using either a radiolucent guide or free hand (Barcak et al., 2016).

Although recent innovations in IM nail design have increased its indications in the treatment of tibia fractures, challenges including reduction, distal penetration of the fracture, inadequate fixation, and potential articular involvement still limit its use. Angular malalignment is a common complication of IM nailing of distal tibia fractures. Increased ankle pain and accelerated joint degenerative changes have been reported with as little as 5 degrees of malalignment of the distal tibia. Since metaphysis consists of mostly cancellous bone, maintaining control of the distal fragment is difficult because the stability of fracture fixation is dependent on good purchase with the distal interlocking screws. The cortical flare of the distal tibia metaphysis reduces the intrinsic stability of the nail construct because it reduces bone-to-implant contact. Techniques such as blocking screws, multiplane locking screws and fibula fixation have been reported in the literature as ways to increase stability and reduce malalignment (Kayali, Ağuş, Eren, & Ozlük, 2009; Kuhn et al., 2015; Piątkowski et al., 2015).

Plating of distal tibia fractures

Historically, distal tibia fractures were treated open reduction and internal fixation (ORIF) of with bone grafting as needed with the goal of restoration of the distal fibula length and the articular surface. With success of staged protocol, delayed ORIF has been associated with better results (Kuo et al., 2015).

Distal tibia plating can either be done through open reduction and internal fixation (ORIF) or through minimally invasive plate osteosynthesis (MIPO) techniques.

Open reduction and internal plate fixation is indicated for fractures that are at risk for malalignment because direct exposure is used to achieve reduction, which may be difficult to achieve with a nail or minimally invasive plating. In simple articular split fractures small fragment screws can be used to achieve articular reduction. Fractures with extensive soft tissue damage can be treated with plating in a staged fashion after initial external fixation (Zelle et al., 2006).

Multiple surgical approaches for open reduction and internal fixation (ORIF) with plating of distal tibia fractures have been described in literature and include anteromedial, anterolateral, posterolateral, and direct lateral approaches. Preoperative planning including the assessment of soft tissue injury, degree of comminution, and type of fracture pattern are important for good outcome. Reduction techniques include the use of bone clamps and external fixators. Intra-articular reduction is essential and should be achieved before meta-diaphyseal realignment and fixation. The availability of pre-contoured locking plates facilitates reduction of the meta-diaphyseal region to the plate and improves construct stability (Richard et al., 2014).

When compared with external fixation, ORIF has been found to be superior with regards to wound complications, rates of nonunion and malunion. In a prospective clinical study by Wyrsch et al., (1996) on the treatment of distal tibia fractures, patients were randomized to either external fixation definitive treatment or external fixation with delayed definitive ORIF groups. The study found that infections and malunions occurred more commonly in the external fixation group. In a meta-analysis by Richards et al., (2012) to compare external fixation with ORIF for the treatment of distal tibia fractures found that delayed union or nonunion occurred in 22.2% of patients in the external fixation group 3.7% of patients in the ORIF group. The infection rates were equal in the two groups.

However, ORIF with plating require greater soft tissue dissection which carries a risk of infection, wound breakdown and devitalisation of the surrounding tissue. Patients with diabetes mellitus, open fractures, or those with hemorrhagic fracture blisters overlying the desired incision site are particularly prone to suffer from more soft tissue problems when treated using ORIF. Minimally invasive plate osteosynthesis (MIPO) with locking compression plate (LCP) has therefore emerged as an alternative treatment option because it respects biology of distal tibia and fracture hematoma and also provides biomechanicaly stable construct. MIPO is one such method where percutaneously inserted plate is fixed at a distance proximal and distal to the fracture site through minimal exposure (Muzaffar, Bhat, & Yasin, 2014).

Ronga et al., (2010) studied the effectiveness of minimally invasive locked plates among patients for a minimum period of 2 years. They higher union rate, lower rates of infection when compared with conventional ORIF with plates.

2.6 Functional outcome after treatment of distal tibia fractures

Successful treatment of distal tibia fractures is dependent on the management of the soft tissue injury, anatomical reduction in the joint surface and restoration of mechanical alignment. Treatment outcomes of distal tibia fractures are variable.

Most studies that report treatment outcomes of distal tibia fractures have assessed patients at a single point in time and report an average length of follow up. Marsh et al., (2010) did prospective observational study is to assess the recovery of ankle function and general health status at multiple time points during the first 24 months after an isolated distal tibia fracture treated with a specific technique of joint spanning external fixation. Factors such as age, gender, fracture classification, articular comminution, treatment type, quality of reduction, associated fibula fracture, and education, medical co-morbidities, employment status, plans to return to work, involvement in legal action due to injury, and compensation status were also assessed found to affect patient outcome and determine the pace of recovery.

Olerud-Molander Ankle Score (OMAS)

Several tests have been developed to assess ankle function following fractures about the ankle joint. The Olerud-Molander Ankle Score (OMAS) is one such tool. OMAS is a disease-specific questionnaire devised for patients with ankle fractures and has been frequently used to evaluate subjectively scored function in patients with distal tibia fractures (Oh, Kyung, Park, Kim, & Ihn, 2003). OMAS has been validated against: Linear Analogue Scale (LAS) assessing subjective evaluation of ankle function presence of distal tibia fractures, osteoarthritis, and fracture-dislocations of the ankle joint. It has also been found to discriminate for subjectively ankle instability and muscle strength in the ankle flexors (Nilsson et al., 2013). Van der Wees et al., (2012) examined concurrent validity in patients with acute ankle ligament injuries and compared the Ankle Function Score (AFS) and the OMAS. The concurrent validity between the two scores at baseline and at follow-up was found to be good. OMAS is a self-administered questionnaire. The score is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and work/activities of daily living.

OMAS is well known and has been used in many studies for several years. Mioc et al., (2018) did a prospective study to compare the outcomes of IM nail and MIPO osteosynthesis in the treatment of distal tibia fractures using OMAS as the functional outcome tool. They found that after the six-month follow-up the average OMAS scores were 75.55 (20–100) for the IM nailing group and 74.23 (20–90) for the MIPO group, without finding any statistical difference between the two groups. Im et al., (2005) in a study to compare closed intramedullary nailing with open plate and screw fixation in the treatment of distal fractures, also found no statistical difference between the average scores in the two groups (88 versus 88.5).

Anglen et al., (1999) compared patients treated with the hybrid fixator with patients treated with open reduction and internal fixation with plating using OMAS to assess functional outcome, and found that patients treated with hybrid fixation had lower ankle functional scores, slower return to function.

Collinge et al., (2007) did study is to evaluate clinical results and outcomes of high-energy injuries of the metaphyseal distal tibia with minimal or no intra-articular involvement treated using the minimally invasive plating concept using OMAS as functional assessment tool. The average OMAS was 86 and the only patient or injury variable that influenced functional outcomes as determined by OMAS was the occurrence of a secondary surgery, which was found to be associated with poorer function. Associated lower-extremity fracture, other injuries, intra-articular extension, bone loss, open fracture, or the time to union were not found to be associated with poorer function on OMAS.

CHAPTER THREE: METHODOLOGY

3.1 Study location

The study was carried out at the Orthopedic and Trauma Wards and Fracture Clinic units at Moi Teaching and Referral hospital (MTRH).

MTRH is a national referral hospital and serves as the teaching hospital for the Moi University School of Medicine. The hospital is located in Eldoret town in Uasin-Gishu County and has bed capacity of 1000. It provides a range of curative, preventive and rehabilitative services as a referral hospital for the Western part of Kenya, with a catchment population of about 15 million people and also serves patients from neighboring countries; Uganda, Sudan, South Sudan and Rwanda. The hospitals' orthopaedic unit is located in three wards namely, Sergoit, Longonot and Rehema. The staff allocated to the orthopedic unit includes orthopedic surgeons, orthopedic residents, medical officer interns, clinical officer interns, nurses, orthopedic clinical officers and orthopedic technologists. Patients are admitted into the unit from A & E department and orthopedic clinics by the clinical officers, medical officers, and registrars and orthopedic surgeons. Definitive management and further follow up after treatment is performed by orthopaedic registrars and orthopedic surgeons in consultation with other specialists depending on the patient condition (Kilonzo et al., 2014).

3.2 Study design

A prospective observational study design was used. This design enabled follow up of participants for six months noting treatment offered and measured outcomes.

3.3 Study population

The target population consisted of adult patients with acute traumatic distal tibia fracture at MTRH during the study period while the study population was those who met the inclusion criteria.

3.3 Eligibility criteria

3.3.1 Inclusion criteria

Skeletally mature patients (aged 18 years and above) with distal tibia fractures admitted during the study period.

3.3.2 Exclusion criteria

a) Multiply injured patients

b) Patients who were already on follow up before the study begun

3.4 Sampling technique

Patients who met the inclusion criteria were consecutively sampled into the study. In case there was no consent the next patient was included. This continued for 12 consecutive months

3.5 Sample size

Eighty-five patients were recruited into the study.

3.6 Outcome measures

3.6.1 Olerud and Molander Ankle Score (OMAS)

Functional outcome was assessed using the Olerud and Molander Ankle Score (OMAS). OMAS was used for evaluating the ankle function because it is a disease-specific test (ankle fractures) that has been validated and it also showed high test retest reliability. The score is based on nine different items: pain, stiffness, swelling, stair climbing, running, jumping, squatting, supports and work/activities of daily living. The scoring system correlates well with parameters considered to summarize the results after this type of injury and is therefore recommended for use in scientific investigations because it has been proven to be an effective, practical clinical and research instrument with good responsiveness and acceptability for assessment of disability caused by impairment in the lower limb. An OMAS score of more than 91 points will be considered excellent; 61–90 points, good; 31–60 points, fair; and less than 30, poor. Excellent and good OMAS grades were rated as satisfactory while fair and poor OMAS grades were rated as unsatisfactory.

3.6.2 Other Outcomes

Malunion: Bony alignment was assessed from the post-intervention X-Ray and recorded.

A documentation of infections, wound dehiscence, vascular and neurological injury was kept.

3.7 Data collection

A pretested structured data collection form was used to collect data. Each patient was assigned a study number. The data collection form included socio-demographic patient's age, gender, mobile phone numbers and address, cause of injury, treatment offered, co-morbidities, clinical examination and radiographic findings.

Patients' date of birth, in-patient number and study number were used as unique identifiers. Functional outcome assessment was done by using the OMAS administered at baseline and 6 months.

3.8 Execution of the study

This study took place between October 2015 and March 2017. Patients who met the inclusion criteria were approached for their consent and data such as age, sex, premorbid conditions, mechanism of injury and clinical characteristics were obtained from both the patient and the files and recorded. Radiographs and case summaries were presented for discussion in the Trauma meeting (attended by consultant orthopaedic surgeons and registrars) where fracture and injury classification were done together with discussion on initial management. Fractures with associated soft tissue injuries were classified using Gustillo-Anderson classification for open injuries and Tscherne classification for closed injuries while distal tibia fractures were classified using the Arbeitsgemeinschaftfür Osteosynthesefragen (AO) classification system. Definitive treatment was determined by the consultants of the admitting firm. Patients were then reviewed at 72hours, 2 weeks, 6 weeks, 3 months and 6 months to assess clinical outcomes and complications. Functional outcome was assessed using Olerud and Molander Ankle Score (OMAS) at 6 months after treatment using a self-administered questionnaire during clinic visits.

Sufficient efforts were made to ensure minimum loss to follow-up, such as collection of multiple contact addresses and telephone numbers, mobile telephone numbers and email addresses.

3.9 Data analysis

Data was analyzed using STATA statistical software version 13. Descriptive statistics such as median and interquartile range were used for continuous data while frequency listing was used for categorical data. Graphical summaries included bar charts. Chi square test was used to determine the significance of associations between categorical variables. In cases where the cell count was below 5, Fisher's exact test was used. Kruskal Wallis and Mann-Whitney U tests were used to compare median for continuous variables since the data was skewed. Functional outcome was assessed using Olerud and Molander Score (OMAS). Multi-variate analysis with Fisher's exact test was used to test associations between the possible predictive variables and OMAS. The variables included sex, injury type, method of treatment, fracture comminution, malunion,and infections. All analysis was performed at 95% level of confidence.

3.10 Ethical consideration

Permission was sought from Institutional Research and Ethics Committee (IREC) of Moi University College of Health Sciences/MTRH and the hospital Director. IREC approval number: 0001489. Written informed consent was sought from each patient.

Confidentiality was maintained and patient information de-identified. Neither coercion nor payment was used to have patients join the study. All patients were informed of their freedom to exit the study at any time if they felt so and that their exiting could not affect the quality and the nature of their continued care at MTRH. Results from this study will be published in peer reviewed journals.

3.11 Study limitations

This was a prospective study and the long duration of data collection predisposed the patients to loss to follow up. This was mitigated by collecting multiple contacts and physical addresses from each patient and reminding them of their clinic appointment dates.

CHAPTER FOUR: RESULTS

4.1 Demographic characteristics

A total of 85 patients were recruited into the study. Seven patients were lost to follow-up and two underwent limb amputation, thus 76 (92%) patients were reviewed for clinical and functional evaluation at final follow up.

Seven (9.2%) patients had pre-morbid conditions including 4 patients with hypertension and 3 patients with asthma. Up to 58 (76.3%) patients came directly from home or scene of injury to MTRH, and 18 (23.7%) patients were referred from other hospitals.

Most patients (63.2%) were male with a male to female ratio of 1.7:1. The median age was 40.0 (IQR: 30.0, 52.0) years with a range of 19 to 91 years. Majority of patients, (52.6%) were aged 40 years and below. Among those patients aged 40 years and below, there was a preponderance of male (Male: Female=3:1). There was a fairly equal distribution of fractures between the two sexes after the age of 41 years; however the number of affected male reduces with advancing age as shown in table 4.1.1 below.

Table 4.1.1: Age and gender characteristics

Sex	<40 years	41-60 years	>61 years	Total
Male	30(39.5%)	15(19.7%)	3(3.9%)	48(63.2%
Female	10(13.2%)	13(17.1%)	5(6.6%)	28(36.8)%
Total	40(52.6%)	28(36.8%)	8(10.5%)	

4.2 Injury characteristics

Most of the injuries were as a result of road traffic accidents (RTA) in 37 patients and falls in 29 patients as shown in Figure 4.2.1 below. The patients who had sustained fractures caused by falls had a higher median age 61.2 years (32, 81) compared with the patients who had sustained fractures from RTA, assaults, sports and industrial accidents combined (34.7 years, Range 19, 67) ($p<0.001$).

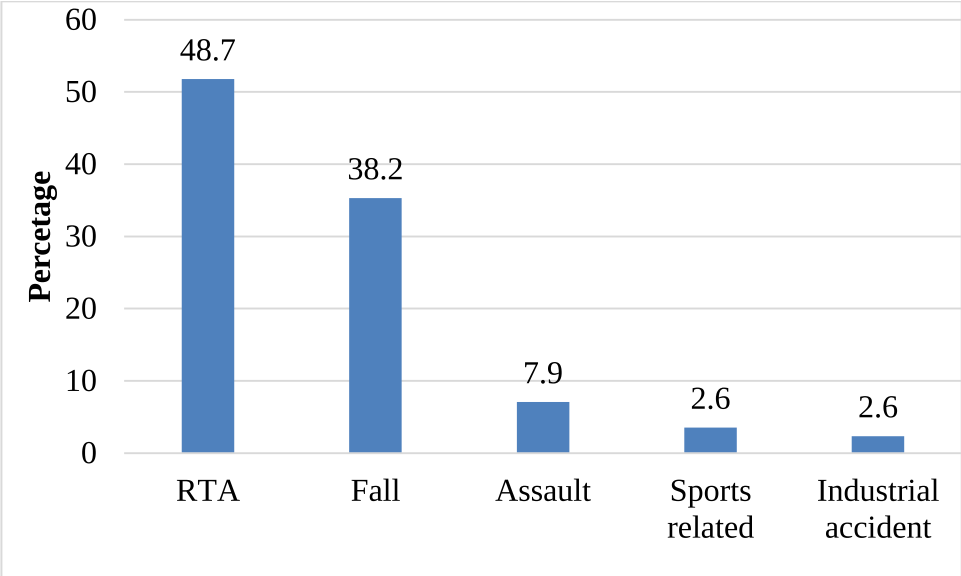


Figure 4.2.1: Mechanism of injury

There were no vascular injuries. Majority of the injuries were closed and were classified according to the Tscherne classification. Most of the closed injuries were Tscherne grade 2 and there were no Tscherne grades 0 and 3 injuries. Open fractures were classified according to the Gustilo-Anderson classification and majority were type II injuries and there were no type IIIC injuries. Table 4.2.1 on the next page shows the injury characteristics and classifications.

Table 4.2.1: Injury characteristics and classifications

Variable	Category	n (%)
Nature of injury	Closed	48 (63.2%)
	Open	28 (36.8%)
Ipsilateral fibular fracture		37 (48.6%)
Deformity	None	6 (8%)
	Varus	56 (74%)
	Vulgus	14 (18%)
Tscherne Classification for closed injuries	Grade 1	20 (41.7%)
	Grade 2	28 (58.3%)
Gustillo-Anderson Classification for open injuries	Type I	3 (18%)
	Type II	13 (46%)
	Type IIIA	7 (25%)
	Type IIIB	3 (11%)

Distal tibia fractures were classified according to the AO/OTA classification system as shown in Table 4.2.2 below.

Table 4.2.2: AO/OTA Classification of distal tibia fractures

Subgroup	43 A (n=40)	43 B (n=28)	43 C (n=8)
Subgroup 1	15	16	4
Subgroup 2	13	10	3
Subgroup 3	12	2	1

The extra-articular AO/OTA type A fractures were the most common and constituted 52.6% of all the distal tibia fractures. AO/OTA type B constituted 36.8% of the distal tibia fractures while type C was rare (10% of the fractures). Among the fracture subgroups, the most common fracture patterns were: Type 43B1 (21%), type 43A1, (19.7%), type 43A2, (17%) and type 43A (15.8%).

4.3 Definitive treatment of distal tibia fractures

Patients were treated using either non-operative treatment with casting (23%) or operative treatment (67%) with plating and external fixation. Table 4.3.1 below shows the distribution of the treatment options according to demographic and clinical characteristics.

Table 4.3.1: Treatment according to demographic and clinical characteristics

Variable	**Category**	**Non-operative n=25**	**Operative n=51**	**Total**	***p*-value**
Sex	Female	8	20	28	0.540*
	Male	17	31	48	
Injury type	Closed	20	28	48	**0.033***
	Open	5	23	28	
AO classification	Extra-articular	13	27	40	0.531**
	Partial-articular	8	20	28	
	Intra-articular	4	4	8	
Fracture comminution	Comminuted	13	18	31	0.164*
	Non-comminuted	12	33	45	

**Fishers Exact test; * Chi square

Demographic characteristics and fracture classification were similar in the two types of treatments, operative and non-operative. Among patients with closed fractures, majority (58%) underwent operative treatment. Equally 82% of the patients with open fractures were treated operatively. Operative treatment was the most common treatment option used for both open and closed injuries (p=0.033).

Operative treatment options included fixation with external fixators (23 patients) and fixation with plating (28 patients). The two operative treatment methods were similar with respect to gender, AO/OTA fracture classification and fracture comminution as shown in Table 4.3.2 below.

Table 4.3.2: Operative treatments of distal tibia fractures

Variable	**Category**	**Plating**	**Ext-fix**	**Total**	***p*-value**
Sex	Female	11	9	20	0.991*
	Male	17	14	31	
Injury type	Closed	23	5	28	**<0.001***
	Open	5	18	23	
AO classification	Extra-articular	16	11	27	0.834**
	Partial-articular	10	10	20	
	Intra-articular	2	2	4	
Fracture comminution	Comminuted	11	7	18	0.567
	Non-comminuted	17	17	34	

**Fishers Exact test; * Chi square

However, plating was mostly used on closed injuries and external fixation was mostly used to treat open injuries ($p<0.001$).

4.4 Treatment outcomes of distal tibia fractures

Union was assessed at the end of six months using X-Ray. All fractures achieved radiological union (100% union rate) by the end of six months.

Complications occurred in 32 (42.1%) patients. The overall rates of complications for non-operative treatment, plating and external fixation were 72%, 25% and 52% respectively. Table 4.4.1 on the next page shows the distribution of complications in each mode of treatment.

Table 4.4.1: Distribution of complications in each method of treatment

Method of treatment	**Complications**			**Total**
	Infections	Infections & Malunion	Malunion	
Non-Operative	1	5	6	12
Plating	4	2	1	7
External Fixation	11	4	3	18

There were 27 infections including 15 pin-site infections, 3 chronic osteomyelitis and 9 wound infections. There were 21 malunions and the rate of malunion was 44% among the nonoperatively treated patients and 19.6% for those operatively treated. Table 4.4.2 below summarizes the complications observed with each method of treatment.

Table 4.4.2: Mode of treatment and associated complications

Variable	**Category**	**Non-operative**	**Operative**	**Total**	***p*-value**
Infections	No	19	30	49	0.142
	Yes	6	21	27	
Malunion	No	14	41	55	**0.025**
	Yes	11	10	21	
Chi square					

Infections occurred more commonly in the operatively treated patients, although this is not statistically significant (*p*=0.142). Non-operative treatment was associated with a higher rate of malunion (*p*=0.025).

Among the patients who were operatively treated, 15 patients developed pin-tract infection. Twelve of these had at least one pin-tract infection diagnosed as discharge, redness, and swelling. In 4 patients pins were replaced and in one patient they were removed and not replaced after the injury already displayed bridging callus. Three patients developed chronic osteomyelitis in a diaphyseal pin tract. Debridement and external fixation revision together with oral antibiotics were done and the infections resolved. Table 4.4.3 below shows operative treatment and associated complications.

Table 4.4.3: Operative treatment and associated complications

Variable	**Category**	**Plating**	**External Fixation**	**Total**	***p*-value**
Infections	No	22	8	30	**0.002***
	Yes	6	15	21	
Malunion	No	25	16	41	0.154**
	Yes	3	7	10	

**Fishers Exact test; * Chi square

There was no statistically significant difference in rate of malunion between plating and external fixation (*p*=0.154). Infections occurred mostly in patients treated using external fixation. (*p*=0.002).

4.5 Functional outcome: OMAS at 6 months

Functional outcome after treatment was assessed using Olerud and Molander ankle scores (OMAS) system.

The median OMAS was good, 64 (IQR: 30, 85) points with a minimum and a maximum of 21 and 95 respectively. Table 4.5.1 below shows median OMAS and patient characteristics.

Table 4.5.1: Median OMAS and patient characteristics

Variable	Category	Median	IQR	Min	Max	P-value
Sex	Female	80	43, 86.5	23	95	0.117
	Male	56	29, 84.5	21	95	
Injury type	Closed	78	37.5, 86.5	21	95	0.106
	Open	53.5	30, 75	22	94	
Treatment	Non-Operative	52	29, 79	21	94	**0.003***
	Plating	85	60.5, 90	23	95	
	Ext-fixation	54	28, 78	22	94	
Fracture severity	Severe	84	45, 90	27	95	**0.021**
	Simple	56	28, 80	21	95	
Infection	No	80	56, 90	23	95	<**0.001**
	Yes	32	27, 58	21	90	
Malunion	No	78	41, 87	21	95	**0.008**
	Yes	45	29, 56	24	91	

Mann Whitney U test   ** Kruskal Wallis test*

The median OMAS was higher among female patients compared to male, although this was not statistically significant (*p*=0.117). The median OMAS was significantly higher among the patients who underwent treatment by plating compared to those who were either non-operatively treated or underwent external fixation. Patients who had complications (infection and malunion) had lower median OMAS than those who did not have complications.

OMAS was poor in 20 patients, fair in 17, good in 28 and excellent in 11. Figure 4.5.1 below is a pie chart on the OMAS scores of the patients at final follow up of 6 months.

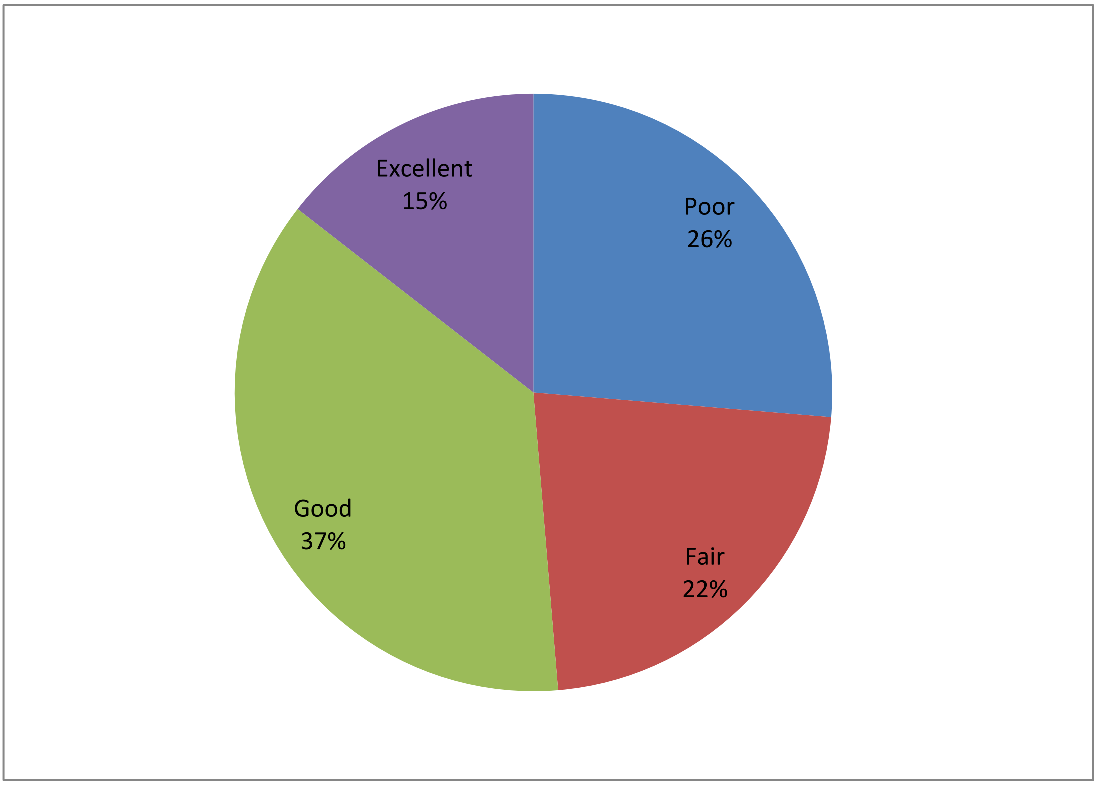


Figure 4.5.1: OMAS scores after six months

Majority of patients had good-to-excellent (Satisfactory) OMAS scores at 6 months.

4.6 Factors affecting outcome

Table 4.6.1 below shows results for Univariate analysis of clinical, demographic and treatment characteristics associated with functional outcome.

Table 4.6.1 : Univariate analysis of Correlation demographic and clinical and treatment characteristics associated with functional outcome

		Outcome (0=Poor/Fair; 1=Good/Excellent)		
Variable	**Category**	**Poor/Fair**	**Good/Excellent**	***p*-value**
Sex	Female	10	18	
	Male	27	21	0.084
Injury type	Closed	19	29	
	Open	18	10	**0.038**
Fracture comminution	Comminuted	12	19	
	Non-comminuted	25	20	0.149
Treatment option	Conservative	17	8	
	Operative	20	31	**0.018**
Treatment option	Plating	7	21	
	Exo-fix	13	10	**0.022**
Infections	No	16	33	
	Yes	21	6	**<0.001**
Malunion	No	20	35	
	Yes	17	4	**0.001**
		Chi Square		

Patients' sex and fracture comminution were not associated with functional outcome.

Having a closed injury and undergoing operative treatment by plating were associated with good-to-excellent (satisfactory) functional outcome.

Presence of complications (infections and malunions) was associated with poor-to-fair (unsatisfactory) functional outcome.

Table 4.6.2 below shows results for multiple logistic regressions for assessing factors associated with outcome.

Table 4.6.2: Multivariate analysis of demographic, clinical and treatment characteristics associated with functional outcome

		Outcome (0=Poor/Fair; 1=Good/Excellent)		
Variable	**Category**	**OR**	**95% CI**	***p*-value**
Sex	Female	1		
	Male	0.476	0.116 – 1.948	0.302
Injury type	Closed	1		
	Open	0.431	0.099 – 1.871	0.261
Fracture severity	Comminuted	1		
	Simple	0.240	0.056 – 1.032	**0.055**
Treatment option	Non-Operative	1		
	Operative	12.461	2.262 – 22.649	**0.005**
Infections	No	1		
	Yes	0.036	0.006 – 0.207	**0.001**
Malunion	No	1		
	Yes	0.052	0.009 – 0.298	**0.001**
Adjusted OR				

Having a comminuted fracture had 76% reduced odds for good-to-excellent (satisfactory) functional outcome scores adjusting for sex, injury type and complications. Although this was not significant (p=0.055).

The odds of having a good-to-excellent (satisfactory) functional outcome scores following operative treatment was 12 times that of non-operative treatment adjusting for sex, injury type, fracture comminution and presence of complications (p=0.005).

Presence of infections and malunion had 96% and 95% respectively reduced odds for good-to-excellent (satisfactory) functional outcome scores adjusting for sex, fracture comminution and type of treatment (p<0.001).

CHAPTER FIVE: DISCUSSION

5.1 Demographic and general clinical characteristic

This study found the average age of patients with distal tibia fractures to be 40 years and a male preponderance of 63.2%. This is in agreement with the findings from other studies on distal tibia fractures. Bhairi et al., (2017) studied patients whose average age was 39.5 years and a male preponderance of 65%. Shah et al., (2019) found that the average age of patients was 46 years with the male predominance of 70%. In another study by Stephens et al., (2015) to evaluate the use of the SIGN® intramedullary (IM) nail in distal metaphyseal tibia fractures in three developing countries including Kenya, Ethiopia and Pakistan, it was found that distal tibia fractures were four times more common in males than in females.

Most distal tibia fractures were as a result of road traffic accidents (48%) and falls (38%). This is in agreement with the findings by Wennergren et al., (2018) in a study done to describe the epidemiology and incidence of distal tibia fractures in Sweden and reported that road traffic accidents (RTA) (39%) and falls (22%) are the most common causes of distal tibia fractures.

The rate of ipsilateral fibular fracture was low in this study (48%). This rate was similar to that reported by Joveniaux et al., (2010) who found the rate of ipsilateral fibular fracture to be 46%. However a study by Bonnevialle et al., (2010) found a higher rate of 93% of ipsilateral fibular fracture. This difference may be explained by the difference in the mechanism of injury between the two studies. Concomitant fibula fractures occur in high energy injuries to the distal tibia. Indeed there were fewer higher-energy injuries in this study (68%) compared to in Bonnevialle et al., (2010) study (96%) and therefore the lower rate of associated fibular fractures.

With respect to AO classification system, the findings of this study contradicts those of Bhairi et al., (2017) who found a higher proportion of extra-articular fracture patterns (A2 30% and A3 35%) than intra-articular fractures. This study had higher proportion of Type B (partial articular) fracture patterns. Compared to Bhairi et al., (2017) who found 30% open fracture rate (type 1-20%, type 2-10%), this study found a higher rate of open injuries (63%).

5.2 Treatment outcomes of distal tibia fractures

Operative treatment options in this study were limited to only open reduction and internal fixation with plating and external fixation. Other operative techniques such as fixation with locked intramedullary (IM) nails and closed reduction and fixation by minimally invasive plate osteosynthesis (MIPO) have been reported in literature and in most instances as having superior outcomes compared to open plating and external fixation.

Stephens et al., (2015) reviewed 162 distal tibia fractures treated with the SIGN® intramedullary (IM) nail in 3 developing countries including Kenya, Ethiopia and Pakistan and showed excellent results similar to studies from more developed nations regarding union rates, rates of mal-alignment, incidence of infection, and need for revision surgery. The authors concluded that SIGN® intramedullary nail can be used for the treatment of distal tibia fractures with satisfactory results. Although recent changes in IM nail design have extended the spectrum of fractures amenable to this type of fixation, its role in the treatment of distal tibia metaphyseal fractures has not been clearly defined. Concerns regarding difficulties with reduction, distal propagation of the fracture, hardware failure, and inadequate distal fixation leading to mal-alignment have slowed the acceptance of intramedullary nailing as a treatment for distal tibia metaphyseal fractures (Shah et al., 2019).

Minimally invasive plate osteosynthesis (MIPO) respects biology of distal tibia and fracture hematoma and also provides biomechanicaly stable construct. Ronga et al., (2010) reported higher union rates, less wound complication and good functional outcome with MIPO technique. MIPO was not used in the orthopedic department during the time of this study.

The rate of malunion among patients who were non-operatively treated in this study was high. Similar high malunion rate was reported by Böstman et al., (1984) who reviewed 103 patients managed initially with a long leg cast and subsequent intramedullary (IM) nailing if there was loss of reduction. A malunion rate of 26.4% was observed in the nonoperatively managed group. However this finding contradicts that reported by Sarmiento and Latta, (2004) who reviewed 450 cases of closed fractures of the distal tibia and reported rate of malunion of 13.1%. This difference can be explained in part by the large number of patients in the study by Sarmiento and Latta, (2004) compared to this study and Böstman et al., (1984) study.

Comparing the results on the outcome of the two operative techniques used in this study, external fixation was significantly associated with more wound complications than plate fixation (p=0.002). This finding contradicts that of Babis et al., (2010) who studied 48 patients with distal tibia fracture treated definitively using hybrid external fixators and conventional open reduction and internal fixation and found that, hybrid external fixation was associated with satisfactory clinical results and limited infection complications. Other studies have reported varied results when using external fixation compared with conventional open reduction and fixation with plating. Wang et al., (2015) performed a meta-analysis of complications associated with ORIF versus with external fixation. They found no significant differences in bone healing complications, superficial and deep infections, arthritis symptoms or chronic osteomyelitis between the two groups. In the studies by Babis et al., (2010) and Wang et al., (2015) only hybrid external fixators were used whereas in this study, various constructs of uniplanar and ankle spanning external fixators were used. It is possible that the type of external fixation affects clinical outcomes. Papadokostakis et al., (2008) reviewed the merits of ankle-spanning versus non-spanning frames and found a higher rate of superficial and deep infection in the spanning group. It is also possible that plating is associated with better clinical outcome since open reduction and internal fixation with a plate permits a correct and stable fracture fixation therefore limiting complications.

5.3 Functional outcome

The average OMAS score in this study was 64, which was rated as good. These outcome scores are not in agreement with the findings of Oh et al., (2003) and Collinge et al., (2007) who evaluated clinical results and outcomes of distal tibia fractures treated using the minimally invasive plating concept with a follow up duration of 24 months and 20 months respectively and reported average OMAS scores of 89 and 84 respectively. The difference between the findings of this study and the above two studied can be explained in part by use of multiple treatment methods and shorter duration of follow up in this study.

This study found that the characteristics that influenced functional outcomes as determined by OMAS were non-operative treatment, presence of infections and malunion, which were found to be associated with poorer functional scores (all had p values < 0.005). Sex, type of injury and fracture comminution were not found to be associated with poorer function on OMAS. These findings are in agreement with that of Collinge et al., (2010) who found that open fracture pattern, fracture comminution, sex and age were not associated with either poorer or higher OMAS scores and the only patient or injury characteristic that influenced functional outcomes was the occurrence of a secondary surgery for treatment of complications. In contrast to this study in which both operative and non-operative treatments were studied, Collinge et al., (2010) only studied operative treatments.

With respect to functional outcome (OMAS) and type of operative treatment, this study found that undergoing operative treatment by plating resulted in satisfactory outcome compared to external fixation. Similar observation was made by Wyrsch et al., (1996), who compared definitive treatment by means of open reduction and internal fixation with external fixation. The authors found that the average clinical scores in the group treated with plating were higher than for patients treated with external fixation. In this study, no special external fixators were used. The standard external fixators that were used in this study are indicated for initial stabilization of fractures in a staged treatment protocol and therefore they are not ideal as definitive treatment. It is possible that this might have contributed to worse functional outcome.

CHAPTER SIX: CONCLUSIONS AND RECOMMENDATIONS

6.1 Conclusions

1. Distal tibia affected predominantly male of economically active age group
2. At MTRH majority of distal tibia fractures were treated operatively by plating and external fixation
3. Characteristics such as non-operative treatment, occurrence of infections and malunion were significantly associated with unsatisfactory functional outcome.
4. Treatment by plating was associated with satisfactory functional outcome.

6.2 Recommendations

1. Distal tibia fractures should be treated operatively using plating for a better functional outcome.
2. Standard external fixators should be reserved for temporary stabilization of fractures before definitive treatment.

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APPENDICES

APPENDIX 1: IREC APPROVAL LETTER

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/2015/124
Approval Number: 0001489

8th September, 2015

Dr. Jared Oeba,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
08 SEP 2015
APPROVED

Dear Dr. Oeba,

RE: FORMAL APPROVAL

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

"Patterns and Outcomes of Distal Tibia Fractures among Adult at MTRH, Eldoret, Kenya."

Your proposal has been granted a Formal Approval Number: ***FAN: IREC 1489*** on 8th September, 2015. You are therefore permitted to begin your investigations.

Note that this approval is for 1 year; it will thus expire on 7th September, 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,

For

PROF. E. WERE
CHAIRMAN
INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE

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

APPENDIX 2: MTRH APPROVAL LETTER

MOI TEACHING AND REFERRAL HOSPITAL

Telephone: 2033471/2/3/4
Fax: 61749
Email: director@mtrh.or.ke
Ref: ELD/MTRH/R.6/VOL.II/2008

P. O. Box 3
ELDORET

8th September, 2015

Dr. Jared Oeba,
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:-

"Patterns and Outcomes of Distal Tibia Fractures among Adult at MTRH, Eldoret, Kenya".

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 3: APPROVAL OF AMENDMENT

INSTITUTIONAL RESEARCH AND ETHICS COMMITTEE (IREC)

MOI TEACHING AND REFERRAL HOSPITAL
P.O. BOX 3
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MOI UNIVERSITY
SCHOOL OF MEDICINE
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Tel: 33471/2/3

14th January, 2016

Reference: IREC/2015/124
Approval Number: 0001489

Dr. Jared Oeba,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
14 JAN 2016
APPROVED
P. O. Box 4606-30100 ELDORET

Dear Dr. Oeba,

RE: APPROVAL OF AMENDMENT

The Institutional Research and Ethics Committee has reviewed the amendment made to your proposal titled:-

"Characteristics and Outcomes of Distal Tibia Fractures among Adult at MTRH, Eldoret, Kenya".

We note that you are seeking to make amendments as follows:-

1. To modify the title to characteristics and outcomes of distal tibia fractures among adults at MTRH. The word pattern which was previously approved has been replaced with characteristics.
2. Omitted one objective on the proportion of distal tibia fractures.
3. Modify the inclusion criteria; Patients who are not ambulant before surgery will be excluded as the outcome assessment involves basically ambulation.
4. Modify sample size; You have used cochcrane formula to calculate the sample size since the primary outcome of the study is the outcome of distal tibia fractures.
5. Execution of the study: The duration of recruitment will be 12 months not 6 months.
6. Questionnaire: Item No.9 omission of AQ type C.

The amendments have been approved on 14th January, 2016 according to SOP's of IREC. You are therefore permitted to continue with your research.

You are required to submit progress(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 -	SPH	Dean -	SOM
	Principal-	CHS	Dean -	SOD	Dean -	SON

APPENDIC 4: CONTINUING 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
Tel: 33471/2/3

Reference: IREC/2015/124
Approval Number: 0001489

13th October, 2016

Dr.Jared Oeba,
Moi University,
School of Medicine,
P.O. Box 4606-30100,
ELDORET-KENYA.

INSTITUTIONAL RESEARCH & ETHICS COMMITTEE
13 OCT 2016
APPROVED
P.O. Box 4606-30100 ELDORET

Dear Dr.Oeba,

RE: CONTINUING APPROVAL

The Institutional Research and Ethics Committee has reviewed your request for continuing approval to your study titled:-

"Characteristics and Outcomes of Distal Tibia Fractures among Adults at MTRH, Eldoret Kenya".

Your proposal has been granted a Continuing Approval with effect from 13th October, 2016. You are therefore permitted to continue with your study.

Note that this approval is for 1 year; it will thus expire on 12th October, 2017. 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: C.E.O - MTRH
Dean - SOM

APPENDIX 5: CONSENT FORM

INTRODUCTORY LETTER/CONSENT TO PARTICIPATE IN THE STUDY

Consent form for the patient involved in the study.

I am conducting a study titled: *Characteristics and Treatment Outcomes of Distal Tibia fractures among adult patients at MTRH, Eldoret, Kenya.*

This study involves getting clinical information on you by looking at the file. I will also ask you to provide information regarding your injury that is not in your file. I do not intend to carry out any extra test on you apart from those the primary doctor seeing you will request.

I intend to compare the findings from this study with other studies and possibly influence future policies on the treatment of distal tibia fractures in MTRH and other similar centres. There is no direct benefit for participating in this study. Taking part in this study is voluntary. You may choose not to take part or to leave the study at any time. Your decision will not affect your relationship with your doctor or with MTRH and will not result in any penalty or loss of your right to medical treatment to which you are otherwise entitled. I therefore request for your permission to involve you in this study.

If you have any questions which you feel the investigator explaining to you has not handled or you would want another opinion, feel free to contact the **Principal Investigator, Dr. Jared Oeba 0716066890**

I have read this consent form or I have had it read to me. I have been told what to expect if I take part in this study. I have had a chance to ask questions and have had them answered to my satisfaction. I have been told that the people listed in this form will answer any questions that I have in the future. By signing below, I am volunteering to participate in this research study.

Patient's name____

Signature: ____Date: _________

____

Investigator ____

____

Signature: ____Date: _________

____

APPENDIX 6: DATA COLLECTION TOOL

1. Biodata

Study number ______________________ IP Number ______________________

Age ________ years Sex __________ Occupation ______________________

Phone number ____________________ Email address ______________________

County of Residency ________________ Nearest primary school ______________

2. Mode of referral

Home ☐ Hospital ☐ Other (specify) ____________________

3. Injury details

Time since injury took place ____

Hours ☐ Days ☐

Mechanism of injury

Fall ☐ RTA ☐ Industrial accident ☐

Assault ☐ Sports related ☐

Others (specify) ____

4. Known premorbid conditions

Hypertension	Yes	☐	No	☐
Diabetes mellitus	Yes	☐	No	☐
Respiratory	Yes	☐	No	☐

Other (Specify) ____

5. Active smoking Yes ☐ No ☐

6. Active alcohol use Yes ☐ No ☐

7. Clinical evaluation

(i) Skin

Bruise ☐ Contusion ☐

Crush ☐ Wound ☐

(ii) Oedema

Present ☐ Absent ☐

(iii) Deformity

None ☐ Varus ☐ Vulgus ☐

(iv) Vascular assessment(Dorsalis pedis artery pulse)

Present ☐ Absent ☐

(v) Pain

Present ☐ Absent ☐

(vi) Injury

Open ☐ Closed ☐

(a) If open injury, **Gustillo-Anderson classification**

I ☐ II ☐ IIIA ☐ IIIB ☐ IIIC ☐

(b) If closed, **Tscherne classification**

Grade 0 (No appreciable soft tissue injury) ☐

Grade 1 (Abrasion or contusion to skin or subcutaneous tissue) ☐

Grade 2 (Deep abrasion or contusion to the muscle) ☐

Grade 3(Crush, avulsion, and severe muscle damage) ☐

8. Distal tibia fracture

(i) Fracture site

Distal metaphysis ☐

Tibial plafond ☐

Ipsilateral fibula fracture ☐

(ii) Fracture displacement Yes ☐ No ☐

If yes, type of displacement

Angulation ☐

Depression ☐

Shortening ☐

Gap ☐

9. AO classification of the distal tibia fracture

Type A fracture (Extra-articular fracture)

A1 (simple) ☐

A2 (wedge) ☐

A3 (complex) ☐

Type B fracture (Partial articular fracture)

B1 (pure split) ☐

B2 (split-depression) ☐

B3 (multi-fragmentary depression) ☐

Type C fracture (Complete articular fracture)

C1 (articular simple, metaphyseal simple) ☐

C2 (articular simple, metaphyseal multi-fragmentary) ☐

C3 (articular multi-fragmentary) ☐

10. Treatment

(i) Time of injury to treatment_______________________________

Minutes ☐ Hours ☐ Days ☐

(ii) Closed reduction and POP ☐

(iii) Operative treatment

Distal tibia plate ☐ Ring External fixator ☐

Multi-axial external fixator ☐ Intramedullary Nailing ☐

K-wires ☐ LC-DCP Low ☐

Cloverleaf plate ☐ Spoon plate ☐

OUTCOME ASSESSMENT

11. Immediate treatment outcome (12-72 hours)

(i) Baseline OMAS

Excellent (Above 91) ☐ Good (61-90) ☐

Fair (31-60) ☐ Poor (below 30) ☐

(ii) Clinical evaluation

Oedema Yes ☐ No ☐

Pain Yes ☐ No ☐

Motor present: Yes ☐ No ☐

Dorsalis pedis pulse: Present ☐ Absent ☐

(iii) Radiological assessment(Check X-Ray)

Adequate reduction ☐

Inadequate reduction ☐

12. OUTCOME AT 2 WEEKS AFTER TREATMENT

(i) Clinical assessment

Wound dehiscence	Present	☐	Absent	☐
Wound sepsis	Present	☐	Absent	☐

(ii) Radiological assessment

Reduction maintained ☐ Re-displaced ☐

13. OUTCOME ASSESSMENT AT 3 MONTHS

(i) Pain present

Yes ☐ No ☐

(ii) Ankle stiffness

Yes ☐ No ☐

(iii) Malunion

Yes ☐ No ☐

If yes, type of malunion

Angulation ☐ Shortening ☐ Rotation ☐

(iv) Delayed union present

Yes ☐ No ☐

(v) Revision surgery

Yes ☐ No ☐

14. OUTCOME AT 6 MONTHS

(i) OMAS

Excellent (Above 91) ☐ Good (61-90) ☐

Fair (31-60) ☐ Poor (below 30) ☐

(ii) Pain present

Yes ☐ No ☐

(iii) Ankle stiffness

Yes ☐ No ☐

(iv) Malunion

Yes ☐ No ☐

If yes, type of malunion

Angulation ☐

Shortening ☐

Rotation ☐

(v) Non-union

Yes ☐ No ☐

(vi) Revision surgery

Yes ☐ No ☐

APPENDIX 7: OUTCOME ASSESSMENT TOOL

The ankle scoring system of Olerud and Molander (1984)

Aspect	**Maximum Score**	**Patient's Score**
Pain		
None	**25**	
Walking on uneven surface	20	
Walking on even surface	10	______
Walking indoors	5	
Constant and severe	0	
Stiffness		
None	**10**	______
Stiffness	0	
Swelling		
None	**10**	
Evenings	5	
Constant	0	______
Stair-climbing		
No problems	**10**	
Impaired	5	
Impossible	0	______
Running		
Possible	**5**	
Impossible	0	______
Jumping		
Possible	**5**	
Impossible	0	______
Squatting		
No problems	**5**	
Impossible	0	______
Supports		
None	**10**	
Tape, wrapping	5	
Stick or crutch	0	______
Work, activities of daily living		
Same as preinjury	**20**	
Reduced	15	
Change of job	10	______
Severely impaired	0	
Total	**100**	______

Excellent; More than 91 points; **Good**; 61–90 points, **Fair**; 31–60 points; and **Poor** less than 30

APPENDIX 8: WORK PLAN

ACTIVITY	START	END	Responsibility
Proposal Writing	January 2015	April 2015	Researcher and Supervisors
Presentation of Proposal to the Orthopedics department	May 201	End of May 2015	Researcher
IREC Review	July 2015	August 2015	IREC and Reviewer
Collection of Data	January 2016	June 2017	Researcher and Assistants
Data Analysis	July 2017	December 2017	Researcher and Supervisors
Thesis writing and presentation to the orthopedics department	January 2018	May 2018	Researcher
Presentation of Thesis to the School of Medicine for Examination purposes and Defense	April 2019	July 2018	Researcher and Supervisors
Oral defense		September 10th 2019	Researcher, supervisors, examiners and Dean
Submission for binding		October 2019	Researcher and Supervisors

APPENDIX 9: BUDGET

ITEM	QUANTITY	UNIT COST [Kshs]	TOTAL [Kshs]
Laptop computer	1	50,000	50,000
Box files	10	1,000	10,000
USB/Flash disc	2	3,000	6,000
Printing cartridges	2	10,000	20,000
Printing paper	30	500	15,000
Folders	100	50	5,000
Airtime	20	1000	20,000
Printer	1	20,000	20,000
Filing Cabinet	1	12,000	12,000
Training expenses	2 days	6,000	12,000
Allowances for research assistants	180 days	300	108,000
Proposal	4	500	2,000
Thesis	6	2000	12,000
Contingencies	10% of total		31,980
Total			**351,780**

Funds for this study were be sourced by the investigator using private means