A Cross-Sectional Study of Early Functional Outcomes of Casting of Tibial Shaft Fractures at the University Teaching Hospitals- Adult Hospital, Lusaka Zambia.

By

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A dissertation submitted to the University Of Zambia in partial fulfillment of the Requirements for the Master of Medicine in Orthopaedic and Trauma Surgery

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DECLARATION

I, **Rowland Mhone,** hereby declare that this dissertation herein presented for the Degree of Master of Medicine (Orthopaedic and Trauma Surgery) has not been previously submitted wholly or in part for any other degree at this or any other university nor is it being currently submitted for any other degree.

Signed..... (Candidate)

By ..... (Supervisor 1)

By .....(Supervisor 2)

APPROVAL

This dissertation of **Dr. Rowland Mhone** is approved as fulfilling part of the requirements for the award of the Degree of Master of Medicine in Orthopaedic and Trauma Surgery by the University of Zambia, subject to the examiner's report

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ABSTRACT

Tibial shaft fractures are a common presentation following high energy trauma such as road traffic accidents. The gold standard for the treatment of such injuries is by Intramedullary nailing, but in a resource-limited setting, the casting of such injuries is considered as appropriate. At the University Teaching Hospital most tibial shaft fractures were treated with casting due to several reasons including socioeconomic status and lack of theatre space.

The functional outcome following such an intervention locally was assumed not to be as good as alluded to in literature. This was evidence by the indications of most of the Intramedullary nailing being failed non-operative management. The purpose of this study was to investigate the early functional outcomes of tibial shaft fractures treated by casting at the University Teaching Hospital. The results of the study will guide the rationale of continuing on the current path of treatment locally.

Using a cross-sectional analysis, participants at three months post-injury with tibial shaft fracture presenting to the orthopedic clinic for their scheduled review appointment were randomized and 138 were enrolled and assessed using the Johner- Wruhs criteria. The results of this study were examined against those stated in the literature.

The 138 participants comprised 102 (73.9%) males and 36(26.1%) females with an age range of 19-64years. The median age was 34.5 (IQR14).

The result of the study showed that 75.4% of the participants had good to excellent results following casting at three months post-injury. Fair to poor results was seen in 24.6% of the participants

The study demonstrates that the results of tibial shaft fractures treated with casting at the UTH are good. It is in tandem with the results that are shown in similar studies done elsewhere in a similar socioeconomic setting.

Keywords: Functional outcomes**;** intramedullary nailing; Johner- Wruh criteria; Casting.

DEDICATION

I would like to dedicate this research work to my children, Khondwani kapyela Mhone, Mwaka Lutanda Mhone and Ketase Zoe Mhone, whose time I stole in committing to this work.

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ABBREVIATIONS AND ACRONYMS

AO/ASIF	Arbeitsgemeinschaft fur Osteosynthesefragen/ Association for the study of internal fixation
AP	Anteroposterior
ATLS	Advanced Trauma Life Support
GA	Gustilo-Anderson Classification
IBM	International Business Machines
IMN	Intramedullary Nailing
IQR	Interquartile Range
OTA	Orthopedic Trauma Association
MIPO	Minimally Invasive Plate Osteosynthesis
POP	Plaster of Paris
PTB	Patella Tendon Bearing Cast
RTA	Road Traffic Accident
RTSA	Road Transport And Safety Agency
SD	Standard Deviation
SPSS	Statistical Package for the Social Sciences
USA	United States of America
UTH	University Teaching Hospital
UNZABREC	University of Zambia Biomedical Research Ethics Committee
WOMAC Questionnaire	Western Ontario and McMaster University Osteoarthritis

DEFINITIONS

Early outcomes: in this research early outcomes are defined as outcomes occurring within three months of injury.

Tibial Shaft Fracture: fracture occurring in the diaphysis of the tibia bone.

Intramedullary Nailing: operative procedure where an intramedullary device (nail) is placed to fix the fracture.

Casting: a procedure where a Plaster of Paris or Fibre Glass is applied, usually following manipulation under anesthesia, to splint the fracture.

1 CHAPTER ONE: INTRODUCTION

Background

Tibial fractures commonly occur following high energy trauma such as road traffic accidents (Maruthi and Shivanna, 2015). The diaphysis of the tibia is the part mostly fractured (Rockwood et al., 2010).

There are various ways in which tibia shaft fractures are classified. The classifications take into account the soft tissue covering of the bone and also the pattern of fracture sustained by the bone. Classification of the fractures helps in the management of the fracture as it provides a prognostic framework that guides treatment and also serves as a means of communication between surgeons and clinician-scientists(Gaston et al., 1999). A study by Gaston (1999) investigating if the outcome of a Tibia fracture could be predicted, showed that many commonly used classification systems had little predictive value.

AO/OTA (Arbeitsgemeinschaft fur Osteosynthesefragen / orthopedic trauma association):

This is the most common classification of Tibia fractures (Rockwood et al., 2010). It has an alphanumerical structure combining localization and morphology of the fracture offering the clinician a precise and consistent way of a verbal description of fractures. In this system, tibia shaft fractures are classified into three basic types depending on their morphology. Type A: simple fractures; a fracture with a circumferential disruption of the diaphysis. It can be spiral, oblique or transverse. Type B: wedge fractures; these are characterized by contact by the main fragments

after reduction thereby restoring the length. Type C: multi-fragmentary ‘complex’ fractures, these fractures consist of many fragments and multiple fracture lines. This classification is arranged in a hierarchy of severity from simple to complex fractures. The three types A, B and C are further divided into groups denoting increasing severity. The groups are also further subdivided into subgroups depending on the relationship with the level of associated fibula fracture.

Gustilo- Anderson classification of open tibia fractures:

This classification is of prognostic value in that it predicts orthopedic infections associated with open tibia fractures(Kim and Leopold, 2012). Here open tibia fractures are categorized into three based on wound size, level of contamination and osseous injury. Type I: an open fracture with a wound less than 1 cm long and no contamination; Type II: an open fracture with a wound greater than 1 cm without extensive tissue damage, flaps or avulsions and with moderate contamination; Type III: either an open segmental fracture, an open fracture with extensive soft tissue damage, or a traumatic amputation. Type III has special categories being gunshot injuries, any open fracture caused by farm injury, and an open fracture with accompanying vascular injury requiring repair. Type III injuries are thus subclassified into A, B and C according to the severity of the soft tissue injury, need for vascular reconstruction, and worsening prognosis. Type IIIA: open fractures with adequate soft tissue cover of a fractured bone despite extensive soft tissue laceration or flaps, or high energy trauma regardless of the size of the wound; Type IIIB: open fractures with extensive soft tissue loss with periosteal stripping and bone exposure usually associated with massive contamination(Kim

and Leopold, 2012); Type IIIC: open fractures associated with arterial injury requiring repair(Kim and Leopold, 2012).

Literature suggests that the best treatment option for tibia shaft fracture is operative with intramedullary nailing (IMN) (Karaarslan et al., 2016). IMN is considered the gold standard of treatment of these fractures and produces superior results compared to casting(Browner, 2009).

A common practice at UTH is that patients who present to these institutions with tibia shaft fractures are stabilized following the Advanced Trauma Life Support (ATLS) principles. After this initial stabilization, the patient's limb is manipulated under anesthesia and plaster of Paris (POP) back slab is applied to allow for swelling to subside.

The patient with a stable tibial shaft fracture planned for casting is taken for a closed reduction following the AO principles (Trafton, 2003); this is followed by the application of a long leg back slab or a split cylinder cast for the patient with associated soft tissue swelling. Once the swelling subsides, a complete long leg cast is applied and an X-ray is done to ensure that the reduction is acceptable, if some angulation is evident, the wedging of the plaster is done within three days (Ghosh, 2015). Once comfortable with the use of crutches, the patient is allowed to ambulate non- weight-bearing for a period of 6- 8 weeks. Weekly X-rays are done in this period to ensure the reduction is not lost for the first 4 weeks. Thereafter, the cast is converted to a below-knee cast or a patella tendon bearing (PTB) cast and the patient is gradually progressed from partial weight bearing to full weight bearing until radiological union. The radiological union is defined as bridging

callus in at least 3 of 4 cortices in the anteroposterior and lateral radiographs (Ghosh, 2015).

Unpublished data from the UTH records (emergency theatre log and emergency admissions ward log) show that an average of 60 cases are seen monthly in the emergency admission ward with fractures of the tibial shaft, yet only an average of 6 patients are operated on with IMN fixation. The larger proportion of these patients is treated with casting.

Anecdotal evidence suggests that locally these patients treated with casting end up with a poor functional outcome despite the initial reduction being acceptable. Elective theatre logs at the UTH show that the common indication for operative management of tibia shaft fractures is failed non-operative management as these patients present later on with malunion or non-union.

This study endeavored to determine the functional outcomes of patients with tibia shaft fractures treated conservatively with casting locally. The result of this is cardinal in providing the clinician with evidence to support best practice for a resource-limited setting.

Statement of the Problem

At UTH most tibial shaft fractures are treated by casting as shown by unpublished hospital records (emergency admission logs, emergency theatre logs). It has been observed anecdotally that more than half of these fractures end up with functional outcomes that are not acceptable (malunion, nonunion, shortening); this is so

despite the reviewed literature showing comparable functional results with tibial nailing (IMN) and casting being an acceptable alternative.

Study Justification

Unpublished UTH data from emergency theatre log, elective theatre log and emergency admissions ward log shows that on average 20 patients with tibial fractures are seen weekly and an average of 2 IMNs are done in a week. The balance of patients is treated with casting.

Tibial shaft fractures treated definitively with casting at the UTH have been observed to end up with functional outcomes that are less desirable such as rotational and angular deformity and are therefore nailed secondarily (anecdotal data) to correct this outcome. This is not in keeping with the expectations from literature, which suggests that casting is an acceptable alternative, and gives acceptable results.

IMN of tibial shaft fractures is the Gold standard, but at UTH most patients are treated by casting definitively due to the poor socioeconomic status (anecdotal data), as patients are unable to afford to buy the required implants.

The outcome of such a treatment modality needs to be established locally so as to inform practice for the clinicians.

Research question

What are the early functional outcomes of tibial shaft fractures among adults treated with casting at UTH?

General objective:

To explore the early functional outcomes of tibial shaft fractures treated with casting.

Specific Objectives:

1. to determine the rotational deformity at the fracture site
2. to determine the angular deformity at the fracture site
3. to determine the range of motion at the Knee, Ankle and Subtalar joint
4. to determine the factors associated with functional outcomes of casting

2 CHAPTER TWO: LITERATURE REVIEW

Epidemiology

Tibia shaft fractures have an incidence of 16.9/100000/year(Larsen et al., 2015). The most common type of fracture occurring in the shaft of the tibia was a simple spiral fracture (AO- type 42-A1), representing 34% of all tibial shaft fractures(Larsen et al., 2015). Tibia fractures occur more commonly in men (21.5/100000) than in women (12.3/100000), with most fractures occurring in the second decade of life for men and the third decade of life for women(Larsen et al., 2015). These fractures are among the most common long bone fractures and are usually a result of Road Traffic Accidents (Court-Brown and McBirnie, 1995) or other high energy injuries such as falls from heights(Court-Brown and McBirnie, 1995).

Unpublished data from the UTH records shows that the commonest cause of tibia fractures seen at the UTH is Road Traffic Accidents; the other causes are fall from heights and assault.

Treatment of tibia shaft fractures

Advanced Trauma Life Support protocols are observed for the acutely injured person with tibia fracture suspected or obvious. The patient is stabilized with the limb aligned and splinted. Further investigation once the patient is stable may be necessary to better characterize the fracture, and as such imaging studies with plain radiographs may be obtained. Standard X-rays for a tibia shaft fracture include anterior-posterior (AP) and lateral views from the knee joint proximally to the ankle joint distally.

Subsequent treatment of a fractured tibia is determined by the extent of the soft tissue involvement and the characteristics of the fractures itself. The fracture can be managed operatively or non- operatively with casting. Operative treatment options vary from closed intramedullary nailing, open intramedullary nailing, open plate, and screw osteosynthesis, minimally invasive plate osteosynthesis (MIPO), external fixation. The goal is a healed functional limb with minimal pain and deformity and without an unduly long period of disability (Trafton, 2003).

Treatment of these fractures is greatly influenced by the association of soft tissue injury; it can be operative or non-operative(Schmidt, 2003). Operative management is indicated for, among other indications, failed non-operative management; multiple fracture patients; unstable fracture patterns(Schmidt, 2003). Type of operative management will depend on the type of fracture, i.e. whether open or closed and location of the fracture (diaphyseal or metaphyseal). It includes plate and screw osteosynthesis, external fixation or intramedullary nailing. Intramedullary nailing is one of the most commonly used methods for tibia shaft (diaphyseal) fractures. Most surgeons consider intramedullary nailing to be the Gold standard for the treatment of these fractures (Karaarslan et al., 2016)

Closed tibial shaft fractures have been treated traditionally by manipulation and cast bracing but recent studies show that IMN of these fractures has better functional and clinical outcomes (Ghosh, 2015; Obremskey et al., 2017). Casting or IMN have their advantages and disadvantages, but generally the functional outcomes of intramedullary nailing of these fractures are much better (Obremskey

et al., 2017). In resource-limited countries, tibia shaft fractures treated with IMN only show a small increase in rates of infection(Young et al., 2013).

Non-operative management involves the anatomical reduction or reduction to acceptable parameters then casting of the limb followed by a period of none-weight bearing to allow for fracture healing, this is based on the premise that most fractures of the tibia will heal if treated non operatively (Egol, 2015). Once healed the limb is rehabilitated through partial weight-bearing to full weight-bearing. Acceptable parameters being less than 5 degrees of varus/valgus angulations; less than 10 degrees of anterior/ posterior angulation; less than 10 degrees of rotational deformity; less than 1cm shortening; more than 50% cortical contact(Egol, 2015).

Functional outcomes

Several variables may be used in determining outcome after tibial shaft fracture. These include rotation, length, angulation and mobility at the foot, ankle and knee (Trafton, 2003). The many valid indicators have led to the formulation of different summary scales used to assess functional outcomes (Trafton, 2003). In this study, Johner- Wruh criteria were used.

In an ideal setting, the casting of tibial shaft fractures is indicated for stable fractures which are initially minimally displaced(Thomas et al., 2007). In a study done by Toivanen et al 87 patients with closed or open GA 1 simple or wedge tibial shaft fractures caused by low energy, trauma was looked at. The study compared the outcomes of these fractures treated with a cast to IMN. They found no difference between the two groups as assessed by the Johner- Wruhs criteria

(Toivanen et al., 2001). Another multicentre cohort study by Obremskey et al attempted to establish the optimal treatment of stable tibial shaft fractures comparing casting to IMN, followed up patients at 6 weeks, 3 months and 6 months. At 3 months differences noted where in return to work (3/17 vs. 6/15 p <0.05); ankle dorsiflexion (12◦ vs. 7◦, p < 0.05); plantar flexion (39◦vs 28◦, p<0.05). At the 6 month follow-up, malalignment was noted in 3/15 in the cast group and 1/17 in the IMN group (p= 0.02)(Obremskey et al., 2017).

In another study by Bone et al done in 1997 involving 99 patients with unilateral isolated displaced closed tibia shaft fractures followed up for 4.4years; they found that the group treated with IMN had a better score on evaluating the Knee function using the Iowa Knee Evaluation and Ankle evaluation rating system, compared to the casting group. The mean scores were 96 points (range 62 to 100points) and 97 points (range 74 to 100 points) for the IMN group respectively and 89 points (range 62 to 100 points) and 84 points (range 62to 100 points) respectively for the casting group(Bone et al., 1997). Karladani et al in a randomized prospective cohort study compared displaced tibia shaft fractures treated conservatively with casting to those treated with IMN. It was found that at 3months, the IMN group scored better results when assessed by the Nottingham Health Profile index score. Cast group had delayed union; malunion; and restricted range of motion at the ankle joint as common complications(Karladani, 2000).

Treatment of tibia shaft fractures with casting is associated with a high rate of varus or valgus malunion; anterior or posterior angulation; shortening(Hooper et al., 1991). In a randomized prospective trial looking at conservative management

or IMN for tibia shaft fracture by Hooper et al done in New Zealand in 1991, involving 62 participants; they found that 9 of 33 had varus-valgus deformity; 3 of 33 had anterior or posterior angulation; 15 of 33 had shortening in the casting group. In the IMN group 0 of 29 had neither varus/ valgus deformity or anterior/posterior angulation, only 2 of 29 had shortened. They concluded that IMN is the treatment of choice for displaced tibia shaft fracture(Hooper et al., 1991).

In a resource-limited setting, however, casting provides an acceptable alternative to IMN(Schmidt, 2003). Casting has advantages over IMN in that there is a negligible risk of infection, fewer problems with knee pain and no risk of added surgery during hardware removal. IMN advantages over casting are that it offers better control of alignment; offers the ability to institute an early range of motion of the knee and ankle; improved mobility of the patient; and early return to work (Schmidt, 2003). With regards to the long term functional outcomes, Batta et al found no statistical difference in the functional outcome at 4.3 years when assessed using the Johner and Wruh's criteria (Batta et al., 2012). This study was done in a developing world setting, that is to say, in a resource-limited setting.

Problems associated with casting

The casting of tibial shaft fractures frequently results in loss of alignment which is of major concern with malunion rates reported to be between 25- 50% with conservative management (Toivanen et al., 2001). The problem with malalignment is the predisposition of the adjacent joint to osteoarthritic changes (Toivanen et al., 2001). 22- 30% of patients treated with casting are reported to develop joint

stiffness of the ankle joint and it occurs mostly in patients who are in a cast for more than 24weeks (Toivanen et al., 2001).

Milner et al investigated the long- term outcomes after tibia shaft fractures healed with a malunion. In this study they enrolled 164 individuals with a history of tibial shaft fracture 30- 40 years ago and assessed them using the WOMAC (Western Ontario and McMaster University osteoarthritis questionnaire). They found that 15% reported moderate knee pain; 6% reported moderate ankle pain (Milner et al., 2002).

Tool for assessment

Johner Wruhs criteria were used to assess the functional outcome. This is an objective assessment tool developed by Johner R. and Wruhs O. which provides a four-level scale of assessing functional outcomes (Trafton, 2003). Parameters given in this tool were within the scope of this study hence its use.

3 CHAPTER THREE: METHODOLOGY

Study design

This was a cross-sectional study. Participants were considered for enrolment as they presented to the orthopedic clinics (clinic 3). The researcher collected data onto the data collection sheet, which was later entered in Excel and then exported to Statistical software (SPSS). There was no follow up for the enrolled patient.

Study population

Participants presenting to orthopedic clinic 3 at three months post POP application for their scheduled review.

Sample size

Formula used: $\mathbf{n = [Z^2P\ (1\text{-}P)]/e^2}$ (formula for population proportions)

Z: Z score of the confidence level

P: Expected proportion

e: disered precision

n: population size

The confidence interval of 95%. The proportion of 0.10 (Ghosh, 2015)

Sample size: 138 participants

Sampling

Systematic Random Sampling was used. An estimated average of 5 patients was seen with tibial shaft fractures at the orthopedic clinic (clinic 3) of UTH per day as per clinic register, and an estimate of 300 patients was seen in 3 months, therefore a Kth value of 2 was used.

A random starting point was picked between 1 and 2, and every second patient seen was considered for enrolment.

Site

The study site was the University Teaching Hospital- Adult Hospital.

Participants

3.1.1 Inclusion Criteria:

- Previously accepted fracture reduction (from patients records and post reduction xrays)
    1. Tibia fractures with < 50% displacement
    2. Tibia fractures with < 10◦ angulation
    3. Tibia fractures with < 10mm shortening
- Fracture type A or B according to the AO- classification system
- Fracture GA </= IIIa
- Previously Ambulatory patient
- Skeletally mature patients (age >18years)
- Signed consent
- 3 months post-injury

3.1.2 Exclusion Criteria:

- Pathological fractures
- Multiple fractures
- Patients with previous pathologies affecting gait
    - Genuvalgum/ Genuvarus

Procedure

Participants were enrolled by the researcher as they presented to the orthopedic clinic (clinic 3) at three months post-injury or casting. The data collection sheet was used to collect the data from patient examination and x-ray reviews. Xray and file review confirmed that the reduction was acceptable post reduction. Limb length was measured using a tape measure; rotation, range of motion of the knee ankle and Subtalar joints were measured using a goniometer during patient examination. Varus/ Valgus, Anterversion/Recurvatum were measured from the patients radiographs.

Study variables

Number	Independent variable	Dependent variable
1	**Age**	**Varus/Valgus**
2	**Sex**	**Anteversion/ Recurvatum**
3	**Osteomyelitis**	**Rotation**
4	**Gait**	**Shortening**
5	**Pain**	**Knee mobility**
6	**Strenuous activity**	**Ankle mobility**
7	**Neurovascular disturbance**	**Subtalar mobility**
8	**Smoking**	
9	**Physiotherapy attendance**	
10	**Fractures type**	

Data analysis

Data were de-identified and entered into a spreadsheet, after checking for completeness. It was then exported to statistical software. SPSS version 25.0 (statistical software) was used for data management. Descriptive statistics were used for numerical variables and summarized as means+/- standard deviation (SD).

Qualitative data were presented as percentages and analyzed using the X^2-test. A *P*-value <0.05 was considered statistically significant. The data were presented as tables and graphs.

Table: Data analysis strategy.

SPSS v25 IBM corp		
Goal of Analysis	**Parametric (normally distributed)**	**Non-Parametric (not normally distributed)**
To compare categorical variables between two groups e.g. sex, fracture type	Chi-square Test (Fischer exact test if any of the cells is < 5) was used to determine associations	
To compare continuous variables between two groups such as age	Means and Standard Deviations	Median and Interquartile Ranges
To compare continuous variable between groups, e.g. rotation	Unpaired T-test	Mann-Whitney Test (Wilcoxon)
To correlate two continuous variables e.g. shortening, varus/valgus	Pearsons Correlation	Spearman correlation
P value < 0.05 at 95% confidence interval was considered statistically significant.		

Ethical consideration

Ethical approval was obtained from the University of Zambia Biomedical Research Ethics Committee (UNZABREC), as the study involved dealing with people.

Written consent was obtained from the participants.

The minimal risk was ascribed to the study as it involved standard procedures that are carried out on patient examination.

There was no monetary benefit for the participants but the study benefited the population as it provided information essential in the management of tibia shaft fractures.

4 CHAPTER FOUR: RESULTS AND DATA ANALYSIS

Social demographic characteristics of the study participants

The target sample size of 138 participants was reached as 138 (100%) participants were enrolled in the study. The demographic distribution of the participants is summarized in table 4.1 below.

Table 4. 1: Demographic and Characteristic Data of Participants involved

Variable			Frequency (%)	Confidence interval (CI)		p-value
				Lower	Upper	
age	median	34.50 (IQR 14)				
	range	19- 64				
sex	male		102(73.9%)	0.964	1.00	<0.001
	female		36(26.1%)	0.903	1.00	<0.001
cause of injury	RTA		73(52.9%)	0.951	1.00	<0.001
	fall from Height		13(9.4%)	0.753	1.00	<0.001
	industrial		10(7.2%)	0.692	1.00	0.002
	Assault		17(12.3%)	0.805	1.00	<0.001
	Others		25(18.1%)	0.863	1.00	<0.001
side affected	right		70(50.7%)	0.421	0.593	0.932
	left		68(49.3%)	0.421	0.593	0.932

Note: "Others" includes causes of injury other than the ones thought to be common and stated in literary from similar social economic setting. It includes:

- Sports injuries
- Falls in ditches or trenches
- Falls whilst running
- High velocity missles such as gun shots

4.1.1 Age, sex and limb distribution of the participants

The median age of 34.50 (IQR 14) and the age ranged from 19yrs to 64yrs. The median age for males was 35(IQR 14) and for females it was 32(IQR 16). The mean age for males was 35.77(p 0.434) and for females it was 34.97(p 0.988). Age and sex distributions are shown in figures 4.1 to figure 4.4 below.

A total of 102 (73.9%) males and 36(26.1%) females were analyzed. The distribution in terms of limbs involved was 70(50.7%) and 68(49.3%) participants with right and left limb fractures respectively (Figure 4.5 below).

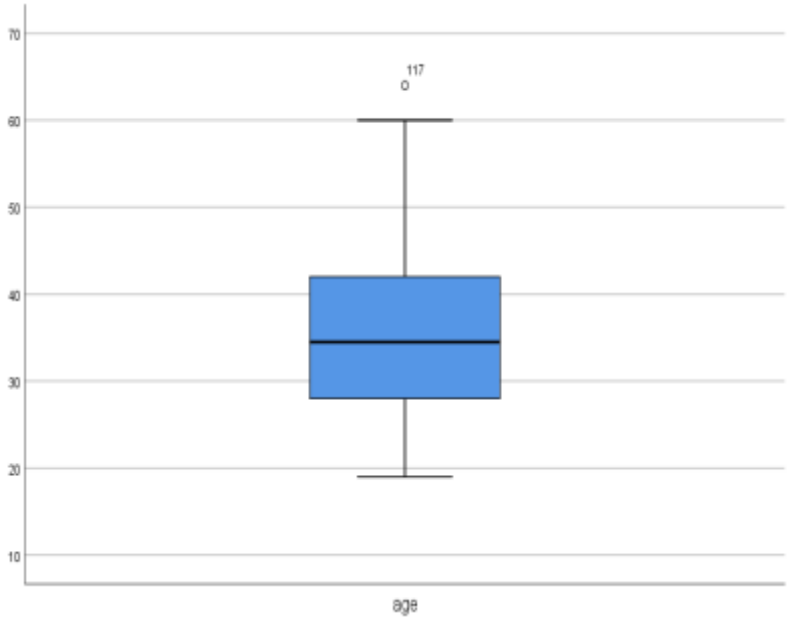

Figure 4. 1: Age distribution

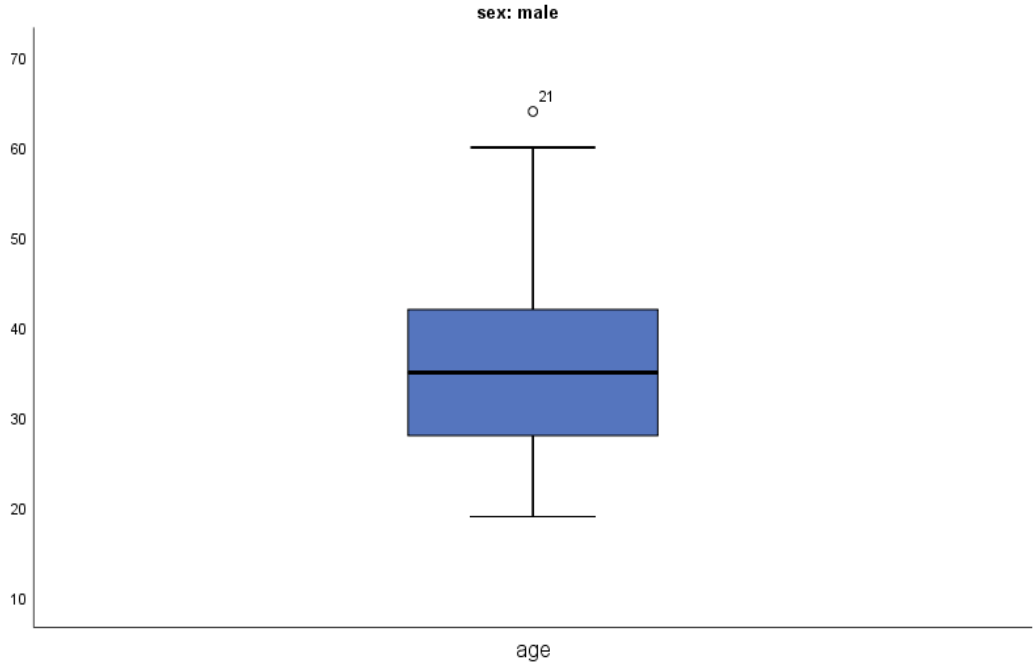

Figure 4. 2: Age distribution for males

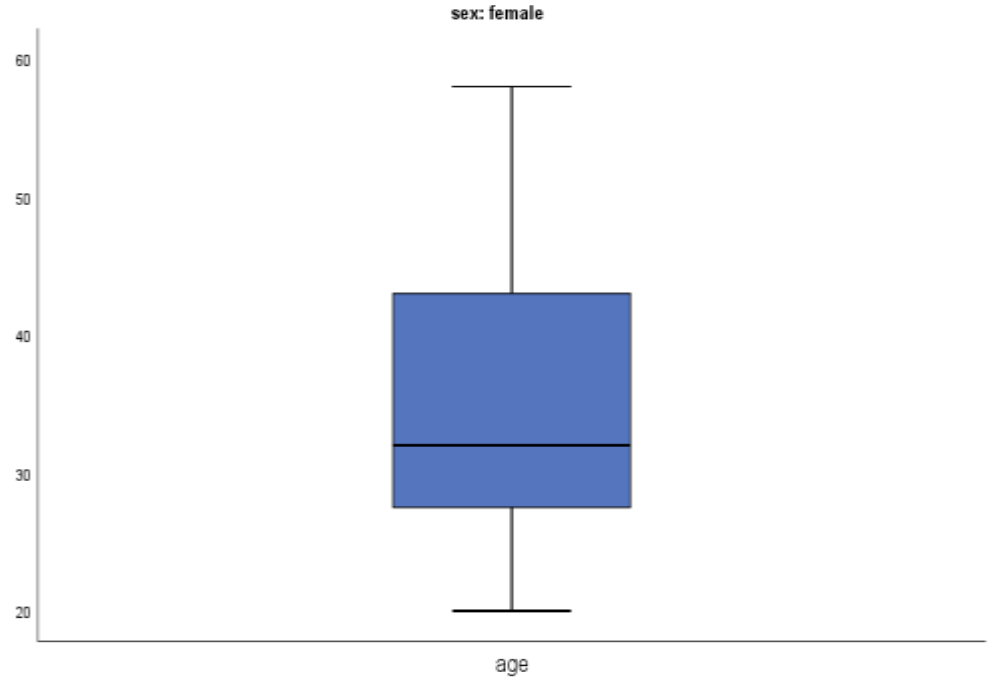

Figure 4. 3: Age distribution for females

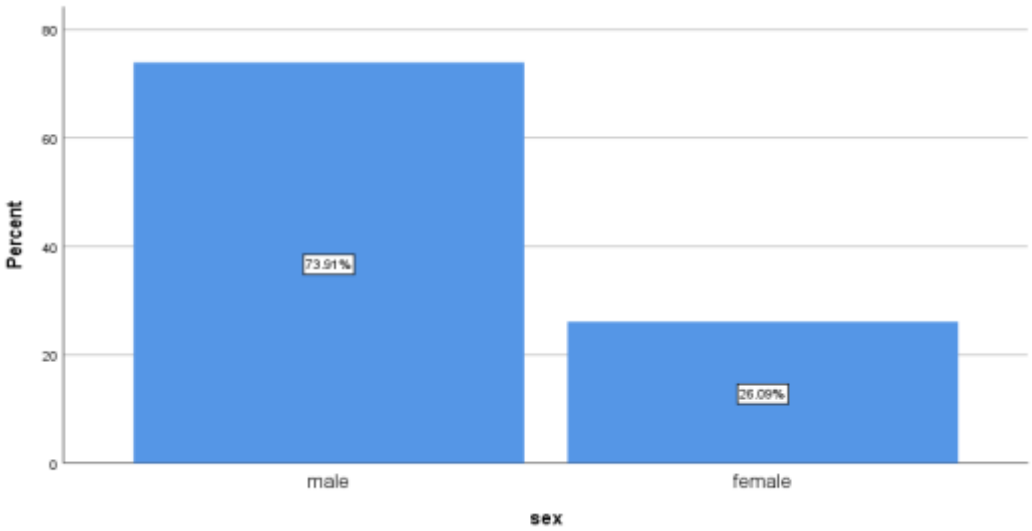

Figure 4. 4: Sex Distribution

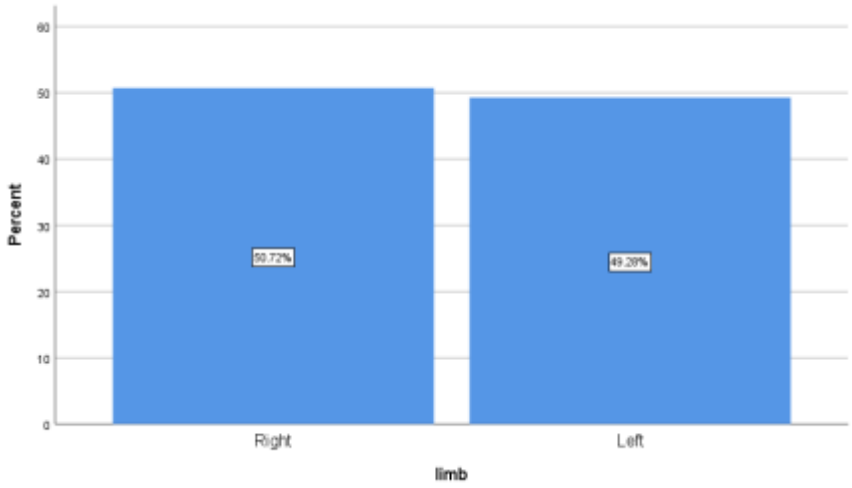

Figure 4. 5: Limb Involved

4.1.2 Cause of injury.

Road traffic accidents caused 73(52.9%) of the injuries, 13(9.4%) were caused by falls from a height, 10(7.2%) were caused by industrial accidents, 17(12.3%) were caused by assault and 25(18.1%) of the injuries were caused other causes of injuries. This is as depicted in figure 4.6 below. Amongst the males 57(55.9%) of the injuries where due to RTAs and 16(44.4%) amongst the females were caused by RTAs.

Females had the same chances of having an RTA as being male (p0.505). That is to say being female was not protective of having an RTA. Males had an equal chance of having an RTA or Other causes of injury (assault, industrial accident, fall from a height, other) (0.235).

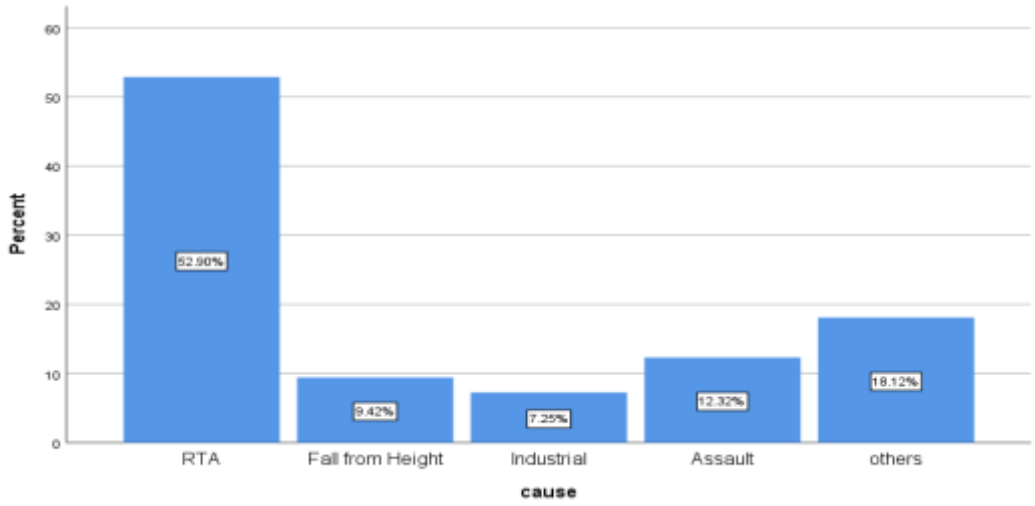

Figure 4. 6: Cause of Injury

Clinical characteristics of the participants.

The clinical characteristics are summarized in Table 4.2 and Table 4.3 below. Table 4.3 shows the characteristics as listed in the Johner-Wruhs criteria**.** Open fractures were 62(44.9%) and closed fractures were 76(55.1%). **The final functional outcomes at 3 months were 37% (51) for excellent, 38% (53) for good, 19% (26) for fair and 6% (8) for poor outcome**. Table 4.4 below shows the correlation between the functional outcomes found in the study and those found in a study by karaaslan (2016). It shows that the result of the study where statistically similar to those found in the stated study.

The functional outcomes between males and females were found to be different (p 0.008). Females had better functional outcomes than males in Figure 4.7 below.

There was no correlation found between the cause of injury and the state of the fracture open or closed (p 0.001).

Table 4. 2: Clinical Characteristics of the Participants.

Variable		Frequency	Proportion (%)	Confidence interval (CI)		p-Value
				lower	upper	
fracture type	AO42A1	48	34.8	0.926	1.00	0.01
	AO42A2	29	21	0.881	1.00	0.01
	AO42A3	42	30.4	0.916	1.00	0.01
	AO42B2	19	13.8	0.824	1.00	0.01
GA type	GA I	14	10.1	0.768	1.00	0.001
	GA II	19	13.8	0.824	1.00	0.001
	GA IIIa	29	21	0.881	1.00	0.001
	closed	76	55.1	0.953	1.00	0.001
physiotherapy attendance	yes	11	7.97	0.715	1.00	0.001
	no	127	92.03	0.001	0.029	0.001
smoking	yes	17	12.32	0.805	1.000	0.001
	no	121	87.68	0.001	0.030	0.001

Table 4. 3: Proportions of the variables in the Johner -Wruh Criteria

Measure	Frequencies (Proportions %)			
	excellent	**Good**	**Fair**	**Poor**
non union, Osteomyelitis, amputation	100(72.5%)	6(4.3%)	11(8.0%)	21(15.2%)
neurovascular disturbance	138(100%)	0	0	0
varus/ valgus deformity	**51(37%)**	**53(38.4%)**	**26(18.8%)**	**8(5.8%)**
Ant/Recurvatum	72(52.2%)	43(31.2%)	16(11.6%)	7(5.1%)
rotation	91(65.9%)	32(23.2%)	12(8.7%)	3(2.2%)
knee mobility	122(88.4%)	12(8.7%)	4(2.9%)	0
ankle mobility	110(79.7%)	20(14.5%)	6(4.3%)	2(1.4%)
Subtalar mobility	129(93.5%)	8(5.8%)	1(0.7%)	0
pain	25(18.1%)	56(40.6%)	51(37.0%)	6(4.3%)
gait	45(32.6%)	6(4.3%)	61(44.2%)	26(18.8%)
strenuous activity	39(28.3%)	64(46.4%)	15(10.9%)	20(14.5%)

Table 4. 4: Chi-Square (X^2)

observed results	51	53	26	8
expected %	40	32	16	12
Expected result	55	44	22	16

Degree of freedom= 3

Null hypothesis ($H_\circ$): The observed study percentages are not different from the expected values. Expected values are as reported by Karaarslan (2016).

X^2 **6.86**

X^2c **7.81**

Therefore the observed percentages are not different from the expected percentages as the Null hypothesis can not be rejected.

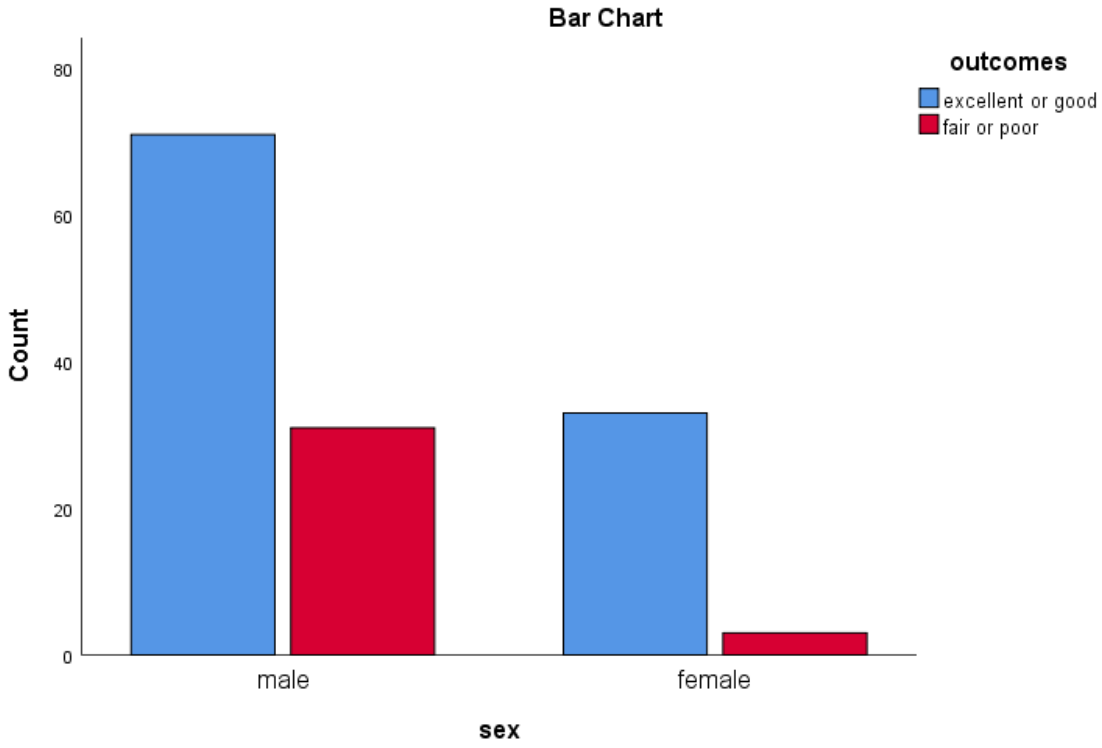

figure 4. 7: Outcomes comparing males and females

4.1.3 Fracture type

Participants with fracture type AO42A1 (simple spiral diaphyseal fracture) were 48(34.8%), AO42A2 (simple oblique diaphyseal fracture) were 29(21%), AO42A3 (simple transverse diaphyseal fracture) were 42(30.4%) and AO42B2 (diaphyseal intact wedge fracture) were 19(13.8%).

Participants with open fractures Gustilo-Anderson (GA) type I, II, IIIa, were 14(10.1%), 19(13.8%) and 29(21%) respectively. Closed fractures were

76(55.1%). Fracture type and GA class distribution are shown in figures 4.8 and 4.9 below.

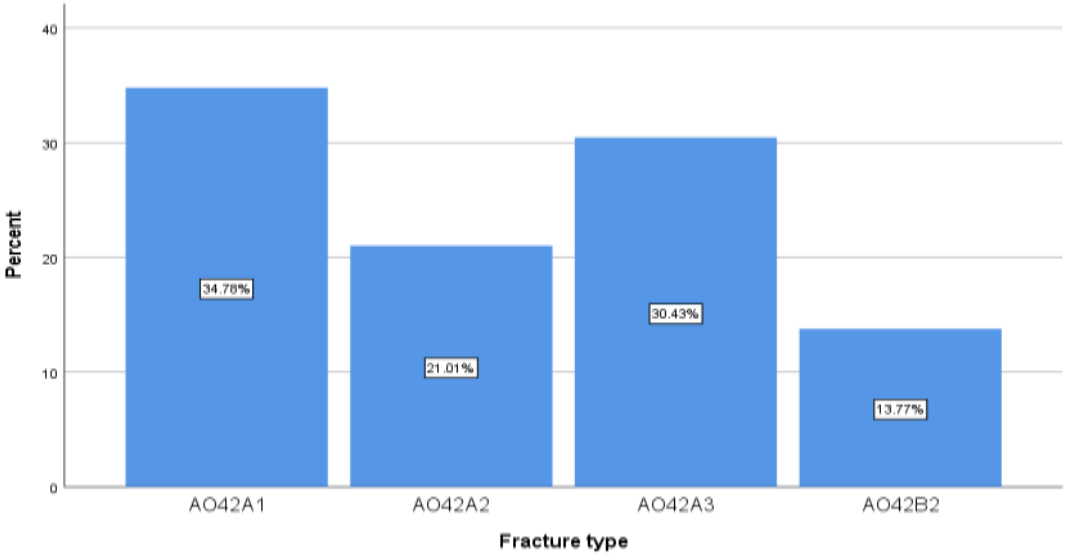

Figure 4. 8: Fracture type

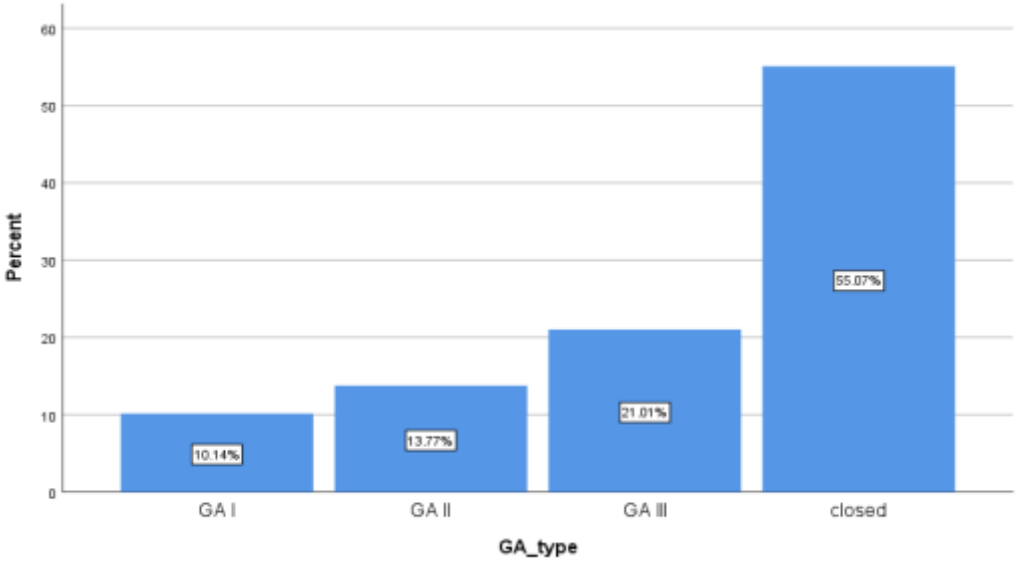

Figure 4. 9: Gustilo-Anderson Classification

4.1.4 Distribution of angular deformity across the Gustilo-Anderson classifications

The more angular deformity was observed in the higher GA class. This is shown in figures 4.7 and 4.8 below. This was expected from this study as it has been noted in other similar studies.

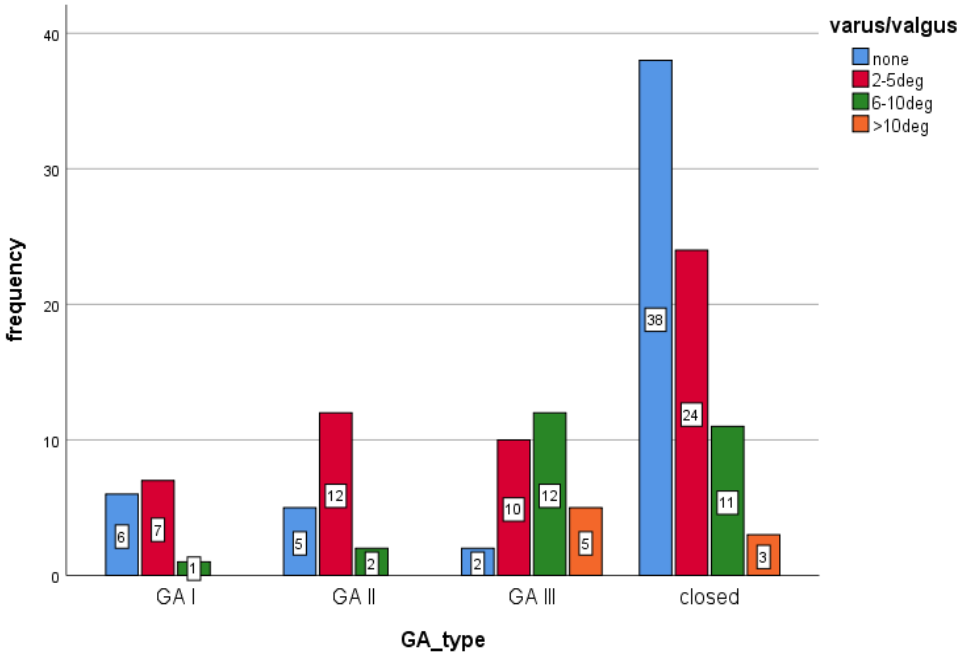

Figure 4. 10: Distribution of Varus/ Valgus deformity across the GA classification

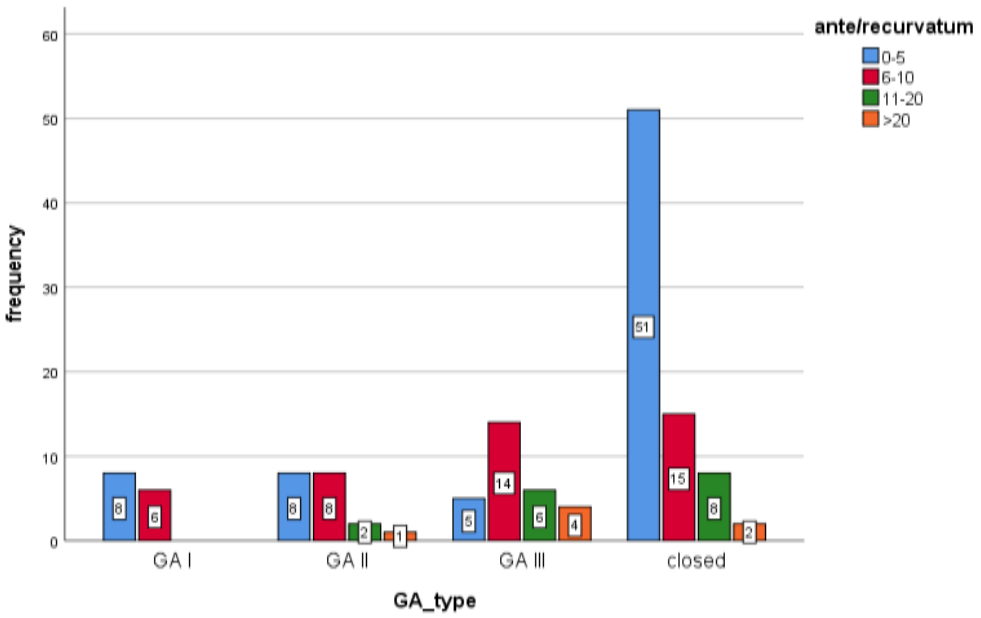

figure 4. 11: distribution of ante/recurvatum across the GA classification

Relationship of fracture type and Gustilo-Anderson classification to the different outcomes:

4.1.5 Fracture type to Varus/valgus angulation:

Varus/valgus angulation is not equally associated with the fracture type (p=0.02), more angulations were seen with the higher class of the fracture type (AO42B2). This is shown in figure 4.12 below.

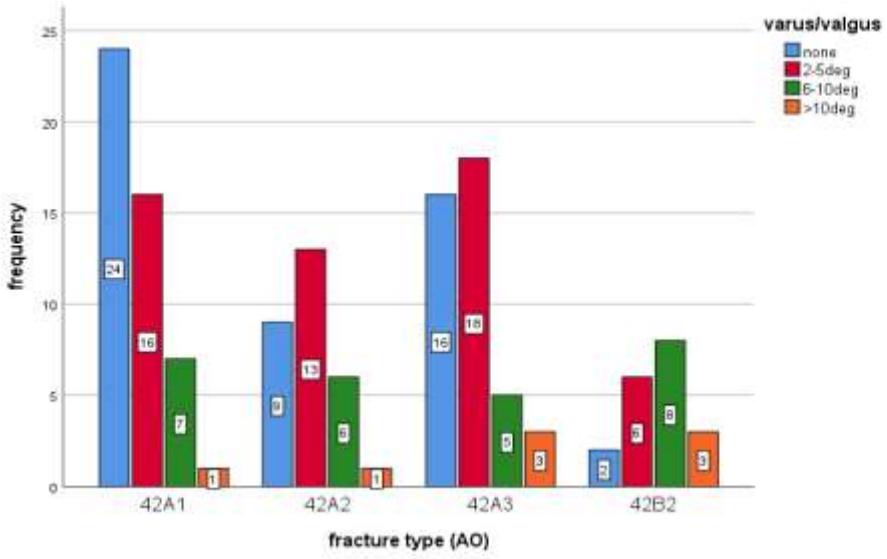

Figure 4. 12: Varus / valgus vs. fracture type

4.1.6 Fracture type and Ante/Recurvatum:

The distribution of ante/recurvatum was not the same across categories of fracture types (p=0.002). This is shown in figure 4.13 below.

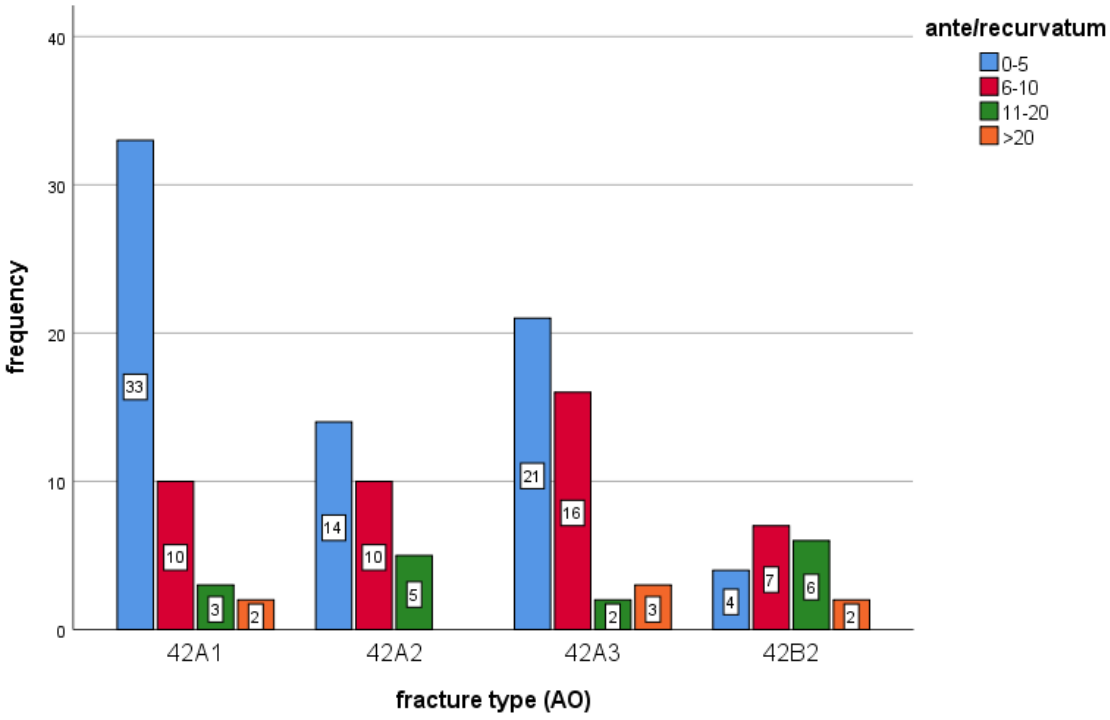

Figure 4. 13: Ante/Recurvatum Vs. Fracture type

4.1.7 Gustilo-Anderson to outcomes

The results suggested that the state of the fracture, open or closed, did not influence or have an association with the outcome of the fracture. This is summarized in the chi-square test in table 4.5 below.

Table 4. 5: Chi-square Gustilo-Anderson vs Outcome

			outcomes		
			good	poor	Total
Gustilo-anderson	Open fracture	Count	42	20	62
	Closed fracture	Count	62	14	76
Total		Count	104	34	138

P= 0.061

Relationship of smoking and physiotherapy to outcomes

4.1.8 Relationship of smoking to the final functional outcome

The result showed that there was no relationship between smoking and the final functional outcome (p 0.91), that is when the excellent and good results are grouped in one group and the fair and poor result in another.

4.1.9 Relationship of physiotherapy attendance to the final functional outcome

The study results seem to suggest that there was an association between physiotherapy attendance and the outcome observed (p 0.065, fishers exact).

5 Discussion

This study undertook to characterize the early functional outcomes of tibial Shaft fractures treated with casting in a defined population at the University Teaching hospital- Adult Hospital. It did so by examining the variables characterized in a validated functional score, the Johner –Wruhs criteria. Participants that met the inclusion criteria were enrolled from the orthopedic clinic (clinic 3) of the UTH.

Age distribution

The age of the participants was not normally distributed as shown by the Shapiro-Wilk test, skewness and kurtosis and Q-Q plots of the age. Therefore the median age was reported and it was found to be 34.50 (IQR 14). The median age of males was 35(IQR 14) and 32(IQR 16) for females. The two median ages were not statistically different (p 0.434) as would be expected given the average age of the participant who had tibial fractures. This compares relatively well with a study done in a similar socioeconomic status in Tanzania where the average age was reported to be 40yrs (Clelland et al., 2016). The proposed reason for this age group was that this age group undertakes high-risk behaviors and are usually under the influence of alcohol (Clelland et al., 2016).

Sex distribution

The study enrolled 102(73.9%) males and 36(26.1%) females representing a 3:1 male to female ratio. This ratio is consistent with the findings in other studies of tibia shaft fractures done in similar socioeconomic setting (Ghosh, 2015; Hooper et al., 1991). In India it was shown that RTA was a major burden to their health

system and that it mostly involved young males as opposed to females (Garg and Hyder, 2016). Closer to this study is the study was done in Tanzania which found that males are more commonly involved in road traffic accidents with a ratio of 2:1(Clelland et al., 2016), the study also showed that men were four times more likely to sustain tibia fractures. It attributed this to the fact that this subgroup is more likely to pursue dangerous occupations such as street vending and is usually under the influence of alcohol.

Cause of injury

In this study four (4) causes, which were observed to be common causes, were looked at. Other causes such as sports injuries**;** Falls in ditches or trenches; Falls whilst running; High velocity missles such as gun shots; were grouped together. The study showed that these causes of injuries were not normally distributed. Road Traffic Accidents (RTA) were significantly higher with a value of 73(52.9%) (p 0.01). This is in tandem with other similar studies done elsewhere and it has been noted to be a common finding in cities such as Lusaka were this study was conducted. In densely populated residential areas, it's observed that motor vehicles mix with pedestrians where the roads are either constructed without a pedestrian walk-way or the walk-way is turned into trading space by street vendors (Mudenda, 2014). Mudenda (2014) noted that in "harsh" economies, street vendors tend only to mind how they are going to make ends meet and overlook road safety and thus making them prone to be involved in RTAs.

The RTSA 2016 annual report noted that amongst the respective road users, pedestrians were at risk the most and were ranked number one and contributed up

to 42.5% of RTA fatalities (RTSA, 2016), this proportion increases to 63% of the road traffic fatalities in the RTSA 2019 annual report. This was attributed to the poor roads that do not have pedestrian walkways and also the disregard by pedestrians to follow road safety rules and cross at predetermined pedestrian crossings (RTSA, 2016). The RTSA 2016 survey also showed that errors in pedestrian crossing the road contributed 88.78% to the total of pedestrian causes of accidents, the second being that of pedestrians standing or walking in the road (7.13%).

Another study in Zambia showed that most road traffic accidents occurred during the day and in areas densely populated with street vendors as opposed to the assumption that the accidents would occur at night (Ikabongo and Hangoma, 2015). It was noted in the same paper that road traffic accidents increased in the year 2012 when a pronouncement was made allowing street vending in the central business district of Lusaka. Although this study didn't endeavor to study the socioeconomic status or occupation of its participants, it can be inferred that a similar demographic prevails.

A study done in the neighboring country of Tanzania on the epidemiology and management of Tibia and fibula fractures showed a similar result of 78% of fractures being caused by RTAs (Clelland et al., 2016). Elsewhere, in India for instance, RTAs contributed the most to the cause of injury with a proportion of 86.67% (Patel et al., 2019). In places, with a significant difference in the socioeconomic status the findings are strikingly different. In the U.S a study by

Court- brown showed that RTA only contributed 37.5% which is lower than the finding of this study (Court-Brown and McBirnie, 1995).

This study however did not evaluate whether its participants were involved in RTAs as passenger drivers or as pedestrians. A quick review of the admission notes however showed that most participants were involved in a pedestrian versus motor vehicle accident.

There was no statistical difference in the frequency of the limb affected. Left and right lower limbs were affected equally. 50.7% of the participants had right limb affectation whilst 49.3% had left limb affectation. This shows that there is an equal probability of getting either limb affected in trauma. This is an expected finding as an accident will not have a predilection to the limb involved, each limb has a 50% chance of being involved in this case.

Fracture Type and Gustilo-Anderson classification

Closed fractures were more than open fractures in this study with a frequency of 76 (55.1%) and 62 (44.9%) respectively. When tested to see if the state of the fracture, open or closed, had a bearing on the final functional outcome it was found that there was no relationship (p 0.061). Of course in this study only open fracture which had adequate soft tissue coverage were recruited. Open fractures with soft-tissue defects requiring flaps or skin grafts were excluded from the study. Therefore it can be further inferred that closed fractures and open fractures up to GA IIIa have similar functional outcomes.

Amongst the open fractures enrolled, GA IIIa fractures were more common 29(21%). This can be attributed to the observation that patient delay in presenting

to the hospital, especially when they first pass through their primary health facility where no formal debridement of the wounds is done. Thus when they do present to the hospital (UTH) it is already more than eight (8) hours post-trauma and their fractures are classified higher into a GA IIIa class due to the presumed contamination (Kim and Leopold, 2012).

For the AO classification, the most frequent fracture type was the AO 42A1 fractures 48(34.8%) followed by AO 42A3 42(30.4%). In the USA the distribution of fractures was found to be AO42A1 16.8%, AO42A2 13.3%, AO42A3 23.9% and AO42B2 10.0%(Court-Brown and McBirnie, 1995). This finding was different from what the study findings were. This could be also be explained by the cause of the fractures that have been noted already.

Moving from a higher GA class to closed fractures showed a decrease of angular deformity and conversely more angular deformities were seen in higher types of AO fracture types, that is, AO42B2 had more angular deformity than AO42A1 fractures.

Effects of smoking and physiotherapy attendance on functional outcomes

The study revealed poor physiotherapy attendance by the participants. Of all the participants enrolled, only 11 (7.97%) attended physiotherapy sessions by professional physiotherapists. Attending physiotherapy as an outpatient has cost implications for the participant as the participant has to find transportation and in some instances pay for the physiotherapy service, this poses a barrier to physiotherapy and could be offered as an explanation for the low attendance. The study showed that physiotherapy attendance has a relationship with the functional

outcome (p 0.065). The participants who attended physiotherapy had a better functional outcome. A study done in Boston USA concluded that there finding was consistent with other studies done earlier on the beneficial effects of physiotherapy on the outcome (Castillo et al., 2008). Physiotherapy improves functional outcomes.

This study did not show any relationship between smoking and the final functional outcome of tibial fractures (p 0.91). The number of people that smoke in the study was significantly lower than those that did not smoke, 17(12.3%) against 121(87.68%), therefore it is difficult to rely on the findings with such a low number of representatives. In one study it was shown that nicotine, which is a major component of cigarette smoke, does harm fracture healing and contributed to the rate of wound infection (Raikin et al., 1998).

Final functional outcome

The functional outcome was 51(37%) for excellent, 53(38.4%) for good, 26(18.8%) fair and 8(5.8%) poor. When these values were tested against expected values, as shown in a study by Karaarslan in 2016, using chi-square they proved to be the same as the expected values. From this it can be assumed that the functional outcomes are the same as those stated in this literature. This study showed that the functional outcome of the participants enrolled in the study was mostly better than those stated in the above literature. This finding disproves the early thought that locally the functional outcomes of tibial shaft fractures are poor. This could be attributed to the fact that due to theatre space challenges and unaffordable

implants, casting remains the only option giving the 'Pop casters' a lot of experience and practice in perfecting the skills (anecdotal).

When compared males versus females, it was found that females had a better functional outcome than males (p 0.008). The chances of having an RTA were the same between the two sexes (p 0.505). the possible explanation for this is that more females attended physiotherapy than males and have a less severe fracture type when compared to the males. Both sexes had more chances of having RTA as opposed to any other cause of injury since RTAs where more common than other causes.

Study limitations

1. This study looked into the functional outcomes of tibia fractures treated with casting at one particular point in time (at 3 months). It looked at those fractures that were treated at UTH, and as they came for their three month's review. However, patients that were treated with casts at UTH but were not available for review at 3 months for various reason such as lost to follow-up, or patients that opted to continue care elsewhere due to distance and transport challenges; were not accounted for in the study and are presumed to have a contribution to assessing the practice obtaining.
2. Patients whose course of treatment was changed before three months due to loss of reduction weren't accounted for in this study as it was a cross-sectional study that only included patients at three months from time of injury. A different study design such as a prospective cohort study would have helped to analyze for these.

3. The study relied on the accuracy of the adequacy of the initial xrays to infer the situation at the beginning of treatment. And there was no followup in the study hence no control of what happened from the period of casting to presentation at three months which could potentially influence outcomes.

6 Conclusion and Recommendations

Conclusion

1. The functional outcomes of tibia shaft fractures treated with P.O.P. cast at the University Teaching Hospital at three months post-injury fall in the category good to excellent 75.4% of the time. 24.6% of the outcomes fall in the fair to poor category.
2. Rotational deformity at the fracture site fell within an acceptable range of less -than ten degrees (10^{o}) in 89.1 % (n=123) of the participants (Egol, 2015).
3. Varus / valgus deformity was acceptable in 37 % (n=51) of the participants. Antervertion/ recurvatum was acceptable in 83.4 % (n=115) of the participants.
4. Mobility of the adjacent joints (knee, ankle and Subtalar joints) was generally not affected at 3 months after tibial shaft fracture as the results were excellent in 88.4%, 79.7% and 93.5% of the time respectively. The anticipated stiffness of these joints seemed to resolve as the participants began to mobilize.

5. Physiotherapy attendance seemed to show some association to the good functional outcome whilst smoking had none, although this cannot be stated with certainty owing to the design of the study.

Recommendation

1. Tibia shaft fractures treated with casting at the UTH show good functional outcomes and as such the use of this treatment modality should be continued at the UTH
2. A larger multicenter study needs to be done to get a sample that represents tibial shaft fractures and not only those that present to the U.T.H. and possibly and interventional study should be done to ascertain the relevance of POP casting, especially in our socioeconomic setting.

7 References

Batta, V., Dwyer, A.J., Gulati, A., Prakash, J., Mam, M.K. and John, B., 2012. No difference in the long term final functional outcome after nailing or cast bracing of high energy displaced tibial shaft fractures. *Journal of trauma management & outcomes*, *6*(1), pp.1-6.

Bone, L.B., Sucato, D., Stegemann, P.M., Rohrbacher, B.J., 1997. Displaced Isolated Fractures of the Tibial Shaft Treated with Either a Cast or Intramedullary Nailing. An Outcome Analysis of Matched Pairs of Patients*. JBJS 79, 1336.

Browner, B.D., 2009. Skeletal Trauma: Basic Science, Management, and Reconstruction. Elsevier Health Sciences.

Castillo, R.C., MacKenzie, E.J., Archer, K.R., Bosse, M.J., Webb, L.X., 2008. Evidence of Beneficial Effect of Physical Therapy After Lower-Extremity Trauma. Arch. Phys. Med. Rehabil. 89, 1873–1879. https://doi.org/10.1016/j.apmr.2008.01.032

Clelland, S.J., Chauhan, P., Mandari, F.N., 2016. The epidemiology and management of tibia and fibula fractures at Kilimanjaro Christian Medical Centre (KCMC) in Northern Tanzania. Pan Afr. Med. J. 25. https://doi.org/10.11604/pamj.2016.25.51.10612

Court-Brown, C.M., McBirnie, J., 1995. The epidemiology of tibial fractures. J. Bone Joint Surg. Br. 77, 417–421.

Egol, K.A., Koval, K.J. and Zuckerman, J.D., 2010. *Handbook of fractures*. Lippincott Williams & Wilkins.

Garg, N., Hyder, A.A., 2016. Review Article: Road traffic injuries in India: A review of the literature: Scand. J. Public Health. https://doi.org/10.1080/14034940510032149

Gaston, P., Will, E., Elton, R.A., McQueen, M.M., Court-Brown, C.M., 1999. Fractures of the tibia: CAN THEIR OUTCOME BE PREDICTED? J. Bone Joint Surg. Br. 81-B, 71–76. https://doi.org/10.1302/0301-620X.81B1.0810071

Ghosh, P.K., Ray, D., Adak, S., Chatterjee, B., Naiya, S. and Dey, A., Comparison of Results of Conservative and Operative (Interlocking Nail) Treatment of Closed Isolated Diaphyseal Tibial Fracture in Adult. *Group*, *12*(5), p.8.

Hooper, G.J, Keddell, R.G. and Penny, I.D., 1991. Conservative management or closed nailing for tibial shaft fractures. A randomised prospective trial. *The Journal of bone and joint surgery. British volume*, *73*(1), pp.83-85.

Ikabongo, M., Hangoma, M.P., 2015. University of Zambia School of Medicine Department of Public Health 41.

Karaarslan, A.A., Acar, N., Aycan, H., Sesli, E., 2016. The functional results of tibial shaft fractures treated with intramedullary nail compressed by proximal tube. Strateg. Trauma Limb Reconstr. 11, 25–29. https://doi.org/10.1007/s11751-016-0242-x

Karladani, A.H., Granhed, H., Edshage, B., Jerre, R. and Styf, J., 2000. Displaced tibial shaft fractures: a prospective randomized study of closed intramedullary nailing versus cast treatment in 53 patients. *Acta Orthopaedica Scandinavica*, *71*(2), pp.160-167.

Kim, P.H., Leopold, S.S., 2012. Gustilo-Anderson Classification. Clin. Orthop. Relat. Res. 470, 3270–3274. https://doi.org/10.1007/s11999-012-2376-6

Larsen, P., Elsoe, R., Hansen, S.H., Graven-Nielsen, T., Laessoe, U., Rasmussen, S., 2015. Incidence and epidemiology of tibial shaft fractures. Injury 46, 746–750. https://doi.org/10.1016/j.injury.2014.12.027

Maruthi, C.V., 2015. Tibial shaft fractures managed by intramedullary interlocking nail: a prospective study. *Journal of Evolution of Medical and Dental Sciences*, *4*(72), pp.12530-12537.

Milner, S.A., Davis, T.R.C., Muir, K.R., Greenwood, D.C., Doherty, M., 2002. Long-Term Outcome After Tibial Shaft Fracture: Is Malunion Important? JBJS 84, 971.

Mudenda, T., 2014. Epidemiology of Road Traffic Accidents in Lusaka, Zambia: 2014 153.

Obremskey, W.T., Cutrera, N., Kidd, C.M., Consortium, T.S.F., 2017. A prospective multi-center study of intramedullary nailing vs casting of stable tibial shaft fractures. J. Orthop. Traumatol. 18, 69–76. https://doi.org/10.1007/s10195-016-0429-4

Patel, Dr.J., Patel, Dr.V., Oakley, J., Reddy, Dr.C.S.S., Jain, Dr.A., Mani, Dr.C., Desai, Dr.S.M., 2019. Study of interlocking nail in shaft tibia fracture. Int. J. Orthop. Sci. 5, 354–358. https://doi.org/10.22271/ortho.2019.v5.i2g.48

Raikin, S.M., Landsman, J.C., Alexander, V.A., Froimson, M.I., Plaxton, N.A., 1998. Effect of Nicotine on the Rate and Strength of Long Bone Fracture Healing: Clin. Orthop. 353, 231–237. https://doi.org/10.1097/00003086-199808000-00027

Rockwood, C.A., Bucholz, R.W., Court-Brown, C.M., Heckman, J.D., Tornetta, P., 2010. Rockwood and Green's Fractures in Adults. Lippincott Williams & Wilkins.

Road Transport and Safety Agency (RTSA), Annual Road Traffic Accident Report 2016 https://www.rtsa.org.zm/wp-content/uploads/2019/09/RTSA-Annual-Accident-Report-2016.pdf

Schmidt, A.H., Finkemeier, C.G. and Tornetta III, P., 2003. Treatment of closed tibial fractures. *JBJS*, *85*(2), pp.352-368.

Thomas, P., Richard, E., Christopher, G. Moran CG, R. T. P. B. R. (2007) AO Principles of Fracture Management. 2nd expand. switzerland: AO Publishing Group.

Toivanen, J.A.K., Honkonen, S.E., Koivisto, A.-M., Järvinen, M.J., 2001. Treatment of low-energy tibial shaft fractures: plaster cast compared with intramedullary nailing. Int. Orthop. 25, 110–113. https://doi.org/10.1007/s002640000083

Trafton, peter (2003) Skeletal Trauma. 3rd edition. Edited by trafton pg Browner, Bruce D. jupiter jb, lavine AM. saunders.

Young, S., Lie, S.A., Hallan, G., Zirkle, L.G., Engesæter, L.B., Havelin, L.I., 2013. Risk Factors for Infection after 46,113 Intramedullary Nail Operations in Low- and Middle-income Countries. World J. Surg. 37, 349–355. https://doi.org/10.1007/s00268-012-1817-4

8 Appendices

Participants information sheet

8.1.1 Title of research:

A Cross Sectional Study of Early Functional Outcomes of Casting of Tibial Shaft Fractures at the University Teaching Hospitals: Adult Hospital, Lusaka Zambia.

Principle investigator: Dr. Rowland Mhone

8.1.2 Introduction

You are being asked to take part in this research study, which will be explained to you in the content of this form. This study is being conducted by Dr. Rowland Mhone Bsc HB, MB ChB in the Department of Surgery at the University Teaching Hospital (UTH).

This research is being conducted in partial fulfillment of Master of Medicine Orthopedics as required by the University of Zambia, under the supervision of Professor Y. Mulla Bsc HB, MB ChB, MMed (Surgery), O.D.T.S (RCS ENG), MCh (Orth)-Liverpool, FCS (ECSA) and Dr. G. Phiri Bsc HB, MB ChB, MMED Orth (UNZA).

There may be some words or procedures that you may not understand. Kindly ask me to stop and I will take time to elaborate further as we go through the information.

8.1.3 Purposes of the Study

The purpose of this study is to learn more about the outcomes, in terms of function, of treating a broken leg with Plaster of Paris (POP) cast.

You have been selected to take part in this study simply because you have/had a broken leg which has been treated with casting and you presented to this

institution and therefore we are inviting all patients who have a similar problem as yours to take part. Your participation will be of great value to this study.

8.1.4 Description of Procedures

This study involves examining you and your records to find out what outcomes you have had after your treatment with POP casting. You will be asked a bit more questions regarding the functional status of your leg and this shall be documented. No further contact shall be required from you later.

8.1.5 Risks and Discomforts

There is little to no risk associated with participating in this study, except for the mild frustration associated with answering questions and the discomfort of examining you. There is no medically invasive procedure or medications that shall be administered. You may decide at any time to quit the study.

8.1.6 Benefits

You shall not receive any monetary benefit from this study. The knowledge gained from this study may eventually benefit others.

8.1.7 Who can join this study?

All patients that have been or are being treated with a POP cast for a fractured Tibial shaft at the UTH, and are three months post-treatment are eligible for enrolment. You are asked to take part because you meet this criterion. A total of 138 participants shall be recruited.

8.1.8 Financial Considerations

No payments will be made for participating in this study.

8.1.9 Confidentiality

Any information about you obtained as a result of your participation in this research will be kept as confidential as legally possible. Your research records and

radiographs, just like hospital records, maybe subpoenaed by court order without your additional consent.

The information shall be used for this research and any subsequent research that may arise without any further consent from you.

In addition, there are certain instances where the researcher is legally required to give information to appropriate authorities. These would include mandatory reporting of infectious diseases, mandatory reporting of information about behavior that is imminently dangerous to you or others, such as suicide, child abuse, etc.

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

8.1.10 Voluntary Participation

Participating in this study is voluntary. You are free to withdraw your consent to participate in this study at any time.

Refusal to participate or withdrawal will not affect the treatment of your broken leg and will involve no penalty to you.

8.1.11 Person to contact

If you have any questions or if the study has harmed you in any way and you wish to make a complaint about the conduct of the study, you can contact the following:

Dr. Rowland Mhone, Department of Surgery, University Teaching Hospital, P.O.Box 50110, Lusaka. Email: rowland.mhone@yahoo.com Cell: 0977764575 or The University of Zambia, Biomedical Research Ethics Committee, Ridgeway Campus, P.O.Box 50110, Lusaka Zambia, E-mail: unzarec@unza.zm. Telephone: 256067.

Consent Form:

Title of Research:

A Cross Sectional Study of Early Functional Outcomes of Casting of Tibial Shaft Fractures at the University Teaching Hospitals: Adult Hospital, Lusaka Zambia.

Researcher: Dr. Rowland Mhone

		Tick in box
1.	I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	☐
2.	I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason, without my rights being affected and that I can refuse to answer any questions I deem personal.	☐
3.	I understand that I can at any time ask for access to the information I provide and I can also request the destruction of that information if I wish.	☐
4.	I understand that I will not be identified or identifiable in any report subsequently produced by the researcher.	☐
5.	I accept that taking part in this study is voluntary and I confirm that any risks associated with this have been explained to me.	☐
6.	I agree to take part in the above study.	☐

I willingly consent to participate in this research.

Printed Name: _____

Signature of Subject: _____ or thumb print_____

Date: _____ Time:_____

Printed Name: _____

Signature of Witness: _____

Date:_____ _____ Time: _____

For more information about this research, you may contact Dr Rowland Mhone on cell number 0977764575. Or email: rowland.mhone@yahoo.com

Data Collection Sheet

Demographics:

1. serial number:_____
2. age in year at last birthday:_____
3. gender: 1) M 2) F

Injury:

4. cause of injury
    1. RTA
    2. Fall From Height
    3. Industrial
    4. Assault
    5. Others
5. Limb injured 1) R 2)L
6. Fracture Type: 1) 42 A1 2)42 A2 3)42 A3 4)42 B2
7. Gustilo Anderson type: 1) I 2)II 3)IIIa 4) closed

Johner Wruh criteria:

	Excellent (left to right)	Good	Fair	Poor
8. **Non-union, osteomyelitis, amputation**	**1. None**	**2. None**	**3. None**	**4. Yes**
9. **Neurovascular disturbances**	**1. None**	**2. Minimal**	**3. Moderate**	**4. Severe**
10. **Deformity Varus/valgus, °**	**1. None**	**2. 2–5**	**3. 6–10**	**4. > 10**
11. **Anteversion / recurvation, °**	**1. 0–5**	**2. 6–10**	**3. 11–20**	**4. > 20**
12. **Rotation, °**	**1. 0–5**	**2. 6–10**	**3. 11–20**	**4. > 20**

13. **Shortening, mm**	**1. 0–5**	**2. 6–10**	**3. 11–20**	**4. > 20**
14. **Mobility, % Knee Normal**	**1. Normal**	**2. > 80**	**3. > 75**	**4. < 75**
15. **Ankle Normal**	**1. Normal**	**2. > 75**	**3. > 50**	**4. < 50**
16. **Subtalar joint**	**1. Normal**	**2. > 75**	**3.,> 50**	**4. < 50**
17. **Pain**	**1. None**	**2. Occasional**	**3. Moderate**	**4. Severe**
18. **Gait**	**1. Normal**	**2. Normal**	**3. Insignificant limp**	**4. Significant limp**
19. **Strenuous activities**	**1. Possible**	**2. Limited**	**3. Severed limited**	**4. Impossible**

20. Physiotherapy attendance: 1) yes 2) no

21. Smoking 1)Yes 2)No

Permissions

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE

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Telegram: UNZA, Lusaka
Telex: UNZALU ZA 44370
P.O Box 50110
Lusaka, Zambia
Email: assistantdeanpgmedicine@unza.zm

3 June 2019

Dr. Rowland Mhone
UNZA, School of Medicine
C/O Department of Surgery
LUSAKA

Dear Dr. Mhone

RE: GRADUATE PROPOSAL PRESENTATION FORUM

Following the presentation of your proposal entitled **"A Cross Section of Early Functional Outcomes of Tibial Shaft Fractures at the University Teaching Hospitals: Adult Hospital, Lusaka, Zambia"** your supervisor has confirmed that the necessary corrections to your research proposal have been done.

You can proceed and present to the Research Ethics.

Yours faithfully,

Dr. P. Machona
ASSISTANT DEAN, POSTGRADUATE

cc: Head, Department of Surgery

UNIVERSITY OF ZAMBIA
SCHOOL OF MEDICINE
ASSISTANT DEAN (PG)
P.O. BOX 50110, LUSAKA.

REPUBLIC OF ZAMBIA
MINISTRY OF HEALTH
University Teaching Hospitals
ADULT AND EMERGENCY HOSPITAL

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Fax: +260 211 250305
e-mail: mduth@yahoo.com

OFFICE OF THE SENIOR MEDICAL SUPERINTENDENT

Our Ref:

Your Ref:

31st May, 2019

The Head of Department
The University of Zambia
Department of Surgery
LUSAKA

Dear Sir/Madam,

RE: RESEARCH PROJECT: DR.MHONE ROWLAND

Reference is made to your letter dated 31st May, 2019.

I wish to inform you that permission has been granted to Dr. Mhone Rowland to conduct research entitled **"A Cross Sectional Study of Early Functional Outcomes of Casting of Tribal Shaft Fractures" at the University Teaching Hospitals** (UTH): Lusaka. He is advised to liaise with the Head of Department.

Yours faithfully,

Dr. Charles Mutemba
Head Clinical Care
for **/Director Clinical Care and Diagnostic services**
UNIVERSITY TEACHING HOSPITALS-ADULT

Cc: Dr. Mhone Rowland