Short term outcome of patients with open tibia Diaphyseal fracture treated with external fixator at Muhimbili Orthoepedic Institute

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SHORT TERM OUTCOME OF PATIENTS WITH OPEN TIBIA DIAPHYSEAL FRACTURE TREATED WITH EXTERNAL FIXATOR AT MUHIMBILI ORTHOEPEDIC INSTITUTE

By

Said Rajab Nondo

A Dissertation Submitted in (Partial) Fulfillment of the Requirements for the Degree of Master of Medicine (Orthopaedics and Trauma) of the Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
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CERTIFICATION

The undersigned certifies that, he has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled*;"**Short term outcome of patients with open tibia diaphyseal fracture treated with external fixator at Muhimbili Orthoepedic Institute.**"* in (partial) fulfillment of requirement for degree of Master of Medicine (Orthopaedics and Trauma) of Muhimbili University of Health and Allied Sciences

_____

Dr. Anthony Assey

Supervisor

_____

Date

DECLARATION

AND

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I, **Said Rajab Nondo**, declare that, this **dissertation** is my own original work and that it has not been presented and will not be presented to any other University for similar or any other degree award.

Signature……..... **Date**…….....

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It would have never been possible to complete this dissertation without the support and encouragement from my beloved wife who have always stood by me and dealt with all of my absence from many family occasions with a smile.

DEDICATIONS

This dissertation is dedicated to my mother and my wife

ABSTRACT

Title: Short term outcome of patients with open tibia diaphyseal fracture treated with external fixator at Muhimbili Orthoepedic Institute.

Objective: To determine the short term treatment outcome of tibia diaphysial fractures treated with external fixator at MOI.

Methodology: A prospective descriptive study done on adult patients 18 years and above with open tibial shaft fractures treated by AO tubular EF. This study was conducted at MOI for a period of twelve months from beginning April 2016 to the end of March 2017. Eighty patients met the inclusion criteria and were recruited after signing the informed consent. Data was collected using guided structured questionnaire including wound status, callus formation, malalignment and weight bearing stutus. Other tools like tape measure and goniometer were used to collect necessary information during follow up clinic at 2^{nd}, 6^{th}, 10^{th}, and 12^{th} week post-surgery. The obtained data for short term outcome were analyzed by SPSS version 20.

Results

During this study a total of 80 patients with open tibial shaft fractures were enrolled and followed up. The proportion of open tibia diaphyseal fractures among all open fractures was found to be 7.2 %. Of these 80 patients males were 69(86.2%) and females 11(13.8%), with approximated male to female ratio of 6:1.The majority of patients were in the age group of 18-30 years (47.5%) with a mean age of (33.61 +/- 10.71) years. In this study motorcycles were the leading mechanism of injury, contributing 53 (66.2%) patients, followed by motor vehicles 23(28.8%), then falls from the height 4(5%) patients. In all these motor traffic crashes (76 patients), 38(50%) were passengers, 26(34.2%) drivers and 12 (15.8%) were pedestrians. Grade II fractures were most common 47 (58.8%) patients, followed by grade IIIA, 26(32.5%) patients, grade IIIB 6(7.5%) patients and least was grade I, 1(1.3%) patient. In these fracture the average time of initial callus formation visible on x ray was 10 weeks, it ranged from 6 weeks to 12 weeks ,with the mean RUST score of 7 at the end of the follow up.

In this study, 7(8.8%) patients had superficial wound infection and 3(3.7%) had deep wound. Patients with grade III injury develop infection more (70%) compared to grade II injury (30%) and there were no wound infection in grade I. It was statistically significance that grade III fractures had high rate of infection compared to other grade with p-value of 0.031.

Following the use of external fixator, 53(66.3%) develop pin tract infection. Duration of stay for the shantz pin in a patient affect the chance for pin tract infection, the longer it stay the higher the chance of infection. This was statistically significance under chi square test with P-value of less than 0.001 within 95% confidence interval. Out of 80 patients of study population 38 (47.5%) had malunion which include shortening (7.5%) and angular deformity (40%). Reoperation was planned for 22(27.5%) patients; malalignment(23.7%) and deep infection (3.8%) were the main cause.

Conclusion

Motor traffic crashes were the main cause of open tibia diaphyseal fractures. Younger population constitutes a larger number of the injured. Treatment of these fractures with AO tubular EF resulted in high complication rate.

Recommendation

Due to high complication rate AO tubular EF should be used only temporarily in case there is high level of contamination, severe soft tissue or bone damage with or without compartment syndrome and high fracture grades such as grade III fractures. This is for wound care as well as fracture stabilization since internal fixation cannot be used primarily in that condition.

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ABBREVIATIONS

AO/OTA	Arbeitsgemeinschaftfür Osteosynthesefragen/ Othoepaedic and Tauma Association
EF	External Fixator
EMD	Emergency Medical Department
FWB	Full Weight Bearing
IV	Intravenous
MMED	Masters of Medicine
MoHSW	Ministry of Health and Social Welfare
MOI	Muhimbili Orthopaedic Institute
MTC	Motor Traffic Crash
MUHAS	Muhimbili University of Health and Allied Sciences
NWB	Non Weight Bearing
PWB	Partial Weight Bearing
RUST	Radiological union scale for tibia
SD	Surgical Debridement
SPSS	Statistical Program for Social Sciences
TT	Tetanus Toxoid

CHAPTER ONE

INTRODUCTION

An open fracture is one in which the fracture hematoma or fracture site communicate with external environment as a result of skin breakage which usually acts as the barrier to external environment. Open fractures occur under a wide spectrum of conditions with specific consequences. Bacteria from the environment may contaminate the area of injury, and the quantity of gross contamination may differ with the environment [1,2].

Statistics have shown that injuries are on the increase in many developing countries including Tanzania[3,4]. Unlike in the past when falling from height particularly from trees, were the major causes of injuries in developing countries. Currently road traffic crushes and interpersonal violence, including the use of various firearms contribute a high proportion of injuries[3, 5]Open fractures occur commonly in the tibia due to its location which exposes it to frequent injury[1]. Secondly tibia is subcutaneous throughout most of its length owing to its paucity of muscular coverage. The prognosis in open fractures is determined primarily by the amount of devitalized soft tissue and the level and type of bacterial contamination. The interplay of these two factors, rather than the fracture pattern alone, is the primary determinant of the outcome[2]

Various classification systems to grade the extent of the initial injury have been proposed in an effort to decide the optimal management and to offer useful prognostic clues. Gustilo and Anderson which describes three groups of increasing severity based on the size of the open wound, the degree of its contamination and the extent of soft-tissue injury is common used in fracture of tibia shaft[1,6,7]. The classification of an open fracture should be established at the time of operative debridement of the wound. Attempts to classify an open fracture and therefore determine treatment before thorough debridement and assessment of the wound and soft-tissue injury can be misleading [2,8].The choice of technique for stabilization of open tibial fractures has not been analyzed.

External fixation has been popular because of the relative ease of application and the limited effect on the blood supply of the tibia, but these advantages have been outweighed by the high incidence of pin-track infection, difficulties relating to soft-tissue management and the potential for malunion[9].

History of external fixator started almost 2400 years ago. Hippocrates described a form of external fixation to splint a fracture of the tibia. The device consisted of closely fitting proximal and distal Egyptian leather rings connected by four wooden rods from a cornel tree. In 1840, Jean-Francois Malgaigne described a spike driven into the tibia and held by straps to immobilize a fractured tibia. In 1843 he used a claw-like device to percutaneous hold the fragments of a fractured patella. Clayton Parkhill of Denver, Colorado and AlbineLambotte of Antwerp, Belgium independently invented the modern concept of unilateral external fixation, in 1894 and 1902, respectively. Lambotte was the first to use threaded pins, however, his device necessitated initial, open fracture reduction and then pin insertion and fixator placement.

In 1938, Raoul Hoffmann of Geneva, Switzerland, building on the work of others, realized that major improvements were essential to make the external fixator more clinically relevant. He developed a technique based on closed reduction with guided percutaneous pin placement. Hoffmann's technique exemplified the first application of minimally invasive orthopaedic surgery. In the 1950s, Gavriil Ilizarov of Kurgan, Soviet Union, devised and developed a new method for treating fractures, deformities and other bone defects. A metal frame that encircles the limb is attached to the underlying bone by crossing (X) pins inserted through the bone and limb. The external rings are linked to each other by threaded rods and hinges that allow moving the position of the bone fragments without opening the fracture site, then the fragments can be fixed in rigid position until complete healing.

The current standard external fixator (AO tubular fixator) includes the Schanz pin B, Connecting rods A, and Clamps. C, D, E as shown in a Fig.1 below.

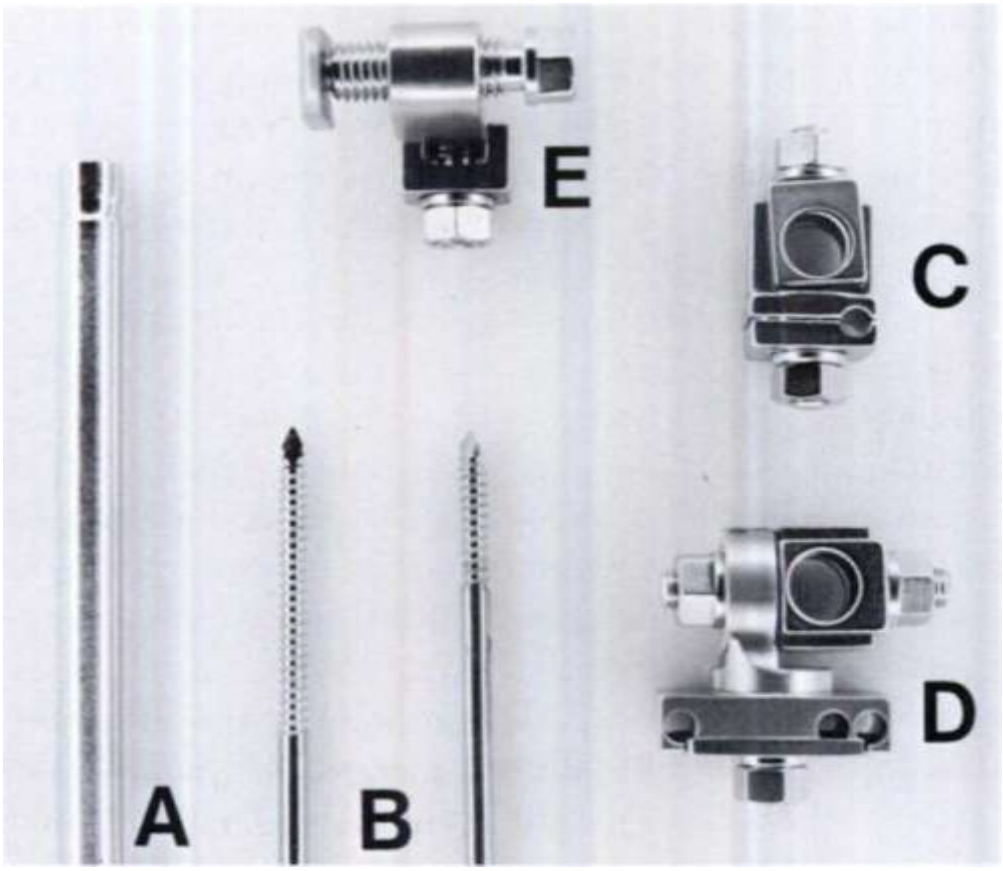


Figure1: The basic components of the AO tubular fixator: [9]

External fixation is a surgical treatment used to stabilize bone and soft tissues at a distance from the operative or injury focus. They provide unobstructed access to the relevant skeletal and soft tissue structures for their initial assessment and also for secondary interventions needed to restore bony continuity and a functional soft tissue cover.[9]

External fixation of fractures of the leg may give uneven results and a high rate of complications. Three basic principles can govern the optimal use of these devices, the external fixation frame should avoid damage to vital anatomical structures, it should allow access to the injured area and it should meet the mechanical demands of the patient and the injury[9].

An external fixation frame should be safe, non-obstructive, adaptable to a wide variety of injuries and stiff enough to maintain alignment and it should allow full weight bearing. A review of the literature and experience with a number of different devices and frames suggested that these goals could be attained by adherence to three basic principles, the frame should not damage vital anatomical structures, the frame should provide sufficient access for debridement and secondary procedures, and that it should fulfill the mechanical demands of the patient and the injury.

The safe soft-tissue corridor for pin insertion is determined by the anatomy. Cross-sections of the leg show that in the proximal tibia pin placement is safe within a 220 arc from the posteromedial border of the tibial plateau to the tibiofibular joint, excluding a small rectangular area overlying the patellar tendon[9]. Below the tibial tubercle this anteromedial corridor decreases to 140 and is therefore unsafe for transfixion. Posterior pin exit areas may injure the posterior tibial neurovascular structures. In the distal third, the anterior tibial vessels are vulnerable along the lateral tibial cortex. Whenever possible, pin insertion should be limited to the subcutaneous areas of the tibia.

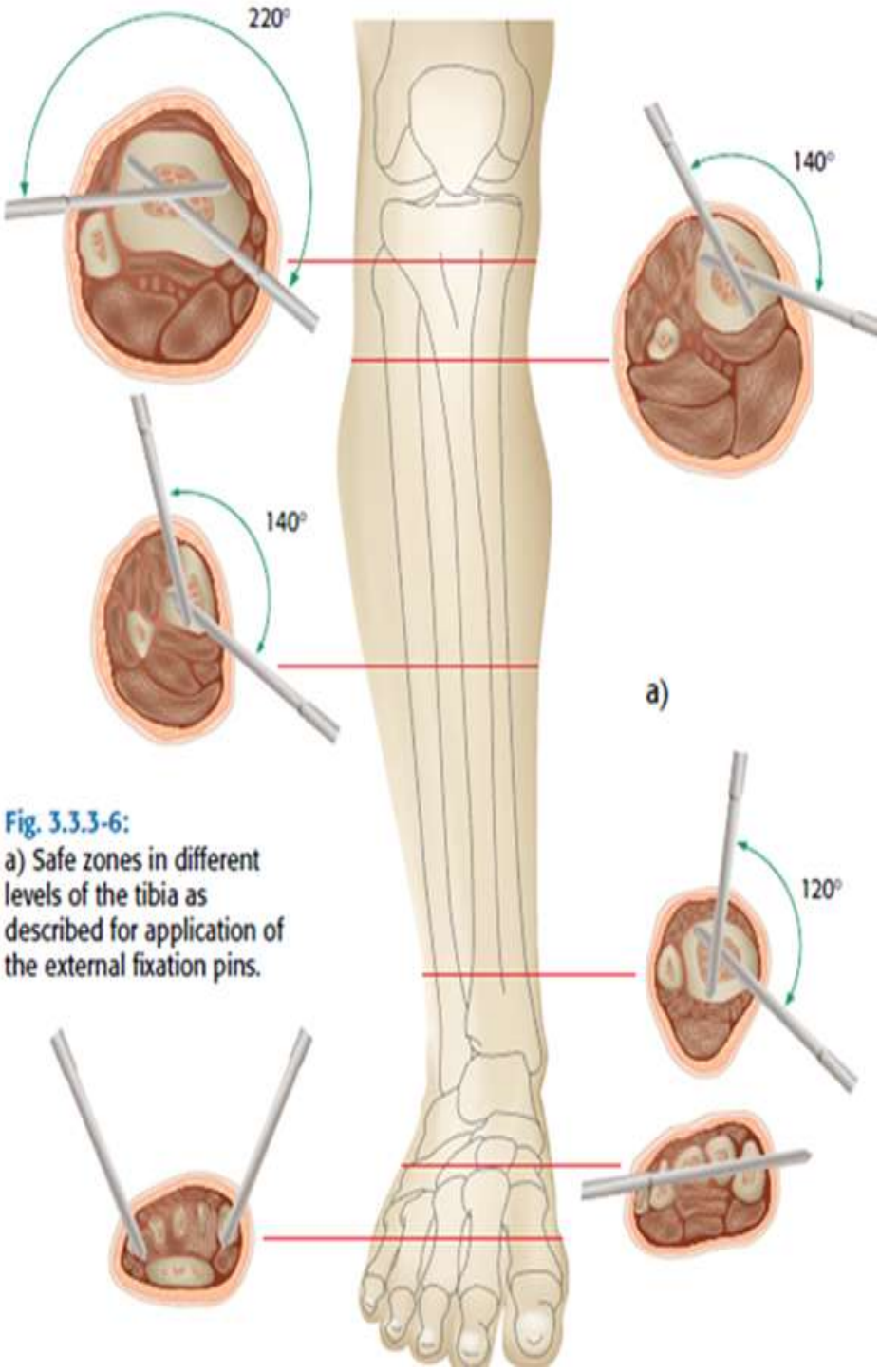


Fig. 3.3.3-6:
a) Safe zones in different levels of the tibia as described for application of the external fixation pins.

Figure 2 : Safe zone for external fixation in tibia[(10)]

LITERATURE REVIEW

Incidence of open tibia fracture:

Open tibia fractures are among common fracture of the extremities in both developed and developing African countries. The tibia shaft is the most common long bone to sustain an open fracture due to its location which exposes it to frequent injury; secondly its surface is subcutaneous throughout most of its length owing to its paucity of muscular coverage

In developed countries, Behrens et al reported an incidence of 2 open tibia fractures per 1000 injuries per year in a defined population group in an industrialized western society; this is 0.2% of all injuries[9]. The incidence and severity has been reported to be even higher in the developing world. Isefanya et al 2008 from Ibadan, Nigeria and Twagirayezu et al 2008 from Kigali Rwanda found the incidence of open tibia fracture among all open fracture to be 66% and 69% respectively[11,12]. In Tanzania the incidence of open tibia fracture was reported by Mcharo et al 2001 and Mhembelo KS 2004, to be 54% and 59% respectively where the incidence specifically for tibia diaphysis was 2.7% among all tibia fracture[3, 13].With the present status where motorcycle and motorcars has increased in number as means of transportation, motor traffic crushes are observed to increase as well, hence the new incidence should be reviewed

Mechanism of open Tibia fractures:

Statistics have shown that injuries are on the increase in many developing countries including Tanzania [3,4] Unlike in the past when falling from height particularly from trees, were the major causes of injuries in developing countries. Currently road traffic accidents and interpersonal violence, including the use of various firearms contribute high proportion [4,5].

Open Tibia fractures may be resulted from multiple etiologies, including motor traffic accidents, fall from a height, farm injuries as well as assault and bullet injuries.

Arginine et al 2008 in Ibadan Nigeria, evaluate the etiology, severity and mechanisms of injuries responsible for tibia fractures. The causes of injury were motor vehicular crashes (35%), pedestrian injuries (29%), falls (16%) and motorcycle crashes (10%).[11]

Current in developing countries including Tanzania, motorcycle has been a means of transport in both rural and urban area, thus motorcycle accident has becoming the major etiology of open fracture of tibia. In Tanzania, Mcharo et al 2001, reported motorcycle crash to contribute 36.5% of all cause of open fracture while Mhembelo KS 2004, found various causes including road traffic accident (70.8%), fall from a height (13.9%), assault (12.5%), bullet and sport injuries (1.4%) [3,13]. Local statistical data available are more than 10 years, and due to rapidly increase in urbanization new statistical might be high.

Complication of External Fixator as treatment of Open Diaphysis Tibia fracture:

The choice of technique for stabilization of open tibia fractures has not been analyzed. External fixation has been popular because of the relative ease of application and the limited effect on the blood supply of the tibia, but these advantages have been outweighed by the high incidence of pin-track infection, difficulties relating to soft-tissue management, the potential for malunion and high reoperative rate.

Infection rate

Superficial infection which occurs within 30 days after the operation and involves only skin or subcutaneous tissue is the most common form of infection in open fracture treated with external fixator. Beltsion 2009 evaluates the effectiveness of unilateral external fixator as primary and definitive treatment for open tibia fractures, and found pin track infections in 42% of the study population (6). Superficial infection if uncontrolled can complicate further to deep infection in which Museru et al 2001, found 7% of the study population developed osteomyelitis(3). Other studies reported the infection rate to range from 14% to 42%.[3, 13, 14] .Nowadays the use of broad spectrum antibiotic as prophylaxis just before operation and good surgical would care could have decrease the rate of infection and this should be addressed.

Malunion

External fixation of fractures of the leg may give uneven results and a high rate of complications including malunion of the bone in different plains. Malunion is defined as varus or valgus deformity of 5 degrees or more, anterior or posterior angulation of 10 degrees or more, shortening of 1 cm or more or rotational deformity of 10 degrees or more as compared

with the contralateral leg. Tornetta et al 2002 in USA found 14% of study population (29 patients) to develop malunion which was assessed clinically and by using X ray. Other studies report the rate of malunion is ranging from 7% to 20%.[13, 15]

Reoperative rate:

Due to various complications that occur in management of open diaphysis tibia fracture by external fixator reoperation are usually indicated. The untolerated complication including osteomyelitis, shanz pin loosening, nonunion and severe malunion. Reoperative rate has not been documented in local studies but in a study done by Beltsion 2009 to evaluate the effectiveness of unilateral external fixator as primary and definitive treatment for open tibial fractures, in 139 open fractures, reoperation was performed in (19%) of all fracture. The causes for reoperation were 18 nonunions, 21 delayed unions, 3 with osteomyelitis, 4 malunions and 7 half pin revisions due to infection or loosening.[6]

Rate of callus formation:

A normal healing by hard callus formation is define as union within 6 months also union is defined as dense callus bringing at least three cortices , while delayed union as healing between 6 and 8 months, and nonunion as the absence of healing after 8 months[6]. The fracture union is assessed clinically and radiologically in each visit. The absence of pain and local tenderness on stressing the fracture site or on full weight bearing on the operated limb indicate fracture union.

Mean time to fracture union for the 139 open fractures that did not required a change of fixation method or bone graft was 25 weeks (ranged 17–32, median time 28) reported by Beltsion 2009 [6]. Another study done by Mhembelo KS 2004 found that the mean duration for fracture tibia to unite is 16 weeks with the range of 7 to 27 weeks.[13]

Treatment of open tibia diaphysis fracture by External Fixator

All open fractures need to be formally treated in the operating room on an urgent basis with meticulous irrigation and thorough debridement of devitalized soft tissue and devascularized bone fragments[2,16] .

Usually the goal of treatment in open fractures includes preventing infection, achieving early wound healing with full soft tissue recovery, Obtaining union, returning the involved limb to normal function, restoration of anatomy and avoidance of complications.[17, 18] .The precarious blood supply and the lack of enough soft-tissue cover of the shaft of the tibia make these fractures vulnerable to nonunion and infection. These complications have been reduced by basic concepts of the current strategy which include, immediate intravenous antibiotics, urgent and repeated surgical debridement, immediate skeletal stabilization, appropriate soft-tissue coverage and subsequent early bone grafting beneath stable soft-tissue cove

One of the choices of technique for stabilization of open tibia fractures is external fixation. External fixation has been popular because of the relative ease of application and the limited effect on the blood supply of the tibia, but these advantages have been associated by the high incidence of pin-track infection, difficulties relating to soft-tissue management and the potential for malunion[19].The treatment of open fractures of the tibia shaft still remains controversial. Throughout the 1980's, external fixation was the treatment method recommended most often for open tibia fractures. But currently, most traumatologists prefer intramedullary nailing for Gustilo type I, type II and type IIIA open fractures[16] where there is minimal contamination, good soft tissue status and bone coverage.

PROBLEM STATEMENT

An open fracture of tibia is the common cause of admission at MOI hospital. Mcharo etal 2001,reported that 54 % of all open fractures of extremities were open fracture of tibia(3). And according to Mhembelo KS 2004, about 2.7% of all open fractures were diaphysis fracture of tibia bone[13]

AO Tubular External fixator has been used to stabilize open fracture of tibia diaphysis fracture at MOI despite of complication in clinical outcome. The overall complication rate is about 30% which include malialigment, infections, and delay union while reoperative rate due to various complication range from 5% to 19%[3,6,13,20).]

All complications arises in clinical outcome due to external fixator in management of tibia diaphyseal fractures should be known and addressed in our local environment.

RATIONALE

MOI has few published research that has been done in the recent past to look into appropriate immediate stabilization of open tibial shaft fractures and efficiency in reducing postoperative complications. Most of the papers available are from developed part of the world and they are retrospective studies. Currently there are changes in term of incidence and management of open tibia fracture including modern antibiotics to prevent infection at MOI and use of intramedullary nail

Hence the current status on the incidence, efficiency and complication of open tibia fracture treated with external fixator should be addressed in order to come up with the standard management protocol as well as to think of alternative method of managing open tibia diaphysial fracture.

This study is being done as a partial fulfillment for the award of the degree of Master of Medicine in Orthopaedics and Trauma of the MUHAS

OBJECTIVES OF THE STUDY

Broad Objective

To determine the short term treatment outcome of tibia diaphyseal fractures treated with external fixator at MOI from beginning of April 2016 to the end of March 2017

Specific Objectives

1. To determine proportional of open tibia diaphyseal fractures among all open fracture attended at MOI.

2. To determine aetiologies of open tibia diaphyseal fractures treated with external fixator at MOI.

3. To determine the rate of callus formation of open tibia diaphyseal fractures treated with external fixator at MOI.

4. To determine post-operative infection rate of open tibia diaphyseal fractures treated with external fixator at MOI.

5. To determine malunion rate of open tibia diaphyseal fractures treated with external fixator at MOI

6. To determine reoperative rate of open tibia diaphyseal fractures attended at MOI

CHAPTER TWO

METHODOLOGY

Study Design

This was a hospital based descriptive prospective study, patients who met inclusion criteria were recruited as they came in the hospital. Written consent form was used followed by social demographic data records and initial assessment of the patient, then patients were followed in a scheduled clinic for assessment of short term outcome within three months post-surgery where a characteristic of interest were detected and recoded.

Study Area

The study was conducted at Muhimbili Orthopaedic Institute (MOI) located at Dar-es-salaam, Tanzania, which is a specialized institute of orthopedics, traumatology and neurosurgical care as the main referral center for patients with skeletal trauma serving both for the city of Dar es Salaam and other regions.

Study Population

Patients aged 18 years or above with open fractures tibia diaphyseal admitted at MOI.

Inclusion Criteria

i. Presentation to hospital within 24 hours of injury with isolated open diaphyseal tibia fracture
ii. ii. Patient who agree with study and fill the consent form

Exclusion Criteria

i. Polytrauma patients.
ii. Patients with comorbidities like diabetes, known vascular disease
iii. Psychiatric ill patients
iv. Pathological fracture of the tibia shaft
v. Patients with deformity on affected limb eg previous injury, polio etc

Study Period

This study was conducted for one year period, from the beginning of April 2016 to the end of April 2017, this include proposal preparation, data collection, analysis and report writing.

Sample size estimation and sampling technique

A retrospectively pilot survey for 3 months from beginning of January 2016 to the end of March 2016 was done and revealed a total number of patients with open fractures attended at MOI emergency department were 1195. Number of patients with open tibia diaphysis fractures from beginning of January 2016 to the end of March 2016 was 60. Proportion of patients with open tibia diaphysis fractures to all open fracture:

60/1195=0.0502=5.02%

Sample size was estimated using the formula

$$n = \frac{t^2 \times p\,(1-p)}{m^2}$$

n = minimum required sample size

t = confidence level at 95% (standard value of 1.96)

p = 5.02%, prevalence of open tibia diaphysis fractures

m = Precision of 5% (standard value of 0.05)

n = (1.96/5)2x (5.02(100-5.02) = 73

Therefore the minimum sample size was 73 patients, but 80 patients were recruited to compensate loss of follow up

Data Collection Process

The data collection procedure started as soon as the patients attended to the hospital prospectively. For all patients who met inclusion criteria and they were willing to participate

in the study, demographic data and initial assessment of the fracture were done and documented

All patients were managed as per hospital procedures on emergency basis by analgesics, antibiotics and surgical debridement then stabilized by external fixation. The wound assessment was done and classified according to Gustilo and Anderson of open fracture classification during the operation procedure.

Post operation evaluation of the wound and control x rays were done followed by a scheduled clinic follow up at 2nd, 6th, 10^{th} and 12 week post-surgery, where state of the wound, any signs of infection, callus formation, and degree of malunion were assessed and documented in a hand-written form.

Other tools such as tape measure to measure true limb length, goniometer to measure degree of rotational, range of motion of adjacent joints and angular malalignment together with control X-rays were used in clinic to collect this information. Scores such as, radiographic union scale for tibia fracture (Rust) score and Thoresen score were used to assess callus formation and malallignment of the fractured bone respectively from the 6^{th} week of clinic follow up. The expected minimum time to remove the external fixator was 12 weeks, in which a P.O.P was used to complete the course of treatment; the follow up ended up as soon as the external fixator was removed. Reproducibility was assured by using universal standard definition for all variables, as well as standard classification and scores system e.g Gustilo, Therosen and Rust score.

Patient's treatment method and evaluation

All patients with open tibia shaft fractures treated with AO tubular EF were included in this study after consenting to participate and meeting inclusion criteria. All patient approached were agreed and sign the consert.

Preoperative:

Social demographic data such as gender, age, education level and residence were collected and recorded in a questionnaire. General examination of the patient, vital signs and local

examination the affected limb were assessed by a researcher, and the open tibia shaft fracture was be classified by Gustilo and Anderson Classification.

Plain radiographs i.e. both Anteroposterior in a supine postion with full extended knee and Lateral views in lateral position of patient's affected tibia and adjacent joints were taken pre-operatively by a radiographer in the Radiology department to determine the fracture configuration.

Operative procedure:

In the operating room patients were anaesthetized by spinal or general anaesthesia then received 3rd generation cephalosporine 1 gram intravenous upon anaesthesia induction. Surgical site was prepared following aseptic technique and isolated by sterile towels. Surgical debridement by refreshing wound edges, removing foreign bodies, devitalized tissue and irrigation were done. EF applied and most of the wounds were closed primarily while very few left open due to extensive soft tissue loss, and these were planned for rotational flaps.

Postoperative care and follow-ups:

Control X ray were taken immediately post operation then assessed by researcher, analgesia and iv antibiotics were continued for three day in the ward before discharge. No cast or brace were applied and the patients discharged within 2 to 5 days post-operative depending on his/her clinical strength (stable vital and no post operation complications). After being discharged study participants were trained and requested to continue daily wound dressing with normal saline and iodine at nearby hospital and to attend a follow-up clinic on the 2nd week post operatively Then additional followed-up visit were scheduled at 6th, 10th, 12th week postoperatively

Assessment of open fracture by Gustilo and Anderson

Open fracture of tibia are classified into five classes according to Gustilo and Anderson as follows

Table 1: Classification of open fracture by Gustilo and Anderson.[8]

Gustilo Type	I	II	IIIA	IIIB	IIIC
Energy	Low energy	Moderate	High	High	High
Wound Size	**< 1 cm**	**> 1cm**	>10cm	>10cm	>10cm
Soft Tissue	Minimal	Moderate	Extensive	Extensive	Extensive
Contamination	Clean	Moderate contamination	Extensive	Extensive	Extensive
Fracture Pattern	Simple fx pattern with minimal comminution	Moderate comminution	**Severe comminution or segmental fractures**	Severe comminution or segmental fractures	Severe comminution or segmental fractures
Periosteal Stripping	No	No	**Yes**	Yes	Yes
Skin Coverage	Local coverage	Local coverage	Local coverage including	**Requires free tissue flap or rotational flap coverage**	Typically requires flap coverage
Neurovascular Injury	Normal	Normal	Normal	Normal	**Exposed fracture with arterial damage that requires repair**

On the visit, the researcher assessed the surgical wound for color, tenderness, smell or discharge, ICD 10 criteria was used to diagnose wound infections. During same visits, tibia alignment and shortening were assessed. Anteroposterior and lateral tibia X-rays were obtained whereby rate of union assessed.

For stable fractures (none comminuted, no bone loss and good alignment) early weight-bearing were recommended. The fracture union was assessed clinically and radiologically in each visit. The absence of pain and local tenderness on stressing the fracture site and on full weight bearing on the operated limb was used as clinical criteria for fracture union.

On the other end, the presence of a callus around the fracture with a density which is similar to that of the adjacent cortex, or the obliteration of the fracture line, was considered as the radiological union of the fracture[23]. In case of implant failure, severe malalignment, or severe infection, patient were be planned for reoperation.

Measurement of limb length discrepancy

True limb length discrepancy was determined by comparing the true limb length of affected and normal limb. The patient was asked to lie supine on examination table with the body as straight as possible. Before taking measurements of affected limb, the normal limb was placed in the anatomical position and there should not be tilting of pelvis as determined by a line joining the two anterior superior iliac spines (ASIS)

To check for true limb lengths discrepancy, the examiner identified patient's right ASIS and place the free end of tape measure onto it. The patient was asked to hold the end in place so that the examiner can unwind the tape measure in a straight line towards the distal tip of medial malleolar. The examiner records the distance and performs the same on left lower extremity. A true limb length discrepancy was considered present if the lengths were differing significantly; shortening deformity was considered whenever the affected limb length became shorter than the normal limb.

Measurement of rotational malalignment

Malrotation defined as an internal/external rotation deformity greater than 10degrees, this was assessed clinically by observing the position of the patella in relation to a tight held tape measure extended from ASIS to the second toe on the same side[(21)].

If patellar was in line with the tape measure it indicates no rotational deformity present. If the patella lied lateral to the tape measure it indicates presence of external rotation deformity and if patella lies medial to the tape measure it indicates the presence of internal rotation deformity.

The degree of limb rotation deformity was assessed in patient at resting position, the patient is asked to lie comfortably on examination table with hips and knee extended, and then by using goniometer the angle between an imaginary line along medial border of the foot and vertical axis is measured. These measurements were done in a normal limb, followed by an affected limb and then, angles obtained were compared.

When both angles were the same it meant no limb rotation deformity, but when the affected limb rotation angle was larger than the normal limb rotation angle it considered as external rotation deformity and when the affected side rotation angle was less than the normal limb rotation angle it considered as internal rotation deformity. Malunion was defined as more than 5 degrees of angular deformity in the sagittal or coronal planes, malrotation of at least 10 degrees and more than one centimeter of limb length discrepancy as compared with the uninjured side. Outcomes were classified using Thoresen scoring system.

Table 2: Thoresen scoring system for measuring malaligment[(22)]

Thoresen scoring system.

Variables	**Excellent**	**Good**	**Fair**	**Poor**
Malalignment				
Varus/valgus(degree)	<5	5	10	>10
Procuvatum/recurvatum(degree)	5	10	15	>15
Internal rotation (degree)	5	10	15	>15
External rotation (degree)	10	15	20	>20
Shortening (in cm)	1	2	3	>3
Range of motion (knee)				
Flexion (degree)	>120	120	90	<90
Extension deficit (degree)	5	10	15	>15
Pain or swelling	None	Sporadic	Minor significant	Severe

Measurements of the callus formation in tibia fractures

A radiographic union scale for tibia diaphyseal fractures (RUST) was used to assess the extent of callus formation in tibia fractures during 6th, 10th and 12th weeks of follow up. AP and lateral view X rays of the injured tibia were obtained and radiological assessment on all four cortices at fracture site (medial, lateral, dorsal and volar) were evaluated for fracture line visibility and presence or absence of callus, then scored from 1 to 3 as shown in table 3. The individual cortical scores (dorsal, volar, medial and lateral) are added to provide RUST value which range from 4 to 12. The score on each cortex are added, resulting in a total value for each set of radiographs, 4 is the minimum score, indicating that the fracture is not healed and 12 is the maximum score, indicating that the fracture completely cured. A score greater than 9 is equivalent to minimum of three cortices with bone callus. A fracture of this score was considered as radiologically consolidated.

Table 3: Radiographic union scale for tibial fractures (rust)([23])

Cortex	Fracture line, no callus (score= 1)	Fracture line, visible callus (score= 2)	No fracture line, bridging callus (score 3)	Total scores: Min= 4, Max=12
Dorsal				
Volar				
Medial				
Lateral				

Data management and analysis

Data obtained were managed by statistical software (SPSS version 20), for analysis. Statistics, including frequencies, proportions, and percentage, were compiled for all demographic, clinical and radiological measures. To analyses relationship between described categorical variable in specific objectives such e.g. grades of open fracture with infection rate or malunion, Chi square test or Fisher exact test was used. The differences were considered statistically significant at P value of less or equal to 0.05.

Ethical Consideration

Ethical clearance was obtained from the ethical clearance committee of MUHAS. The aims of study were explained to the patients. The participants were allowed to ask questions about the study. During and after the study period, the patient's confidentiality was maintained. The obtained information was used for research purpose only. The participants in this study signed the consent after agreed to participate. The participants were free to withdraw from study at any time during the study

CHAPTER THREE

RESULTS

A total of 80 patients who met the study inclusion criteria were treated by surgical debridement and standard AO external fixator and then followed for 12 weeks schedule clinic without loss of follow up. Males were 69(86.2%) and females 11(13.8%), with approximated male to female ratio of 6:1. The age ranged from 19 to 70 years with a mean age of (33.61 +/- 10.71) years. The majority of patients were in the age group of 18-30 years, which accounted for 47.5%, and the minority age group was above 50 years who were only 6(7.5%.) patients

Level of education of the patients at the time of injury majority were attained primary school 40(50%) and other were in secondary school level 37(46.2%), college 1(1.3%) and university level 2(2.5%).

Majority of patients where coming from Dar es salaam 76(95%), and 4(5%) from other regions which where Tanga and Pwani. In Dar essalaam, Kinondoni district contributed much 27% followed by Temeke 23%, Ilala 20%, Ubungo 18% and the lowest from Kigamboni district 12%

Table 4: Demographic characteristics of the study population

Variables		Frequency	Percentage
Age groups	18 - 30	38	47.5%
	31-40	26	32.5%
	41-50	10	12.5%
	50 +	6	7.5%
Total		80	100%
Gender	Male	69	86.3%
	female	11	13.7%
Total		80	100%
Education level	Primary	40	50%
	Secondary	37	46.3%
	College	1	1.3%
	University	2	2.5%
Total		80	100%
Residence	Dar es salaam	76	95%
	Other regions	4	5%
Total		80	100%
Status of passengers in motor traffic crush	Drivers	26	34.2%
	Passenger	38	50%
	Pedestrians	12	15.8%
Total		76	100%

2. Proportional of open tibia diaphyseal fracture in a study population among all open fracture.

During the study recruitment period from the end may 2016 to the end of October 2016, a total of 1176 patients with open fractures were admitted, out of these 292(49.7%) were open tibia fracture. The open tibia diaphyseal fractures contribute 85(7.2%) out of all 1176 open fracture who were treated in the study period

3. Aetiologies of open tibia diaphyseal fracture in a study population.

In this study two main causes for open tibia diaphyseal fracture were determined for all 80 patients of study population. The leading cause was motor traffic crash accounted for 76 (95%) patients in which 38(50%) were passengers, 26(34.2%) drivers and 12 (15.8%) were pedestrians. and followed by falling from a height 4 (5%) patients. Among all 80 patients, motorcycles were the leading cause of open tibia diaphyseal fractures which contributing 53 (66.2%) patients, followed by motorvehicles 23(28.8%) then falls from the height 4(5%) patients.

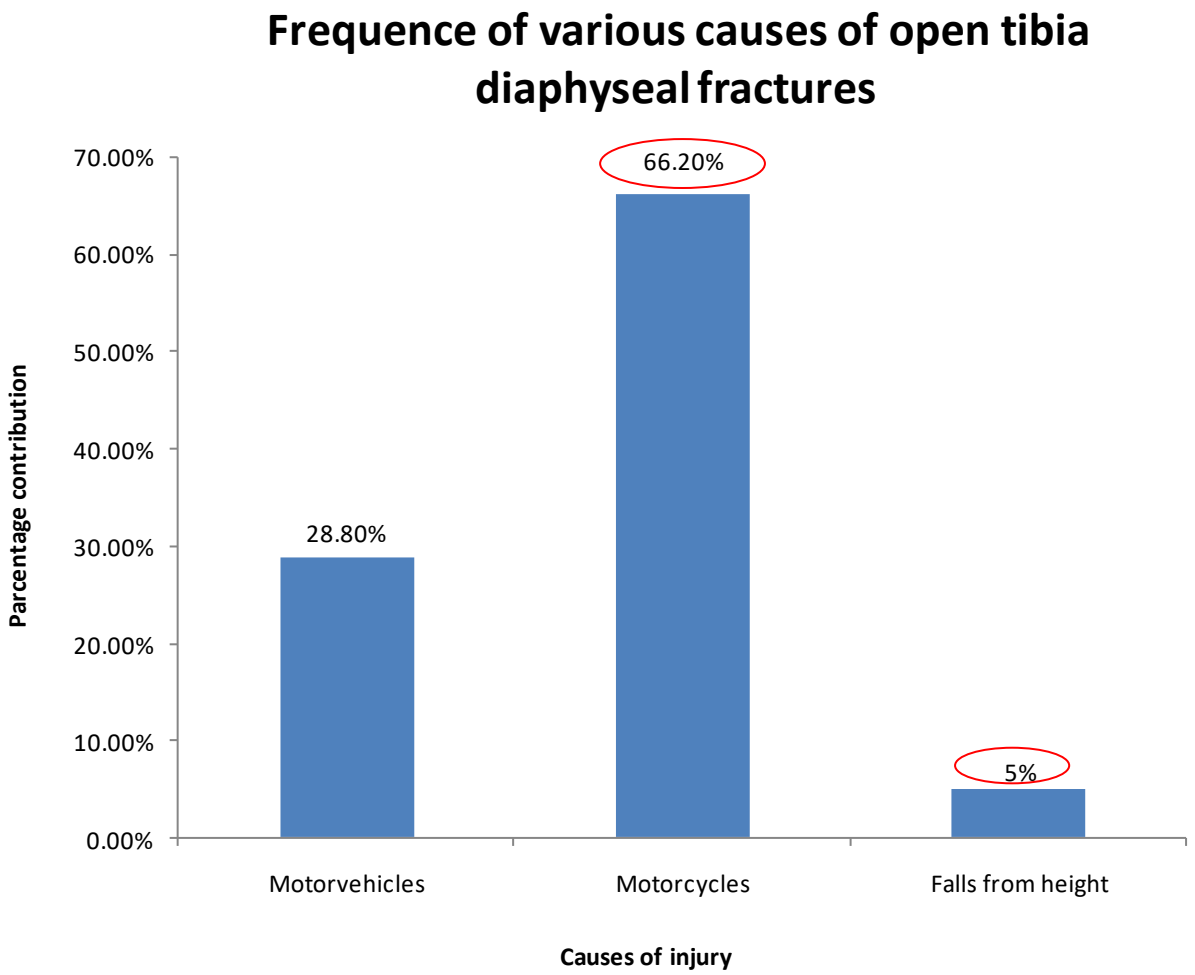


Figure3: Frequency of various causes of open tibia diaphyseal fractures in the study population.

Acording to Gustilo and Anderson classification of open fracture most patients were classified as type II fractures which accounted for 47 (58.8%) patients, and least was grade I, 1(1.3%) patients as grades are shown in Fig. 4

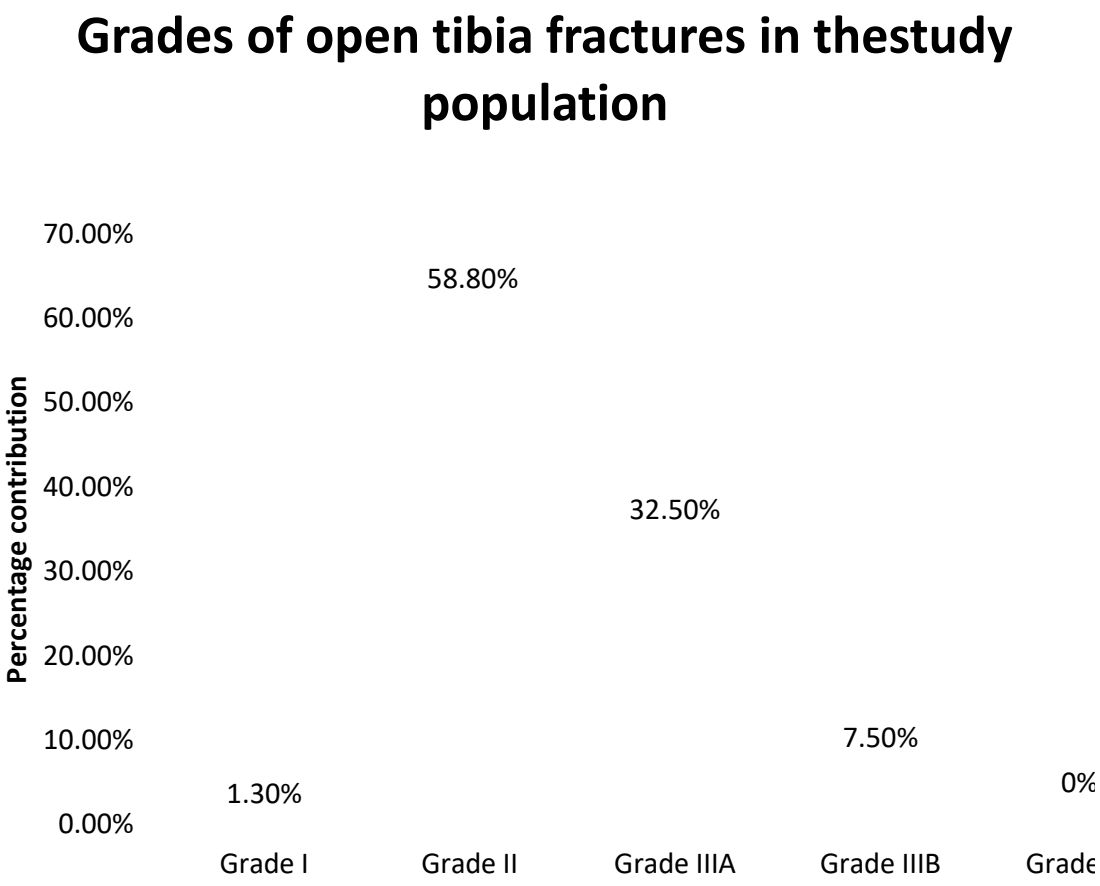


Figure 4: Grades of open tibia diaphyseal fractures in the study population

4. Rate of callus formation of open tibia diaphyseal fracture treated with external fixator at MOI

In this study, the average rate of initial callus formation visible on x ray was 10 weeks, it range from 6 weeks to 12 weeks in which majority 27(38.8%) patients had initial callus formation at 10^{th} week, others as shown in Fig. 5. Up to the end of study follow up period (12 weeks) only 6(7.5%) had no initial callus at all.

At 12^{th} weeks the mean number of cortices with callus for all 74 patients with callus formation was 3 cortices, ranging from one cortex to 4 cortices. Only 34(45.9%) patients had 3 cortices

with callus at fracture site at the end of follow up and the mean RUST score was 7 ranging from 4 to 11 at 12th weeks visit.

Clinical fracture union by neither pain nor tenderness at full weight bearing was assessed and the mean time for clinical union was 10 weeks range from 6 to 12 weeks, at the end of study follow 64(80%) patients had clinical union.

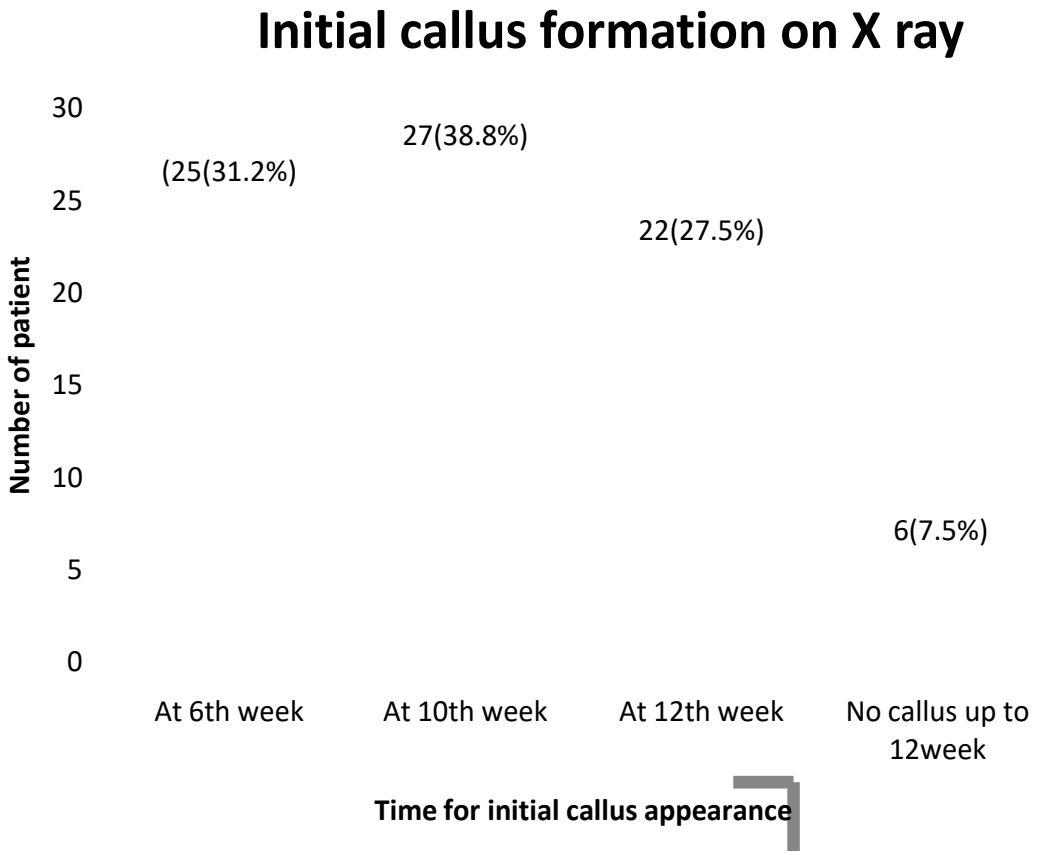


Figure 5: Initial callus formation observed on X ray with respect to time.

5. Post-operative infection rate of open tibia diaphysis fracture treated with external fixator at MOI.

Ten patients (12.5%) developed wound infection of whom 7(8.8%) had superficial wound infection and 3(3.7%) had deep wound infection according to ICD 10 clinical criteria for surgical site infection. Out of 10 patients with wound infection, 7 (70%) patients were grade

III injury and 3(30%) were grade II injury, there were no wound infection in grade one. Grade III fractures is the group affected most in wound infection, and it is statistically significance compared to other grade I and grade II with p-value of 0.031

Table 5: Cross tabulation between fracture grade and wound infection

Fracture grade	Wound Infected	Wound Not infected	Total	P-Value (fisher's Exact test at 95% CI)
Grade I	0 (0%)	1 (100)	1 (100%)	
Grade II	3 (6.4%)	44 (93.6%)	47 (100%)	
Grade IIIA	4 (15.4%)	22 (84.6%)	26 (100%)	0.031
Grade IIIB	3(50%)	3 (50%)	6 (100%)	
Grade IIIC	0(0%)	0(0%)	0(0%)	
Total	10 (12.5%)	70 (87.5%)	80 (100%)	

Following the use of external fixator, 53(66.3%) develop pin tract infection, most of the pin tract infection developed at the 12^{th} week in which 27(51%) of all pin tract infection occur. Duration of stay for the shantz pin in a patient affect the chance for pin tract infection, the longer it stay the higher the chance of infection. This was statistically significance under chi square test with P-value of less than 0.001 within 95% confidence interval.

Table 6: Cross tabulation between pin tract infection and time of occurrence

Pin tract infection categories	Pin tract infection		Total	P value (Pearson's χ^2 test at 95% CI)
	Yes	No		
Less than 6 weeks infection	19(23.8%)	0 (0.0%)	19 (23.8%)	
More than 6 weeks infection	34(42.5%)	0 (0.0%)	34 (42.5%)	< 0.001
No infection	0 (0.0%)	27(33.8%)	27 (33.8%)	
Total	53(66.2%)	27(33.8%)	80(100.0%)	

6. Malunion rate of open tibia diaphysis fracture treated with external fixator at MOI.

In this study, malunion occurred to be the common complication among patient treated with external fixator after tibia shaft fracture. Angular deformity was the common form of malunion observed in a study population during the study period. Out of 80 patients of study population 38 (47.5%) had malunion which included shortening and angular deformity, there were neither lengthening nor malrotation observed during study period. All 6 (7.5%) patients with shortening were less than 2cm and were not planned for reoperation.

Angular malunion was found in 32 (40%) patients, most of them being a valgus malunion (40.6%) out of all angular malunion. In these 32 patients who had angular deformity, 19 patients had deformed angle greater than 10 degrees which is poor outcome according to Thoresen score and were planned for reoperation. Among 32 patients with angular malunion, 10(31.2%) patients had malaligment on the post operation X ray which suggesting technical error during reduction, all of them were less than 10 degrees.

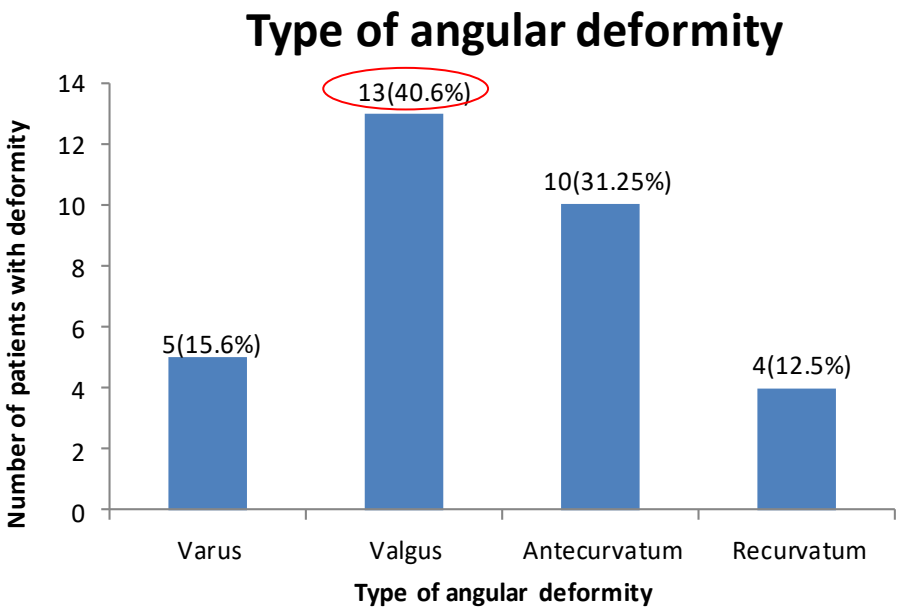


Figure 6: Type of angular deformities in the study population

5. Re operation rate of open tibia diaphysis fracture attended at MOI

In this study there were patients who had complications which required reoperation. Infection and malaligment were the main cause of reoperation, out of 80 enrolled patients 22(27.5%) were planned for reoperation in which 19(23.7%) patients were due to malalignment and 3(3.8%) patienst due to deep infection.

Table7: Plan for reoperation in various complications.

Complication	Plan for Reoperation		Total
	Yes	No	
Malunion	19 (50%)	19 (50%)	38 (100%)
Wound infection	3 (30%)	7 (70%)	10 (100)
Pin tract infection	0 (0%)_	53 (100%)	53 (100%)

CHAPTER FOUR

DISCUSSION

The incidence of open tibialdiaphyseal fractures varies in different places and different institution depending on many factors, including number of patients they receive and incidence of various causes of open tibia diaphyseal fracture such as road traffic crashes, assaults and fall from height. In this study, the proportion of open tibia fractures among all open fracture attended at MOI during study period was 49.7% were specifically for open tibia diaphyseal fractures was 7.2%.In Tanzania the incidence of open tibia fracture was reported by Mcharo et al 2001 and Mhembelo K 2004, to be 54% and 59% respectively where the incidence specifically for tibia diaphysis was 2.7% among all tibia fracture[3,13]. In other African countries,Isefanya et al 2008 from Ibadan, Nigeria and Twagirayezu et al 2008 from Kigali Rwanda found the incidence of open tibia fracture among all open fracture to be 66% and 69% respectively.[11,12]

These findings are high but comparable with most of the studies done in developing countries possibly because these countries have poor similar infrastructure condition, modality of transport as well as law enforcement on road users. In developed countries the findings are found to be low, Behrens et al reported an incidence of 2 open tibia fractures per 1000 injuries per year in a defined population group in an industrialized western society; this is 0.2% of all injuries[9] and this could be due to good infrastructures , safe transport and seriousness on law enforcement on road users

In this study males were 69(86.2%) and females 11(13.8%), with approximated male to female ratio of 6:1. The majority were young aged between 18-30 years, which accounted for 47.5%. This conforms with other series in both developing and developed countries where it has been established that injuries mostly affect young males with the mean age range from 31 to 35 years and male to female ratio range from 3:1 to 5:1 [3, 11, 12, 13, 14]. The reason why the youth especially male are more involved, could be explained by the fact that at this age group majorities are engaged in productive activities that require them to move fast enough from one

area to another and in so doing are predisposed to risks of being involved in road traffic crashes.

Motor traffic crashes, especially motorcycles has been found to be the leading cause of open tibia fractures in most studies but at different incidence,[3,11,13,14]. The lowest incidence reported by Courte-Brown etal was 40.7% and highest incidence was found by Twagirayezu etal, to be 71.5%. In all these two studies motor traffic crashes was the leading cause [12, 14].

In this study only two causes for open tibia diaphyseal fracture were determined in the study population. The leading cause was motor traffic crashes accounted for 76 (95%) patients and followed by falling from a height 4 (5%) patients, motorcycles contributing 53 (66.2%) and motor vehicles 23(28.8%) patients out of those motor traffic crashes. The high contribution of motor traffic crashes to open tibia fractures all over the world could be explained by increase in urbanization, population and uses of both motor vehicles and motorcycles as major means of transport. Also these open injuries usually require higher energy which is encountered in motor traffic crashes. Unprotected body, exposed legs and easily loss of control in motorcycles could make them the main cause of open tibial fractures in motor traffic crashes.

In other series, assaults, occupation injuries and sports were found as other causes open tibia diaphyseal fractures but at low incidence [3, 11, 13, 14]. These causes were not identified in this study possibly because of small sample size, time limit or by chance compared to others studies. Passengers were the most affected group in motor traffic injuries which contribute 50%, followed by drivers (34.2%) and last pedestrian (15.8%). This finding conform with study done by Court-Brown etal[14] but differ in the study done by Mhembelo K [13], in which pedestrian(72.6%) was the most contributing group in patients with open tibia shaft fractures, According to Gustilo and Anderson classification for open fracture most patients were classified as grade II (58.8%) followed by grade III which account for (40 %) in total, grade IIIA 32.5% and grade IIIB 7.5% and the least was grade I (1.3%) there was no grade IIIC.

Comparable to other studies which found grade I to be the small group in open tibia fractures [11,13,14], but Mhembelo KS, Isefanya etal and court-Brown etal found the major group of open

tibia diaphyseal to be grade III, 52.8%, 32.3 and 59.8% respectively. The high grade tibia fracture for open tibia diaphyseal fracture could be explained by high energy injury as common mechanism and lack of enough soft tissue coverage for tibia bone.

In this study, the average rate of initial callus formation visible on x ray was 10 weeks, it range from 6 weeks to 12 weeks in which majority 27(38.8%) patients had initial callus formation at 10^{th} week,. At 12^{th} weeks the mean number of cortices with callus for all 74 patients with callus formation was 3 cortices, ranging from one cortex to 4 cortices. Most of them 34(45.9%) patients had 3 cortices with callus at fracture site at the end of follow up and the mean RUST score was 7 ranging from 4 to 11 at 12^{th} weeks visit. These findings are similar to those found by Mhembelo KS [13] where the average union with more than three cortices was 16 weeks ranging from 7 to 27 weeks.

The similarity could be because of same ethnic and geographical environment as well as type of external fixator used. Beltsion etal,[6] found it to be a little bit higher, mean time for complete union with three or more cortices to be 25 weeks range from 14 weeks to 31 weeks. Clinical fracture union by neither pain nor tenderness at full weight bearing was assessed and the mean time for clinical union was 10 weeks which conform with radiological union and it range from 6 to 12 weeks, at the end of study follow 64(80%) patients had clinical union. This clinical finding was not reported by many of articles.

Infection is one of complication found in different similar series, in this study, out of the 80 patients enrolled, 10(12.5%) patients developed wound infection of whom 7(8.8%) had superficial wound infection and 3(3.7%) had deep wound infection according to ICD 10 clinical criteria for surgical site infection. Other studies reported the infection rate to range from 14% to 42%.[3,13,14,15] which is a bit higher compared to this study.

Patients with grade III injury develop infection more (70%) compared to grade II injury (30%) and there were no wound infection in grade I and it was statistically significant by a p-value of 0.032. This may be explained by extent of soft tissue injury and high level of contamination in grade III injuries compared to grade I and grade II. This result was similar to other studies

in which grade III fractures were mostly infected [13, 14]. Following the use of external fixator, 53(66.3%) develop pin tract infection, most of the pin tract infection developed at the 12th week in which 27(51%) of all pin tract infection occur. This also conforms with other studies which reported high rate of pin tract infection range from 27% to 58% [6, 9, 10, 13, 14, 15]. All pin tract infection where not severe and managed by antibiotics and dressing. This high rate of pin tract infection could be due to poor care to pin tract at home as well as long stay of the construct to the patients.

In this study there were patients who had complications which required reoperation, out of 80 enrolled patients 22(27.5%) were planned for reoperation, in which 19(23.7%) patients were due to malalignment and 3(3.8%) patients due to deep infection. Beltson etal and Bhandari etal reported similar result of reoperation rate in management of tibia shaft fracture with external fixator in which 13% to 20% patients were reoperated, the main cause being nonunion followed by malunion and infection[6,20]. High reoperation rate of patient with tibia diaphyseal fractures treated with external fixator which have been found in various studies could be explained by less stability of uniplanar construct, and poor wound and pin tract care by patients at home which may result into malunion and infection respectively.

Malunion is the commonest complication among patient treated with external fixator after tibia shaft fracture in different studies. In this study the rate of malunion was high compared to similar study done in several areas, out of 80 patients of study population 38 (47.5%) had malunion which include shortening and angular deformity, Tornetta et al 2002 in USA found 14% of study population (29 patients) to develop malunion which was assessed clinically and by using X ray([17]. Other studies report the rate of malunion is ranging from 7% to 20%[13, 15, 16]., the use of uniplanar type of external fixator might contribute to malunion rate. Ten (31.2%) patients had malaligment on the post operation x ray which suggesting technical error during reduction, all of them were less than 10 degrees. Angular deformity was the commonest form of malunion (40%) observed in a study population most of them being a valgus malunion and insiginificant shortening which was less than 2cm occur in 6 patients.

CHAPTER FIVE

CONCLUSION

Proportion of open tibia diaphyseal fractures among all open fractures attended at MOI has been increasing and predominantly occurs in males of the productive age who are involved in motor traffic crashes. This study reveal motorcycles crashes has high contribution to tibia diaphyseal fractures which most of them being grade II and passengers were most affected.

In this study, treatment of open tibia diaphyseal fractures at MOI using AO tubular external fixator has been found to have high infection, malalignment and reoperation rate despite of having early rate of callus formation.

RECOMMENDATIONS

High complication rate such as infection, malunion and reoperation rate were found in different mentioned studies and conform with this study . Hence tubular uniplanar EF should be used only temporarily in case there is high level of contamination, severe soft tissue or bone damage with or without compartment syndrome and high fracture grades such as grade III fractures. This is for wound care as well as fracture stabilization since internal fixation cannot be used primarily in that condition.

Need for randomized study with a larger study sample and longer duration to compare a uniplanar external fixator, multiplanar external fixator and intramedullary nail so as to adequately assess rate of callus, infection, malunion and non-unions.

STUDY LIMITATIONS

1. Due to the time limit the number of sample size was small and follow up was short to have very strong evidence on results and to reveal more complications or benefits in a long term period.

2. Laboratory and bacteriological tests were not done to confirm wound infection due to investigation cost, instead clinical findings and ICD 10 criteria was used to diagnose wound infections.

REFERENCES

1. Bucholz M, Robert W, Heckman, James D. Court-Brown, Charles M. Rockwood and Green's Fractures in Adults. 6th Edition. Philadelphia: *Lippincott Williams & Wilkins; 2006: 391p*

2. Olson SA. Open Fractures of the Tibial Shaft . *J Bone Joint Surg Am. 1996; 78(9): 1428–37.*

3. Mcharo CN, Museru LM, Assey AB. The incidence and treatment outcome of open fractures of the extremities at MOI. *Tanzania Med J. 2005;20(1):19–21.*

4. Museru LM, Mcharo CN, Leshabari MT. Road Traffic Accidents in Tanzania: A Ten Year Epidemiological Appraisal. *East Cent Afr J Surg. 2002;7(1):23–6.*

5. Mathers C, Boerma T, Ma Fat D. *The global burden of disease 2004. Update. 2004: 36p*

6. Beltsios M, Savvidou O, Kovanis J, Alexandropoulos P, Papagelopoulos P. External fixation as a primary and definitive treatment for tibial diaphyseal fractures. *Strategies Trauma Limb Reconstr. 2009;4(2):81–7.*

7. Giannoudis P V, Papakostidis C, Roberts C. A review of the management of open fractures of the tibia and femur. *J Bone Joint Surg Br. 2006;88(3):281–9.*

8. Gustilo RB, Anderson JT. Prevention of infection in the treatment of one thousand and twenty five open fractures of long bones. *J Bone Joint Surg Am. 1976;58(A):453–8.*

9. Behrens F SK. External fixation of the tibia: Basic concepts and prospective evaluation. *J Bone Joint Surg Br . 1986;68(2):1–9.*

10. Clifford RP, Ruedi TP, Murphy WM... AO principles of fractures management: Open fractures. 2nd ed. New-york: *Thieme Stuttgart; 2000. p. 616–38.*

11. Isefanya AO. Trends In The Pattern Of Tibial Fractures In Nigeria: A Review Of 70 Cases. *J Orthop Trauma. 2008,5(2)e4*

12. Twagirayezu E. Open Fractures in Rwanda: The Kigali Experience . *East Cent Afr J Surg. 2008;13(1) : 77-83*

13. Mhembelo KS. Management of open tibial shaft fractures at Muhimbili orthopaedic institute clinical outcome after surgical debridement and use of the dispofix external fixator. *Forthcoming. 2004: p4-5*

14. Court-Brown CM, Wheelwright EF, Christie J, McQueen MM. External fixation for type III open tibial fractures. *J Bone Joint Surg Br. 1990;72(5):801–4.*

15. Edge AJ, Denham RA. External fixation for complicated fracture. *J Bone Joint Surg Br 1981; 63(1):92–7.*

16. Clifford RP, Lyons TJ, Webb JK. Complications of external fixation of open fractures of the tibia. *The British Journal of Accident Surgery. 1987;18(3):174–6.*

17. Tornetta P, Bergman M, Watnik N, Berkowitz G, Steuer J. Treatment of grade-IIIb open tibial fractures. A prospective randomised comparison of external fixation and non-reamed locked nailing. *J Bone Joint Surg Br. 1994;76(1):13–9.*

18. Court-Brown CM, Wheelwright EF, Christie J, McQueen MM. External fixation for type III open tibial fractures. *J Bone Joint Surg Br. 1990;72(5):801–4.*

19. Van Winkle B a, Neustein J. Management of open fractures with sterilization of large, contaminated, extruded cortical fragments. *Clinical orthopaedics and related research. 1987;233 :75–81.*

20. Bhandari M, Guyatt GH, Swiontkowski MF et al. Treatment of open fractures of the shaft of the tibia: a systematic overview and meta-analysis. *J Bone Joint Surg Br. 2001;83(1):62-8.*

21. Milner SA. A more accurate method of measurement of angulation after fractures of the tibia. J *Bone Joint Surg Br. 1997; 79(B): 972–4.*

22. Paul P, Jeremy F, Andrew C. Outcome measurement in orthopaedic and orhopaedic trauma.Toronto: *Hodder Arnold Publication. 2nd ed . 2003: 288p*.

23. Whelan, Daniel B, Bhandari, Mohit, Stephen, David, Kreder, Hans, McKee, Michael D, Zdero, Rad, Schemitsch, Emil H. Development of the Radiographic Union Score for Tibial Fractures for the Assessment of Tibial Fracture Healing After Intramedullary Fixation. *Journal of Trauma-Injury Infection & Critical Care. 2010; 68(3): 629-632.*

APPENDICES

Appendix I: Informed Consent Form- English version

Consent to participate in the study titled "SHORT TERM OUTCOME OF PATIENT WITH OPEN TIBIA DIAPHYSEAL FRACTURE TREATED WITH EXTERNAL FIXATOR AT MUHIMBILI ORTHOEPEDIC INSTITUTE. (APRIL 2016 TO APRIL 2017)

Greetings: I am Dr Said Rajab Nondo, a resident in Orthopaedics and Traumatology expecting to do a study on "short term outcome of patient with open tibia diaphyseal fracture treated with external fixator at Muhimbili Orthoepedic Institute.

Purpose of the Study: To determine the short-term outcome of patients with open tibia diaphyseal fractures treated with external fixation at MOI - 2016

What participation involves: If you agree to participate in this study, you will be asked questions and examined. Then you will be followed up for the entire period of six months.

Confidentiality: All the information obtained will be kept confidential and it will be entered into computer with only an identification number; your name will not be included.

Risk: We ensure that there is no harm in engaging into the study.

Rights to withdraw: Taking part in this study is completely voluntary and refusal to participate or withdrawal will not involve penalty or loss of any benefits to which you are entitled. You will be treated and followed up as per the usual treatment protocol of the Institute for all patients with open tibia diaphyseal fractures.

Benefits: If you agree to participate in this study, you will be followed-up closely and be assessed on the progress of your condition by the investigating doctor. We hope that the obtained information from this study will benefit others.

Who to contact: If you have any other questions regarding this study, feel free to contact me, the investigator, Dr Said Rajab Nondo, Muhimbili Orthopaedic Institute, P.O. Box 65474, Dar es Salaam, Tel No 0717483565.

If you have any questions concerning your rights as a participant, you may contact Prof. Said Aboud, Chairman of the Research and Publication committee, P.O. Box 65001, Dar es Salaam. Telephone: 2152489.

Do you agree to participate?

Signature……

I, ……..have read the consent form and my questions have been answered and I agree to participate in this study.

Signature of Participant……..

Signature of Investigator…… Date of signed consent…….

Aappendix II: Informed Consent Form - Swahili version

Ruhusa ya Kushiriki Utafiti Kuhusu kuangalia matokeo ya matibabu ya wagonjwa wenye kidonda na mivunjiko ya mfupa uliochini ya goti kwa kutumia vyuma aina ya external fixator vinavyowekwa nje ya mfupa katika taasisi ya mifupa MOI-2016/2017.

Salaam!

Mimi naitwa Dr. Said Rajab Nondo ni mwanafunzi wa udhamili Chuo Kikuu cha Tiba Muhimbili, nachunguza matokeo ya matibabu ya wagonjwa wenye kidonda na mivunjiko ya mfupa ilio chini ya goti kwa kutumia vyuma external fixator vinavyowekwa nje ya mfupa katika taasisi ya mifupa MOI-2016

Dhumuni la utafitihuu: Kupata taarifa muhimu ya matokeo ya matibabu ya mifupa kwa kutumia vyuma vilivyotajwa hapo juu na kutoa mapendekezo ya uboreshaji.

Ushiriki: Kama unakubali kushiriki kwenye utafiti huu utaulizwa maswali, utachunguzwa kwa kina na utafuatiliwa hata baada ya upasuaji katika klini kiyetu

Usiri: Taarifa zote za uchunguzi zitaingizwa kwenye kompyuta na nambari ya utambulisho; jina halitanukuliwa.

Madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu

Haki ya kujitoa kwenye utafiti: Kushiriki katika utafiti huu ni hiari, na kutokubali kushiriki au kujitoa hautaadhibiwa au kupoteza haki yako ya matibabu. Utatibiwa na kuendelea kufuatiliwa kama taratibu za hospitali zinavyoelekeza kwa mtu aliye na mvunjiko na kidonda kwenye mfupa uliochi ni yagoti.

Kutokea kwa madhara: Tunategemea kwamba hakuna madhara yoyote yatokanayo na utafiti huu. Hata hivyo kama madhara ya mwili yatatokea kutoka na utafiti huu, utatibiwa kulingana na kanuni na taratibu za matibabu ya Tanzania.

Faida ya kushiriki kwenye utafiti: Kama utakubali kushiriki kwenye utafiti huu, Faida utakazopata ni pamoja na kuonwa na kufuatiliwa kwa ukaribu na daktari anayefanya utafiti. Tunatumaini kwamba taarifa zitakazopatikana zitawanufaisha wenginepia

Kwa mawasiliano zaidi: Kama unamaswali au maelezo kuhusu utafiti huu, uwetayari kuwasiliana na mtafiti, Dr. Said Rajab Nondo, Muhimbili Orthopaedic Institute, P.O. Box 65474,DSM. simu: 0717483565. . Kama una maswali kuhusu haki yako kama mshiriki wasiliana naProf. Said Aboud, Mwenyekiti wa kamati ya utafiti, P.O. Box 65001, DSM. Simu 2152489.

Je, umekubali kushiriki? .....

Saini:…….

Mimi…….Nimesoma maelezo na kuyaelewa vizuri, na nimekubali kushiriki kwenye utafiti huu.

Sahihi ya Mshiriki……...

Sahihi ya Mtafiti…….

Tarehe …….

Appendix III: Research Questionnaire - English Version

TITLE: SHORT TERM OUTCOME OF PATIENT WITH OPEN TIBIAL DIAPHYSIS FRACTURE TREATED WITH EXTERNAL FIXATOR AT MUHIMBILI ORTHOEPEDIC INSTITUTE.

(MARCH 2016 TO APRIL 2017)

TITLE: SHORT TERM OUTCOME OF PATIENT WITH OPEN TIBIAL DIAPHYSIS FRACTURE TREATED WITH EXTERNAL FIXATOR AT MUHIMBILI ORTHOEPEDIC INSTITUTE.

PART A: PREOPERATIVE EVALUATION:

1. Form number: ……

2. Registration NO …….

3. Age: ……. Sex…….. a) Male b) Female …….

4. Place of residency: …… Phone no: …….

5. Level of education:…….

a) Never been to school b) Primary education c) Secondary education

d) College e) University

6. Cause of injury:

a) Road Traffic Injury

b) Missile injury c) Farm injury d) Falling from height e) Sports injury

f) Assault g) Industrial f) others: specify……..

7. Type of Road Traffic Injury

a). Motor vehicle……

b). Motorcycle……

c) Bicycle……

d) Others (specify)……

8. Status of the patient in MTC

a) Driver b) Passenger c) Padestrian

PART B: POST- OPERATIVE EVALUATION AND MANAGEMENT

8. What is the grade of open tibia fracture a) Grade I b) Grade II c) Grade IIIA

d) Grade IIIB e) Grade IIIC

9. Post op control x-rays- alignment:

a) Good alignment b) Mal alignment……. If good alignment go QN 1

10. If mal alignment:

a) Varus b) Valgus c) Anterior angulation d) Posterior angulation

11. Degree of angulation of mal-alignment:

a) Less than 5 b) 5- 10 degrees c) 10-15 degrees d) More than 15 degrees

12. Affected Limb length post operatively:

    a) Normal length b) Shortening c) Lengthening

13. If there is change in limb length: specify ……..

    a) Less than 1 cm b) 1 cm- 2cm c) More than 2 cm

14. Limb rotation deformity:

    a) Yes…… b) No ……..

15. Type of rotational deformity:

    a) External rotation b) Internal rotation

16. Degree of rotational deformity:

    a) < 5 degrees b) 5-10 degrees c) 10 -15 degrees d) More than 15 degrees

PART C: 2nd WEEK POST OPERATIVE EVALUATION AND MANAGEMENT

17. Is there wound problem? a) Yes……. b) no……

18. Type of wound problem……..

    a) Delayed healing b) Persistent drain c) Superficial infection d) Deep infection

19. Is there pin tract infection? a) Yes…… b) no……

PART D: POST OPERATIVE PATIENT FOLLOW-UP AT 6TH, 10TH, AND 12TH

20. Weight bearing status:

(i) At 6th week (a) FWB (b) PWB (c) NWB

(ii) At 10th week (a) FWB (b) PWB (c) NWB

(iii) At 12th week (a) FWB (b) PWB (c) NWB

21. Clinical assessment of fracture union by pain and tenderness at fracture site on full weight bearing

(i) At 6th week (a) Painfull (b) Painless

(ii) At 10th week (a) Painfull b) Painless

(iii) At 12th week (a) Painfull b) Painless

22. Callus formation on control X-ray using RUST score:

i) At 6th week a) Yes…… b) No……

ii) At 10th week a) Yes …….. b) No ……

iii) At 12th week a) Yes …….. b) No ……

23. Limb length deformity >1cm:

i) At 6th week a) Yes…… If yes specify (type and cm)……b) No……..

ii) At 10th week a) Yes…… If yes specify (type and cm)……b) No…….

iii) At 12th week a) yes …. If yes specify (type and cm)……b) No……

24. Limb rotation deformity:

i) At 6th week a) Present ……. Specify (type/ degree)…… b) Absent……

ii) At 10th week a) Present …….specify (type/degree) ……b) Absent…….

iii) At 12th week a) present …… specify (type/degree)…… b) Absent…….

25. Angular deformity:

i) At 6th week a) Present ……. Specify (type/ degree)…… b) Absent……

ii) At 10th week a) Present …….specify (type/degree) ……b) Absent…….

iii) At 12th week a) present …… specify (type/degree)…… b) Absent…….

26. Wound infection:

i) At 6th week a) Present ……. Specify ……. b) Absent

ii) At 10th week a) Present ……. Specify ……b) Absent

iii) At 12th week a) Present ……. Specify ……b) Absent

27. Pin tract infection:

i) At 6th week a) Yes…… b) No……..

ii) At 10th week a) Yes… b)No…….

iii) At 12th week a) yes …. b) No……

28. Plan for reoperation?

a) Yes..... b) No.....

Reasons for reoperation	**At 2nd week**	**At 6th week**	**At 10th week**	**At 12th week**
Infection				
Non union				
Malalignment				
Loosening of Schanz screw				
Others				